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Item 4 (c) (v) of the provisional agenda*

Technical work: review of notifications of final regulatory action: chlorpyrifos-methyl

Chlorpyrifos-methyl: supporting documentation provided by the European Union

Note by the Secretariat

As is mentioned in the note by the Secretariat on chlorpyrifos-methyl: notifications of final regulatory action (UNEP/FAO/RC/CRC.20/9), the annex to the present note sets out documentation provided by European Union to support its notification of final regulatory action for chlorpyrifos-methyl in the pesticide category. The present note, including its annex, has not been formally edited.

* UNEP/FAO/RC/CRC.20/1.

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Annex

Chlorpyrifos-methyl: supporting documentation provided by the European Union

List of documents:

1. European Commission, 2019. Commission Implementing Regulation (EU) 2020/17 of 10 January 2020 concerning the non-renewal of the approval of the active substance chlorpyrifos-methyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. (Official Journal of the European Union L 7, 13.1.2020, p. 11) https://eur-lex.europa.eu/eli/reg_impl/2020/17/oj.

2. European Commission, 2019. FINAL Renewal report for the active substance chlorpyrifos-methyl Regulation SANTE/11942/2019 Rev 2.

3. European Food Safety Authority (EFSA), 2019. Updated statement on the available outcomes of the human health assessment in the context of the pesticides peer review of the active substance chlorpyrifos-methyl. EFSA Journal 2019 ; 17(11) :5908. https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5908.

4. European Commission, 2015. Final Review report for the active substance chlorpyrifos-methyl. Chlorpyrifos-methyl SANCO/3061/99 – rev. 2, 20 March 2015. https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=as.details&as_id=549.

5. European Commission, April 2017. Draft Renewal Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009. Chlorpyrifos-Methyl, Volume 1.

COMMISSION IMPLEMENTING REGULATION (EU) 2020/17

of 10 January 2020

concerning the non-renewal of the approval of the active substance chlorpyrifos-methyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ([1]), and in particular Article 20(1) and Article 78(2) thereof,

Whereas:

(1) Commission Directive 2005/72/EC ([2]) included chlorpyrifos-methyl as an active substance in Annex I to Council Directive 91/414/EEC ([3]).

(2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([4]).

(3) The approval of the active substance chlorpyrifos-methyl, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 January 2020.

(4) Applications for the renewal of the approval of the active substance chlorpyrifos-methyl were submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ([5]) within the time period provided for in that Article.

(5) The applicants submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The applications were found to be complete by the rapporteur Member State.

(6) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 3 July 2017.

(7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the renewal assessment report to the applicants and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.

(8) On 4 July 2018, the Authority requested that the applicants supply additional information to the Member States, the Commission and the Authority. The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the form of an updated renewal assessment report.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Commission Directive 2005/72/EC of 21 October 2005 amending Council Directive 91/414/EEC to include chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb, and metiram as active substances. (OJ L 279, 22.10.2005, p. 63).

([3]) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

([4]) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

([5]) Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

(9) The Authority organised an expert discussion in April 2019, to discuss certain elements related to the human health risk assessment. Due to concerns about genotoxicity and developmental neurotoxicity raised during that discussion, on 1 July 2019 the Commission sent a mandate to the Authority requesting a statement on the available outcomes of the human health assessment and an indication whether the active substance can be expected to meet the approval criteria which are applicable to human health as laid down in Article 4 of Regulation (EC) No 1107/2009.

(10) On 31 July 2019, the Authority sent its initial statement ([6]) to the Commission on the available outcomes of the human health assessment. On 11 November 2019, the Authority sent its updated statement ([7]) to the Commission following an additional expert discussion held in September 2019. In its updated statement, the Authority confirmed its conclusions on the human health assessment that critical areas of concerns exist. A genotoxic potential of chlorpyrifos-methyl cannot be ruled out, when taking into account the concerns raised for chlorpyrifos and the available scientific open literature on chlorpyrifos-methyl in a weight of evidence approach. During the peer review, experts considered a read-across approach between the two substances justified as they are structurally similar and have similar toxicokinetic behaviour. Consequently, it is not possible to establish health-based reference values for chlorpyrifos-methyl and to conduct the relevant consumer and non-dietary risk assessments. Furthermore, concerns were identified concerning developmental neurotoxicity (DNT) for which epidemiological evidence exists, showing an association between exposure to chlorpyrifos and/or chlorpyrifos-methyl during development and adverse neurodevelopmental outcomes in children. Moreover, the peer review experts indicated that it may be appropriate to classify chlorpyrifos-methyl as toxic for reproduction, category 1B, in accordance with the criteria established under Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([8]).

(11) The Commission invited the applicants to submit their comments on the statements of the Authority. Furthermore, in accordance with the third subparagraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, the Commission invited the applicants to submit comments on the draft renewal report. The applicants submitted their comments, which have been carefully examined.

(12) However, despite the arguments put forward by the applicants, the concerns regarding the active substance could not be eliminated.

(13) Consequently, it has not been established, with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. The environmental risk assessment, although not finalised, cannot alter this conclusion since the approval criteria related to the effects on human health are not satisfied and should therefore not delay further the decision-making on the renewal of the approval of the active substance. It is therefore appropriate not to renew the approval of the active substance chlorpyrifos-methyl in accordance with Article 20(1)(b) of that Regulation.

(14) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(15) Member States should be given sufficient time to withdraw authorisations for plant protection products containing chlorpyrifos-methyl.

(16) For plant protection products containing chlorpyrifos-methyl, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should not exceed 3 months from the date of entry into force of this Regulation.

(17) Commission Implementing Regulation (EU) 2018/1796 ([9]) extended the approval period of chlorpyrifos-methyl to 31 January 2020, in order to allow the renewal process to be completed before the expiry of the approval period of that substance. However, given that a decision on the non-renewal of the approval is being taken ahead of the expiry of that extended approval period, this Regulation should apply as soon as possible.

([6]) EFSA (European Food Safety Authority), 2019. Statement on the available outcomes of the human health assessment in the context of the pesticides peer review of the active substance chlorpyrifos-methyl. *EFSA Journal* 2019;17(5):5810. https://doi.org/10.2903/j.efsa.2019.5810.

([7]) European Food Safety Authority (EFSA), 2019. Updated statement on the available outcomes of the human health assessment in the context of the pesticides peer review of the active substance chlorpyrifos-methyl. *EFSA Journal* 2019;17(11):5908, 21 pp. https://doi.org/10.2903/ j.efsa.2019.5908.

([8]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

([9]) Commission Implementing Regulation (EU) 2018/1796 of 20 November 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, bifenox, chlorpyrifos, chlorpyrifos-methyl, clofentezine, dicamba, difenoconazole, diflubenzuron, diflufenican, dimoxystrobin, fenoxaprop-p, fenpropidin, lenacil, mancozeb, mecoprop-p, metiram, nicosulfuron, oxamyl, picloram, pyraclostrobin, pyriproxyfen and tritosulfuron (OJ L 294, 21.11.2018, p. 15).

(18) This Regulation does not prevent the submission of a further application for the approval of chlorpyrifos-methyl pursuant to Article 7 of Regulation (EC) No 1107/2009.

(19) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Non-renewal of the approval of the active substance

The approval of the active substance chlorpyrifos-methyl is not renewed.

Article 2

Amendment to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 112, on chlorpyrifos-methyl, is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing chlorpyrifos-methyl as an active substance by 16 February 2020.

Article 4

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall expire by 16 April 2020.

Article 5

Entry into force

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 January 2020.

For the Commission

The President

Ursula VON DER LEYEN

Chlorpyrifos-methyl
SANTE/11942/2019 Rev 2
6 December 2019

FINAL Renewal report for the active substance **chlorpyrifos-methyl**

finalised in the Standing Committee on Plants, Animals, Food and Feed
at its meeting on 6 December 2019
in view of the non-renewal of the approval of chlorpyrifos-methyl as an active substance
in accordance with Regulation (EC) No 1107/2009[1]

1. Procedure followed for the re-evaluation process

This renewal report has been established as a result of the evaluation of **chlorpyrifos-methyl**, in accordance with Regulation (EC) No 1107/2009[2] and Commission Implementing Regulation (EU) No 844/2012[3] following the submission of an application to renew the approval of this active substance expiring in January 2020.

Chlorpyrifos-methyl is a substance that was included in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market, by Commission Directive 2005/72/EC[4]. Chlorpyrifos-methyl is deemed to have been approved under Regulation (EC) No 1107/2009 and is listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011[5].

Separate applications for the renewal of the approval of chlorpyrifos-methyl were submitted by Dow AgroSciences Limited and by SAPEC Agro S.A. in accordance with Article 1 of Regulation (EU) No 844/2012.

The approval period of chlorpyrifos-methyl, originally expiring on 30 June 2016, has been extended three times in accordance with Article 17 of Regulation (EC) No 1107/2009:

- Commission Implementing Regulation No 762/2013[6] extended until 31 January 2018 the period of approval of chlorpyrifos-methyl as part of the organisation of the AIR3 renewal programme[7].

1 Renewal Report established in accordance with Art. 14 of Regulation (EU) No 844/2012; does not necessarily represent the views of the European Commission.
2 OJ L 309, 24.11.2009, p. 1.
3 OJ L 252, 19.9.2012, p. 26.
4 Commission Directive 2005/72/EC of 21 October 2005 amending Council Directive 91/414/EEC to include chlorpyrifos-methyl, chlorpyrifos-methyl-methyl, mancozeb, maneb, and metiram as active substances. OJ L 279, 22.10.2005, p. 63.
5 OJ L 153, 11.6.2011, p. 1.
6 OJ L 213, 8.8.2013, p. 14.
7 To ensure that ‘new’ data requirements under Commission Implementing Regulations (EU) No 283/2013 and 284/2013 would apply to the dossiers and to distribute work in a more manageable fashion for EFSA.

- Commission Implementing Regulation (EU) 2018/84[8] extended until 31 January 2019 the period of approval of chlorpyrifos-methyl to allow the completion of its review due to delays in the scientific assessment process.
- Commission Implementing Regulation (EU) 2018/1796[9] extended until 31 January 2020 the period of approval of chlorpyrifos-methyl to allow the completion of its review due to delays in the scientific assessment process.

Commission Implementing Regulation (EU) No 686/2012[10] designated the rapporteur Member States and the co-rapporteur Member States which had to submit the relevant renewal assessment reports and recommendations to the European Food Safety Authority (EFSA), for substances whose approval expired on or before 31 December 2018.

For chlorpyrifos-methyl the rapporteur Member State was Spain and the co-rapporteur Member State was Poland.

On 3 July 2017, Spain sent to the Commission and EFSA a draft renewal assessment report (RAR). This RAR included a recommendation concerning the decision to be taken with regards to the renewal of the approval of chlorpyrifos-methyl for the supported uses.

In accordance with Article 13 of Implementing Regulation (EU) No 844/2012, EFSA organised an intensive consultation of technical experts from Member States, to review the RAR and the comments received thereon (peer review). EFSA also launched a public consultation on the RAR.

In April 2019, EFSA convened an expert meeting to discuss certain elements related to mammalian toxicology and human health. The results of the expert discussions led the Commission to send, on 1 July 2019, a mandate to EFSA asking for a statement on the main findings of the assessment related to human health, and to indicate whether chlorpyrifos-methyl can be expected to meet the approval criteria which are applicable to human health as laid down in Article 4 of Regulation (EC) No 1107/2009.

On 31 July 2019, EFSA sent to the Commission a statement on the outcomes of the risk assessment for human health[11] for chlorpyrifos-methyl, in which it took the view that the active substance cannot be expected to meet the approval criteria. Furthermore, in September 2019, EFSA convened a second expert meeting to further discuss the read-across approach that it indicated required further discussion in its statement of 31 July 2019. On 11 November 2019, EFSA sent to the Commission an updated statement on the outcomes of the risk assessment for human health[12] for chlorpyrifos-methyl taking into account the outcome of the expert meeting held in September 2019.

According to the provisions of Article 14 of Implementing Regulation (EU) No 844/2012, the Commission referred a draft renewal report to the Standing Committee on Plants, Animals, Food and Feed, for examination on 22 October 2019. The draft renewal report was finalised in the meeting of the Standing Committee on 6 December 2019.

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8 OJ L 16, 20.1.2018, p. 8.

9 OJ L 294, 21.11.2018, p. 15.

10 OJ L 200, 27.7.2012, p. 5.

11 EFSA (European Food Safety Authority), 2019. Statement on the available outcomes of the human health assessment in the context of the pesticides peer review of the active substance chlorpyrifos-methyl. EFSA Journal 2019;17(5):5810 DOI: 10.2903/j.efsa.2019.5810.

12 EFSA (European Food Safety Authority), 2019. Updated statement on the available outcomes of the human health assessment in the context of the pesticides peer review of the active substance chlorpyrifos-methyl. EFSA Journal 2019;17(11):5908, 21 pp. https://doi.org/10.2903/j.efsa.2019.5908.

The present renewal report contains the conclusions of the final examination by the Standing Committee. Given the importance of the statement of EFSA and the RAR these documents are also considered to be part of this renewal report.

2. Purposes of this renewal report

This renewal report, including the documents referred to above, has been developed and finalised in support of **Commission Implementing Regulation (EU) 2020/17**[13] concerning the non-renewal of approval of chlorpyrifos-methyl as an active substance under Regulation (EC) No 1107/2009.

This renewal report will be made available to the public.

The information in this renewal report is, at least partly, based on information which is confidential and/or protected under the provisions of Regulation (EC) No 1107/2009. It is therefore recommended that this renewal report would not be accepted to support any registration outside the context of that Regulation, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this renewal report is based.

3. Overall conclusion in the context of Regulation (EC) No 1107/2009

The overall conclusion of the evaluation in relation to impacts on human health, based on the information available and the proposed conditions of use, is that:

- **the information available indicates that the approval criteria** as set out in Article 4(1) to (3) of Regulation (EC) No 1107/2009 are not satisfied as **concerns were identified** with regards to:

  - The genotoxic potential of chlorpyrifos-methyl, which cannot be ruled out when taking into account the concerns raised for chlorpyrifos concerning chromosome aberration and DNA damage that may also apply to chlorpyrifos-methyl[14]. In addition, the available scientific open literature on chlorpyrifos-methyl, although presenting some limitations, should be considered in a weight of evidence approach and raises some concerns about the potential for chlorpyrifos-methyl to damage DNA. Consequently, health based reference values cannot be established for chlorpyrifos-methyl and the dietary and non-dietary risk assessments cannot be conducted. This outcome was confirmed during the second expert meeting held in September 2019.
  - Developmental neurotoxicity (DNT) – the available DNT study on chlorpyrifos-methyl did not allow for a full assessment of effects on brain development, in particular since effects on cerebellum height could not be evaluated due to the lack of controls in females and a no observed adverse effects level 'NOAEL' for DNT could not be established. Since DNT effects were observed in the available developmental neurotoxicity on chlorpyrifos (adverse effects were seen at the lowest dose tested in rats and a NOAEL could not be established) concerns exist also for chlorpyrifos-methyl. Moreover, epidemiological evidence exists showing an association between exposure to chlorpyrifos

13 OJ L 7, 13.1.2020, p. 11.

14 Experts discussed the structural similarity between chlorpyrifos and chlorpyrifos-methyl and the similar toxicokinetics of the two molecules and agreed to read across between chlorpyrifos and chlorpyrifos-methyl.

and/or chlorpyrifos-methyl[15] during development and adverse neurodevelopmental outcomes in children.

- Based on the evidence for DNT, experts during the peer review suggested that classification of chlorpyrifos-methyl as toxic for the reproduction category 1B, H360D 'May damage the unborn child', in accordance with the criteria set out in Commission Regulation (EC) No 1272/2008[16] may be appropriate.

In conclusion, from the assessments made on the basis of the available information (RAR, comments thereon, EFSA statement, applicant comments on the EFSA statement and draft renewal report), no plant protection product containing the active substance chlorpyrifos-methyl is expected to satisfy the requirements laid down in Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011.

The approval of chlorpyrifos-methyl in accordance with Regulation (EC) No 1107/2009 should therefore not be renewed.

[15] Taking into account that the methodology used for determining exposure (measurement of the common metabolite, trichloro-pyridinol (TCP), in urine) cannot discriminate between exposure to chlorpyrifos and chlorpyrifos-methyl.

[16] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. (OJ L 353, 31.12.2008, p. 1).

EFSA Journal

STATEMENT

APPROVED: 8 November 2019
doi: 10.2903/j.efsa.2019.5908

Updated statement on the available outcomes of the human health assessment in the context of the pesticides peer review of the active substance chlorpyrifos-methyl

European Food Safety Authority (EFSA)

Abstract

In July 2019, the European Commission asked EFSA to provide a statement on the available outcomes of the human health assessment in the context of the pesticides peer review for the renewal of approval of the active substance chlorpyrifos-methyl conducted in accordance with Commission Implementing Regulation (EC) No 844/2012. Accordingly, EFSA delivered a statement to the Commission providing a summary of the main findings of the assessment related to human health following the pesticides peer review expert discussions in mammalian toxicology held between 1 and 5 April 2019, as well as EFSA's additional considerations, including whether the active substance can be expected to meet the approval criteria applicable to human health as laid down in Article 4 of Regulation (EC) No 1107/2009. A follow-up mandate was received to update the statement issued on 31 July 2019 with the outcome of the expert meeting in mammalian toxicology held on 5 September 2019 during which chlorpyrifos-methyl was rediscussed. The concerns identified in the previous statement are maintained.

Keywords: chlorpyrifos-methyl, pesticide, insecticide, peer review, human health assessment

Requestor: European Commission

Question Number: EFSA-Q-2019-00619

Correspondence: pesticides.peerreview@efsa.europa.eu

Acknowledgements: EFSA wishes to thank the following for the support provided to this scientific output: Antonio Hernandez and Susanne Hougaard Bennekou.

Note: This scientific output, approved on 8 November 2019, supersedes the previous output published on 28 August 2019 (EFSA, 2019).

Suggested citation: European Food Safety Authority (EFSA), 2019. Updated statement on the available outcomes of the human health assessment in the context of the pesticides peer review of the active substance chlorpyrifos-methyl. EFSA Journal 2019;17(11):5908, 21 pp. https://doi.org/10.2903/j.efsa.2019.5908

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Summary

Chlorpyrifos-methyl is an active substance covered by the third batch of the renewal programme for pesticides ('AIR3') in accordance with Commission Implementing Regulation (EU) No 844/2012.

Applications (June 2013) and supplementary dossiers (July 2015) for the renewal of approval of the active substance chlorpyrifos-methyl were submitted by Dow AgroSciences and by Sapec Agro SA (currently Ascenza Agro S.A.).

An initial evaluation of the dossiers was provided by the rapporteur Member State (RMS) Spain in the Renewal Assessment Report (RAR) which was submitted to the European Food Safety Authority (EFSA) in July 2017. Subsequently, EFSA initiated a peer review of the pesticides risk assessment on the RMS evaluation in line with the provisions of Commission Implementing Regulation (EU) No 844/2012.

The commenting period was completed and included a public consultation on the RAR. Following evaluation of the comments received as well as the additional information provided by the applicants in response to a request in accordance with Article 13(3) of Regulation (EU) No 844/2012, a meeting of experts from EFSA and Member States, including relevant experts from the EFSA Panel on Plant Protection Products and their Residues (PPR Panel), took place in April 2019 to discuss certain elements related to mammalian toxicology.

After the Pesticides Peer Review Experts' meeting in April 2019, EFSA reconsidered the read-across approach applied for the hazard identification of chlorpyrifos-methyl after a full comparison of the available toxicological data: it was agreed to rediscuss this issue in an additional 'ad hoc' experts' meeting since EFSA considered that the outcome of the discussions might had an impact on the assessment of specific studies, on the possibility to consider if criteria for classification may be met, as well as on the setting of reference values for chlorpyrifos-methyl. EFSA therefore organised an expert meeting, which took place on 5 September 2019.

On 31 July 2019, upon mandate of the European Commission, EFSA delivered a statement containing a summary of the main outcome of the assessment related to mammalian toxicology and human health following the Pesticides Peer Review Expert discussions in mammalian toxicology held between 1 and 5 April 2019, where the approach taken by the experts for chlorpyrifos-methyl was largely based on its structural similarity with chlorpyrifos. In addition, EFSA included considerations whether the active substance can be expected to meet the approval criteria which are applicable to human health as laid down in Article 4 of Regulation (EC) No 1107/2009. During the experts' meeting held in September 2019, the majority of experts confirmed the conclusions reached at the April 2019 meeting.

The available regulatory genotoxicity data set submitted for chlorpyrifos-methyl did not show any concern. The experts highlighted that very limited literature data were retrieved specifically for chlorpyrifos-methyl. Considering also the read-across discussion, most experts decided to precautionary apply to chlorpyrifos-methyl the same conclusions as for chlorpyrifos. Therefore, the experts concluded that the genotoxicity potential of chlorpyrifos-methyl remains as unclear as that of chlorpyrifos.

As for the developmental neurotoxicity (DNT), a DNT study was available, which did not show relevant effects, however, it had significant limitations related to the few controls available, making a reliable statistical analysis not possible. Therefore, all the experts, but one, agreed that, the DNT study on chlorpyrifos-methyl being inconclusive, a specific DNT no observed adverse effect level (NOAEL) could not be set and the lowest observable adverse effect level (LOAEL) of 0.3 mg/kg body weight (bw) per day derived from the data on chlorpyrifos (study from 1998; Spain, 2019b) could be conservatively applied to chlorpyrifos-methyl.

Based on the above, also in the case of chlorpyrifos-methyl, the experts agreed that no reference values could be set, a fact that made it impossible to perform a risk assessment for consumers, operators, workers, bystanders and residents.

The experts conservatively applied the same approach as for chlorpyrifos, considering that chlorpyrifos-methyl would also meet the criteria for classification as toxic for reproduction category 1B (regarding developmental toxicity). EFSA expresses some reservations on this approach since such a conservative approach may not apply to classification and labelling.

Based on the above, it is considered that the approval criteria which are applicable to human health as laid down in Article 4 of Regulation (EC) No 1107/2009 are not met.

Table of contents

1. Introduction

Chlorpyrifos-methyl is an active substance covered by the third batch of the renewal programme for pesticides ('AIR3') in accordance with Commission Implementing Regulation (EU) No 844/2012[1].

Applications (June 2013) and supplementary dossiers (July 2015) for the renewal of approval of the active substance chlorpyrifos-methyl were submitted by Dow AgroSciences and by Sapec Agro SA (currently Ascenza Agro S.A.). The rapporteur Member State (RMS) is Spain and the co-rapporteur Member State (co-RMS) is Poland.

An initial evaluation of the dossiers was provided by the RMS in the Renewal Assessment Report (RAR) which was submitted to the European Food Safety Authority (EFSA) on 3 July 2017 (Spain, 2017). On 18 October 2017, EFSA initiated a peer review of the pesticides risk assessment on the RMS evaluation, by dispatching the RAR to the Member States and applicants for consultation and comments in line with the provisions of Commission Implementing Regulation (EU) No 844/2012. In addition, a public consultation was also conducted.

After the completion of the commenting period, and following a comment evaluation phase, on 4 July 2018, EFSA requested the applicants to provide certain additional information related to all areas of the assessment including mammalian toxicology in accordance with Article 13(3) of Regulation (EU) No 844/2012, which was evaluated by the RMS and presented in an updated RAR (Spain, 2019a). Subsequently, in April 2019, a meeting of experts from EFSA and Member States, including relevant experts from the EFSA PPR Panel, took place to discuss certain elements related to mammalian toxicology.

By means of the mandate received on 1 July 2019 from the European Commission, prior to completion of the full peer review process, EFSA was requested to provide a statement with an overview of the available outcomes of the human health assessment in the context of the peer review of chlorpyrifos-methyl.

Accordingly, on 31 July 2019, EFSA delivered a statement outlining the main findings of the assessment related to mammalian toxicology and human health following the pesticides peer review expert discussions in mammalian toxicology held in April 2019, including EFSA's additional considerations and an indication whether the active substance can be expected to meet the approval criteria which are applicable to human health as laid down in Article 4 of Regulation (EC) No 1107/2009[2].

After the Pesticides Peer Review Experts' meeting in April 2019, EFSA reconsidered the read-across approach applied for the hazard identification of chlorpyrifos-methyl after a full comparison of the available toxicological data: it was agreed to rediscuss this issue in an additional experts' meeting. EFSA considered that the outcome of the discussions might had an impact on the assessment of the specific studies, on the possibility to consider if criteria for classification may be met, as well as on the setting of reference values for chlorpyrifos-methyl. EFSA therefore organised an expert meeting which took place on 5 September 2019, in particular to reconsider the read-across with chlorpyrifos, the genotoxicity potential and the possibility of setting of reference values, taking also into account the comments submitted by the applicants on the previous statement (EFSA, 2019).

Following rediscussion of the substance, EFSA updated its statement issued on 31 July 2019 to complete the assessment related to human health following the two rounds of expert meetings.

The list of endpoints for the active substance and the representative formulations assessed in the context of the peer review with regard to the impact on human health is available in Appendix A.

1.1. Background and Terms of Reference as provided by the requestor

On 1 July 2019 EFSA was mandated by the European Commission to provide a statement with an overview on the available outcomes of the human health assessment in the context of the pesticides peer review for the renewal of approval of the active substance chlorpyrifos-methyl conducted in accordance with Commission Implementing Regulation (EU) No 844/2012.

[1] Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 252, 19.9.2012, p. 26.

[2] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1.

In addition, EFSA was requested to indicate, whether the active substance chlorpyrifos-methyl can be expected to meet the approval criteria which are applicable to human health as laid down in Article 4 of Regulation (EC) No 1107/2009.

Accordingly, EFSA delivered a statement to the Commission on 31 July 2019. Following re-discussion of the substance in the Pesticides Peer Review Experts' meeting on mammalian toxicology held on 5 September 2019, by means of a follow up mandate received on 24 September 2019, EFSA was requested to update the statement issued on 31 July 2019 to take into account the outcome of that expert meeting. EFSA was requested to deliver the updated statement by 31 October 2019 for further consideration during the decision-making phase.

2. Assessment

2.1. Mammalian toxicity

The toxicological profile of the active substance chlorpyrifos-methyl was discussed at the Pesticides Peer Review Experts' Meetings 01 (April 2019) and 11 (September 2019) and assessed based on the following guidance documents: SANCO/10597/2003-rev. 10.1 (European Commission, 2012), Guidance on dermal absorption (EFSA PPR Panel, 2012), ECHA/EFSA Guidance for the identification of endocrine disruptors (ECHA and EFSA, 2018) and Guidance on the application of the classification, labelling and packaging (CLP) Criteria (ECHA, 2017).

The hazard assessment of chlorpyrifos-methyl discussed in the Pesticides Peer Review Experts' meeting in April 2019 was largely based on the structural similarity with chlorpyrifos. After the experts' meeting, EFSA considered to rediscuss the read-across approach applied for the hazard identification in a dedicated experts' meeting, which took place in September 2019.

It was recognised that in chlorpyrifos-methyl, although the chemical structure is similar to chlorpyrifos, the different length of the two alkoxy groups attached to the phosphorus atom (methoxy for chlorpyrifos-methyl and ethoxy for chlorpyrifos) has uneven consequences on their interaction with serine hydrolases. In addition, differences in the steric orientation of the moiety attached to the enzyme between chlorpyrifos and chlorpyrifos-methyl could affect the stability of the phosphorylated enzyme leading to variations in the rates of regeneration and ageing of the inhibited AChE (acetylcholinesterase). Differences in the rates of reactivation or ageing due to the structural differences could contribute to the toxicity differences of the two compounds.

Besides, both compounds have different acute toxicity (LD_{50} chlorpyrifos-methyl > LD_{50} chlorpyrifos), slightly different potency upon short-term exposure (being chlorpyrifos-methyl ten times less potent than chlorpyrifos in rats and dogs), but the same level of toxicity upon long-term exposure likely due to cumulative AChE inhibition over time. In addition to inhibition of the nervous system and RBC AChE, observed after administration of both chlorpyrifos and chlorpyrifos-methyl, chlorpyrifos-methyl presented additional critical effects in short-term and long-term toxicity studies on the adrenals.

Regarding the technical specifications of the substance placed on the market by either of the two applicants, they are not supported by the toxicological assessment since most impurities were not tested at the levels in the technical specification. However, regarding the toxicological relevance of the impurities, considering the toxicological profile of chlorpyrifos-methyl, as discussed in the April 2019 peer review meeting, it is not expected that the impurities present in the technical specification would have the potential to add additional hazard established for the parent. Two impurities (sulfotemp and sulfotemp ester) have been considered as toxicologically relevant by the European Commission (European Commission, 2012) who established a maximum level of 5 g/kg. Therefore, their maximum levels in the newly proposed technical specification of 5 and 3 g/kg, respectively, are in agreement with these requirements. The analytical methods used in the toxicological studies were not available for most of the studies, representing a concern in particular for the genotoxicity assessment (based on regulatory studies) but not for the critical findings which were retrieved for chlorpyrifos from the published literature (such as the Columbia Center for Children's Environmental Health (CCCEH) study).

In rats, chlorpyrifos-methyl is extensively absorbed after oral administration, it is widely distributed, extensively metabolised through de-methylation, hydrolysis and conjugation, and eliminated mostly through urine within 72 h. An *in vitro* metabolism study indicates that the metabolic profiles in rat and human are qualitatively similar, but different in quantitative terms. Chlorpyrifos-methyl metabolism rate in humans is lower compared to that of rats *in vitro*.

In the acute toxicity studies, chlorpyrifos-methyl showed low toxicity when administered by the oral, dermal or inhalation routes. The substance did not elicit a potential for skin or eye irritation, or for phototoxicity, but was shown to be a skin sensitiser. Accordingly, chlorpyrifos-methyl is classified according to the CLP criteria as Skin Sens 1, H317 'may cause an allergic skin reaction', as established in Annex VI of Regulation (EC) No 1272/2008[3] regarding human health.

At the April 2019 Peer Review Experts' meeting, the experts considered[4] that criteria for classification of chlorpyrifos-methyl as acute neurotoxicant STOT SE 1, in accordance with the criteria set out in Regulation (EC) No 1272/2008, may be met, based on the available toxicological data set.

The main effect following short- to long-term repeated oral administration of chlorpyrifos-methyl was the inhibition of acetylcholinesterase (AChE) activity, which, at high-dose levels, was leading to endogenous cholinergic overstimulation resulting in typical cholinergic symptoms. Erythrocyte (red blood cell (RBC)) AChE inhibition was the critical effect in all studies conducted with rats, mice and dogs. Additionally, the adrenals (increased weight, hypertrophy and vacuolation of cells of the zona fasciculata) were identified as target organ of chlorpyrifos-methyl in rats. The relevant no observed adverse effect level (NOAEL) for short-term toxicity was 0.65 mg/kg body weight (bw) per day from the 28-day toxicity study in mice and 0.1 mg/kg bw per day for long-term exposure from the 2-year study in rats based on significant decrease of RBC AChE activity in both studies and adrenal toxicity upon long-term exposure in rats only. No evidence for a carcinogenicity potential was found upon chlorpyrifos-methyl administration in rats or mice.

No information has been provided on the immunotoxic potential of chlorpyrifos-methyl, therefore a data gap was identified.

2.2. Genotoxicity

During the Pesticides Peer Review 01 Experts' meeting in April 2019, the experts discussed the *in vitro* and *in vivo* regulatory studies provided in the RAR:

- gene mutation: the experts considered that the results from the three bacterial and the two mammalian gene mutations assays overall showed that chlorpyrifos-methyl does not induce gene mutations *in vitro*.
- chromosome aberration *in vitro*: the results of two different assays were discussed and chlorpyrifos-methyl was considered positive in the presence of rat liver metabolic activation system (S9) in Chinese hamster ovary (CHO) cells but negative in rat lymphocytes both in the absence and in the presence of S9.
- unscheduled DNA synthesis (UDS): one *in vitro* study was submitted and produced negative results.
- *in vivo* studies in somatic cells (mouse bone marrow micronucleus test): the two studies available in the dossier and evaluated in the RAR showed negative findings.
- *in vivo* rat liver DNA repair test (UDS): chlorpyrifos-methyl did not damage DNA in rat liver.

The regulatory data package showed positive findings just in one *in vitro* chromosome aberration study in CHO cells in the presence of S9. Overall, the data package did not show any concern and the experts discussed whether DNA damage was sufficiently covered by the available studies. It was also noted that there is no public literature available for chlorpyrifos-methyl with regard to the genotoxic potential, while several publications were available for chlorpyrifos instead. The experts discussed the structural similarity between chlorpyrifos and chlorpyrifos-methyl and the similar toxicokinetics of the two molecules and agreed to read across between chlorpyrifos and chlorpyrifos-methyl. Since concerns were raised for chlorpyrifos with regard to chromosome aberration, DNA damage (oxidative stress and topoisomerase II inhibition), the experts concluded that a data gap is present for chlorpyrifos-methyl with regard to DNA damage. All the experts agreed that these uncertainties should be considered in the risk assessment of chlorpyrifos-methyl as well, i.e. it cannot be excluded that chlorpyrifos-methyl may have DNA damaging potential.

The regulatory database submitted for chlorpyrifos-methyl did not show any specific concern; very limited literature data on chlorpyrifos-methyl, including its genotoxicity potential were retrieved. Therefore, the experts concluded that also the genotoxicity potential of chlorpyrifos-methyl remains unclarified as that of chlorpyrifos. It is noted however that, after the experts' meeting, EFSA reconsidered the read-across approach applied by the experts and this has been rediscussed in the

[3] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.

[4] It should be noted that classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.

Pesticides Peer Review Experts' meeting 11 on 5 September 2019. In particular, the experts took into consideration the differences/similarities in chemical structure between the two molecules, their interaction with serine hydrolases and the mammalian toxicological endpoints in acute, short- and long-term studies. Regarding the molecular structure, the experts considered that the differences between chlorpyrifos and chlorpyrifos-methyl (the presence of the ethyl group instead of the methyl) would not justify a difference in the genotoxicity potential between the two molecules. However, this minor structural difference may contribute to quantitative differences in the acetylcholinesterase (AChE)-inhibitory effect (and likely other serine- hydrolases). In particular, organophosphates (OPs) with a P = O moiety bind covalently to the serine hydrolase residue in the active site of AChE; the phosphorylated enzyme cannot hydrolyse the neurotransmitter acetylcholine. Once phosphorylated, the enzyme may spontaneously reactivate thus regenerating the enzyme (a very slow rate process) or lose one of the two O,O-dialkyl groups of the phosphate moiety leaving a hydroxyl group in its place and an aged AChE that can no longer be reactivated ('ageing' process). AChE ageing occurs much faster for dimethyl OPs poisoning than for diethyl OPs poisoning.

In addition, the RMS conducted an additional literature search in view of the peer review meeting of September 2019 and found some new public literature studies on chlorpyrifos-methyl (Pandey et al., 2011; Singh et al., 2012; Zhou et al., 2012; Shin et al., 2014, 2015; Hayat et al., 2019; Yang et al., 2019) providing some evidence along the same line as those considered for chlorpyrifos. All experts agreed that the genotoxicity data package in regulatory studies for chlorpyrifos-methyl is complete and overall negative. However, the majority of experts considered that the public literature indications, although presenting some limitations (e.g. literature search methodology, no guideline compliant studies, no data reported for positive controls, etc.), should be considered in a weight-of-evidence approach and raised concerns over the potential for DNA damage for chlorpyrifos-methyl, by adopting a conservative approach.

EFSA notes that US EPA concluded that chlorpyrifos-methyl is likely less toxic than chlorpyrifos-ethyl based on a side-by-side comparison of cholinesterase inhibition levels in existing studies. US EPA has also concluded that given the structural similarities between the two chemicals, toxicity data using chlorpyrifos-ethyl could be used to address data gaps for chlorpyrifos-methyl (https://www.govinfo.gov/content/pkg/FR-2004-07-07/pdf/04-15209.pdf).

The previous conclusions regarding a concern for genotoxicity of chlorpyrifos-methyl raised during the April 2019 expert's meeting were therefore confirmed by the majority of experts, and the genotoxic potential of chlorpyrifos-methyl is considered inconclusive. No reference values could be set.

2.3. Reproductive/developmental toxicity and endocrine disruption

In a two-generation reproductive toxicity study in rats, chlorpyrifos-methyl did not affect the reproductive performance up to the highest dose of 10 mg/kg bw per day tested, while RBC AChE inhibition and adrenal toxicity were the critical effects related to parental toxicity with a NOAEL of 1 mg/kg bw per day; in this study, RBC AChE inhibition was the critical effect in pups with a NOAEL of 3 mg/kg bw per day. Developmental toxicity was investigated in rats and rabbits. Erythrocyte AChE and brain AChE inhibition were the critical effects identified regarding maternal toxicity in rats, while no adverse effect was observed in rabbits. No developmental adverse effects were observed in either rats or rabbits.

The availability of a multigenerational study conducted according to the most recent test guideline showed no evidence for endocrine-mediated adversity for the androgen, oestrogen and steroidogenesis pathways at dose levels not producing signs of overt toxicity (AChE inhibition). The same conclusion was reached for the thyroid endocrine-mediated pathway. On this basis, it was concluded that mechanistic studies are not required to assess the endocrine disruption potential of chlorpyrifos-methyl following the guidance for identification of endocrine disruptors (ECHA and EFSA, 2018). On this basis, all experts agreed that chlorpyrifos-methyl is not an endocrine disruptor in humans.

2.4. Developmental neurotoxicity (DNT)

During the Pesticides Peer Review 01 Experts' meeting in April 2019, Member State experts and two experts from EFSA's Panel on Plant Protection Products and their Residues (PPR Panel), discussed the available data regarding developmental neurotoxicity (DNT) of chlorpyrifos-methyl. They took into consideration and discussed in detail: (a) the DNT study in rats from 2015 (Spain, 2019a); (b) public literature presented in the systematic review provided by the applicants; (c) additional literature provided by the experts or during the commenting period.

In the DNT study in rats, pregnant rats were exposed to different levels of chlorpyrifos-methyl (0, 2, 10 and 50 mg/kg bw per day) from day 6 of gestation until lactation day 21. The only effects observed were test substance-related and statistically significant lower RBC AChE and brain AChE activity values compared to the control group in maternal generation at 10 and 50 mg/kg bw per day. Regarding offspring toxicity, pup growth, survival and clinical conditions were unaffected; according to the RMS, no test substance-related effects were observed on body weights, body weight gains, attainment of developmental landmarks, detailed clinical observations, motor activity, auditory startle, learning and memory, macroscopic examinations and measurements, neuropathology or brain morphometry at any dietary concentration at any age. However, it should be noted that a significant decrease in the height of cerebral hemisphere on post-natal day (PND) 72 was observed in males at the top dose. In addition, a statistically significant inhibition of RBC AChE was observed in males at 50 mg/kg bw per day on PND 21. At the experts' meeting in April 2019, all the experts agreed to set a maternal NOAEL at 2 mg/kg bw per day based on decreased RBC AChE and brain AChE activity. The experts noted that, despite the study was performed according to current OECD 426 guideline (OECD, 2007), the cerebellum height in pups (considered the most sensitive endpoint in the DNT study performed with chlorpyrifos) could not be evaluated since just three control samples in females were available on PND 72. Therefore, considering the low statistical power, no reliable analysis could be performed, representing a major deviation from the study protocol. No changes in cerebellum height were reported for males and females at PND 21 and for males at PND 72, but the measurement was only available at the highest dose. In addition, it should be noted that cerebellum height was not corrected by brain weight and reanalysis of the data corrected for brain weight would be useful to compare also the results presented by Mie et al. (2018) in the case of chlorpyrifos, although recognising that statistical analysis could not be performed in the absence of sufficient control samples in females.

All the experts, but one, agreed that, the DNT study on chlorpyrifos-methyl being inconclusive, a DNT NOAEL could not be set and the LOAEL of 0.3 mg/kg bw per day derived from the data on chlorpyrifos (study from 1998; Spain 2019b) could be conservatively applied to chlorpyrifos-methyl. During the Pesticides Peer Review Experts' meeting in September 2019, the experts confirmed that the genotoxic potential of chlorpyrifos-methyl is inconclusive and therefore no toxicological reference values could be set. Therefore, the developmental neurotoxicity potential of chlorpyrifos-methyl was not further discussed. However, as already pointed out during the experts' meeting in April 2019, the RMS reiterated that several parameters related to cerebellum were not reported in the DNT study due to the insufficient number of data. In more detail, the RMS presented the raw data on cerebellum height in the controls and high dose treated pups on both PND 21 and 72: it was noted that on PND 21, the number of samples available in both the controls and high dose treated males was quite low (n = 4 and 2, respectively, instead of 10 samples, as foreseen) and in females, it was limited (n = 7 and 5, respectively); on PND 72, the number of samples available for control and high dose treated males was quite high (n = 9 and 9, respectively), while insufficient in females (n = 1 – not 3 as erroneously indicated in the experts' meeting in April 2019 – and 3, respectively). The applicant Ascenza Agro S.A. acknowledged that there were insufficient data to evaluate the height of cerebellum on PND 72 control females and proposed to combine males and females together (to have 10 control animals and 12 high dose animals in total); however, although useful, it was noted that this approach represents a deviation from the protocol. By combining the data, no effect on cerebellum height was shown; in addition, Ascenza Agro S.A. considered that the data of cerebellum height corrected by brain weight were not necessary since brain weight data were not significantly different. The RMS also indicated that the data on measurement of the base of the lobule 9 of cerebellum on PND 72 in females were missing for all control samples and in 9 out of 10 samples. The experts agreed that particularly the insufficient number of data related to cerebellum height should be regarded as an important deficiency, since the measurement of cerebellum height was considered a critical parameter to assess developmental neurotoxicity for chlorpyrifos.

Furthermore, according to the RMS, the relevance of the significant difference observed in the height of cerebral hemisphere in 50 mg/kg bw per day treated males at PND 72 when compared to control males cannot be discarded just because no other signs had been observed. Especially considering that the indications from the initial experimental design specified that the correct follow-up after this observation should had been to measure the same parameter in the low and intermediate dose treated animals. However, this was not applied in this case. Therefore, these deficiencies lead the RMS to consider this study acceptable with reservations.

The experts discussed the epidemiological evidence showing associations between chlorpyrifos and chlorpyrifos-methyl exposure during neurodevelopment and adverse health effects (attention deficit/ hyperactivity disorders, decrease in intelligent quotient and working memory, etc.). In particular, three main birth cohort studies were considered: the Columbia Center for Children's Environmental Health (CCCEH) study (US EPA, 2016), the Center for the Health Assessment of Mothers and Children of Salinas (CHAMACOS) (Castorina et al., 2010; Marks et al., 2010) and Mt. Sinai study (Sebe et al., 2005). Using different biomarkers of exposure, these studies show that prenatal exposure to organophosphates (OPs) produces a consistent pattern of early cognitive and behavioural deficits (Rauh et al., 2012). The experts discussed also other epidemiological evidence from the public literature. The majority of the experts considered that the results from some of these studies (mainly from CCCEH study, Rauh et al., 2012; Engel et al., 2011; Silver et al., 2017) contribute to the evidence of DNT effects in humans due to the exposure to chlorpyrifos and chlorpyrifos-methyl and occurring at doses lower than that causing 20% inhibition of AChE. Therefore, this would represent a concern to be taken into consideration for the risk assessment. In addition, it should be noted that in the CHAMACOS study measurement of trichloro-pyridinol (TCP) in urine,[5] common metabolite of both chlorpyrifos and chlorpyrifos-methyl contributed to the evidence of DNT effects in humans due to the exposure to chlorpyrifos and/or chlorpyrifos-methyl. The applicant Ascenza Agro S.A. indicated that no epidemiological studies are available for chlorpyrifos-methyl; however, as indicated above, the measurement of TCP in urine cannot discriminate between the selective exposure to chlorpyrifos or chlorpyrifos-methyl.

Taking into consideration the DNT study outcome (reduction in cerebellum height for chlorpyrifos – that could not be explained by the maternal AChE inhibition), the epidemiological evidence showing an association between chlorpyrifos/chlorpyrifos-methyl exposure during development and neurodevelopmental outcomes, and the overall analysis of the published literature (*in vivo*, *in vitro* and human data), the experts indicated that chlorpyrifos-methyl, based on the available toxicological data set, may be expected to meet the criteria for classification[4] as toxic for the reproduction, REPRO 1B, H360D 'May damage the unborn child' in accordance with the criteria set out in Regulation (EC) No 1272/2008. EFSA expresses some reservations on this approach, as based on the current experience the criteria for classification would normally be based on the specific effects recorded in good quality data. However, the European Chemicals Agency (ECHA) will be responsible for the final decision.

3. Conclusions

During the Pesticides Peer Review 01 Experts' meeting in April 2019, all the experts, but one, agreed that the Point of Departure (PoD) for setting the reference values for chlorpyrifos-methyl, in the absence of data on cerebellum height corrected by brain weight in the DNT study with chlorpyrifos-methyl (2015; Spain, 2019a), should be, as a conservative assumption, the DNT LOAEL of 0.3 mg/kg bw per day from the DNT study on chlorpyrifos (1988; Spain, 2019b), based on the severity of the effects, until there is no evidence for the contrary. The subject has been rediscussed in the Pesticides Peer Review Experts' meeting in September 2019.

In the peer review meeting in April 2019, the experts concluded that:

- the concerns raised for chlorpyrifos with regard to chromosome aberration and DNA damage (oxidative stress and topoisomerase II inhibition) may apply to chlorpyrifos-methyl, resulting in an unclear genotoxicity potential;
- the DNT effects observed at the lowest dose tested in the DNT study with chlorpyrifos (decrease in cerebellum height corrected by brain weight), indicating a health concern, would be conservatively applied to chlorpyrifos-methyl;
- the epidemiological evidence supports the developmental neurological outcomes in children for both chlorpyrifos and chlorpyrifos-methyl.

Overall, considering the unclear genotoxicity effects reported with chlorpyrifos and the bridging with chlorpyrifos-methyl, the experts agreed that no toxicological reference values could be established for chlorpyrifos-methyl. Furthermore, additional significant uncertainties were linked to the concerns

[5] Post-meeting note: it is also possible that a significant portion of TCP present in urine samples can result from direct intake of TCP preformed in the environment and not as a result of chlorpyrifos or chlorpyrifos-methyl ingestion (Eaton et al., 2008).

identified in the DNT study with chlorpyrifos, which was considered applicable to chlorpyrifos-methyl, supported by the available epidemiological evidence related to developmental neurological outcomes in children. Due to the lack of toxicological reference values, a risk assessment for consumers, operators, workers, bystanders and residents cannot be conducted. This issue represents a critical area of concern for chlorpyrifos-methyl.

Based on the above and also considering the recorded toxicological effects meeting the criteria for classification as toxic for reproduction category 1B (regarding developmental toxicity), it is considered that the approval criteria which are applicable to human health as laid down in Article 4 of Regulation (EC) No 1107/2009, are not met. EFSA expresses some reservations on this approach since such a conservative approach may not apply to classification and labelling.

The hazard assessment of chlorpyrifos-methyl discussed in the Pesticides Peer Review Experts' meeting in April 2019 was largely based on the structural similarity with chlorpyrifos. It is noted that, after the experts' meeting, EFSA reconsidered the read-across approach applied for the hazard identification after a full comparison of the available toxicological data: it was agreed to rediscuss this issue in an additional experts' meeting. EFSA therefore organised an expert meeting which took place on 5 September 2019, in particular to reconsider the read across with chlorpyrifos, the genotoxicity potential and the possibility of setting of reference values, taking also into account the comments submitted by the applicants on the previous statement (EFSA, 2019).

Since Member State experts confirmed that the genotoxic potential of chlorpyrifos-methyl is inconclusive, it was also confirmed that no toxicological reference values could be set.

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Glossary and abbreviations

AAOEL	acute acceptable operator exposure level
AChE	acetylcholinesterase
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
AUC	area under the blood concentration/time curve
bw	body weight
CCCEH	Columbia Center for Children's Environmental Health
CHAMACOS	Center for the Health Assessment of Mothers and Children of Salinas
CHO	Chinese hamster ovary
CLP	classification, labelling and packaging
Cmax	concentration achieved at peak blood level
CNS	central nervous system

co-RMS	co-rapporteur Member State
DNT	developmental neurotoxicity
EATS	oestrogen, androgen, thyroid, steroidogenesis
ECHA	European Chemicals Agency
HGPRT	hypoxanthine-guanine phosphoribosyl transferase
LC50	lethal concentration, median
LD50	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
OP	organophosphate
PND	post-natal day
PoD	point of departure
ppb	parts-per-billion (10^9)
PPR panel	EFSA's Panel on Plant Protection Products and their Residues
QSAR	quantitative structure–activity relationship
RAR	Renewal Assessment Report
RBC	red blood cells
RMS	rapporteur Member State
S9	rat liver metabolic activation system
t1/2	half-life (define method of estimation)
UDS	unscheduled DNA synthesis
US EPA	United States Environmental Protection Agency

Appendix A – List of end points for the active substance and the representative formulations with regard to impact on human health

Impact on human and animal health

Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) No 283/2013, Annex Part A, point 5.1)

Rate and extent of oral absorption/systemic bioavailability	> 80% urinary excretion within 72 h, following single and repeat dose administration
Toxicokinetics	C_{max}: 1.12 µg/mL (m) and 1.39 µg/mL (f) 6h and 4h after administration, respectively Plasma $t_{1/2}$: 6.6 hours (m) and 7.8 hours (f) AUC_{last} 13.9 h*µg/ml (m) and 17.4 h*µg/ml (f)
Distribution	Widely distributed but at low level, < 1 mg/kg (liver)
Potential for bioaccumulation	No potential for accumulation
Rate and extent of excretion	Almost complete within 72 h, mainly via urine in both single dose and repeated dose studies
Metabolism in animals	Extensively metabolied Through de-methylation, hydrolysis, conjugation Major metabolites included TCP and des-methyl chlorpyrifos-methyl (DEM)
In vitro metabolism	Metabolic profiles in rat and human similar qualitatively, but constantly different in quantitative terms regarding parent compound, TCP and DEM. Chlorpyrifos-methyl metabolism rate in human *in vitro* is lower compared to the rat
Toxicologically relevant compounds (animals and plants)	Chlorpyrifos-methyl
Toxicologically relevant compounds (environment)	Chlorpyrifos-methyl

Acute toxicity (Regulation (EU) No 283/2013, Annex Part A, point 5.2)

Rat LD_{50} oral	5 000 mg/kg bw	
Rat LD_{50} dermal	> 2 000 mg/kg bw	
Rat LC_{50} inhalation	> 0.67 mg/L air per 4 h max attainable concentration (whole-body)	
Skin irritation	Non-irritant	
Eye irritation	Non-irritant	
Skin sensitisation	Sensitiser (GMPT)	H317
Phototoxicity	Not phototoxic	

LD50: lethal concentration, median; LC50: lethal dose, median; bw: body weight.

Short-term toxicity (Regulation (EU) No 283/2013, Annex Part A, point 5.3)

Target organ / critical effect	Rat: Nervous system/RBC and brain AChE inhibition Adrenals: ↑ weight, hypertrophy and vacuolation of cells of the zona fasciculata Mouse: RBC AChE inhibition Dog: RBC and brain AChE inhibition	
Relevant oral NOAEL	28-day, mouse: 0.65 mg/kg bw per day 90-day, rat: 1 mg/kg bw per day 90-day and 2-year, dog: 1 mg/kg bw per day	
Relevant dermal NOAEL	28-day, rat: LOAEL 10 mg/kg bw per day, based on slight vacuolation in adrenals	
Relevant inhalation NOAEL	14-day, rat: NOAEC 0.1 mg/m^3 (18 ppb, the highest dose tested)	

NOAEL: no observed adverse effect level; RBC: red blood cells; AChE: acetylcholinesterase; bw: body weight; LOAEL: lowest observable adverse effect level.

Genotoxicity (Regulation (EU) No 283/2013, Annex Part A, point 5.4)

In vitro studies	Bacterial gene mutation tests: 3 tests negative Mammalian cells gene mutation tests: 2 tests negative (CHO/HGPRT) Chromosome aberration tests: – 1 positive +S9 (in CHO cells) – 1 negative (rat lymphocytes) UDS: negative (primary rat hepatocytes)	
In vivo studies	Micronucleus tests: 2 tests negative UDS: 1 test negative (primary rat hepatocytes) DNA damage: not covered by the available studies with chlorpyrifos-methyl; since concerns were raised for chlorpyrifos with regard to DNA damage (e.g. topoisomerase II inhibition), it could not be excluded that chlorpyrifos-methyl can produce DNA damage	
Photomutagenicity	Not required	
Potential for genotoxicity	DNA damaging potential cannot be ruled out for chlorpyrifos-methyl (based on data available on chlorpyrifos, with a closely related chemical structure)	

UDS: unscheduled DNA synthesis; CHO: Chinese hamster ovary; HGPRT: hypoxanthine-guanine phosphoribosyl transferase.

Long-term toxicity and carcinogenicity (Regulation (EU) No 283/2013, Annex Part A, point 5.5)

Long-term effects (target organ/critical effect)	Rat: adrenals (vacuolation of the zona fasciculata); RBC AChE inhibition Mouse: RBC and brain AChE inhibition	
Relevant long-term NOAEL	0.1 mg/kg bw per day (2-year rat) 0.4 mg/kg bw per day (18-month, mouse)	
Carcinogenicity (target organ, tumour type)	No carcinogenic potential	
Relevant NOAEL for carcinogenicity	Rat: 50 mg/kg bw per day (highest dose tested in the 2-year study) Mouse: 40 mg/kg bw per day (highest dose tested in the 18-month study)	

NOAEL: no observed adverse effect level; RBC: red blood cells; AChE: acetylcholinesterase; bw: body weight.

Reproductive toxicity (Regulation (EU) No 283/2013, Annex Part A, point 5.6)

Reproduction toxicity

Reproduction target / critical effect	Parental toxicity: RBC AChE inhibition, adrenal glands (increased weight and histopathology (cell vacuolation in the zona fasciculata) No reproductive adverse effects Offspring's toxicity: RBC AChE inhibition.	
Relevant parental NOAEL	1 mg/kg bw per day	
Relevant reproductive NOAEL	10 mg/kg bw per day (highest dose tested)	
Relevant offspring NOAEL	3 mg/kg bw per day	

NOAEL: no observed adverse effect level; RBC: red blood cells; AChE: acetylcholinesterase; bw: body weight.

Developmental toxicity

Developmental target / critical effect	Rat: Maternal toxicity: RBC and brain AChE inhibition. Developmental toxicity: no adverse effects observed (AChE was not investigated) Rabbit: Maternal and developmental toxicity: no adverse effects observed	
Relevant maternal NOAEL	Rat: 1 mg/kg bw per day Rabbit: 16 mg/kg bw per day (highest dose tested)	
Relevant developmental NOAEL	Rat: 50 mg/kg bw per day (highest dose tested) Rabbit: 16 mg/kg bw per day (highest dose tested)	

NOAEL: no observed adverse effect level; RBC: red blood cells; AChE: acetylcholinesterase; bw: body weight.

Neurotoxicity (Regulation (EU) No 283/2013, Annex Part A, point 5.7)

Acute neurotoxicity	Inhibition RBC AChE activity NOAEL = 10 mg/kg bw	STOT SE 1
Repeated neurotoxicity	Inhibition RBC and brain AChE activity NOAEL = 1 mg/kg bw per day	
Additional studies (delayed neurotoxicity)	No delayed neurotoxicity after acute or 90-day toxicity studies in hen	
Additional studies (developmental neurotoxicity)	Developmental neurotoxicity study: Maternal NOAEL= 2 mg/kg bw per day, based on RBC and brain AChE activity inhibition Developmental neurotoxicity NOAEL could not be set since cerebellum height (considered the most sensitive endpoint in the DNT study performed with chlorpyrifos) cannot be evaluated DNT potential of chlorpyrifos-methyl cannot be dismissed on the basis of the evaluation of the DNT study provided in the RAR on chlorpyrifos, the epidemiological evidence and analysis of the overall literature (*in vivo*, *in vitro* and human data)	H360D

NOAEL: no observed adverse effect level; RBC: red blood cells; AChE: acetylcholinesterase; bw: body weight; DNT: developmental neurotoxicity; RAR: Renewal Assessment Report.

Other toxicological studies (Regulation (EU) No 283/2013, Annex Part A, point 5.8)

Supplementary studies on the active substance	• Evidence for skin sensitisation in humans • 14-days human study: NOAEL = 0.3 mg/kg bw per day • 28-days human study: NOAEL = 0.1 mg/kg bw per day • The immunotoxic potential of chlorpyrifos-methyl could not be determined
Endocrine disrupting properties	Based on a complete dataset for the oestrogen, androgen, thyroid and steroidogenesis (EATS) modalities, no endocrine-mediated pattern of adversity has been observed at doses not causing overt signs of systemic toxicity (due to AChE inhibition)
Studies performed on metabolites or impurities 3,5,6-trichloro-2-pyridinol (TCP)	• Rat oral LD_{50} is estimated in 3129 mg/kg bw in females • TCP did not show a genotoxic potential (Ames test, *in vitro* UDS and mammalian cell gene mutation, *in vivo* micronucleus) • 90-day, rat: NOAEL = 30 mg/kg bw per day based on ↑ liver and kidney weight • 1-year, dog: NOAEL = 12 mg/kg bw per day (based on based on ↓ body weight, haematological and clinical chemistry effects. • Developmental toxicity in rats: – Maternal NOAEL = 50 mg/kg bw per day based on ↓ in body weight gain – Developmental toxicity NOAEL = 150 mg/kg bw per day (highest dose tested) • Developmental toxicity in rabbit: – Maternal NOAEL = 100 mg/kg bw per day based on ↓ in body weight gain – Developmental toxicity NOAEL = 25 mg/kg bw per day based on ↑ incidence of foetal and litter CNS malformations • QSAR assessment: TCP is expected to be less toxic than chlorpyrifos **ADI = 0.06 mg/kg bw per day** (based on the NOAEL of 12 mg/kg bw per day from the 1-year study in dogs and applying an uncertainty factor of 200) **ARfD = 0.25 mg/kg bw** (based on the NOAEL of 25 mg/kg bw from the rabbit developmental toxicity study and applying an uncertainty factor of 100)
2,3,5-trichloro-6-methoxypyridine (TMP)	• Rat oral LD_{50} > 2 000 mg/kg bw in females • Three *in vitro* genotoxicity studies: negative (±S9) (Ames test, *in vitro* mammalian cells gene mutation and chromosome aberration assays)

3,6-dichloro-2-pyridinol (3,6-DCP)	• Rat oral LD_{50}: > 2 000 < 5 000 mg/kg bw (females) • Ames test (±S9): negative
Des-methyl chlorpyrifos-methyl (DEM)	• Rat oral LD_{50}: 500 mg/kg bw • Ames test and *in vitro* micronucleus test: both negative • QSAR assessment: expected to be less toxic than parent

NOAEL: no observed adverse effect level; bw: body weight; AChE: acetylcholinesterase; LD50: lethal concentration, median; RBC: red blood cells; LOAEL: lowest observable adverse effect level; UDS: unscheduled DNA synthesis; ADI: acceptable daily intake; ARfD: acute reference dose; QSAR: quantitative structure–activity relationship; CNS: central nervous system.

Medical data (Regulation (EU) No 283/2013, Annex Part A, point 5.9)

	Minimal cases of inhibition of plasma and RBC acetyl-cholinesterase activity in manufacturing plant personnel Epidemiological studies (taken together toxicity literature studies) suggest that chlorpyrifos-methyl might be acting on the developing nervous system through unknown mechanisms (H360D)

RBC: red blood cells

Summary[6] (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

	Value	Study	Uncertainty factor
Acceptable Daily Intake (ADI)	Open(1, 2)	–	–
Acute Reference Dose (ARfD)	Open(1, 2)	–	–
Acceptable Operator Exposure Level (AOEL)	Open(1, 2)	–	–
Acute Acceptable Operator Exposure Level (AAOEL)	Open(1)	–	–

(1) Reference values could not be derived since a genotoxic potential could not be excluded for chlorpyrifos-methyl.

(2) Previously set toxicological reference values of chlorpyrifos-methyl (European Commission, 2005, 2015): ADI 0.01 mg/kg bw per day, ARfD 0.1 mg/kg bw, AOEL 0.01 mg/kg bw per day.

[6] for metabolites, refer to section: Studies performed on metabolites or impurities.

Dermal absorption (Regulation (EU) No 284/2013, Annex Part A, point 7.3)

Representative formulation (GF-1684 EC, 225 g/L)	Concentrate: 2% Spray dilution (1.10 g/L): 10% Spray dilution (0.45 g/L): 13% Based on triple pack approach
Representative formulation (SAP200CHLORI CS, 200 g/L)	Concentrate: 25% Spray dilution: 70% Based on default values

Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)

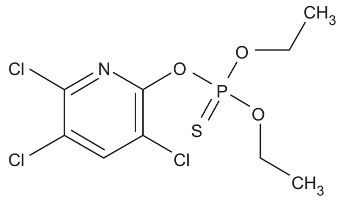
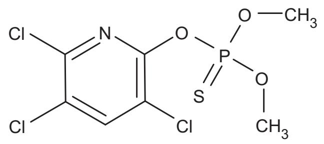
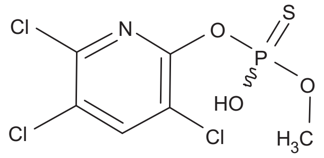
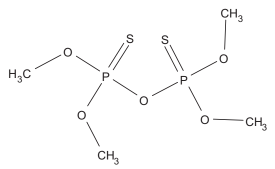
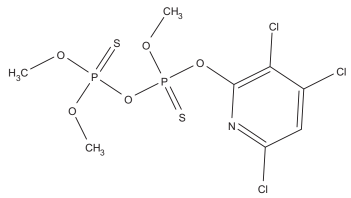
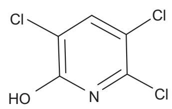
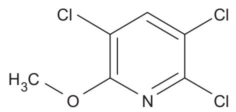
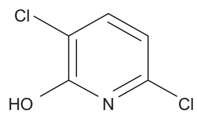
Operators	Open. Risk assessment cannot be conducted in the absence of toxicological reference values
Workers	Open. Risk assessment cannot be conducted in the absence of toxicological reference values
Bystanders and residents	Open. Risk assessment cannot be conducted in the absence of toxicological reference values

Classification with regard to toxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance:	Chlorpyrifos-methyl
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][7]:	Skin Sens.1 H317 'May cause an allergic skin reaction'
According to the peer review, criteria for classification may be met for:	Skin Sens.1 H317 'May cause an allergic skin reaction' STOT SE 1, H370 'causes damage to organs' REPRO 1B, H360D 'may damage the unborn child'

[7] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1–1355.

Appendix B – Used compound codes

Code/trivial name	IUPAC name/SMILES notation/InChIKey[(a)]	Structural formula[(b)]
chlorpyrifos	*O,O*-diethyl *O*-3,5,6-trichloro-2-pyridyl phosphorothioate Clc1cc(Cl)c(Cl)nc1OP(=S)(OCC)OCC SBPBAQFWLVIOKP-UHFFFAOYSA-N	
chlorpyrifos-methyl	*O,O*-dimethyl *O*-3,5,6-trichloro-2-pyridyl phosphorothioate Clc1cc(Cl)c(Cl)nc1OP(=S)(OC)OC HRBKVYFZANMGRE-UHFFFAOYSA-N	
des-methyl chlorpyrifos-methyl (DEM)	*O*-methyl *O*-(3,5,6-trichloro-2-pyridyl) hydrogen phosphorothioate Clc1cc(Cl)c(Cl)nc1OP(O)(=S)OC DYESOQMZDNCQNZ-UHFFFAOYSA-N	
sulfotemp	*O,O,O′,O′*-tetramethyl dithiopyrophosphate COP(=S)(OC)OP(=S)(OC)OC XKBNJDRCYDBEAH-UHFFFAOYSA-N	
sulfotemp ester	*O,O,O′*-trimethyl *O′*-(3,4,6-trichloro-2-pyridyl) dithiopyrophosphate Clc1c(OP(=S)(OC)OP(=S)(OC)OC)nc(Cl)cc1Cl WDHGBTACZJLMHA-UHFFFAOYSA-N	
TCP	3,5,6-trichloro-2-pyridinol Clc1cc(Cl)c(Cl)nc1O WCYYAQFQZQEUEN-UHFFFAOYSA-N	
TMP	2,3,5-trichloro-6-methoxypyridine Clc1cc(Cl)c(Cl)nc1OC RLIVUWLXZBDMBL-UHFFFAOYSA-N	
3,6-DCP	3,6-dichloro-2-pyridinol Oc1nc(Cl)ccc1Cl UGPDKBDRRLFGFD-UHFFFAOYSA-N	

(a): ACD/Name 2018.2.2 ACD/Labs 2018 Release (File version N50E41, Build 103230, 21 Jul 2018).
(b): ACD/ChemSketch 2018.2.2 ACD/Labs 2018 Release (File version C60H41, Build 106041, 07 Dec 2018).

COMMISSION STAFF WORKING DOCUMENT[1]

Chlorpyrifos-methyl
SANCO/3061/99 – rev. 2
20 March 2015[2]

FINAL
Review report for the active substance **chlorpyrifos-methyl**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
3 June 2005
in view of the inclusion of chlorpyrifos-methyl in Annex I of Directive 91/414/EEC

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of chlorpyrifos-methyl, made in the context of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EEC) No 3600/92([3]) laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 2266/2000([4]), has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Chlorpyrifos-methyl is one of the 90 existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 of Regulation (EEC) No 3600/92, United Phosphorus Ltd on 26 July 1993 and DowElanco Europe on 15 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance chlorpyrifos-methyl in Annex I to the Directive.

1 Does not necessarily represent the views of the Commission.

2 On 20 March 2015, the Standing Committee on Plants, Animals, Food and Feed took note of the revision 2 of the review report finalised after the assessment of the confirmatory data referred to in point 7 of this report (cfr. infra) and the assessment of new toxicological study for the setting of Acute Reference Dose referred to in point 3 and Appendix II of this report. As already stated in Chapter 1 of this review report, documents providing clarifications on the assessment, finalised after a decision has been taken, shall be considered as background document C and as such they are part of this review report.

3 OJ No L 366, 15.12.1992, p.10.

4 OJ No L 259, 13.10.2000, p.27.

In accordance with the provisions of Article 5 of Regulation (EEC) No 3600/92, the Commission, by its Regulation (EEC) No 933/94([5]), as last amended by Regulation (EC) No 2230/95([6]), designated Spain as rapporteur Member State to carry out the assessment of chlorpyrifos-methyl on the basis of the dossier submitted by the notifier. In the same Regulation, the Commission specified furthermore the deadline for the notifiers with regard to the submission to the rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EEC) No 3600/92, as well as for other parties with regard to further technical and scientific information; for chlorpyrifos-methyl this deadline was 30 April 1995.

Only DowElanco Europe submitted in time a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore DowElanco Europe was considered to be the main data submitter.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Spain submitted on 16 September 1997 to the Commission the report of its examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of chlorpyrifos-methyl in Annex I to the Directive. Moreover, in accordance with the same provisions, the Commission and the Member States received also the summary dossier on chlorpyrifos-methyl from DowElanco Europe, on 19 November 1997.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the draft assessment report to all the Member States on 09 December 1997 as well as to DowElanco Europe, on 08 September 1999.

The Commission organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review), in particular on each of the following disciplines:

- identity and physical /chemical properties,
- fate and behaviour in the environment,
- ecotoxicology,
- mammalian toxicology,
- residues and analytical methods,
- regulatory questions.

The meetings for this consultation were organised on behalf of the Commission by the Biologische Bundesanstalt für Land und Forstwirtschaft (BBA) in Braunschweig, Germany, from November 1999 to July 2000.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 15 June 2001 for comments and further clarification.

In accordance with the provisions of Article 6(4) of Directive 91/414/EEC concerning consultation in the light of a possible unfavourable decision for the active substance the Commission organised a tripartite meeting with the main data submitter and the rapporteur Member State for this active substance on 23 October 2000**.**

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[5] OJ No L 107, 28.04.1994, p.8.

[6] OJ No L 225, 22.09.1995, p.1.

According the Decision 2001/134/CE[7], the Commission specified the deadline for the notifier with regard to the submission to the rapporteur Member States of the additional data with regard to further technical and scientific information; for chlorpyrifos-methyl this deadline was 30 April 2002.

The Commission organised a second intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the assessment of the additional data submitted before the deadline and the comments received thereon (peer review), in particular on each of the following disciplines:

- identity and physical /chemical properties,
- fate and behaviour in the environment,
- ecotoxicology,
- mammalian toxicology,
- residues and analytical methods,
- regulatory questions.

The meetings for this consultation were organised on behalf of the Commission by the Biologische Bundesanstalt für Land und Forstwirtschaft (BBA) in Braunschweig, Germany, from November 2002 to July 2003.

In accordance with the provisions of Article 6(4) of Directive 91/414/EEC concerning consultation in the light of a possible unfavourable decision for the active substance the Commission organised the second tripartite meeting with the notifier and the rapporteur Member State for this active substance on 03 February 2004.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossier, the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications on the remaining issues, received after the peer review were referred to the Standing Committee on the Food Chain and Animal Health, and specialised working groups of this Committee, for final examination, with participation of experts from all Member States. This final examination took place from July 2003 to November 2004, and was finalised in the meeting of the Standing Committee on 3 June 2005.

The review did not reveal any open questions or concerns which would have required a consultation of the Scientific Committee on Plants.

The present review report contains the conclusions of the final examination; given the importance of the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications submitted after the peer review as basic information for the final examination process, these documents are considered respectively as background documents A, B and C to this review report and are part of it.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, has been developed and finalised in support of the Directive 2005/72/EC[8] concerning the inclusion of

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7 OJ No L49, 20.2.2001, p13.

8 OJ No L 279, 22.10.2005, p. 63-69

chlorpyrifos-methyl in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing chlorpyrifos-methyl they have to take in accordance with the provisions of that Directive, and in particular the provisions of Article 4(1) and the uniform principles laid down in Annex VI.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 7(6) of Regulation (EEC) No 3600/92, Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request. Moreover, the Commission will send a copy of this review report (not including the background documents) to all operators having notified for this active substance under Article 4(1) of this Regulation.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion from the evaluation is that it may be expected that plant protection products containing chlorpyrifos-methyl will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each chlorpyrifos-methyl containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the main data submitter and mentioned in the list of uses supported by available data (attached as Appendix IV to this Review Report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The International Estimated Daily Intake (IEDI); excluding water and products of animal origin for a 60 kg adult is 26% of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). This IEDI was calculated considering the supervised trials median residue (STMR) and the processing factor for cereals and covers only grape and stored grain as supported uses and the residue definition that was considered

to perform the risk assessment for consumers was for grapes: Methyl-Chlorpyrifos + TCP + conjugates expressed as methyl-chlorpyrifos and for stored grain: sum of chlorpyrifos-methyl and desmethyl chlorpyrifos-methyl expressed as chlorpyrifos-methyl.
Estimates of acute dietary exposure of adults and toddlers in table grape and wheat do not exceed the Acute Reference Dose (ARfD).

On 20 March 2015 the Standing Committee on Plants, Animals, Food and Feed took note of the revision 2 of this review report after the assessment of a new toxicological study on acute oral neurobehavioural and cholinesterase inhibition in rats (Marty et al. 2013) on the basis of which it was confirmed the value of ARfD at 0.1 mg/kg bw. This assessment has been carried out in line with the Guidance document on the evaluation of new active substance data post approval (SANCO/10328/2004 rev.8) for the assessment of new data following inclusion of an active substance.The Appendix II of this report has been updated to include the new reference study.

The review has identified several acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC, provided that certain conditions are taken into account as detailed in section 6 of this report.

4. Identity and Physical/chemical properties

The main identity and the physical/chemical properties of chlorpyrifos-methyl are given in Appendix I.

There are not FAO specification for Chlorpyrifos-methyl at the moment this review report was written.

The review has established that for the active substance notified by DowElanco Europe, the impurities O,O,O,O – tetramethyl dithiopyrophosphate (Sulfotemp) and O,O,O – trimethyl-O-(3,5,6-trichloro-2-pyridinyl) diphosphorodithioate (Sulfotemp-ester) were considered, on the basis of information currently available, of toxicological or environmental concern and a maximum level of 5.0 g/kg was established in the technical specifications of chlorpyrifos-methyl for each impurity.

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in Appendix II.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing chlorpyrifos-methyl

On the basis of the proposed and supported uses (as listed in Appendix IV), the following particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

- Member States must pay particular attention to the protection of birds, mammals, aquatic organisms, bees and non-target arthropods and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures.

7. List of studies to be generated

Member States shall request the submission of further studies to confirm the risk assessment for birds and mammals.

They shall ensure that the notifiers at whose request chlorpyrifos-methyl has been included in Annex I of Council Directive 91/414/EEC provide such studies to the Commission within 2 years from the entry into force of the Directive of inclusion.

Some other endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. This may particularly be the case for: additional studies on non-target arthropods for uses other than those supported.

On 20 March 2015 the Standing Committee on Plants, Animals, Food and Feed took note of the revision 2 of this review report after the assessment of the above confirmatory data. This assessment has been carried out in line with the Guidance document on the procedures for submission and assessment of confirmatory data following inclusion of an active substance in Annex I of Council Directive 91/414/EEC available at the time of assessment[9]. The Committee agrees that, on the basis of the outcome, the conclusions of the original risk assessment are not modified by the evaluation of the submitted confirmatory data.

8. Information on studies with claimed data protection

For information of any interested parties, Appendix III gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available to the Commission services at the time this review report was prepared; but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC neither does it commit the Commission.

[9] Doc. SANCO/5634/2009 rev. 3, 2.10.2009.

9. Updating of this review report

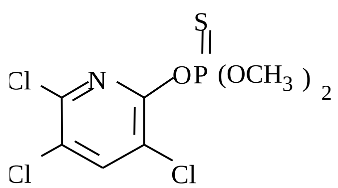
The technical information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Such adaptations will be examined and finalised in the Standing Committee on Plants, Animals, Food and Feed, in connection with any amendment of the inclusion conditions for chlorpyrifos-methyl in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

Chlorpyrifos-methyl

Common name (ISO)	Chlorpyrifos-methyl
Chemical name (IUPAC)	O,O-dimethyl-O-3,5,6-trichloro-2-pyridyl phosphorothioate
Chemical name (CA)	O,O-dimethyl-O-(3,5,6-trichloro-2-pyridinyl) phosphorothioate
CIPAC No	486
CAS No	5598-13-0
EEC No	EEC: 227-011-5
FAO SPECIFICATION	No FAO specification
Minimum purity g/kg	960
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	O,O,O,O – tetramethyl dithiopyrophosphate < 5 g/kg (Sulfotemp) O,O,O – trimethyl-O-(3,5,6-trichloro-2-pyridinyl) diphosphorodithioate < 5 g/kg (Sulfotemp-ester)
Molecular formula	$C_7H_7Cl_3NO_3PS$
Molecular mass	322.6
Structural formula	



Melting point	46 °C 99.8 %
Boiling point	> 360 °C 97 %
Appearance	Amorphous solid, pale yellow. (96.9 %) Mild mercaptan odour (from database)
Relative density	1.67 (96.9 %)
Vapour pressure	3.0 10^{-3} Pa at 25º C (99.8 %) (1.945 x 10^{-3} Pa at 20°C, by calculation)
Henry's law constant	0.235 Pa m^3 mol^{-1}
Solubility in water	2.74 x 10^{-3} g / L. (20 ºC, 99.8 %)
Solubility in organic solvents	Hexane 154 g/Kg (99.8 %) (20°C)
	Heptane 79 g/l (96.9%) (20°C)
	Toluene: >250.0 g/Kg (99.8 %) (20°C)
	Xilene: >250 g/ l (96.9%) (20°C)
	Dichloromethane: >250.0 g / Kg (99.8 %) (20°C)
	1,2 dichloroethane: : >250 g/ l (96.9%) (20°C)
	Methanol: 193 g/Kg (99.8 %) (20°C)
	Acetone: > 250 g/Kg (99.8 %) (20°C)
	Ethyl acetate: > 250 g/Kg (99.8 %) (20°C)
Partition co-efficient (log P_{ow})	log P_{OW} = 4.0 20 °C. 99.8 %
Hydrolytic stability (DT_{50})	pH 4 = 48.7 d (20 °C) pH 7 = 38.1 d (20 °C) pH 9 = 25.6 d (20 °C)
Dissociation constant	Not determinable due to low water solubility.
Quantum yield of direct photo-transformation in water at λ >290 nm	2.6 10^{-3}
Flammability	Not lammable. Auto ignition 272 º C.
Explosive properties	Non explosive
UV/VIS absorption (max.)	Significant absorption (ε > 10; λ > > 290 nm) λ_{max} = 288.9 nm.
Photostability in water (DT_{50})	DT_{50} = 8 h.

APPENDIX II

END POINTS AND RELATED INFORMATION

Chlorpyrifos-methyl

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Rats: 83%-85% %, urinary excretion within 72 h, following a single-dose exposure
Distribution:	Widely distributed.
Potential for accumulation:	No potential for accumulation.
Rate and extent of excretion:	Almost completely, within 72 h, mainly via urine (83%-85%), following a single-dose exposure.
Toxicologically significant compounds:	Parent compound and metabolites
Metabolism in animals:	Extensively metabolized. De-methylation, hydrolysis, conjugation

Acute toxicity

Rat LD_{50} oral:	2814 mg/kg bw
Rat LD_{50} dermal:	>2000mg/kg bw
Rat LC_{50} inhalation:	> 0.67 mg/l (whole-body).
Skin irritation:	Non-irritant
Eye irritation:	Non-irritant
Skin sensitization (test method used and result):	Sensitiser (M&K). (R 43).

Short term toxicity

Target / critical effect:	Nervous system /Acetyl-cholinesterase inhibition
Lowest relevant oral NOAEL / NOEL:	1 mg/kg bw/day; 90-day dogs (JMPR criteria)
Lowest relevant dermal NOAEL / NOEL:	Not required
Lowest relevant inhalation NOAEL / NOEL:	Not required

Genotoxicity	No genotoxic potential

Long term toxicity and carcinogenicity

Target / critical effect:	Nervous system/ Acetyl-cholinesterase inhibition
Lowest relevant NOAEL:	1 mg/kg bw/day: 2-years rats (JMPR criteria).
Carcinogenicity:	No carcinogenic potential.

Reproductive toxicity

Target / critical effect - Reproduction:	At 3 mg/Kg bw/day, cytoplasmic vacuolisation of the zona fasciculata of the adrenal glands in females of both generations and 65% RBC AChE inhibition.
Lowest relevant reproductive NOAEL / NOEL:	Parental NOAEL= 1 mg/kg bw/day in rats, and for developmental and reproductive toxicity a NOEL = 10 mg/Kg bw/day in rat.
Target / critical effect - Developmental toxicity:	No developmental toxicity at maternal toxic doses (rats, rabbits).
Lowest relevant developmental NOAEL / NOEL:	>16 mg/kg bw/day (rabbits)

Delayed neurotoxicity

No indication of delayed neurotoxicity (13-weeks, hens)

(Chlorpyrifos)NOAEL= 10 mg/kg bw/day (13-weeks, rats)

Other toxicological studies

Evidence for skin sensitisation in humans.

14-days human study: NOAEL=0.3mg/kg bw/day

28-days human study: NOAEL=0.1mg/kg bw/day

Medical data

Slight inhibition of plasma and RBC Acetyl-cholinesterase activity in manufacturing plant personnel. No effects in general populations reported.

Summary

	Value	Study	Safety factor
ADI:	0.01 mg/kg bw	Rat, 2-years.	100
AOEL systemic:	0.01 mg/kg bw/day	Dog, 90d study	100
AOEL inhalation:	Not required		
AOEL dermal:	Not required		
ARfD (acute reference dose):	0.1 mg/kg bw	Acute oral neurobehavioural and cholinesterase inhibition study in in rats [10]	100

Dermal absorption

1% based on human dermal study with chlorpyrifos

[10] On 20 March 2015 the Standing Committee on Plants, Animals, Food and Feed took note of the revision 2 of this review report after the assessment of a new toxicological study on acute oral neurobehavioural and cholinesterase inhibition in rats (Marty et al. 2013) on the basis of which it was confirmed the value of the ARfD at 0.1 mg/kg bw.

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:	23-69% AR
Non-extractable residues after 100 days:	17-26% AR
Major metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)	TCP up to 43% AR after 7 days Unknown metabolites MET 5 and Met 6 from previous aerobic studies have been identified as isomers of N-methyl-dichloro-2-pyridinone and N-methyl -TCP respectively.

Supplemental studies

Anaerobic:	No data submitted
Soil photolysis:	No data submitted
Remarks:	No required

Rate of degradation

Laboratory studies

DT_{50}lab (20 °C, aerobic):	DT_{50lab} (20°C, aerobic): 1-4 days <u>TCP</u> $DT_{50(lab)}$ (20ºc, aerobic):10-67 days (EU soils n=4).
DT_{90}lab (20 °C, aerobic):	DT_{90lab} (20°C, aerobic): 17-47 days <u>TCP</u> DT_{90lab} (20°C, aerobic): 35-221 days (EU soils n= 4).
DT_{50}lab (10 °C, aerobic):	DT_{50lab} (10°C, aerobic,): 129 days (EU soil) DT_{90lab} (10°C, aerobic,): 426 days (EU soil)
DT_{50}lab (20 °C, anaerobic):	DT_{50lab} (20°C, anaerobic): No data submitted
	Degradation in the saturated zone: No data submitted

Field studies (country or region)

DT_{50f} from soil dissipation studies:	DT_{50f}: No data submitted TCP $DT_{50\ f}$ Europe=8-96 (n=2; Spain and France field studies)
DT_{90f} from soil dissipation studies:	DT_{90f}: No data submitted TCP $DT_{90\ f}$ Europe= 8-113 (n=4) $DT_{90\ f}$ Europe=27-319 (n=2; Spain and France field studies following ***chlorpyrifos*** application
Soil accumulation studies:	No potential for accumulation
Soil residue studies:	No relevant

Remarks: e.g. effect of soil pH on degradation rate	None

Adsorption/desorption

K_f / K_{oc}: K_d: pH dependence:	Chlorpyrifos-methyl Koc 1189-8100 n=10 US soils Kd 4-407 n=10 US soils No pH dependence TCP Koc 67.2-315 n=5 EU soils Kd 1.21-13.6 n=5 EU soils No pH dependence TMP Koc 565-1308 n=5 EU soils Kd 7.70-39.4 n=5 EU soils No ph dependence

Mobility

Laboratory studies:

Column leaching:	0.2-2.2% AR in leachate (non characterised)
Aged residue leaching:	10% AR in leachate (1.2-3.8% AR as CO2, rest as TCP, no parent compound residues detected) (Distribution in aged soil before leaching: 19% AR parent; 56% AR TCP; 6% AR TMP)

Field studies:

Lysimeter/Field leaching studies:	No data – none required

Remarks:	None

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:	pH 4: 27 days at 25ºC (extrapolated) At 50ºc TCP 20% AR, Unknown-1 70%
	pH 7: 21 days at 25ºC (extrapolated) At 50ºc TCP 20% AR, Unknown-1 70%
	pH 9:13 days at 25ºC (extrapolated) At 50ºc TCP 37% AR, Unknown-1 26%, Unknown-2 35%
	pH 4: 7 days at 50 ºC Desmethyl-CPM 61.6% AR.
	pH 9: 7 days at 50 ºC Desmethyl-CPM 21.6% AR.
Major metabolites:	TCP and desmethyl
Photolytic degradation:	2-9 days (June) 0.8-3.8 months (December)
Major metabolites:	None

Biological degradation

Readily biodegradable:	No
Water/sediment study:	
DT_{50} water:	2.2-3.6 days
DT_{90} water:	7.2-12 days
DT_{50} whole system:	2.6-25.4 days
DT_{90} whole system:	8.5-84 days
Distribution in water / sediment systems (active substance)	15-30% in the sediment form day 0 to 7-30
Distribution in water / sediment systems (metabolites)	TCP up to 20-35% AR in the sediment and up to 37-60% AR in the water phase, after 30 days.
Accumulation in water and/or sediment:	No

Degradation in the saturated zone	No data submitted, none required
Remarks:	None

2.3 Fate and behaviour in air

Volatility

Vapour pressure:	3.0 10-3 Pa at 25º C (99.8 %) (1.945 x 10-3 Pa at 20°C, by calculation)
Henry's law constant:	0.235 Pa m^3 mol^{-1}

Photolytic degradation

Direct photolysis in air:	No data available
Photochemical oxidative degradation in air DT_{50}:	Atkinson calculation DT_{50} 2.11 hours TCP Atmospheric Oxidation Program DT_{50} = 60.5 days
Volatilisation:	From plant surfaces: 79% in 24 hours
	From soil: 18% in 24 hours

Remarks:	None

Monitoring data (data from chlorpyrifos)

Soil: Several studies suggest no accumulation of soil residues due to continuous use -

Surface Water: Valencia (Spain)

	Mean µg/L	Media µg/L	50th percentile µg/L	90th percentile µg/L
Clot	0.012	0.0085	0.0100	0.0284
Irrig channels	0.1347	0.0085	0.0169	0.1597
All data	0.0643	0.0085	0.0128	0.0852

Italy:

Chlorpyrifos (90th percentile exposure)

Regional/catchment scale:

Surface water	<0.05 µg/L
Sediment	<0.01 mg/kg

Field scale:

Surface water (8 m from treated crop)

2000	0.120µg/L
2001	0.275µg/L
All data (2000–2001)	0.135µg/L

	Italy: Chlorpyrifos <u>Regional scale:</u> Surface water <0.05 µg/L Sediment <0.01 mg/kg <u>Catchment scale:</u> Surface water <0.05 µg/L Sediment 0.02 mg/kg
	Review of monitoring and occurrence of chlorpyrifos in groundwater and surface water in Europe. Wright, K. & Horth, H. (2002): The surface water 90th percentile concentration will clearly be significantly less than 0.5 µg/L.
Ground water	Several studies have been submitted. Chlorpyrifos has only been occasionally detected. Only in one study the concentration was higher than 0.1 µg/L (n=139)
Air	No data submitted

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	Rat LD50 = 2814 mg/kg b.w.
Acute toxicity to birds:	Technical: Bobwhite quail LD50 = 923 mg/kg b. w. Formulation: Bobwhite quail LD50 = 227 mg a.i./kg b. w.
Dietary toxicity to birds:	Bobwhite quail LC50= 2010 ppm
Reproductive toxicity to birds:	Mallard duck NOEC = 100 ppm
Short term oral toxicity to mammals:	Rat reproduction NOAEL = 3 mg/kg bw/day

Aquatic Organisms

	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Acute toxicity fish:	technical formulated	Acute	96h LC50	0.41 0.051 (ai/l)
Long term toxicity fish:	technical	Chronic	21d NOEC growth	0.0047
	Metabolite TCP	Chronic	31d NOEC	0.0808
Acute toxicity invertebrate:	technical formulated	Acute	48h EC50	0.00062 0.00024 (ai/l)
Chronic toxicity invertebrate:	Technical	Chronic	21 days NOEC D.magna	0.00001
Acute toxicity algae:	Technical formulated	Acute Chronic	96h EC50 NOEC NOEC	0.54 0.15 0.03 (ai/l)
Microcosm or mesocosm tests	Environmentally Acceptable Concentration (EAC) equivalent to the NOECmesocosm value of 0.1 µg as/L established for chlorpyrifos will be also used for chlorpyrifos-methyl			

Bioconcentration factor (BCF)	1800
Clearance time (CT50)	2.6 days

Honeybees

Acute oral toxicity:	Technical LD50 = 0.11 µg/bee Formulation LD50 = 0.18 µg as/bee
Acute contact toxicity:	Technical LD50 = 0.15 µg/bee Formulation LD50 = 0.15 µg as/bee

Other arthropod species

Test species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	% Effect
Laboratory test					
No data, a high toxicity is expected by comparison with chlorpyrifos					
Extended Laboratory tests					
Typhlodromus pyri	protonymphs	Formulation	0.286 0.050	Mortality	M = 9.0% M = 7.0%
Aphidius rhopalosiphi	Adults	Formulation	0.286 0.050	Mortality	M = 100% M = 100%
Chrysoperla carnea	Larvae	Formulation	0.286 0.050	Mortality	M = 97% M = 74%
Chrysoperla carnea	Larvae		1.0 kg as/hL	Mortality	M = 96.4%
Extended laboratory / semi-field					
Aphidius colemani	Adults	Formulation	0.12 0.48	Mortality	M = 100% M = 100%
Aphidius colemani	pupae within mummified aphids	Formulation	0.12 0.48	Mortality	M = 6.0% M = 29%
Coccinella septempunctata	Larvae	Formulation	0.12 0.48	Mortality	M = 9.0% M = 5.0%
Bembidion lampros	Adults on LUFA soil	Formulation	0.12 0.48	Mortality	M = 95% M = 100%
Bembidion lampros	Adults on field soil	Formulation	0.12 0.48	Mortality	M = 95% M = 100%
Pardosa spp.	Adults	Formulation	0.12 0.48	Mortality	M = 0.0% M = 35%
Field or semi-field tests					

Significant acute effects on several arthropod species was observed. Rapid recovery if recolonisation is possible expected

M.Mead-Briggs 1997
This study demonstrated that residues of Reldan are harmful to adult Aphidius colemani foraging on exposed flag leaves and their effects may persist for 5-8 days, depending on application rate. Although there was evidence that pupal stages of the wasp within the treated crop might survive to emerge subsequently, these results suggest that the emerging wasps might still be exposed to harmful residues levels.

Shonagh Taruza 2001
When applied at rates equivalent to the worst-case drift that might occur following application to either orchard or field crops fresh dried residues of Reldan 22 EC, did not result in statistically significant ($P < 0.001$) levels of mortality or fecundity of the predatory mite Typhlodromus pyri.

Stephen Vinall 2001
When applied at rates equivalent to the worst-case drift that might occur following application to either orchard or field crops fresh dried residues Reldan 22 EC resulted in 100% mortality, were harmful to the wasp.

After 7 days, field-aged residues had no effect on survival or fecundity of the parasitic wasp Aphidius rhopalosiphi.

Bryony Manley 2001

When applied at rates equivalent to the worst-case drift that might occur following application to either orchard or field crops fresh dried residues of Dursban 4 EC and Reldan 22 EC resulted in statistically significant ($P < 0.001$) levels of mortality.

After 7 days, field-aged residues of had no significant ($P > 0.05$) effect on lacewing survival and did not adversely affect fecundity.

M. Mead-Briggs (1997)
This study indicted that both Dursban 4 EC and Reldan 50 EC were harmful to the ground-active carabid Bembidion lampros. At an application rate of 120 g a.i./ha persistence of harmful residues on a field-collected loam was 2-5 days for both products, but at an application rate of 480 g a.i. /ha this increased to 9 days or more.

M. Mead-Briggs 1997
This study indicated that residues of Reldan 22 EC not resulted in significant residual toxicity to the adults ladybirds, aphid-specific predator, Coccinella septempunctata (Colcoptera, Coccinellidae).

M. Mead-Briggs (1997)
This study has demonstrated that the impact of Reldan on Lycosid spiders within mature cereals may be relative small when the products are applied at a rate of 120 g a.i./ha for the control of cereal aphids. At higher treatment rate of 480 g a.i./ha as used for the control of wheat blossom midge, the effects were potentially harmful to these spider.

M.Miles (2000)
Both the insecticides Reldan 40EC applied at 100 g as /hl were initially harmful to C. carnea larvae. However their effects declined over the 14-day study period. Areas treated with Reldan 40 EC become available for re-colonisation between 1-5 days after application

Several studies reported LD50 for several species

Earthworms

Acute toxicity:	Technical 15 days LC50 = 182 mg/kg Formulation 14 days LC50 = 37 mg ai/kg Metabolite TCP 14 days LC50 =9.8 mg/kg
Reproductive toxicity:	Parent: No data no required Metabolite TCP 56-day NOEC 4.60 mg/kg dry soil

Soil micro-organisms

Nitrogen mineralization:	Active substance Reversible effects at 0.5 kg a.i./ha No reversible effects at 5 kg ai/ha Metabolite TCP Reversible effects at 1.41 kg/ha No reversible effects at 15 kg/ha
Carbon mineralization:	No significant effects at 0.5 kg a.i./ha 24% effect at 5 kg ai/ha Metabolite TCP Reversible effects at 15 kg/ha No effects at 3.53 kg/ha

APPENDIX IIIA

Chlorpyrifos-methyl

List of studies for which the main submitter has claimed data protection and which during the re-evaluation process were considered as essential for the evaluation with a view to Annex I inclusion.

B.1 Identity, B.2 Physical and chemical properties, B.3 Data on application and further information, B.4 Proposals for classification and labelling, B.5 Methods of analysis

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[11] on previous use in granting national authorizations
IIA,1.11	N. Richardson and S. Knowles	1999	Five Batch Analysis of chlorpyrifos-methyl technical, RELDAN F; Technical assay and spectral characterisation (A56) Report No. GHE-P-7974 Dow GLP. Unpublished	
IIA,1.11	Litwinski, G. and Chan, K.W.	2001	Multi-Batch analysis for RELDAN Technical DECO GL-AL MD-2000-005770 Dow GLP. Unpublished	
IIA,1.11	Litwinski, G	2001	Determination of Reldan oxygen analog and O,S-dimethyl dithioate impurities in Reldan 8-batch study samples by gas chromatography GL-AL 2001-001718 Dow Not GLP. Unpublished	
IIA,1.11	Moreland, J. and Fonquerne, C.	2001	Determination of sulfotemp ester in RELDAN F Technical and RELDAN 50SM Manufacturers Concentrate GHE-P-9114 Dow GLP. Unpublished	

[11] Entries are based on information received from the Notifier(s) and in certain cases Member States. Neither the Commission nor the Member States are responsible for the completeness or validity of this information received.

Annex point/ reference number	**Author(s)**	**Year**	**Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not**	**Reports[11] on previous use in granting national authorizations**
IIA,1.11	Litwinski, G.R.	2002	Determination of absolute and relative response factors for RELDAN and its process impurities by gas chromatography with FID detection January 2002 DECO GL-AL MD-2002-000245 Dow Not GLP. Unpublished	
IIA - 2.2, 2.4.1.	Knowles, S., Niemtus, K.	1991	Chlorpyrifos-methyl: Determination of Physico-chemical Properties: Part A: Determination of Relative Density. A15 DOE GLP. Unpublished.	
IIA, 2	N. Richardson and A. Comb	1999	Determination of physico-chemical properties (Technical grade Solvent Solubility) (A55) Report No. DWC983/984074 - GHE-P-7780 Dow GLP. Unpublished	
IIA, 2	Boothroyd, S., Cowlyn, T.C	1994	Chlorpyrifos-methyl (pure): Determination of physico-chemical properties.(Relative density). A30 DOE GLP. Unpublished.	
IIA, 2.1.1	Cowlyn, T.C.	1993	Chlorpyrifos-methyl (pure): Determination of Melting Point A22 DOE GLP. Unpublished.	
IIA - 2.1.2, 2.1.3.	Knowles, S & Iosson, I.	1994	Chlorpyrifos-methyl: Generation of NMR and DSC. A29 DOE GLP. Unpublished.	
IIA, 2.1.7	Knowles, S. and Cowlyn, T.C.	1993	Chlorpyrifos-methyl: Solubility in Organic Solvents. A20 DOE GLP. Unpublished.	

Annex point/ reference number	**Author(s)**	**Year**	**Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not**	**Reports[11] on previous use in granting national authorizations**
IIA - 2.3.1., 2.4.1., 2.6., 2.7., 2.9.4.	Cowlyn, T.C.	1993	Chlorpyrifos-methyl: Determination of Physico-chemical Properties A23 DOE GLP. Unpublished.	
IIA, 2.3	Watson, P.A.	2002	Chlorpyrifos-methyl: Calculation of Henry's Law Constant (H) HLC/12 – 2/02 GHE-P-9749 Dow Not GLP. Unpublished	
IIA,2.3	Watson, P.A.	2002	3,5,6-trichloro-2-pyridinol (TCP): Calculation of Henry's Law Constant (H) (A18) HLC/10 – ½ GHE-P-9748 Dow GLP. Unpublished	
IIA, 2.3	Griffin, K.A.	2001	Vapor pressure of 3,5,6-trichloro-2-pyridinol by Knudsen-Effusion Weight loss method (A13) DECO GL-AL MD-2001-002731 Dow GLP. Unpublished	
IIA, 2.5	Knowles, S. and Drossopoulos, M.	1998	Spectral characterisation of 2-pyridinol (AGR143197) (A9) Report No. P098-069 - GHE-P-7361 Dow GLP. Unpublished	
IIA, 2.5	Russell, M.W., Cooper, D., Vorhies, S., Godby, J. and Hilla, S.	2002	Determination of the Mass, Infrared, Nuclear Magnetic Resonance and Ultraviolet/Visible spectra of sulfotemp FAPC023049 Dow GLP. Unpublished	
IIA,2.5.	Boothroyd, S., Ghosh, D., Knowles, S.	1994	Chlorpyrifos-methyl (pure): Generation of Spectral Data (UV-VIS, IR, NMR, MS) A26 DOE GLP. Unpublished.	
IIA, 2.6	Comb, A.L.	2002	Determination of water solubility for chlorpyrifos-methyl DOS/292 Dow GLP. Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[11] on previous use in granting national authorizations
IIA, 2.6	Roulin, S.	2002	Determination of the water solubility of 3,5,6-trichloro-2-pyridinol (TCP) (A16) 01016/DA GHE-P-9491 Dow GLP. Unpublished	
IIA, 2.7	Moreland, J. and Fonquerne, C.	2002	Determination of the solvent solubility of 3,5,6-trichloro-2-pyridinol (A15) 01016/DB GHE-P-9490 Dow GLP. Unpublished	
IIA, 2.8	Comb, A.L.	2001	Determination of partition coefficient for 3,5,6-trichloro-2-pyridinol (A17) DOS/271/014481 NAFST471 Dow GLP. Unpublished	
IIA, 2.9	Cathie, C.	2001	Determination of dissociation constant of 3,5,6-trichloro-2-pyridinol using UV-Visible spectrophotometry (A14) 01-830-AG GHF-P-2357 Dow GLP. Unpublished	
IIA, 2.11.1	Knowles, S., Niemtus, K.	1991	Chlorpyrifos-methyl: Determination of Physico-chemical Properties: Part C: Determination of Flammability of Solids A17 DOE GLP. Unpublished.	
IIA, 2.13	Knowles, S., Niemtus, K.	1991	Chlorpyrifos-methyl: Determination of Physico-chemical Properties: Part D: Determination of Explosive Properties A19 DOE GLP. Unpublished.	
IIA, 2.15	Knowles, S., Niemtus, K.	1991	Chlorpyrifos-methyl: Determination of Physico-chemical Properties: Part E: Determination of Oxidising Properties A18 DOE GLP. Unpublished.	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[11] on previous use in granting national authorizations
IIA - 2.11.2	Richardson, N.	1995	Chlorpyrifos-methyl (technical): determination of Auto-ignition temperature. A31 DOE GLP. Unpublished.	
IIA - 2.3.2.	Watson. P A	1995	Chlorpyrifos-methyl : Calculation of Henry's Law Constant (H) A32 DOE Not GLP. Unpublished.	
IIA - 2.10	Day, S. R. Rüdel, H.	1993	The evaporation of Chlorpyrifos-methyl from soil and leaf surfaces and its persistence in air following application of Reldan 22 RO (EF 1066). K11 DOE GLP. Unpublished.	
IIA - 2.9.1.	Yon, D.A., Müller, J.	1994	Aqueous hydrolysis of chlorpyrifos-methyl. K17 DOE GLP. Unpublished.	
IIA - 2.9.2., 2.9.3.	Yon, D.A., Müller, J.	1994	Aqueous Photolysis of chlorpyrifos-methyl K18 DOE GLP. Unpublished.	
IIA, 4.1	Litwinski, G.R.	2001	Validation of a gas chromatographic method for the determination of Bis-RELDAN in RELDAN technical (O32) DECO GL-AL MD-2000-005768-REV Dow GLP. Unpublished	
IIA - 4.2.1, 6.3/66	Khoshab, A, Chen, S	1993	Residues of chlorpyrifos-methyl in orange peel and pulp at intervals following a single application of Reldan 22E (EF 815) - Spain 1991 N075 DOE GLP. Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[11] on previous use in granting national authorizations
IIA - 4.2.1, 6.3/67	Khoshab, A, Chen, S	1993	Residues of chlorpyrifos-methyl in mandarin peel and pulp at intervals following a single application of Reldan 22E (EF 815) - Spain 1991 N076 DOE GLP. Unpublished	
IIA - 4.2.1, 6.3/68	Khoshab, A, Chen, S	1993	Residues of chlorpyrifos-methyl in lemon peel and pulp at intervals following a single application of Reldan 22E (EF 815) - Spain 1991 N080. DOE GLP. Unpublished	
IIA, 4.2.1	Maliani, N.	2002	Independent laboratory validation of Dow AgroSciences LLC Method GRM 00.10 – Determination of residues of chlorpyrifos-methyl residues in crops and process fractions with a high water content (OR17A) ML02-0995-DOW GH-C 5429 Dow GLP. Unpublished	
IIA, 4.2.2	Schwake, J.D.	1995	Independent Laboratory Validation of Method GRM 92.12.R2 - Determination of 3,5,6-trichloro-2-pyridinol in soil by gas chromatography/Mass Spectrometry (O13B) QMAS94005 GH-C 3821 Dow GLP. Unpublished	
IIA, 4.2.1	Maliani, N.	2002	Independent laboratory validation of Dow AgroSciences LLC Method GRM 02.01 – Determination of residues of chlorpyrifos-methyl and chlorpyrifos in animal tissues by gas chromatography with negative-ion chemical ionisation mass spectrometry (O34A) ML02-0996-DOW GH-C 5437 Dow GLP. Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[11] on previous use in granting national authorizations
IIA, 4.2.3	Olberding, E.L.	1996	Determination of residues of Triclopyr, 3,5,6-trichloro-2-pyridinol and 2-methoxy-3,5,6-trichloropyridine in water by capillary gas chromatography with mass selective detection (O34) GRM 95.18 Dow GLP. Unpublished	
IIA, 4.2.3	Olberding, E.L.	1997	Validation report for the determination of residues of Triclopyr, 3,5,6-trichloro-2-pyridinol and 2-methoxy-3,5,6-trichloropyridine in water by capillary gas chromatography with mass selective detection (O34A) RES 94075 / GH-C 4476 Dow GLP. Unpublished	
IIA, 4.2.3	Harris, E.J.	1997	Independent laboratory validation of DowElanco method GRM 95.18 – Determination of residues of Triclopyr, 3,5,6-trichloro-2-pyridinol and 2-methoxy-3,5,6-trichloropyridine in water by capillary gas chromatography with mass selective detection (O34B) QMAP 97002 / GH-C 4494 Dow GLP. Unpublished	

B.6 Toxicology and metabolism.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 5.2.6	Wilson, C.W.	2000	Technical grade chlorpyrifos-methyl: Dermal sensitization study in guinea pigs – Maximisation design 3504.79/ DECO HET K-046193-112 [000072] Dow GLP.Unpublished	
IIA ,5.4.2	Proudlock, R.J.	1994	Reldan F: *In Vivo* Rat Liver DNA Repair Test. E08 DOE GLP. Unpublished	
IIA,5.5	Barna-Lloyd, T., Szabo, J.R. and Davis, N.L.	1991	Chlorpyrifos-methyl (Reldan* Insecticide): Chronic Dietary Toxicity/Oncogenicity Study in Rats I02 DOE GLP. Unpublished	
IIA, 5.6	Carney, EW; Stebbins, KE; Marable, BR, Liberacki, AB	2002	Chlorpyrifos-methyl: two generation dietary reproduction toxicity study in CD rats dose 011132 Dow GLP. Unpublished	
IIA, 5.6	Marty, M.S.	2000	Results of a three generation, two litter reproduction study on 0,0-dimethyl 0-(3,5,6-trichloro-2-pyridyl) phosphoro-thioate (DOWCO 214) in the rat K-046193-098 Dow Not GLP. Unpublished	
IIA, 5.6.2.2	Bryson, A.M., Marsden, E.K.S., John, D.M., Anderson, A. and Dawe, I.S.	1991	A Study of the Effect of Technical Reldan on Pregnancy of the Rat F07 DOE GLP. Unpublished	
IIA, 5.8	Bruner, R.H. and Gopinath, C.	2000	Chlorpyrifos-methyl (RELDAN Insecticide): Pathology Peer Review – Adrenocortical Vacuolar Change – Dow Study K-046193-031 K-046193-031 DECO TXT: K-046193-031S Dow Not GLP. Unpublished	

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IIA, 5.8	M. S. Marty, R.M. and Golden, D.L. Rick.	2013	Chlorpyrifos-methyl: acute oral neurobehavioral and cholinesterase inhibition study in female Crl (SD) rats. DOW Chemical company study ID 121202; DAS Ref. B27 GLP. Unpublished	

B.7 Residue data.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII, 6.0	Thomas A. D., L. A.; Lindsay, D. A.; Miller, A. M.; Rutherford, L. A.	2002	Frozen storage stability of chlorpyrifos-methyl in whole oranges, grapes, grape wine, tomatoes, tomato juice, and wheat grain (S01) 010118 / GH-C 5410 Dow GLP. Unpublished	
AII, 6.0	Thomas A. D., L. A.; Lindsay, D. A.; Miller, A. M.; Rutherford, L. A.	2002	Frozen storage stability of chlorpyrifos-methyl in beef muscle, beef liver, beef kidney, beef fat, dairy milk, and eggs (S02) 010119 / GH-C 5409 Dow GLP. Unpublished	
AII, 6.1	Graper, L.K.,	2002	Nature of the residues study with 14C-labeled chlorpyrifos applied to cabbage – Interim Report (L014) 010028 /GH-C 5411 Dow Not GLP. Unpublished	
AII, 6.1	Magnussen, J.D.	2002	Chlorpyrifos citrus nature of residue study – Interim report (L015) 010095 /GH-C 5404 Dow Not GLP. Unpublished	
AII, 6.1	L.K.Graper, , J:L:Balcer, S.Hilla,K.P. Smith	2003	A Nature of the Residue Study with 14C-Labeled Chlorpyrifos Applied to Cabbage Additional Characterization of Radioactive Residues. Study ID. 020135 Dow Not GLP. Unpublished	
AII, 6.1	Lewer, P.	1990	Reinvestigation of the nature of the residues in forage from ^{14}C-chlorpyrifos-treated field corn (L012) Report No. GH-C 2291 Dow GLP. Unpublished	
AII/6.1/01	Bauriedel, W.R., Miller, J.H.	1980	The Metabolic Fate of ^{14}C-Chlorpyrifos Applied To An Apple Tree. GH-C 1397 (L06) Dow Not GLP. Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII, 6.1	Bauriedel, W.R. and Miller, J.H.	1981	The metabolic fate of ^{14}-C-chlorpyrifos applied topically to soybeans (L02) Report No. GH-C 1414 Dow Not GLP. Unpublished	
AII, 6.1	Baloch, R. (Dow AgroSciences) and Caley, C. (IRI) // Caley, C.Y. and Kingsley, R.L.	1996	Report Metabolism of Chlorpyrifos-methyl in Tomatoes Report No. GHE-P-6064 (L04) Dow GLP. Unpublished	
AII, 6.1	Baloch, R. (Dow AgroSciences) and Caley, C. (IRI) 77 Caley, C.Y.	1996	Report Metabolism of Chlorpyrifos-methyl in Lettuce Report No. GHE-P-6065 (L05) Dow GLP. Unpublished	
AII, 6.1	Graper, L.K.	2002	Nature of residue study with ^{14}C-labeled chlorpyrifos-methyl applied to tomatoes – Interim Report 010029 / GH-C 5412 Dow Not GLP. Unpublished	
IIA, 6.3	Khoshab, A. and Bolton, A	1995	Residues of chlorpyrifos-methyl in post-harvest stored Wheat and Barley grain following treatment with RELDAN 22 (EF-1066) or RELDAN 50 (EF-917) at two different rates of application N091 DOE GLP. Unpublished	
IIA, 6.3	Teasdale, R.	1996	Residues of chlorpyrifos-methyl in wine grapes at intervals following a single application of RELDAN 22 (EF-1066), Northern and Southern France - 1995 NO92 DOE GLP. Unpublished	
AII, 6.3	Teasdale, R.	2000	Residues of chlorpyrifos-methyl in tomatoes at harvest and processed fractions (canned tomatoes, juice and puree) following multiple applications of RELDAN 22 (EF-1066), Italy – 1999 R99-106 / GHE-P-8661 Dow GLP. Unpublished	

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AII, 6.3	Teasdale, R.	2000	Residues of chlorpyrifos-methyl in tomatoes at intervals grown under cover following multiple applications of RELDAN 22 (EF-1066), Spain – 1999 R99-107 / GHE-P-8662 Dow GLP. Unpublished	
AII, 6.3	Doran, A. and Craig, A.	2001	Residues of chlorpyrifos-methyl in grapes at harvest and processed fractions (wet pomace, must and wine) following applications of RELDAN 22 (EF-1066), Northern France - 1999 369230 / GHE-P-8651 Dow GLP. Unpublished	
AII, 6.3	Doran, A. and Craig, A.	2001	Residues of chlorpyrifos-methyl in grapes at harvest and processed fractions (wet pomace, must and wine) following applications of RELDAN 22 (EF-1066), Southern France - 1999 369272 / GHE-P-8655 Dow GLP. Unpublished	
AII, 6.3	Doran, A. and Craig, A.	2001	Residues of chlorpyrifos-methyl in grapes at harvest following applications of RELDAN 22 (EF-1066), Italy - 1999 369293 / GHE-P-8657 Dow GLP. Unpublished	
AII, 6.3	Doran, A. and Craig, A.	2001	Residues of chlorpyrifos-methyl in grapes at intervals following applications of RELDAN 22 (EF-1066), Spain - 1999 369288 / GHE-P-8656 Dow GLP. Unpublished	
AII, 6.3	Doran, A. and Craig, A.	2001	Residues of chlorpyrifos-methyl in grapes at intervals following applications of RELDAN 22 (EF-1066), Northern France – 1999 369225 / GHE-P-8650 Dow GLP. Unpublished	

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AII, 6.3	Doran, A. and Craig, A.	2001	Residues of chlorpyrifos-methyl in grapes at intervals following applications of RELDAN 22 (EF-1066), Germany - 1999 369246 / GHE-P-8652 Dow GLP. Unpublished	
AII, 6.3	Doran, A. and Craig, A.	2001	Residues of chlorpyrifos-methyl in table grapes at intervals following applications of RELDAN 22 (EF-1066), Southern France - 1999 368267 / GHE-P-8654 Dow GLP. Unpublished	
AII, 6.3	Doran, A. and Craig, A.	2001	Residues of chlorpyrifos-methyl in wine grapes at harvest following applications of RELDAN 22 (EF-1066), Germany - 1999 369251 / GHE-P-8653 Dow GLP. Unpublished	
AII, 6.3	Doran, A. and Clements, B.	2002	Residues of chlorpyrifos-methyl in grapes at harvest following two applications of EF-1066 (RELDAN 22) or GF-71, Northern France – 2000 (N134) 19279 / GHE-P-9437 000219 Dow GLP. Unpublished	
AII, 6.3	Doran, A. and Clements, B.	2002	Residues of chlorpyrifos-methyl in grapes at intervals following two applications of RELDAN 22 (EF-1066), Southern Europe – 2000 (N135) 19953 / GHE-P-9446 000222 Dow GLP. Unpublished	
AII, 6.3	Doran, A. and Clements, B.	2002	Residues of chlorpyrifos-methyl in wine grapes at harvest following two applications of EF-1066 (RELDAN 22) or GF-71, Southern Europe – 2000 (N137) 19952 / GHE-P-9441 000221 Dow GLP. Unpublished	

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AII, 6.3	Doran, A. and Clements, B.	2002	Residues of chlorpyrifos-methyl in grapes at intervals following two applications of RELDAN 22 (EF-1066), Germany – 2000 (N138) 19278 / GHE-P-9430 Dow GLP. Unpublished	
AII, 6.3	Daneu, E.	2000	Residues of Reldan 40 (Chlorpyrifos-methyl) in W. wheat, apples and grapes following registration trials in Russia, 1999 (N150) GHE-P-7245 Dow Not GLP. Unpublished	

B.8 Environmental fate and behaviour.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII, 7.1.1/ AII, 7.2.1	Jackson, R. and Portwood, D.	2000	The generation and identification of water and soil degradation products of Chlorpyrifos-methyl (K28) GHE-P-9032 Dow GLP. Unpublished	
AII, 7.1.1	Reves, G.L.	1994	The Aerobic Soil Degradation of [^{14}C]-Chlorpyrifos-methyl. (K13) Report No. GHE-P-3638 Dow GLP. Unpublished	
AII, 7.1.1	de Vette, H.Q.M. and Schoonmade, J.A.	2001	Study on the route and rate of aerobic degradation of [^{14}C]-TCP (3,5,6-trichloropyridinol) in four European soils (K18) 2302/01 GH-C 5182 Dow GLP. Unpublished	
AII, 7.1.1	Brull, L.p., Donath-van Scholl, I., de Vette, H.Q.M. and Heim L.G.	2002	Investigation into the identity of an unknown metabolite formed during an aerobic soil degradation study using 3,5,6-trichloro-2-pyridinol (K18A) 2302/02 Dow GLP. Unpublished	
AII, 7.1.1.2.2	Old, J.	2000	Dissipation of chlorpyrifos and its major metabolite (3,5,6-trichloro-2-pyridinol) in soil following a single application of DURSBAN 4, UK - 2000 (K119) 397514 [000249] Dow GLP. Unpublished	
AII, 7.1.1.2.2	Old, J.	2000	Dissipation of chlorpyrifos and its major metabolite (3,5,6-trichloro-2-pyridinol) in soil following a single application of DURSBAN 4, France - 2000 (K120) 397535 [000250] Dow GLP. Unpublished	

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AII, 7.1.1.2.2	Old, J.	2000	Dissipation of chlorpyrifos and its major metabolite (3,5,6-trichloro-2-pyridinol) in soil following a single application of DURSBAN 4, Greece - 2000 (K121) 300006 [000251] Dow GLP. Unpublished	
AII, 7.1.1.2.2	Old, J.	2000	Dissipation of chlorpyrifos and its major metabolite (3,5,6-trichloro-2-pyridinol) in soil following a single application of DURSBAN 4, UK - 2000 (K122) 397540 [000252] Dow GLP. Unpublished	
AII, 7.1.2	Damon, A. and Sarff, P.	2001	Adsorption and desorption of ^{14}C-3,5,6-trichloro-2-pyridinol to five European soils (K20) 46261 GH-C 5251 / [000391] Dow GLP. Unpublished	
AII, 7.1.2	Damon, A. and Heim, L.	2001	Adsorption and desorption of ^{14}C-3,5,6-trichloro-2-methoxypyridine to five European soils (K101) 46260 GH-C 5326 / [000392] Dow GLP. Unpublished	
AII, 7.1.3.2	Reves, G.L.	1994	The Leaching Characteristics of Aged [^{14}C]-Chlorpyrifos Soil Residues GHE-P-3758 Dow GLP. Unpublished	
IIA, 7.1.2	Racke, K.D., Lubinski, R.N.	1992	Sorption of 3,5,6-Trichloro-2-Pyridinol in four Soils. K19 DOE GLP. Unpublished	
IIA, 7.1.1.1.2, 7.1.3.2, 7.2.1.4	Racke, K.D., Concha, M., Shepler, K.	1994	Photodegradation of 3,5,6-trichloro-2-pyridinol on soil by natural sunlight K20 DOE GLP. Unpublished	

Annex point/ reference number	**Author(s)**	**Year**	**Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not**	**Reports on previous use in granting national authorizations**
IIA, 7.1.1.1.2, 7.2.1.1, 7.2.1.3.2	Phillips, M. and Hall, B.E.	1994	The Aerobic Degradation of Chlorpyrifos-methyl in Natural Waters and Associated Sediments. K12 DOE GLP. Unpublished	
IIA, 7.1.1.1, 7.1.1.1.2, 7.1.1.2.1, 7.1.3.2	Reeves, G.L.	1994	The Aerobic Soil Degradation of [^{14}C]-Chlorpyrifos-methyl. K13 DOE GLP. Unpublished	
IIA, 7.1.1.2.1, 7.1.3.2, 7.2.1.4	Reeves, G.L.	1994	The Leaching Characteristics of Aged [^{14}C]-Chlorpyrifos-methyl Soil Residues. K14 DOE GLP. Unpublished	
IIA, 7.1.3.1, 7.2.1.4	Reeves, G.L. and O’Connor, J.	1995	BBA Plant Product Evaluation : Determination of the seepage behaviour of chlorpyrifos-methyl by soil column studies (Normal test) K16 DOE GLP. Unpublished	
IIA , 2.9.1, 7.2.1.1	Yon, D.A.and Muller, J.	1994	Aqueous hydrolysis of chlorpyrifos-methyl. K17 DOE GLP. Unpublished	
IIA, 7.2.1.2	Yon, D.A. and Muller, J.	1994	Aqueous Photolysis of chlorpyrifos-methyl K18 DOE GLP. Unpublished	
IIA, 2.10, 7.2.2	Day, S.R. and Rüdel, H.	1993	The evaporation of Chlorpyrifos-methyl from soil and leaf surfaces and its persistence in air following application of Reldan 22 RO (EF 1066). K11 DOE GLP. Unpublished	
AII, 7.2.2	Simon, K.	2001	Estimation of Photochemical Oxidative Degradation of chlorpyrifos and 3,5,6-trichloropyridinol (K21) GH-C 5268 Dow Not GLP. Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII, 7.4	Hernández, F., Sancho, J.V., Roig, A., López, F.J., Morell,, I., Pozo, O., Marin, J.M., Tuñón, J., and Lara, A. Reeves, G	2002	Monitoring chlorpyrifos surface water concentrations following use in citrus orchards, Spain – 2000/2001 (K118) 00378 GHE-P-9667 Dow GLP. Unpublished	
AII, 7.4	Yon, D., Wright, K. and Horth, H.	2002	Review of monitoring and occurrence of chlorpyrifos-methyl in groundwater and surface water in Europe CO 5055 / GHE-P-9756 Dow Not GLP. Unpublished	
AII, 7.4	Pepper, T., Arnold, D. and Reeves, G.	2002	Parameters affecting the deposition of chlorpyrifos spray drift on edge of field water bodies (K125) XACER GHE-P-9790 / [001047] Dow GLP. Unpublished	
AII 7.4	Capri, E.	2002	Monitoring the chlorpyrifos and chlorpyrifos methyl surface water exposure at field, catchment and regional scale in Trentino (N. Italy, 2001-2002) – interim report. (K126) GHE-P-9821 Dow GLP. Unpublished	
AII, 7.4	Capri, E.	2002	Monitoring the chlorpyrifos and chlorpyrifos methyl surface water exposure at field, catchment and regional scale in Sicily (S. Italy, 2001-2002) – interim report. (K127) GHE-P-9822 Dow GLP. Unpublished	
AII, 7.4	Paulsen, R.T.	2002	Evaluating citrus proximity to surface water in Italy and Spain using remote sensing. (K128) [Makhteshim-Agan study] EarthSat R-12463 Dow Not GLP. Unpublished	

B.9 Ecotoxicology.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 8.1.1	Hakin , B.and Johnson, A.J.	1991	RELDAN F : Acute oral toxicity (LD50) to Bobwhite Quail. J33 DOE GLP. Unpublished	
AII, 8.1.1	Rodgers, M.H.	2001	EF-1066: Acute oral toxicity (LD_{50}) to the bobwhite quail DOS 181/004672 / GHE-T-1100 Dow GLP. Unpublished	
AII, 8.1.3	Rodgers, M.H.	1998	Chlorpyrifos-methyl : Effects on reproduction in Mallard duck (J64) Report No. DWC 781/972839 - GHE-P-873 Dow GLP. Unpublished	
AII, 8.2/ IIIA, 10.2.2	van Wijngaarden, R.P.A. and Brock, T.C.M.	2001	Chlorpyrifos algal microcosm experiment (J110) F20507 / GHE-T-1128 Dow Not GLP. Unpublished	
IIA, 8.2.1.	Douglas, M.T.	1992 a	Reldan F. Acute Toxicity to Rainbow Trout (Oncorhynchus mykiss) J37 DOE GLP. Unpublished	
IIA, 8.2.2	Douglas, M.T.	1992 b	Reldan F. Prolonged Toxicity to Rainbow Trout (Oncorhynchus mykiss). J38 DOE GLP. Unpublished	
AII, 8.2.2.1	Marino, T.A., Gilles, M.M., Rick, D.L. and Henry, K.S.	1999	Evaluation of the toxicity of 3,5,6-Trichloro-2-pyridinol (TCP) to the early life stages of the rainbow trout, *Oncorhynchus mykiss* Walbaum (J17) 991173 DECO HET-K-038278-042 Dow GLP. Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 8.2.3	Hawkins, D.R., Mayo, B.C., McEwen, A.B. and Newton, L.V	1992	The assessment of bioaccumulation of ^{14}C-chlorpyrifos-methyl in rainbow trout. J36 DOE GLP. Unpublished	
IIA, 8.2.4	Douglas, M.T	1992 c	Reldan F. Acute Toxicity to Daphnia magna. J39 DOE GLP. Unpublished	
IIA, 8.2.5	Douglas, M.T	1992 d	Reldan F. An Assessment of the Effects on the Reproduction of Daphnia magna. J40 DOE GLP. Unpublished	
IIA, 8.2.6	Douglas , M.T., Bell, G. and MacDonald, I.A.	1992	The algistatic activity of Reldan F J34 DOE GLP. Unpublished	
AII, 8.3.1	Bakker, F.	2002	Effects of RELDAN 22 and DURSBAN 75 WG on honeybees, *Apis mellifera* L, when applied at different times, determined in a cage test DA013AMS Dow GLP. Unpublished	
AII, 8.3.1	Bakker, F.	2002	Effects of RELDAN 22 and DURSBAN 75 WG on honeybees, *Apis mellifera* L, when applied at different times, determined in a cage test (J116) Report No. DA013AMS Dow GLP. Unpublished	
IIA, 8.3.1.1	Cole, J.H.	1992	The acute contact and oral toxicity to Honey Bees of Reldan F Technical. J35 DOE GLP. Unpublished	
IIA, 8.3.1.1, IIIA, 10.4.1	Bell, G	1994	Acute Toxicity of Reldan 22 to Honey bees J45 DOE GLP. Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII, 8.3.2	Manley, B.	2001	Extended laboratory test to determine the effects of fresh and aged residues of drift-rate concentrations of Dursban 4 EC (480 g/L chlorpyrifos) and Reldan 22 (225 g/L chlorpyrifos-methyl), on the green lacewing, *Chrysoperla carnea* (Neuroptera, Chrysopidae) (J115). Laboratory Mambo-Tox, Southampton, UK. Report No. Dow 01-038 GHE-P-9725 Dow GLP. Unpublished	
AII, 8.3.2	Miles, M.	2000	Extended laboratory bioassays to evaluate the duration of effect of RELDAN 40 EC (EF-1548 containing 400 g/L chlorpyrifos-methyl) and DURSBAN 75 WG (EF-1315 containing 750 g/kg chlorpyrifos-ethyl) on the lacewing (*Chrysoperla carnea*) in orchards GHE-P-6278 Dow GLP. Unpublished	
AII, 8.3.2	Mead-Briggs, M.	1997	Extended laboratory and semi-field study to evaluate the effects of DURSBAN 4 EC, RELDAN 50 EC and two reference products on the lycosid spider, *Pardosa* spp. DOW-97-6 / GHE-P-6927 Dow GLP. Unpublished	
AII, 8.3.2	Mead-Briggs, M.	1997	Extended laboratory and semi-field study to evaluate the effects of DURSBAN 4 EC, RELDAN 50 EC and two reference products on the ladybird, *Coccinella septempunctata*, in wheat DOW-97-6 / GHE-P-6926 Dow GLP. Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII, 8.3.2	Mead-Briggs, M.	1997	Extended laboratory and semi-field study to evaluate the effects of DURSBAN 4 EC, RELDAN 50 EC and two reference products on adult and pupal stages of aphid-specific parasitoids in wheat DOW-97-3 / GHE-P-6928 Dow GLP. Unpublished	
AII, 8.3.2	Mead-Briggs, M.	1997	Extended laboratory and semi-field study to evaluate the effects of DURSBAN 4 EC, RELDAN 50 EC and two reference products on the ground beetle, *Bembidion lampros*, in wheat DOW-97-5 / GHE-P-6929 Dow GLP. Unpublished	
AII, 8.3.2	Taruza, S.	2001	Extended laboratory test to determine the effects of fresh and aged residues of drift-rate concentrations of Dursban 4 EC (480 g/L chlorpyrifos) and Reldan 22 (225 g/L chlorpyrifos-methyl), on the predatory mite, *Typhlodromus pyri* (Acari, Phytoseiidae) DOW-01-37 / GHE-P-9449 Dow GLP. Unpublished	
AII, 8.3.2	Vinall, S	2001	Extended laboratory test to determine the effects of fresh and aged residues of drift-rate concentrations of Dursban 4 EC (480 g/L chlorpyrifos) and Reldan 22 (225 g/L chlorpyrifos-methyl), on the parasitic wasp, *Aphidius rhopalosiphi* (Hymenoptera, Braconidae) DOW-01-36 / GHE-P-9455 Dow GLP. Unpublished	
AII, 8.3.2	Maning, B.	2001	Extended laboratory test to determine the effects of fresh and aged residues of drift-rate concentrations of Dursban 4 EC (480 g/L chlorpyrifos) and Reldan 22 (225 g/L chlorpyrifos-methyl), on the green lacewing, *Chrysoperla carnea* (Neuroptera, Chrysopidae) DOW-01-38 / GHE-P-9725 Dow GLP. Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 8.3.2	Brown, K.C.	1991	The effects of Dursban 4 and Reldan 50 on beneficial arthropods in apple orchards. J50 DOE GLP. Unpublished	
IIA, 8.3.4	Hale, K. and Forster, J.	1994	A laboratory assessment of the effects of Reldan 22 (EF 1066) on soil microflora respiration and nitrogen turnover according to BBA guidelines VI 1-1 (1990). K15 DOE GLP. Unpublished	
AII, 8.4.1	Ward, T.J. & Boeri, R.L.	1999	3,5,6-Trichloro-2-pyridinol (TCP): Acute toxicity to the earthworm, Eisenia foetida. (J18) T.R. Wilbury Labs. Inc., Marblehead, MA, USA Study Id. 1860-DO – Report No.: DECO HET-K-038278-041 Dow GLP. Unpublished	
AII, 8.5	Mallett, M.J. & Hayward, J.C.	1999	A laboratory assessment of the effects of 3,5,6-trichloro-2-pyridinol on soil microflora respiration and nitrogen transformation according to OECD Test Guidelines 216 and 217. Dow AgroSciences, unpublished report No. CEMR-1151, 14 December 1999. Ref. TCP/TMP J16. Dow GLP. Unpublished	

APPENDIX IIIB

Chlorpyrifos-methyl

List of studies which were submitted during the evaluation process and were not cited in the draft assessment report:

B.1 Identity, B.2 Physical and chemical properties, B.3 Data on application and further information, B.4 Proposals for classification and labelling, B.5 Methods of analysis.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA,1.11	N. Richardson and S. Knowles	1999	Five Batch Analysis of chlorpyrifos-methyl technical, RELDAN F; Technical assay and spectral characterisation (A56) Report No. GHE-P-7974 Dow GLP. Unpublished
IIA,1.11	Litwinski, G. and Chan, K.W.	2001	Multi-Batch analysis for RELDAN Technical DECO GL-AL MD-2000-005770 Dow GLP. Unpublished
IIA,1.11	Litwinski, G	2001	Determination of Reldan oxygen analog and O,S-dimethyl dithioate impurities in Reldan 8-batch study samples by gas chromatography GL-AL 2001-001718 Dow Not GLP. Unpublished
IIA,1.11	Moreland, J. and Fonquerne, C.	2001	Determination of sulfotemp ester in RELDAN F Technical and RELDAN 50SM Manufacturers Concentrate GHE-P-9114 Dow GLP. Unpublished
IIA,1.11	Litwinski, G.R.		Determination of absolute and relative response factors for RELDAN and its process impurities by gas chromatography with FID detection January 2002 DECO GL-AL MD-2002-000245 Dow Not GLP. Unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA, 2	N. Richardson and A. Comb	1999	Determination of physico-chemical properties (Technical grade Solvent Solubility) (A55) Report No. DWC983/984074 - GHE-P-7780 Dow GLP. Unpublished
IIA, 2.3	Watson, P.A.	2002	Chlorpyrifos-methyl: Calculation of Henry's Law Constant (H) HLC/12 – 2/02 GHE-P-9749 Dow Not GLP. Unpublished
IIA,2.3	Watson, P.A.	2002	3,5,6-trichloro-2-pyridinol (TCP): Calculation of Henry's Law Constant (H) (A18) HLC/10 – ½ GHE-P-9748 Dow GLP. Unpublished
IIA, 2.3	Griffin, K.A.	2001	Vapor pressure of 3,5,6-trichloro-2-pyridinol by Knudsen-Effusion Weight loss method (A13) DECO GL-AL MD-2001-002731 Dow GLP. Unpublished
IIA, 2.5	Knowles, S. and Drossopoulos, M.	1998	Spectral characterisation of 2-pyridinol (AGR143197) (A9) Report No. P098-069 - GHE-P-7361 Dow GLP. Unpublished
IIA, 2.5	Russell, M.W., Cooper, D., Vorhies, S., Godby, J. and Hilla, S.	2002	Determination of the Mass, Infrared, Nuclear Magnetic Resonance and Ultraviolet/Visible spectra of sulfotemp FAPC023049 Dow GLP. Unpublished
IIA, 2.6	Comb, A.L.	2002	Determination of water solubility for chlorpyrifos-methyl DOS/292 Dow GLP. Unpublished
IIA, 2.6	Roulin, S.	2002	Determination of the water solubility of 3,5,6-trichloro-2-pyridinol (TCP) (A16) 01016/DA GHE-P-9491 Dow GLP. Unpublished
IIA, 2.7	Moreland, J. and Fonquerne, C.	2002	Determination of the solvent solubility of 3,5,6-trichloro-2-pyridinol (A15) 01016/DB GHE-P-9490 Dow GLP. Unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA, 2.8	Comb, A.L.	2001	Determination of partition coefficient for 3,5,6-trichloro-2-pyridinol (A17) DOS/271/014481 NAFST471 Dow GLP. Unpublished
IIA, 2.9	Cathie, C.	2001	Determination of dissociation constant of 3,5,6-trichloro-2-pyridinol using UV-Visible spectrophotometry (A14) 01-830-AG GHF-P-2357 Dow GLP. Unpublished
IIA, 4.1	Litwinski, G.R.	2001	Validation of a gas chromatographic method for the determination of Bis-RELDAN in RELDAN technical (O32) DECO GL-AL MD-2000-005768-REV Dow GLP. Unpublished
IIA, 4.2.1	Teasdale, R.	2000	Determination of residues of chlorpyrifos-methyl residues in crops and process fractions with a high water content (OR17) GRM 00.10 Dow Not GLP. Unpublished
IIA, 4.2.1	Maliani, N.	2002	Independent laboratory validation of Dow AgroSciences LLC Method GRM 00.10 – Determination of residues of chlorpyrifos-methyl residues in crops and process fractions with a high water content (OR17A) ML02-0995-DOW GH-C 5429 Dow GLP. Unpublished
IIA, 4.2.1	Olberding, E.L., Arnold, B.H. and Lindsey, A.E.	2002	Determination of residues of chlorpyrifos-methyl in agricultural commodities by gas chromatography with negative-ion chemical ionisation mass spectrometry (OR18) GRM 02.04 GH-C 5425 Dow GLP. Unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA, 4.2.1	Clark, S.	2002	Independent laboratory validation of Dow AgroSciences LLC Method GRM 02.04 – Determination of residues of chlorpyrifos-methyl in agricultural commodities by gas chromatography with negative-ion chemical ionisation mass spectrometry (OR18A) ML02-0998-DOW GH-C 5430 Dow GLP. Unpublished
IIA, 4.2.2	Schwake, J.D.	1995	Independent Laboratory Validation of Method GRM 92.12.R2 - Determination of 3,5,6-trichloro-2-pyridinol in soil by gas chromatography/Mass Spectrometry (O13B) QMAS94005 GH-C 3821 Dow GLP. Unpublished
IIA, 4.2.5	McKellar, R.L.	1979	Determination of chlorpyrifos and 3,5,6-trichloro-2-pyridinol in Whole Blood and Urine by gas chromatography (O35) ACR 79.9 Dow Not GLP. Unpublished
IIA, 4.2.5	Bartels, M.J. and Kastl P.E.	1992	Analysis of 3,5,6-trichloropyridinol in human urine using Negative Chemical Ionisation gas chromatography - Mass Spectrometry (P13) J. Chromatography, 575, 69-74 (1992) Dow Not GLP. Unpublished
IIA, 4.2.1	Wetters, J H, Dishburger, H J	1971	Determination of residues of O,O-Diethyl O-(3, 5, 6-Trichloro-2-pyridyl) phosphorothioate and O,O-Diethyl O-(3, 5, 6-Trichloro-2-Pyridyl) phosphate in peaches by gas chromatography with flame photometric detection. ACR71.14 Dow Not GLP. Unpublished
IIA, 4.2.1	Maliani, N.	2002	Independent laboratory validation of Dow AgroSciences LLC Method GRM 02.01 – Determination of residues of chlorpyrifos-methyl and chlorpyrifos in animal tissues by gas chromatography with negative-ion chemical ionisation mass spectrometry (O34A) ML02-0996-DOW GH-C 5437 Dow GLP. Unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA, 4.2.1	Olberding, E.L. and Lindsey, A.E.	2002	Determination of residues of chlorpyrifos-methyl and chlorpyrifos in animal tissues by gas chromatography with negative-ion chemical ionisation mass spectrometry (O34) GRM 02.01 GH-C 5423 Dow GLP. Unpublished
IIA, 4.2.3	Olberding, E.L.	1996	Determination of residues of Triclopyr, 3,5,6-trichloro-2-pyridinol and 2-methoxy-3,5,6-trichloropyridine in water by capillary gas chromatography with mass selective detection (O34) GRM 95.18 Dow GLP. Unpublished
IIA, 4.2.3	Olberding, E.L.	1997	Validation report for the determination of residues of Triclopyr, 3,5,6-trichloro-2-pyridinol and 2-methoxy-3,5,6-trichloropyridine in water by capillary gas chromatography with mass selective detection (O34A) RES 94075 / GH-C 4476 Dow GLP. Unpublished
IIA, 4.2.3	Harris, E.J.	1997	Independent laboratory validation of DowElanco method GRM 95.18 – Determination of residues of Triclopyr, 3,5,6-trichloro-2-pyridinol and 2-methoxy-3,5,6-trichloropyridine in water by capillary gas chromatography with mass selective detection (O34B) QMAP 97002 / GH-C 4494 Dow GLP. Unpublished
IIA, 4.2.3	Hernandez, F, Serrano, R., Miralles, M.C. and Font, N.	1996	Gas and liquid chromatography and enzyme linked immuno sorbent assay in pesticide monitoring of surface water from the Western Mediterranean (Comunidad Valenciana, Spain) (PK101) Chromatographia, 42, ¾, (1996) Dow Not GLP. Published
IIA, 4.2.3	Olberding, E.L. and Lindsey, A.E.	2002	Determination of residues of chlorpyrifos-methyl in ground water and surface water by gas chromatography with negative-ion chemical ionisation mass spectrometry (O33) GRM 02.08 GH-C 5417 Dow GLP. Unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA, 4.2.4	Rawle, N.W.	2002	Determination of chlorpyrifos-methyl in air by capillary gas chromatography with mass spectrometric detection (O35) GRM 02.17 (CEMR-1807) GHE-P-9777 Dow GLP. Unpublished
IIA, 4.2.5	Brzak, K.A., Harms, D.W. and Bartels, M.J.	1997	Determination of chlorpyrifos, chlorpyrifos-oxon and 3,5,6-trichloro-2-pyridinol in rat and human blood (ODR073) T2.02-195-000-003A Dow Not GLP. Published

B.6 Toxicology and metabolism.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA, 5.1	Nolan, R.J., Dryzga, M.D., Landenberger, B.D., Kastl, P.E.	1987	Chlorpyrifos: Tissue distribution and metabolism of Orally 14 administered C-labelled chlorpyrifos in Fischer 344 rats. HET K-044793-76 Dow GLP. Unpublished
IIA, 5.1	Nolan RJ, Dryzga MD, Landenberger BD & Kastl PE	1987	Tissue distribution and metabolism of orally administered 14C-labeled chlorpyrifos in Fischer 344 rats. Ref. H015 Dow GLP. Unpublished
IIA, 5.2.6	Wilson, C.W.	2000	Technical grade chlorpyrifos-methyl: Dermal sensitization study in guinea pigs – Maximisation design 3504.79/ DECO HET K-046193-112 [000072] Dow GLP.Unpublished
IIA, 5.6	Carney, EW; Stebbins, KE; Marable, BR, Liberacki, AB	2002	Chlorpyrifos-methyl: two generation dietary reproduction toxicity study in CD rats dose 011132 Dow GLP. Unpublished
IIA, 5.6	Marty, M.S.	2000	Results of a three generation, two litter reproduction study on 0,0-dimethyl 0-(3,5,6-trichloro-2-pyridyl) phosphorothioate (DOWCO 214) in the rat K-046193-098 Dow Not GLP. Unpublished
IIA, 5.8	Bruner, R.H. and Gopinath, C.	2000	Chlorpyrifos-methyl (RELDAN Insecticide): Pathology Peer Review – Adrenocortical Vacuolar Change – Dow Study K-046193-031 K-046193-031 DECO TXT: K-046193-031S Dow Not GLP. Unpublished
IIIA, 7.2	Bartels, M.J., Vaccaro, J.R., Hugo, J.M. and Marobito, P.L.	1990	Analysis of gauze patches, air sampling tubes and urine samples in support of the Californian Department of Food and Agriculture chlorpyrifos indoor exposure study (CDFA Protocol WHS 7.15.88) (ODR074) DECO-K-044793-087 Dow Not GLP. Unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIIA, 7.3	Shah, P.V., Monroe, R.J. and Guthrie, F.E.	1981	Comparative rates of dermal penetration of insecticieds in mice (P021) Toxicol. And Appl. Pharm., 59, 414-423, (1981) Not GLP. Published

B.7 Residue data.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
AII, 6.0	Thomas A. D., L. A.; Lindsay, D. A.; Miller, A. M.; Rutherford, L. A.	2002	Frozen storage stability of chlorpyrifos-methyl in whole oranges, grapes, grape wine, tomatoes, tomato juice, and wheat grain (S01) 010118 / GH-C 5410 Dow GLP. Unpublished
AII, 6.0	Thomas A. D., L. A.; Lindsay, D. A.; Miller, A. M.; Rutherford, L. A.	2002	Frozen storage stability of chlorpyrifos-methyl in beef muscle, beef liver, beef kidney, beef fat, dairy milk, and eggs (S02) 010119 / GH-C 5409 Dow GLP. Unpublished
AII, 6.1	Graper, L.K.,	2002	Nature of the residues study with 14C-labeled chlorpyrifos applied to cabbage – Interim Report (L014) 010028 /GH-C 5411 Dow Not GLP. Unpublished
AII, 6.1	Magnussen, J.D.	2002	Chlorpyrifos citrus nature of residue study – Interim report (L015) 010095 /GH-C 5404 Dow Not GLP. Unpublished
AII, 6.1	L.K.Graper, , J:L:Balcer, S.Hilla,K.P. Smith	2003	A Nature of the Residue Study with 14C-Labeled Chlorpyrifos Applied to Cabbage Additional Characterization of Radioactive Residues. Study ID. 020135 Dow Not GLP. Unpublished
IIA, 6.1	Bauriedel, W.R., Miller, J.H.	1977	Uptake of ^{14}C-Chlorpyrifos by corn plants GH-C 1036 (L01) Dow Not GLP. Unpublished
AII, 6.1	Lewer, P.	1990	Reinvestigation of the nature of the residues in forage from ^{14}C-chlorpyrifos-treated field corn (L012) Report No. GH-C 2291 Dow Not GLP. Unpublished
AII, 6.1	Smith, et. al.	1967	Investigations on Dursban Insecticide. Uptake and Translocation of [^{36}Cl] O,O-Diethyl O-3,5,6-Trichloro-2-pyridyl Phosphorathioate and [^{14}C] O,O-Diethyl O-3,4,6-Trichloro-2-pyridyl Phosphorothioate by Beans and Corn Report No. PL002 Dow Not GLP. Published

Annex point/ reference number	**Author(s)**	**Year**	**Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not**
AII/6.1/01	Bauriedel, W.R., Miller, J.H.	1980	The Metabolic Fate of ^{14}C-Chlorpyrifos Applied To An Apple Tree. GH-C 1397 (L06) Dow Not GLP. Unpublished
AII/6.1/02	Bauriedel, W.R., Miller, J.H.	1986	The Metabolic Fate of 14C-Chlorpyrifos Applied to Field Corn at Planting (Soil Application) And In Mid-Season (Foliar Application). GH-C 1807 (L07) Dow Not GLP. Unpublished
AII, 6.2	Bauridel, W.R.	1986	Fate of ^{14}C-Chlorpyrifos Administered to Laying Hens Report No. GH-C-1837 (H13) Dow GLP. Unpublished
AII, 6.1/6.2	Bauridel, W.R.	1982	Compilation of three recent studies of the metabolic fate of ^{14}C-Chlorpyrifos-methyl in stored grain, lactating goats and laying hens (stored grain section) Report No. GH-C-1578 (L03) Dow Not GLP. Unpublished
AII, 6.1	Bauriedel, W.R. and Miller, J.H.	1981	The metabolic fate of ^{14}-C-chlorpyrifos applied topically to soybeans (L02) Report No. GH-C 1414 Dow Not GLP. Unpublished
AII, 6.1	Baloch, R. (Dow AgroSciences) and Caley, C. (IRI) // Caley, C.Y. and Kingsley, R.L.	1996	Report Metabolism of Chlorpyrifos-methyl in Tomatoes Report No. GHE-P-6064 (L04) Dow GLP. Unpublished
AII, 6.1	Baloch, R. (Dow AgroSciences) and Caley, C. (IRI) 77 Caley, C.Y.	1996	Report Metabolism of Chlorpyrifos-methyl in Lettuce Report No. GHE-P-6065 (L05) Dow GLP. Unpublished
AII, 6.1	Graper, L.K.	2002	Nature of residue study with ^{14}C-labeled chlorpyrifos-methyl applied to tomatoes – Interim Report 010029 / GH-C 5412 Dow Not GLP. Unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
AII, 6.3	Teasdale, R.	2000	Residues of chlorpyrifos-methyl in tomatoes at harvest and processed fractions (canned tomatoes, juice and puree) following multiple applications of RELDAN 22 (EF-1066), Italy – 1999 R99-106 / GHE-P-8661 Dow GLP. Unpublished
AII, 6.3	Teasdale, R.	2000	Residues of chlorpyrifos-methyl in tomatoes at intervals grown under cover following multiple applications of RELDAN 22 (EF-1066), Spain – 1999 R99-107 / GHE-P-8662 Dow GLP. Unpublished
AII, 6.3	Doran, A. and Craig, A.	2001	Residues of chlorpyrifos-methyl in grapes at harvest and processed fractions (wet pomace, must and wine) following applications of RELDAN 22 (EF-1066), Northern France - 1999 369230 / GHE-P-8651 Dow GLP. Unpublished
AII, 6.3	Doran, A. and Craig, A.	2001	Residues of chlorpyrifos-methyl in grapes at harvest and processed fractions (wet pomace, must and wine) following applications of RELDAN 22 (EF-1066), Southern France - 1999 369272 / GHE-P-8655 Dow GLP. Unpublished
AII, 6.3	Doran, A. and Craig, A.	2001	Residues of chlorpyrifos-methyl in grapes at harvest following applications of RELDAN 22 (EF-1066), Italy - 1999 369293 / GHE-P-8657 Dow GLP. Unpublished
AII, 6.3	Doran, A. and Craig, A.	2001	Residues of chlorpyrifos-methyl in grapes at intervals following applications of RELDAN 22 (EF-1066), Spain - 1999 369288 / GHE-P-8656 Dow GLP. Unpublished
AII, 6.3	Doran, A. and Craig, A.	2001	Residues of chlorpyrifos-methyl in grapes at intervals following applications of RELDAN 22 (EF-1066), Northern France – 1999 369225 / GHE-P-8650 Dow GLP. Unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
AII, 6.3	Doran, A. and Craig, A.	2001	Residues of chlorpyrifos-methyl in grapes at intervals following applications of RELDAN 22 (EF-1066), Germany - 1999 369246 / GHE-P-8652 Dow GLP. Unpublished
AII, 6.3	Doran, A. and Craig, A.	2001	Residues of chlorpyrifos-methyl in table grapes at intervals following applications of RELDAN 22 (EF-1066), Southern France - 1999 368267 / GHE-P-8654 Dow GLP. Unpublished
AII, 6.3	Doran, A. and Craig, A.	2001	Residues of chlorpyrifos-methyl in wine grapes at harvest following applications of RELDAN 22 (EF-1066), Germany - 1999 369251 / GHE-P-8653 Dow GLP. Unpublished
AII, 6.3	Doran, A. and Craig, A.	2001	Residues of chlorpyrifos-methyl in tomatoes at intervals following multiple applications of RELDAN 22 (EF-1066), Spain – 1999 369309 / R99-103 GHE-P-8658 Dow GLP. Unpublished
AII, 6.3	Doran, A. and Craig, A.	2001	Residues of chlorpyrifos-methyl in cherry tomatoes at harvest grown under cover following multiple applications of RELDAN 22 (EF-1066), Spain – 1999 369314 / R99-104 / GHE-P-8659 Dow GLP. Unpublished
AII, 6.3	Doran, A. and Craig, A.	2001	Residues of chlorpyrifos-methyl in cherry tomatoes at harvest grown under open field conditions following multiple applications of RELDAN 22 (EF-1066), Greece – 1999 369335 R99-105 GHE-P-8660 Dow GLP. Unpublished
AII, 6.3	Doran, A. and Craig, A.	2001	Residues of chlorpyrifos-methyl in tomatoes at harvest grown under cover following multiple applications of RELDAN 22 (EF-1066), Spain – 1999 369340/R99-108 /GHE-P-8663 Dow GLP. Unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
AII, 6.3	Doran, A. and Craig, A.	2001	Residues of chlorpyrifos-methyl in tomatoes at intervals grown under cover following multiple applications of RELDAN 22 (EF-1066), Italy – 1999 369356/R99-109 /GHE-P-8664 Dow GLP. Unpublished
AII, 6.3	Doran, A. and Craig, A.	2001	Residues of chlorpyrifos-methyl in tomatoes at harvest grown under cover following multiple applications of RELDAN 22 (EF-1066), Italy – 1999 369361/R99-110 /GHE-P-8665 Dow GLP. Unpublished
AII, 6.3	Doran, A. and Clements, B.	2002	Residues of chlorpyrifos-methyl in tomatoes at intervals grown under cover following multiple applications of RELDAN 22 (EF-1066), Southern Europe – 2000 (N133) 19938 / GHE-P-9557 000202 Dow GLP. Unpublished
AII, 6.3	Doran, A. and Clements, B.	2002	Residues of chlorpyrifos-methyl in grapes at harvest following two applications of EF-1066 (RELDAN 22) or GF-71, Northern France – 2000 (N134) 19279 / GHE-P-9437 000219 Dow GLP. Unpublished
AII, 6.3	Doran, A. and Clements, B.	2002	Residues of chlorpyrifos-methyl in grapes at intervals following two applications of RELDAN 22 (EF-1066), Southern Europe – 2000 (N135) 19953 / GHE-P-9446 000222 Dow GLP. Unpublished
AII, 6.3	Doran, A. and Clements, B.	2002	Residues of chlorpyrifos-methyl in tomatoes at harvest under open field conditions following multiple applications of EF-1066 (RELDAN 22) or GF-71, Southern Europe – 2000 (N136) 19937 / GHE-P-9558 000201 GLP. Unpublished
AII, 6.3	Doran, A. and Clements, B.	2002	Residues of chlorpyrifos-methyl in wine grapes at harvest following two applications of EF-1066 (RELDAN 22) or GF-71, Southern Europe – 2000 (N137) 19952 / GHE-P-9441 000221 Dow GLP. Unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
AII, 6.3	Doran, A. and Clements, B.	2002	Residues of chlorpyrifos-methyl in grapes at intervals following two applications of RELDAN 22 (EF-1066), Germany – 2000 (N138) 19278 / GHE-P-9430 Dow GLP. Unpublished
AII, 6.3	Daneu, E.	2000	Residues of Reldan 40 (Chlorpyrifos-methyl) in W. wheat, apples and grapes following registration trials in Russia, 1999 (N150) GHE-P-7245 Dow Not GLP. Unpublished
AII, 6.3	Wardman, J. P. and Khoshab, A.	2002	Residues of Chlorpyrifos in citrus fruits at intervals and in process fractions following a single application of EF-1042 or EF-1315, Southern Europe – 2001 21222 /GH-C 9779 Dow GLP. Unpublished

B.8 Environmental fate and behaviour.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
AII, 7.1.1	Bidlack, H.D.	1977	Aerobic degradation of 3, 5, 6-trichloro-2-pyridinol in 15 agricultural soils (K4 TCP/TMP) GH-C 991 Dow Not GLP. Unpublished
AII, 7.1.1/ AII, 7.2.1	Jackson, R. and Portwood, D.	2000	The generation and identification of water and soil degradation products of Chlorpyrifos-methyl (K28) GHE-P-9032 Dow GLP. Unpublished
AII, 7.1.1	Laskowski, L.B., Comeaux, L.B. and Bidlack, H.D.	1977	Aerobic soil decomposition of ^{14}C-labeled 2-methoxy-3,5,6-trichloropyridine (K100) GH-C 964 Dow Not GLP. Unpublished
AII, 7.1.1	Reves, G.L.	1994	The Aerobic Soil Degradation of [^{14}C]-Chlorpyrifos-methyl. (K13) Report No. GHE-P-3638 Dow GLP. Unpublished
AII, 7.1.1	de Vette, H.Q.M. and Schoonmade, J.A.	2001	Study on the route and rate of aerobic degradation of [^{14}C]-TCP (3,5,6-trichloropyridinol) in four European soils (K18) 2302/01 GH-C 5182 Dow GLP. Unpublished
AII, 7.1.1	Brull, L.p., Donath-van Scholl, I., de Vette, H.Q.M. and Heim L.G.	2002	Investigation into the identity of an unknown metabolite formed during an aerobic soil degradation study using 3,5,6-trichloro-2-pyridinol (K18A) 2302/02 Dow GLP. Unpublished
AII, 7.1.1.2.2	Old, J.	2000	Dissipation of chlorpyrifos and its major metabolite (3,5,6-trichloro-2-pyridinol) in soil following a single application of DURSBAN 4, UK - 2000 (K119) 397514 [000249] GLP. Unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
AII, 7.1.1.2.2	Old, J.	2000	Dissipation of chlorpyrifos and its major metabolite (3,5,6-trichloro-2-pyridinol) in soil following a single application of DURSBAN 4, France - 2000 (K120) 397535 [000250] GLP. Unpublished
AII, 7.1.1.2.2	Old, J.	2000	Dissipation of chlorpyrifos and its major metabolite (3,5,6-trichloro-2-pyridinol) in soil following a single application of DURSBAN 4, Greece - 2000 (K121) 300006 [000251] GLP. Unpublished
AII, 7.1.1.2.2	Old, J.	2000	Dissipation of chlorpyrifos and its major metabolite (3,5,6-trichloro-2-pyridinol) in soil following a single application of DURSBAN 4, UK - 2000 (K122) 397540 [000252] GLP. Unpublished
AII, 7.1.2	Damon, A. and Sarff, P.	2001	Adsorption and desorption of ^{14}C-3,5,6-trichloro-2-pyridinol to five European soils (K20) 46261 GH-C 5251 / [000391] Dow GLP. Unpublished
AII, 7.1.2	Damon, A. and Heim, L.	2001	Adsorption and desorption of ^{14}C-3,5,6-trichloro-2-methoxypyridine to five European soils (K101) 46260 GH-C 5326 / [000392] Dow GLP. Unpublished
AII, 7.1.3.2	Reves, G.L.	1994	The Leaching Characteristics of Aged [^{14}C]-Chlorpyrifos Soil Residues GHE-P-3758 Dow GLP. Unpublished
AII, 7.2.2	Simon, K.	2001	Estimation of Photochemical Oxidative Degradation of chlorpyrifos and 3,5,6-trichloropyridinol (K21) GH-C 5268 Dow Not GLP. Unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
AII, 7.4	Hernández, F., Sancho, J.V., Roig, A., López, F.J., Morell,, I., Pozo, O., Marin, J.M., Tuñón, J., and Lara, A. Reeves, G	2002	Monitoring chlorpyrifos surface water concentrations following use in citrus orchards, Spain – 2000/2001 (K118) 00378 GHE-P-9667 Dow GLP. Unpublished
AII, 7.4	Yon, D., Wright, K. and Horth, H.	2002	Review of monitoring and occurrence of chlorpyrifos-methyl in groundwater and surface water in Europe CO 5055 / GHE-P-9756 Dow Not GLP. Unpublished
AII, 7.4	Pepper, T., Arnold, D. and Reeves, G.	2002	Parameters affecting the deposition of chlorpyrifos spray drift on edge of field water bodies (K125) XACER GHE-P-9790 / [001047] Dow GLP. Unpublished
AII 7.4	Capri, E.	2002	Monitoring the chlorpyrifos and chlorpyrifos methyl surface water exposure at field, catchment and regional scale in Trentino (N. Italy, 2001-2002) – interim report. (K126) GHE-P-9821 Dow GLP. Unpublished
AII, 7.4	Capri, E.	2002	Monitoring the chlorpyrifos and chlorpyrifos methyl surface water exposure at field, catchment and regional scale in Sicily (S. Italy, 2001-2002) – interim report. (K127) GHE-P-9822 Dow GLP. Unpublished
AII, 7.4	Paulsen, R.T.	2002	Evaluating citrus proximity to surface water in Italy and Spain using remote sensing. (K128) [Makhteshim-Agan study] EarthSat R-12463 Dow Not GLP. Unpublished
AII, 7.4	Toso, E., Trainotti, A., Lorenzin, M., Flaim, G., Speziati, S, and Pontalti, M.	1994	Rilevamento del Contento di Fitofarmacia: Nelle Acque e Nei Fanghi dei Torrenti e dei fiumi del Trentino (PK104) [Survey and maesurements of the phytopharamceutical materials (Phytotoxic substances): In the sludge and waters of the Trentino Rivers and streams] Not GLP. Published

B.9 Ecotoxicology.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
AII, 8.1.1	Rodgers, M.H.	2001	EF-1066: Acute oral toxicity (LD_{50}) to the bobwhite quail DOS 181/004672 / GHE-T-1100 Dow GLP. Unpublished
AII, 8.1.3	Rodgers, M.H.	1998	Chlorpyrifos-methyl : Effects on reproduction in Mallard duck (J64) Report No. DWC 781/972839 - GHE-P-873 Dow GLP. Unpublished
AII, 8.2/ IIIA, 10.2.2	van Wijngaarden, R.P.A. and Brock, T.C.M.	2001	Chlorpyrifos algal microcosm experiment (J110) F20507 / GHE-T-1128 Dow Not GLP. Unpublished
AII, 8.2.2.1	Marino, T.A., Gilles, M.M., Rick, D.L. and Henry, K.S.	1999	Evaluation of the toxicity of 3,5,6-Trichloro-2-pyridinol (TCP) to the early life stages of the rainbow trout, *Oncorhynchus mykiss* Walbaum (J17) 991173 DECO HET-K-038278-042 Dow GLP. Unpublished
AII, 8.3.1	Bakker, F.	2002	Effects of RELDAN 22 and DURSBAN 75 WG on honeybees, *Apis mellifera* L, when applied at different times, determined in a cage test DA013AMS Dow GLP. Unpublished
AII, 8.3.1	Bakker, F.	2002	Effects of RELDAN 22 and DURSBAN 75 WG on honeybees, *Apis mellifera* L, when applied at different times, determined in a cage test (J116) Report No. DA013AMS Dow GLP. Unpublished
AII, 8.3.2	Manley, B.	2001	Extended laboratory test to determine the effects of fresh and aged residues of drift-rate concentrations of Dursban 4 EC (480 g/L chlorpyrifos) and Reldan 22 (225 g/L chlorpyrifos-methyl), on the green lacewing, *Chrysoperla carnea* (Neuroptera, Chrysopidae) (J115). Laboratory Mambo-Tox, Southampton, UK. Report No. Dow 01-038 GHE-P-9725 Dow GLP. Unpublished

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or not**
AII, 8.3.2	Miles, M.	2000	Extended laboratory bioassays to evaluate the duration of effect of RELDAN 40 EC (EF-1548 containing 400 g/L chlorpyrifos-methyl) and DURSBAN 75 WG (EF-1315 containing 750 g/kg chlorpyrifos-ethyl) on the lacewing (*Chrysoperla carnea*) in orchards GHE-P-6278 Dow GLP. Unpublished
AII, 8.3.2	Mead-Briggs, M.	1997	Extended laboratory and semi-field study to evaluate the effects of DURSBAN 4 EC, RELDAN 50 EC and two reference products on the lycosid spider, *Pardosa* spp. DOW-97-6 / GHE-P-6927 Dow GLP. Unpublished
AII, 8.3.2	Mead-Briggs, M.	1997	Extended laboratory and semi-field study to evaluate the effects of DURSBAN 4 EC, RELDAN 50 EC and two reference products on the ladybird, *Coccinella septempunctata*, in wheat DOW-97-6 / GHE-P-6926 Dow GLP. Unpublished
AII, 8.3.2	Mead-Briggs, M.	1997	Extended laboratory and semi-field study to evaluate the effects of DURSBAN 4 EC, RELDAN 50 EC and two reference products on adult and pupal stages of aphid-specific parasitoids in wheat DOW-97-3 / GHE-P-6928 Dow GLP. Unpublished
AII, 8.3.2	Mead-Briggs, M.	1997	Extended laboratory and semi-field study to evaluate the effects of DURSBAN 4 EC, RELDAN 50 EC and two reference products on the ground beetle, *Bembidion lampros*, in wheat DOW-97-5 / GHE-P-6929 Dow GLP. Unpublished
AII, 8.3.2	Taruza, S.	2001	Extended laboratory test to determine the effects of fresh and aged residues of drift-rate concentrations of Dursban 4 EC (480 g/L chlorpyrifos) and Reldan 22 (225 g/L chlorpyrifos-methyl), on the predatory mite, *Typhlodromus pyri* (Acari, Phytoseiidae) DOW-01-37 / GHE-P-9449 Dow GLP. Unpublished

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or not**
AII, 8.3.2	Vinall, S	2001	Extended laboratory test to determine the effects of fresh and aged residues of drift-rate concentrations of Dursban 4 EC (480 g/L chlorpyrifos) and Reldan 22 (225 g/L chlorpyrifos-methyl), on the parasitic wasp, *Aphidius rhopalosiphi* (Hymenoptera, Braconidae) DOW-01-36 / GHE-P-9455 Dow GLP. Unpublished
AII, 8.3.2	Maning, B.	2001	Extended laboratory test to determine the effects of fresh and aged residues of drift-rate concentrations of Dursban 4 EC (480 g/L chlorpyrifos) and Reldan 22 (225 g/L chlorpyrifos-methyl), on the green lacewing, *Chrysoperla carnea* (Neuroptera, Chrysopidae) DOW-01-38 / GHE-P-9725 Dow GLP. Unpublished
AII, 8.4.1	Ward, T.J. & Boeri, R.L.	1999	3,5,6-Trichloro-2-pyridinol (TCP): Acute toxicity to the earthworm, Eisenia foetida. (J18) T.R. Wilbury Labs. Inc., Marblehead, MA, USA Study Id. 1860-DO – Report No.: DECO HET-K-038278-041 Dow GLP. Unpublished
AII, 8.5	Mallett, M.J. & Hayward, J.C.	1999	A laboratory assessment of the effects of 3,5,6-trichloro-2-pyridinol on soil microflora respiration and nitrogen transformation according to OECD Test Guidelines 216 and 217. Dow AgroSciences, unpublished report No. CEMR-1151, 14 December 1999. Ref. TCP/TMP J16. Dow GLP. Unpublished

APPENDIX IV

List of uses supported by available data

Chlorpyrifos-methyl

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Grape vines	N. & S. Europe	Reldan 22 EC	F	Post-blossom pests	EC	225 g/L	Abmb, HL	Fruiting#	1	N/A	0.045	500	0.225	21	# Timing of application to be consistent with minimal exposure to bees
Wheat grain; post-harvest storage	N. + S. Europe	Reldan 22 EC	I	Grain storage pest complex	EC	225 g/L	Gss	Post-harvest	1	N/A	0.133 – 0.667	0.75-1.5 L/tonne	2.0-5.0 mg/Kg grain	90	Required MSI for <3.0 mg/Kg MRL

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

European Commission

Draft Renewal Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009

Chlorpyrifos-Methyl

Volume 1

Rapporter Member State: Spain
Co-Rapporter Member State: Poland

April 2017

Table of contents

LEVEL 1

Level 1

Statement of subject matter and purpose for which this report has been prepared and background information on the application

CHLORPYRIFOS-METHYL

1. STATEMENT OF SUBJECT MATTER AND PURPOSE FOR WHICH THIS REPORT HAS BEEN PREPARED AND BACKGROUND INFORMATION ON THE APPLICATION

1.1. CONTEXT IN WHICH THIS DRAFT ASSESSMENT REPORT WAS PREPARED

1.1.1. Purpose for which the draft assessment report was prepared

This monograph has been prepared for submission for the Standing Pesticides, Animal Feed and Food Committee so as to enable a decision to be made on the renewal of approval of active substance Chlorpyrifos-methyl submitted under article 14 of Regulation (EU) No 1107/2009. Chlorpyrifos-methyl was included in Annex I to Directive 91/414/EEC on 01 July 2006 by Commission Directive 2005/72/EC.

The use pattern for evaluation for renewal of approval of chlorpyrifos-methyl is provided in **Document D1** and summarised below (Table 1.1.1.01). The representative uses included in this submission are for citrus, pome fruit, peach/nectarine, cherry, plum grape, strawberry, potato, tomato, aubergine, pepper, oilseed rape, soybean, cotton, stored cereal grain and corn/maize.

Table 1.1.1.-1 Summary of the critical GAP

Crop (Zone)	Maximum Rate			Number of applications (minimum interval in days)	PHI (days)	Growth stage at latest application (BBCH)
	g as/ha	g as/hL	Water (L/ha)			
Representative uses						
Citrus (S)	1283	67.5	1900	1	21	BBCH 89
Pome fruit (S/C/N)	900	90	1000	1	21	BBCH 87
Stone fruit, apricot, peach, nectarine (S)	1020	68	1500	1	21	BBCH 87
Stone fruit, cherry, plum (C/N)	750-1000	100	750-1000	1	21	BBCH 87
Grape, Table (S)	608	67.5	900	1	14	BBCH 89
Grape, Wine (S/C/N)	338	67.5	500	2 (14)	14	BBCH 89
Strawberry (S/C/N)	540	-	-	1	5	BBCH 95
Potato (S/C/N)	540	-	750	1	21	BBCH 59
Solanaceous Vegetables, eggplant, pepper, tomato (S/C/N)	675	-	1000	1	5	BBCH 89
Oilseed rape (S/C/N)	450	-	600	1	N/A	BBCH 59
Soybean (S)	450	-	600	1	N/A	BBCH 59
Cotton (S)	680	-	800	1	14	BBCH 89
Stored cereal grain	5 mg/kg grain	-	1.5 L/ tonne grain	1	N/A	
Stored cereal grain (structural treatment)	900 mg as/m^2	-	-	1	N/A	Pre-storage use
Corn/Maize (S)	900	-	400	1	N/A	BBCH 59

Details of other uses applied for to support the setting of MRLs for uses beyond the representative uses

Uses on asparagus, banana, broccoli, brussel sprouts, cabbage, cauliflower, cherry, globe artichoke, lettuce, persimmon, plum, pomegranate, raspberries, and sugar beet are not included in the GAP being used to support Annex I renewal. The studies on these crops have however been produced since Annex I listing and were not included in the new information statement, therefore they are presented for completeness and MRL assessment.

Crops for MRL assessment						
Pomegranate (S)	-	90	1200	2 (60)	15	BBCH 89
Persimmon (S)	-	90	1500	2 (60)	15	BBCH 89
Banana (S)	2250	125	1800	1	21	
Lettuce (S)	675	-	1000	1	15	BBCH 48
Cabbage (S/C/N)	900	-	400	1	21	BBCH 49
Cauliflower (S/C/N)	900	-	400	1	21	
Broccoli (S/C/N)	900	-	400	1	21	
Brussels sprout (S/C/N)	900	-	400	1	21	
Globe artichokes (S/C/N)	608	-	400	1	14	
Asparagus (C/N)	608	-	400	1	N/A	Summer/Autumn
Raspberry (C/N)	500	-	400	1	21	
Sugar beet (S/C/N)	900	-	400	1	60	BBCH 49

1.1.2. Arrangements between rapporteur Member State and co-rapporteur Member State

According to Commission Implementing Regulation (EU) No 686/2012 of 26 July 2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances whose approval expires by 31 December 2018 at the latest: For the purposes of the renewal procedure, the evaluation of each active substance set out in the first column of the Annex, is allocated to a rapporteur Member State, as set out in the second column of that Annex, and to a co-rapporteur Member State, as set out in the third column of that Annex.

ANNEX

Active substance	Rapporteur Member State	Co-rapporteur Member State
Chlorpyrifos-methyl	ES	PL

ES: Spain; PL: Poland

1.1.3. EU Regulatory history for use in Plant Protection Products

COMMISSION DIRECTIVE 2005/72/EC of 21 October 2005 amending Council Directive 91/414/EEC to include chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb, and metiram as active substance:

113	Chlorpyrifos-methyl CAS No 5598-13-0 CIPAC No 486	O,O-dimethyl-O-3,5,6-trichloro-2-pyridyl phosphorothioate	≥ 960 g/kg The impurities O,O,O,O-tetramethyl dithiopyrophosphate (Sulfotemp) and OOO-trimethyl-O-(3,5,6-trichloro-2-pyridinyl) diphosphorodithioate (Sulfotemp - ester) were considered of toxicological concern and a maximum level of 5 g/Kg is established for each impurity.	1 July 2006	30 June 2016	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on chlorpyrifos-methyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 June 2005 shall be taken into account. Member States must pay particular attention to the protection of birds, mammals, aquatic organisms, bees and non-target arthropods and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, such as buffer zones. Member States shall request the submission of further studies to confirm the risk assessment for birds and mammals in case of outdoor uses. They shall ensure that the notifiers at whose request chlorpyrifos-methyl has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.

According to Review Report for the active substance **Chlorpyrifos-methyl (SANCO/3061/99/-rev. 2, 3 June 2005-20 March 2015):**

Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of chlorpyrifos-methyl, made in the context of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EEC) No 3600/92(3) laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 2266/2000(4), has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Chlorpyrifos-methyl is one of the 90 existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 of Regulation (EEC) No 3600/92, United Phosphorus Ltd on 26 July 1993 and DowElanco Europe on 15 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance chlorpyrifos-methyl in Annex I to the Directive.

In accordance with the provisions of Article 5 of Regulation (EEC) No 3600/92, the Commission, by its Regulation (EEC) No 933/94(5), as last amended by Regulation (EC) No 2230/95(6), designated Spain as rapporteur Member State to carry out the assessment of chlorpyrifos-methyl on the basis of the dossier submitted by the notifier. In the same Regulation, the Commission specified furthermore the deadline for the notifiers with regard to the submission to the rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EEC) No 3600/92, as well as for other parties with regard to further technical and scientific information; for chlorpyrifos-methyl this deadline was 30 April 1995.

Only DowElanco Europe submitted in time a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore DowElanco Europe was considered to be the main data submitter.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Spain submitted on 16 September 1997 to the Commission the report of its examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of chlorpyrifos-methyl in Annex I to the Directive. Moreover, in accordance with the same provisions, the Commission and the Member States received also the summary dossier on chlorpyrifos-methyl from DowElanco Europe, on 19 November 1997.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the draft assessment report to all the Member States on 09 December 1997 as well as to DowElanco Europe, on 08 September 1999.

The Commission organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review), in particular on each of the following disciplines:

- identity and physical /chemical properties,
- fate and behaviour in the environment,
- ecotoxicology,
- mammalian toxicology,
- residues and analytical methods,
- regulatory questions.

The meetings for this consultation were organised on behalf of the Commission by the Biologische Bundesanstalt für Land und Forstwirtschaft (BBA) in Braunschweig, Germany, from November 1999 to July 2000.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 15 June 2001 for comments and further clarification.

In accordance with the provisions of Article 6(4) of Directive 91/414/EEC concerning consultation in the light of a possible unfavourable decision for the active substance the Commission organised a tripartite meeting with the main data submitter and the rapporteur Member State for this active substance on 23 October 2000**.**

According the Decision 2001/134/CE7, the Commission specified the deadline for the notifier with regard to the submission to the rapporteur Member States of the additional data with regard to further technical and scientific information; for chlorpyrifos-methyl this deadline was 30 April 2002.

The Commission organised a second intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the assessment of the additional data submitted before the deadline and the comments received thereon (peer review), in particular on each of the following disciplines:

- identity and physical /chemical properties,
- fate and behaviour in the environment,
- ecotoxicology,
- mammalian toxicology,
- residues and analytical methods,
- regulatory questions.

The meetings for this consultation were organised on behalf of the Commission by the Biologische Bundesanstalt für Land und Forstwirtschaft (BBA) in Braunschweig, Germany, from November 2002 to July 2003.

In accordance with the provisions of Article 6(4) of Directive 91/414/EEC concerning consultation in the light of a possible unfavourable decision for the active substance the Commission organised the second tripartite meeting with the notifier and the rapporteur Member State for this active substance on 03 February 2004.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossier, the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications on the remaining issues, received after the peer review were referred to the Standing Committee on the Food Chain and Animal Health, and specialised working groups of this Committee, for final examination, with participation of experts from all Member States. This final examination took place from July 2003 to November 2004, and was finalised in the meeting of the Standing Committee on 3 June 2005.

The review did not reveal any open questions or concerns which would have required a consultation of the Scientific Committee on Plants.

The present review report contains the conclusions of the final examination; given the importance of the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications submitted after the peer review as basic information for the final examination process, these documents are considered respectively as background documents A, B and C to this review report and are part of it.

Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion from the evaluation is that it may be expected that plant protection products containing chlorpyrifos-methyl will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each chlorpyrifos-methyl containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the main data submitter and mentioned in the list of uses supported by available data (attached as Appendix IV to this Review Report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The International Estimated Daily Intake (IEDI); excluding water and products of animal origin for a 60 kg adult is 26% of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). This IEDI was calculated considering the supervised trials median residue (STMR) and the processing factor for cereals and covers only grape and stored grain as supported uses and the residue definition that was considered to perform the risk assessment for consumers was for grapes: Methyl-Chlorpyrifos + TCP + conjugates expressed as methyl-chlorpyrifos and for stored grain: sum of chlorpyrifos-methyl and desmethyl chlorpyrifos-methyl expressed as chlorpyrifos-methyl.

Estimates of acute dietary exposure of adults and toddlers in table grape and wheat do not exceed the Acute Reference Dose (ARfD).

On 20 March 2015 the Standing Committee on Plants, Animals, Food and Feed took note of the revision 2 of this review report after the assessment of a new toxicological study on acute oral neurobehavioural and cholinesterase inhibition in rats (Marty et al. 2013) on the basis of which it was confirmed the value of ARfD at 0.1 mg/kg bw. This assessment has been carried out in line with the Guidance document on the evaluation of new active substance data post approval (SANCO/10328/2004 rev.8) for the assessment of new data following inclusion of an active substance.The Appendix II of this report has been updated to include the new reference study.

The review has identified several acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC, provided that certain conditions are taken into account as detailed in section 6 of this report.

Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing chlorpyrifos-methyl

On the basis of the proposed and supported uses (as listed in Appendix IV), the following particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

- Member States must pay particular attention to the protection of birds, mammals, aquatic organisms, bees and non-target arthropods and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures.

1.1.4. Evaluations carried out under other regulatory contexts

Not applicable.

1.2. APPLICANT INFORMATION

1.2.1. Name and address of applicant(s) for approval of the active substance

Applicant 1:

Central Address	**Dow AgroSciences Limited,** **3B Park Square, Milton Park,** **Abingdon,** **Oxon., OX14 4RN.** **UK**
Telephone	[redacted]
Contact	[redacted]
E-mail	[redacted]

Applicant 2:

Central Address	**SAPEC Agro S.A.** Address: Avenida do Rio Tejo - Herdade das Praias 2910-440 Setúbal Portugal
Telephone	[redacted]
Contact	[redacted]
E-mail	[redacted]

1.2.2. Producer or producers of the active substance

Dow AgroSciences Limited
Site 1:

Address	[redacted]
Telephone	[redacted]
Contact	[redacted]
E-mail	[redacted]

Site 2:

Address	[redacted]
Telephone	[redacted]
Contact	[redacted]
E-mail	[redacted]

Site 3:

Address	[redacted]
Telephone	[redacted]
Contact	[redacted]
E-mail	[redacted]

SAPEC Agro S.A.

Producer	[redacted] Contact: [redacted] <u>Production site:</u> Please refer to Volume IV

1.2.3. Information relating to the collective provision of dossiers

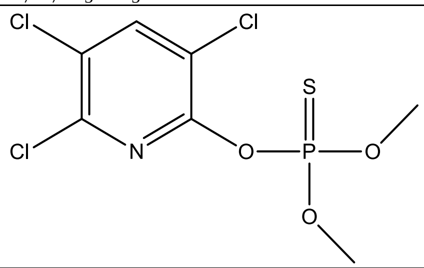
EU Commission working document SANCO/10148/2014 – Rev. 3; 01 October 2014, pursuant to Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012, states that there is one other Notifier of this existing active substance (SAPEC Agro SA).

According Doc B of the dossier submitted by Dow AgroSciences Limited, tt was not possible to reach agreement to provide a collective dossier with SAPEC Agro SA

Considering the nature of the uses of chlorpyrifos-methyl being supported by each party; Dow AgroSciences (foliar application as an aqueous-based spray to a range of fruit, vegetable and arable crops), for which it is believed that higher tier risk assessment, supported by higher tier studies, would be necessary and SAPEC Agro (single spring application at 268 g a.s./ha in grapes), which was believed to be able to demonstrate acceptable risks following lower tier risk assessments then both groups had agreed that there was no common ground for preparation and submission of a joint supplemental dossier.

RMS opinion: Notifier has not taken all reasonable steps to reach agreement to provide a collective dossier. The arguments to not reach an agreements are related to the differences in supported GAP and formulation. There was not any evidence regarding the provisions of Art 62 of Regulation 1107/2009.
RMS considers that arguments provided by notifiers are not sufficient to justify the no agreement to provide a collective dossier. There are many dossiers of active substances with different type of formulations and supported GAPs.

1.3. IDENTITY OF THE ACTIVE SUBSTANCE

1.3.1. Common name proposed or ISO-accepted and synonyms	Chlorpyrifos-methyl Reldan
1.3.2. Chemical name (IUPAC and CA nomenclature)	
IUPAC	O,O-dimethyl O-3,5,6-trichloro-2-pyridyl phosphorothioate
CA	O,O-dimethyl O-3,5,6-trichloro-2-pyridinyl phosphorothioate
1.3.3. Producer's development code number	Dow AgroSciences; DOWCO 214 SAPEC Agro S.A.: None
1.3.4. CAS, EEC and CIPAC numbers	
CAS	5598-13-0
EEC	EINECS: 227-011-5, ELINCS: 015-0186-00-9
CIPAC	486 (221 A)
1.3.5. Molecular and structural formula, molecular mass	
Molecular formula	$C_7H_7Cl_3NO_3PS$
Structural formula	
Molecular mass	322.5

1.3.6. Method of manufacture (synthesis pathway) of the active substance	CONFIDENTIAL information - data provided separately (Volume IV)
1.3.7. Specification of purity of the active substance in g/kg	DOW: Minimum purity: ≥ 960 g/kg SAPEC: Minimum purity: ≥ 985 g/kg
1.3.8. Identity and content of additives (such as stabilisers) and impurities	
1.3.8.1. *Additives*	CONFIDENTIAL information - data provided separately (Volume IV)
1.3.8.2. *Significant impurities*	CONFIDENTIAL information - data provided separately (Volume IV)
1.3.8.3. *Relevant impurities*	DOW: Sulfotemp: maximum level of 0.5% (5 g/kg) and Sulfotemp Ester: maximum level of 0.3% (3 g/kg) SAP: Sulfotemp and Sulfotemp Ester: Not specified Further information can be found in Volume IV - CONFIDENTIAL
1.3.9. Analytical profile of batches	CONFIDENTIAL information - data provided separately (Volume IV)

1.4. INFORMATION ON THE PLANT PROTECTION PRODUCT

1.4.1. Applicant

Name	Dow AgroSciences Limited,
Address	3B Park Square, Milton Park, Abingdon, Oxon., OX14 4RN. UK

1.4.2. Producer of the plant protection product

Name	[redacted]
Address	CONFIDENTIAL information - data provided separately (Volume IV)

1.4.3. Trade name or proposed trade name and producer's development code number of the plant protection product

GF-1684

1.4.4. Detailed quantitative and qualitative information on the composition of the plant protection product

***1.4.4.1.* Composition of the plant protection product**

Technical active substance

Active (including variants)	Technical (at the minimum purity of 960 g/kg)		
	g/kg (g/L)	g/kg (g/L)	g/kg (g/L)
	Nominal	Lower limit	Upper Limit
Chlorpyrifos-methyl technical	?(234)	? (220)	? (248)

FAO tolerance limits for nominal declared content of 100 to 250 g/kg is ± 6%

Pure active substance

Active (including variants)	Pure (at the minimum purity of 1000 g/kg)		
	g/kg (g/L)	g/kg (g/L)	g/kg (g/L)
	Nominal	Lower limit	Upper Limit
Chlorpyrifos-methyl	? (225)	? (212)	? (239)

FAO tolerance limits for nominal declared content of 100 to 250 g/kg is ± 6%

***1.4.4.2.* Information on the active substances**

Type	Chlorpyrifos-methyl/DOWCO 214
ISO common name	Chlorpyrifos-methyl
CAS No	5598-13-0
EC No	EINECS: 2227-011-5, ELINCS: 015-0186-00-9
CIPAC No	486
Salt, ester anion or cation present	Not Applicable

***1.4.4.3.* Information on safeners, synergists and co-formulants**

CONFIDENTIAL information

1.4.5. Type and code of the plant protection product

Emulsifiable Concentrate, EC

1.4.6. Function	Insecticide
1.4.7. Field of use envisaged	GF-1684 is an insecticide used in agriculture to control a wide range of chewing and sucking pests in a range of crops such as grape, citrus, top fruit, vegetable crops, cereals, oilseed rape, corn, cotton, potato, soybean and strawberry
1.4.8. Effects on harmful organisms	GF-1684 is a broad spectrum pesticide that has demonstrated effective control of many sucking and chewing pests, representatives of the classes *Coleoptera*, *Diptera*, *Homoptera* and *Lepidoptera* in a wide range of crops.

1.4.1. Applicant

Name	SAPEC AGRO S.A
Address	[redacted]

1.4.2. Producer of the plant protection product

Name	[redacted]
Address	[redacted]

1.4.3. Trade name or proposed trade name and producer's development code number of the plant protection product

Trade name:
Portugal: EMBAIXADOR 200 CS (Sapec Agro S.A.)
Portugal: METYLFOS 200 CS (Selectis)
Spain: SENTOSAN MAX (Sapec Agro, SAU)
Spain: SUNDEK SMART (Tradecorp)
France: JARKAL 200 CS
Italy: METYLFOS 200 CS
Greece: SAP200CHLORI

Code number: SAP200CHLORI
Chlorpyrifos-Methyl 200 g/L

1.4.4. Detailed quantitative and qualitative information on the composition of the plant protection product

1.4.4.1. **Composition of the plant protection product**

Technical active substance

Active (including variants)	Technical (at the minimum purity of 985 g/kg)		
	% w/w (g/L)	% w/w (g/L)	% w/w (g/L)
	Nominal	Lower limit	Upper Limit
Chlorpyrifos-methyl technical	19.15 (203.0)	18.01 (190.9)	20.30 (215.2)

FAO tolerance limits for nominal declared content of 100 to 250 g/kg is ± 6%

Pure active substance

Active (including variants)	Pure (at the minimum purity of 1000 g/kg)		
	% w/w (g/L)	% w/w (g/L)	% w/w (g/L)
	Nominal	Lower limit	Upper Limit
Chlorpyrifos-methyl	18.87(200)	17.74 (188)	20.00 (212)

FAO tolerance limits for nominal declared content of 100 to 250 g/kg is ± 6%

1.4.4.2. **Information on the active substances**

Type	Name/Code Number
ISO common name	Chlorpyrifos-methyl
CAS No	5598-13-0
EC No	EINECS: 2227-011-5,

	ELINCS: 015-0186-00-9
	CIPAC No: 486
	Salt, ester anion or cation present: Not Applicable
1.4.4.3. **Information on safeners, synergists and co-formulants**	CONFIDENTIAL information
1.4.5. Type and code of the plant protection product	Capsule Suspension, CS
1.4.6. Function	Insecticide
1.4.7. Field of use envisaged	SAP200CHLORI is an insecticide product intended for field use in agriculture on grapes and oilseed rape.
1.4.8. Effects on harmful organisms	Chlorpyrifos-methyl is a non-systemic insecticide with contact, stomach and inhalation action belonging to organophosphate compounds. It acts as a cholinesterase inhibitor.

1.5. DETAILED USES OF THE PLANT PROTECTION PRODUCT

1.5.1. Details of representative uses

For transparency, when referring to studies available for the first inclusion, either reported in the DAR, or provided during the first peer-review, the three letter code (DOW AGROSCIENCE; sole notifier for first inclusion) is used prior to author and year throughout this document. Accordingly for the new studies provided for the purpose of renewal the following two codes are used:

DAS: DOWAGROSCIENCE (dossier submitter 1 for renewal)
SAP: SAPEC (dossier submitter 2 for renewal)

RMS DISCLAIMER (April 2017)

At the end of the evaluation period, Dow AgroScience has proposed to Split out the GAP table. RMS has kept the range of the initial doses.

If EFSA considers the need of to conduct a risk assessment of the new GAP table, then the applicant must to submit the risk assessment for each of the proposed alternative use which are specified below:

Central zone
Wine Grape: reduction the number of applications to one
Pome fruits: reduction of the dose to 0.45 kg as/ha
Solanaceae: reduction of the dose to 0.338 kg as/ha
Stone fruit (cherry): reduction of the dose to 0.75 kg as/ha

Southern Zone
Table grape: reduction of the dose to 0.338 kg as /ha
Wine Grape: reduction the number of applications to one
Solanaceae: reduction of the dose to 0.338 kg as/ha
Strawberry reduction of the dose to 0.338 kg as/ha

DAS

PPP (product name/code)	**GF-1684**	**Formulation type:**	**EC**
active substance	**Chlorpyrifos-methyl**	**Conc. of a.s. :**	**225 g a.s./L**
Applicant:	**Dow AgroSciences**	**professional use**	☒
Zone(s):	**Central EU**	**non professional use**	☐
Verified by MS: yes			

Crop and/or situation	Member State or Country	Product Name	F G or	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
(a)			I (b)	(c)	Type (d-f)	Conc. of a.s. (i)	Method Kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between apps. (min)	kg a.s./hL min max	water (L/ha) min max	kg a.s./ha min max	(l)	(m)
Grapes, Wine	Rep Use GAP: EU Central Zone	All PPPs	F	Grape berry moth	EC	225	Broadcast foliar	BBCH 19 – 89 (spring/ summer)	1 – 2	<u><</u>14	0.0675/0.0675	200/500	**0.135/ 0.338**	14	No applications during flowering (BBCH 60-69)
Oilseed rape	Rep Use GAP: EU Central Zone	All PPPs	F	Weevils (CEUTSP), Pollen beetle (MELISP)	EC	225	Broadcast foliar	BBCH 30 – 59 (sping/ summer)	1	n/a	n/a	300/500	**0.45/0.45**	n/a	
Pome (Apple, Pear, Nashi Pear, Quince)	Rep Use GAP: EU Central Zone	All PPPs	F	Aphids, Codling moth, other Lepidoptera	EC	225	Broadcast foliar	10 – 87 (spring/ summer)	1	n/a	0.09/0.09	750/1000	**0.45/0/9**	21	No applications during flowering (BBCH 60-69)
Potato	Rep Use GAP: EU Central Zone	All PPPs	F	Aphids, Potato beetle	EC	225	Broadcast foliar	BBCH 31 – 59 (spring/ summer)	1	n/a	n/a	500/750	**0.54/0.54**	21	
Solanaceous vegetables (eggplant, peppers, tomato)	Rep Use GAP: EU Central Zone	All PPPs	F	Aphids, thrips, Lepidoptera (*Heliothis*, *Agrotis*)	EC	225	Broadcast foliar	BBCH 11 – 89 (spring/ summer)	1	n/a	0.0675/ 0.0675	500/1000	**0.338/0.675**	5	No applications during flowering (BBCH 60-69)
Stone fruit (cherry, plum))	Rep Use GAP: EU Central Zone	All PPPs	F	Aphids, Codling moth, Lepidoptera	EC	225	Broadcast foliar	BBCH 10 – 87 (spring/ summer)	1	n/a	0.1/ 0.1	750/1000	**0.75/1.0**	21	No applications during flowering (BBCH 60-69)
Strawberry	Rep Use GAP: EU Central Zone	All PPPs	F	Aphids, weevils (OTIOSU)	EC	225	Broadcast foliar	BBCH 35 – 95 (spring/ summer)	1	n/a	n/a	750/1000	**0.54/0.54**	5	No applications during flowering (BBCH 60-69)
Cereal grain	Rep Use GAP: EU Central Zone	All PPPs	I	Stored grain pests (Coleoptera, Lepidoptera, Acari)	EC	225	Directed – grain Structural treatment	n/a Pre-storage use	1 1	n/a n/a	**2.0 – 5 mg/kg grain** **0.45 - 0.9 kg as/hl**	0.75 – 1.5 l/tonne of grain **1hl/1000 m^2**		n/a n/a	

Crop and/or situation (a)	Member State or Country	Product Name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s. (i)	Method Kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between apps. (min)	kg a.s./hL min max	water (L/ha) min max	kg a.s./ha min max		
Citrus (Citron, Grapefruit, Lemon, Lime, Mandarin, Orange)	Rep Use GAP: EU South Zone	All PPPs	F	Scale insects, Aphids,Whitefly	EC	225	Broadcast foliar	BBCH 11 – 89	1	n/a	0.0675/ 0.0675	1500/ 1900	**1.0125 – 1.283**	21	No applications during flowering (BBCH 60-69)
Corn/Maize	Rep Use GAP: EU South Zone	All PPPs	F	Aphids, *Diabrotica* spp.	EC	225	Broadcast foliar	BBCH 12 – 59 (spring/ summer)	1	n/a	n/a	200/400	**0.68/0.90**	n/a	
Cotton	Rep Use GAP: EU South Zone	All PPPs		Aphids, Heliothis, Spodoptera	EC	225	Broadcast foliar	BBCH 30 – 89	1	n/a	n/a	600/800	**0.68/0.68**	14	No applications during flowering (BBCH 60-69)
Grapes, Table	Rep Use GAP: EU South Zone	All PPPs	F	Grape berry moth	EC	225	Broadcast foliar	BBCH 19 – 89 (spring/ summer)	1	n/a	0.0675/0.0675	500/900	**0.338 – 0.608**	14	No applications during flowering (BBCH 60-69)
Grapes, Wine	Rep Use GAP: EU South Zone	All PPPs	F	Grape berry moth	EC	225	Broadcast foliar	BBCH 19 – 89 (spring/ summer)	1 – 2	**MAX** 14	0.0675/0.0675	200/500	**0.135/ 0.338**	14	**Applications are a maximum of 14 days apart** No applications during flowering (BBCH 60-69)
Oilseed rape	Rep Use GAP: EU South Zone	All PPPs	F	Weevils (CEUTSP), Pollen beetle (MELISP)	EC	225	Broadcast foliar	BBCH 30 – 59 (sping/ summer)	1	n/a	n/a	300/600	**0.45/ 0.45**	n/a	
Pome (Apple, Pear, Nashi Pear, Quince)	Rep Use GAP: EU South Zone	All PPPs	F	Aphids, Codling moth, other Lepidoptera	EC	225	Broadcast foliar	10 – 87 (spring/ summer)	1	n/a	**0.09/0.09**	500/1000	0.45/0/9	21	No applications during flowering (BBCH 60-69)
Potato	Rep Use GAP: EU South Zone	All PPPs	F	Aphids, Potato beetle	EC	225	Broadcast foliar	BBCH 31 – 59 (spring/ summer)	1	n/a	n/a	500/750	**0.54/0.54**	21	

Crop and/or situation (a)	Member State or Country	Product Name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s. (i)	Method Kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between apps. (min)	kg a.s./hL min max	water (L/ha) min max	kg a.s./ha min max		
Solanaceous vegetables (eggplant, peppers, tomato)	Rep Use GAP: EU South Zone	All PPPs	F	Aphids, thrips, Lepidoptera (*Heliothis, Agrotis*)	EC	225	Broadcast foliar	BBCH 11 – 89 (spring/ summer)	1	n/a	0.0675/ 0.0675	500/1000	**0.338/ 0.675**	5	No applications during flowering (BBCH 60-69)
Soybean	Rep Use GAP: EU South Zone	All PPPs	F	*Nezara*, Lepidoptera	EC	225	Broadcast foliar	BBCH 30 – 59 (spring/ summer)	1	n/a	n/a	300/600	**0.45/0.45**	21	
Stone fruit (apricot, peach, nectarine)	Rep Use GAP: EU South Zone	All PPPs	F	Aphids, Codling moth, Lepidoptera	EC	225	Broadcast foliar	BBCH 10 – 87 (spring/ summer)	1	n/a	**0.068/ 0.068**	1000/ 1500	0.68/ 1.02	21	No applications during flowering (BBCH 60-69)
Strawberry	Rep Use GAP: EU South Zone	All PPPs	F	Aphids, weevils (OTIOSU)	EC	225	Broadcast foliar	BBCH 35 – 95 (spring/ summer)	1	n/a	n/a	500/750	**0.338/ 0.506**	5	No applications during flowering (BBCH 60-69)
Cereal grain	Rep Use GAP: EU South Zone	All PPPs	I	Stored grain pests (Coleoptera, Lepidoptera, Acari)	EC	225	Directed – grain Structural treatment	n/a Pre-storage use	1 1	n/a n/a	**2.0 – 5 mg/kg grain** **0.45 - 0.9 kg as/hl**	0.75–1.5 l/tonne of grain **1hl/1000 m²**		n/a n/a	

Remarks:
(a) For crops the EU and Codex classifications (both) should be used.
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil borne insects, foliar fungi, weeds
(d) e.g. wettable powder (WP),emulsifiable concentrate (EC), granule (GR)
(e) GIFAP Codes - GIFAP Technical Monograph No. 2, 1989
(f) All abbreviations must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants
(i) g/kg or g/l
(j) Growth stage at last treatment, including where relevant information on season at time of application
(k) The minimum and maximum number of applications possible under practical conditions must be given
(l) PHI - Pre-harvest interval. MSI Minimum storage interval
(m) Remarks may include: Extent of use/ economic importance/restrictions (e.g. feeding/grazing)/minimal intervals between applications. Indicate uses not yet authorised.

SAP

GAP rev. 1, date: 2015-06-15

PPP (product name/code)	**SAP200CHLORI**	**Formulation type:**	**CS**
active substance 1	**chlorpyrifos-methyl**	**Conc. of as 1:**	**200 g/l**
active substance 2	**-**	**Conc. of as 2:**	**-**
safener -		**Conc. of safener:**	**-**
synergist	**-**	**Conc. of synergist:**	**-**
Applicant:	**SAPEC AGRO SA**	**professional use**	**X**
Zone(s):	**SEU/EU**	**non professional use**	

Verified by MS: j/n

1	2	3	4	5	6	7	8	10	11	12	13	14
					Application			**Application rate**				
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
1	PT, SP, FR,IT,GR, BG	Grapes	F	*Lobesia botrana* *Eupoecilia ambiguella* *Scaphoideus titanus*	Foliar spray	BBCH 71-85	a)1 b)1	a)1.7 b)1.7	a) 0.340 b) 0.340	100-600	21	
2	PT, SP, FR,IT,GR, BG	Oil Seed Rape	F	*Ceutorhynchus* spp. *Meligethes aeneus*	Foliar spray	BBCH 10-59	a)1 b)1	a)1.7 b)1.7	a)0.340 b)0.340	200-500	NA	

1.5.2. Further information on representative uses

For transparency, when referring to studies available for the first inclusion, either reported in the DAR, or provided during the first peer-review, the three letter code (DOW AGROSCIENCE; sole notifier for first inclusion) is used prior to author and year throughout this document. Accordingly for the new studies provided for the purpose of renewal the following two codes are used:

DAS: DOWAGROSCIENCE (dossier submitter 1 for renewal)
SAP: SAPEC (dossier submitter 2 for renewal)

DAS

METHOD OF APPLICATION

GF-1684 is typically applied in grapes and tree crops with motorized mist blower or tractor mounted boom hydraulic sprayers. Applications in intensive vegetable crops or strawberry are usually done through manual or power operated hydraulic sprayers, mist blowers and spray robots. Applications in row crops like cereals or large scale vegetable crops like canning varieties of tomato are typically carried out with tractor mounted boom hydraulic sprayers. The application method in storehouses needs special equipments for seed treatment or spraying/fogging the walls.

NUMBER AND TIMING OF APPLICATIONS AND DURATION OF PROTECTION

Maximum number of applications and their timings
Maximum number of applications per season with GF-1684 is one with the exception of grapes where 2 applications are allowed with a minimum of 14 days interval.

Growth stages of crops or plants to be protected
Growth stage of crops to be protected at application will be between BBCH 19-89 in grapes and table grapes; between BBCH 11-89 in citrus and solanaceous vegetables; between BBCH 31-59 in potato; between BBCH 30-89 in cotton; between BBCH 30-59 in oilseed rape; between BBCH 10-87 in stone and pome fruits; between BBCH 12-59 in corn and between BBCH 35-95 in strawberry. Cereals are protected when stored in store houses.

Development stages of the harmful organism concerned
Development stages of harmful organisms concerned will be all stages of the pests including eggs and all larvae development stages as well as adults/imagoes.

Duration of protection afforded by each application
Duration of protection afforded by each application will be, depending on species and their life cycle and weather conditions, is between 5 and 20 days.

Duration of protection afforded by the maximum number of applications
In most crop only one application per season is allowed, therefore duration of protection afforded is the same to that described above. In grape the efficacy length is expected not more than 2 weeks for an application.

NECESSARY WAITING PERIODS OR OTHER PRECAUTIONS TO AVOID PHYTOTOXIC EFFECTS ON SUCCEEDING CROPS

Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops
No waiting period is necessary neither any other precaution for phytotoxic effects on succeeding crops.
Limitations on choice of succeeding crops
No limitation on choice of succeeding crops.

PROPOSED INSTRUCTIONS FOR USE

Existing or proposed labels
This document contains data and information to support a limited range of representative uses of the active substance chlorpyrifos-methyl for which it is intended to demonstrate that, for one or more preparations, the criteria in Article 4 of Regulation (EC) No 1107/2009 can be met. These uses are listed below.

Product	**Country**	**Existing or proposed use**
Reldan 2E	Austria	pome fruit, peach, strawberries, grapes, empty storage rooms
Reldan 22	Czech Republic	chrysanthemum, mustard, empty warehouses, graineries, oilseed rape, apple, brassicaceae veggie, cherry
EXAQ 2M RELDAN 2M ZERTELL 2M	France	clementines, mandarins, lavender, blackcurrant, actinidia (kiwi fruit), peach, nectarine, grapes (wine and table), oil seed rape
Reldan 225 EC	Greece	stone fruits, citrus fruits, pome fruits, grapes (table, vines, raisins), tomatoes, peppers, aubergines, cotton, potatoes, olives
Reldan 22EC	Hungary	cherry, apple, pear, quince, medlar, grapevines, sour cherry, empty warehouse, oilseed rape, mustard, radish, stored cereals
Reldan 22EC	Ireland	Stored cereals(admixture treatment), grain stores - fabric of building
Cleaner 22 Clormetil Clorpir CE Cutis Devox Etifos ME Kukar 22 Metidane 22 Pandar 22 Runner M 22 Runner M Skorpio EC Tecnifos M 22 Terial 22 Vitador	Italy	peach, apple, pear, orange, lemon, mandarin, clementine, grapes (wine) grapes (table), strawberry, tomato, egg plant (aubergine), pepper family, pea, turnip, potato, corn/maize, poplar, ornamentals
Reldan 22	Italy	peach, apple, pear, orange, lemon, mandarin, clementine, grapes (wine) grapes (table), strawberry, tomato, egg plant (aubergine), pepper family, pea, turnip, potato, corn/maize, poplar, ornamentals, palms
Reldan 225 EC	Poland	apple
RELDAN 22EC	Romania	stored cereals/grains, vines, oilseed rape, mustard, apple
Reldan 22	Serbia	non-crop plants, pome fruits
Reldan 22	Slovakia	oilseed rape, mustard, stored cereals, empty warehouses,

Product	Country	Existing or proposed use
		graineries, apple
RELDAN-E	Spain	lemon, mandarin, sweet orange, peach, nectarine, pomme fruits, pear, cotton, tomato, pepper, aubergine, strawberry, lettuce, wheat and barley grains, maize, olive, potato, wines, only empty places. direct spray to walls, roofs and ground
Reldan 22	United Kingdom	Stored cereals(admixture treatment), grain stores - fabric of building

This document provides the existing label for the representative formulation GF-1684 and is intended to include the major commercial applications and represent exposure scenarios sufficiently rigorous to allow adequate evaluation of risk to humans and the environment.

SAP

1.5.3. Further information on representative uses

METHOD OF APPLICATION

SAP200CHLORI is diluted in water and applied as a foliar spray by tractor mounted sprayer or handheld sprayer with hydraulic nozzles. Please refer to Table 3.4-1 above for spray volume in each crop.

NUMBER AND TIMING OF APPLICATIONS AND DURATION OF PROTECTION

Please refer to the GAP Table on the following page.

Growth stages of crops or plants to be protected:
Please refer to the GAP Table on the following page.

Development stages of the harmful organism concerned:
Application is performed at the appearance of pest.

Duration of protection afforded by each application:
A single application protects crop for critical period of intended pests.

Duration of protection afforded by the maximum number of applications:
Not relevant. It is proposed a single application.

NECESSARY WAITING PERIODS OR OTHER PRECAUTIONS TO AVOID PHYTOTOXIC EFFECTS ON SUCCEEDING CROPS

Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops:
Based on active substance data, no waiting periods between last application and sowing or planting succeeding crops are necessary.

Limitations on choice of succeeding crops:

None

PROPOSED INSTRUCTIONS FOR USE

DOSE AND DIRECTIONS FOR USE:

Apply by foliar spray providing a full coverage of the green part of the crop. The applications must be made during the period favorable to insect activity at the schedule and maximum number of treatments per season indicated below.

Recommended rates and volumes are:

Crop	**Target**	**Dose rate**	**Volume rate (L/Ha)**	**No treatments**	**Growth stage**	**Application interval**
Grapes	*Lobesia botrana* *Eupoecilia ambiguella* *Scaphoideus titanus*	1.7 L/Ha	100-600	1	BBCH 71-85	-
Oil Seed Rape	*Ceuthorhynchus* spp. *Meligethes aenus*	0.75 L/Ha	200-500	1	BBCH 10-59	-

Add the recommended quantity of product to spray tank at the beginning of filling it with water and complete the required water volume taking into account the crop area to be treated. Maintain tank shaking continuously during preparation of mix and application of treatment. Not prepare more spray solution than is required.

POST HARVEST INTERVAL:

21 days on Grapes

BIOLOGICAL PRECAUTIONS:

Currently the proposed resistance management strategy for this active ingredient remains an integrated approach to pest control on farm. Insecticide resistance management involves three basic components: monitoring pest complexes for population density and trends, focusing on economic injury levels and integrating control strategies. Elements of this include, but are not limited to the following:

- Monitoring pests; monitoring the progress of insect population development in their fields, both to accurately determine when chemical intervention if warranted but also to recognize when resistance starts to build up is a key starting point of any integrated approach. After treatment, users should continue monitoring to assess pest populations and control.

- Focus on treatment thresholds; chemical intervention should be used only if insects are numerous enough to cause economic losses that exceed the cost of the insecticide plus application.

- Integrating control strategies; correct use and timing of chemicals should be integrated with other on-farm management options. These include cultural methods such as crop rotation to allow introduction of different chemistries with different modes of action and on-farm hygiene to reduce the spread of inoculum between fields, as well as enhancing background levels of natural enemies.

All of the above points form part of what is today best practice for farmers and should continue to be practiced and encouraged alongside effective and targeted chemical products.

PRECAUTIONS

- During the mixing/loading and the application :
    - Wear normal work clothing and gloves.
- Package: Re-use of the package prohibited; rinse the container thoroughly, ensuring to pour the rinse water in the spray tank or in the rinse tank for direct injection. Dispose of empty containers at an organized gathering of a specific service collection.
  For the disposal of unusable products contact an authorized company for the collection and disposal of hazardous materials.
- Keep in original container, tightly closed, in a locked room. Keep out of reach of children. Keep away from food, drink and animal feeding stuffs.

Restrictions on Use:

- To be given according to regulatory decision at registration.

Important

Consider the uses, dose rates, conditions and precautions on the packaging. They were determined based on the product characteristics and the recommended applications. Consider these principles, good agricultural practice for culture and treatments, taking into account your responsibility, all special about your farm, such as the type of soil, weather conditions, cultivation methods, plant varieties, species resistance…
The manufacturer guarantees the quality of its products sold in their original packaging as well as their compliance with the marketing authorization of the Ministry of Agriculture.
Due to the diversity of existing legislation it is recommended, when foodstuff from protected crops with this specialty is intended for export, to check the regulations in force in the importing country.

1.5.4. Details of other uses applied for to support the setting of MRLs for uses beyond the representative uses

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES
(Application on agricultural and horticultural crops)

Address 1: Dow AgroSciences, European Development Centre, 3 Milton Park, Abingdon, OX144RN, UK
Address 2
Address 3

Date : xx
Page :

Pesticide(s) (common name(s)) : Chlorpyrifos-methyl
EEC, CIPAC and CCPR No(s). : 227-011-5, 486 (221.A), 090
Trade name(s) : Reldan 22 EC
Main uses e.g. insecticide, fungicide : Insecticide
Applicant : Dow AgroSciences

Use Pattern

1	2		3	4	5	6			7			8	9
Crop and / or situation	State	NEU SEU G	Pest or group of pests controlled	Formulation		Application			Application rate per treatment			PHI (days)	Remarks:
				Type	Conc. of a.i.	method, kind	growth stage BBCH	number (range)	Kg a.i./hl	water l/ha	Kg a.i./ha		
(a)	(b)		(c)	(d - f)	(i)	(f - h)	(j)					(k)	(l)
001 Citrus fruits (Citron, Grapefruit, Lemon, Lime, Mandarin, Orange)	EU South Zone	NEU & SEU	Scale insects (mealybugs), Whitefly	EC	225	Broadcast foliar	BBCH 11 – 89	1	0.0675/0.0675	1500/ 1900	1.0125 – 1.285	21	No applications during flowering (BBCH 60-69)
Maize / Corn	EU South Zone	NEU & SEU	Aphids, *Diabrotica* spp.	EC	225	Broadcast foliar	BBCH 12 – 59 (spring/ summer)	1	n/a	200/400	0.68/0.90	n/a	

1	2		3	4	5	6			7			8	9
Crop and / or situation	State	NEU SEU G	Pest or group of pests controlled	Formulation		Application			Application rate per treatment			PHI (days)	Remarks:
				Type	Conc. of a.i.	method, kind	growth stage BBCH	number (range)	Kg a.i./hl	water l/ha	Kg a.i./ha		
(a)	(b)		(c)	(d - f)	(i)	(f - h)	(j)					(k)	(l)
Cotton	EU South Zone	SEU	Aphids, Heliothis, Spodoptera	EC	225	Broadcast foliar	BBCH 30 – 89	1	n/a	600/800	0.68/0.68	14	No applications during flowering (BBCH 60-69)
Grapes, Table	EU South Zone	NEU & SEU	Grape berry moth	EC	225	Broadcast foliar	BBCH 19 – 89 (spring/ summer)	1	0.0675/0.0675	500/900	0.338 – 0.608	14	No applications during flowering (BBCH 60-69)
Grapes, Wine	EU Central Zone	NEU	Grape berry moth	EC	225	Broadcast foliar	BBCH 19 – 89 (spring/ summer)	1 – 2 (upto 14 day interval)	0.0675/0.0675	200/500	0.135/ 0.338	14	No applications during flowering (BBCH 60-69)

1	2		3	4 5		6			7			8	9
Crop and / or situation	State	NEU SEUG	Pest or group of pests controlled	Formulation		Application			Application rate per treatment			PHI (days)	Remarks:
				Type	Conc. of a.i.	method, kind	growth stage BBCH	number (range)	Kg a.i./hl	water l/ha	Kg a.i./ha		
(a)	(b)		(c)	(d - f)	(i)	(f - h)	(j)					(k)	(l)
Grapes, Wine	EU South Zone	NEU & SEU	Grape berry moth	EC	225	Broadcast foliar	BBCH 19 – 89 (spring/ summer)	1 – 2 (upto 14 day interval)	0.0675/0.0675	200/500	0.135/ 0.338	14	Note: applications are a maximum of 14 days apart. No applications during flowering (BBCH 60-69)
Rapseed / Canola seeds	EU Central Zone	NEU	Weevils (CEUTSP), Pollen beetle (MELISP)	EC	225	Broadcast foliar	BBCH 30 – 59 (sping/ summer)	1	n/a	300/500	0.45/0.45	n/a	
Rapseed / Canola seeds	EU South Zone	NEU & SEU	Weevils (CEUTSP), Pollen beetle (MELISP)	EC	225	Broadcast foliar	BBCH 30 – 59 (sping/ summer)	1	n/a	300/600	0.45/ 0.45	n/a	
002 Pome fruits FP (Apple, Pear, Nashi Pear, Quince)	EU Central Zone	NEU	Aphids, Codling moth, other Lepidoptera	EC	225	Broadcast foliar	10 – 87 (spring/ summer)	1	0.09/0.09	750/1000	0.45/0/9	21	No applications during flowering (BBCH 60-69)

1	2		3	4	5	6			7			8	9
Crop and / or situation	State	NEU SEU G	Pest or group of pests controlled	Formulation		Application			Application rate per treatment			PHI (days)	Remarks:
				Type	Conc. of a.i.	method, kind	growth stage BBCH	number (range)	Kg a.i./hl	water l/ha	Kg a.i./ha		
(a)	(b)		(c)	(d - f)	(i)	(f - h)	(j)					(k)	(l)
002 Pome fruits FP (Apple, Pear, Nashi Pear, Quince)	EU South Zone	NEU & SEU	Aphids, Codling moth, other Lepidoptera	EC	225	Broadcast foliar	10 – 87 (spring/ summer)	1	0.09/0.09	500/1000	0.45/0/9	21	No applications during flowering (BBCH 60-69)
Potato	EU Central Zone	NEU	Aphids, Potato beetle	EC	225	Broadcast foliar	BBCH 31 – 59 (spring/ summer)	1	n/a	500/750	0.54/0.54	21	
Potato	EU South Zone	NEU & SEU	Aphids, Potato beetle	EC	225	Broadcast foliar	BBCH 31 – 59 (spring/ summer)	1	n/a	500/750	0.54/0.54	21	
012 Fruiting vegetables, other than Cucurbits (eggplant, peppers, tomato)	EU Central Zone	NEU	Aphids, thrips, Lepidoptera (*Heliothis, Agrotis*)	EC	225	Broadcast foliar	BBCH 11 – 89 (spring/ summer)	1	0.0675/ 0.0675	500/1000	0.338/0.67 5	5	No applications during flowering (BBCH 60-69)
012 Fruiting vegetables, other than Cucurbits (eggplant, peppers, tomato)	EU South Zone	NEU & SEU	Aphids, thrips, Lepidoptera (*Heliothis, Agrotis*)	EC	225	Broadcast foliar	BBCH 11 – 89 (spring/ summer)	1	0.0675/ 0.0675	500/1000	0.338/ 0.675	5	No applications during flowering (BBCH 60-69)

1	2		3	4	5	6			7			8	9
Crop and / or situation	State	NEU SEU G	Pest or group of pests controlled	Formulation		Application			Application rate per treatment			PHI (days)	Remarks:
				Type	Conc. of a.i.	method, kind	growth stage BBCH	number (range)	Kg a.i./hl	water l/ha	Kg a.i./ha		
(a)	(b)		(c)	(d - f)	(i)	(f - h)	(j)					(k)	(l)
Soyabeans	EU South Zone	NEU & SEU	*Nezara*, Lepidoptera	EC	225	Broadcast foliar	BBCH 30 – 59 (spring/ summer)	1	n/a	300/600	0.45/0.45	21	
003 Stone fruits (apricot, peach, nectarine)	EU South Zone	NEU & SEU	Aphids, Codling moth, Lepidoptera	EC	225	Broadcast foliar	BBCH 10 – 87 (spring/ summer)	1	0.068/ 0.068	1000/ 1500	0.68/ 1.02	21	No applications during flowering (BBCH 60-69)
003 Stone fruit (cherry, plum))	EU Central Zone	NEU	Aphids, Codling moth, Lepidoptera	EC	225	Broadcast foliar	BBCH 10 – 87 (spring/ summer)	1	0.1/ 0.1	750/1000	0.75/1.0	21	No applications during flowering (BBCH 60-69)
Strawberry	EU Central Zone	NEU	Aphids, weevils (OTIOSU)	EC	225	Broadcast foliar	BBCH 35 – 95 (spring/ summer)	1	n/a	750/1000	0.54/0.54	5	No applications during flowering (BBCH 60-69)
Strawberry	EU South Zone	NEU & SEU	Aphids, weevils (OTIOSU)	EC	225	Broadcast foliar	BBCH 35 – 95 (spring/ summer)	1	n/a	500/750	0.338/ 0.506	5	No applications during flowering (BBCH 60-69)

1	2		3	4	5	6			7			8	9
Crop and / or situation	State	NEU SEUG	Pest or group of pests controlled	Formulation		Application			Application rate per treatment			PHI (days)	Remarks:
				Type	Conc. of a.i.	method, kind	growth stage BBCH	number (range)	Kg a.i./hl	water l/ha	Kg a.i./ha		
(a)	(b)		(c)	(d - f)	(i)	(f - h)	(j)					(k)	(l)
Cereal grain	EU Central Zone	NEU	Stored grain pests (Coleoptera, Lepidoptera, Acari)	EC	225	Directed – grain	n/a	1	2.0 – 5 mg/kg grain	0.75 – 1.5 l/tonne of grain		n/a	
Cereal grain	EU Central Zone	NEU	Stored grain pests (Coleoptera, Lepidoptera, Acari)	EC	225	Structural treatment	Pre-storage use	1	0.45 - 0.9 kg as/hl	1hl/1000 m^2		n/a	
Cereal grain	EU South Zone	NEU & SEU	Stored grain pests (Coleoptera, Lepidoptera, Acari)	EC	225	Directed – grain	n/a	1	2.0 – 5 mg/kg grain	0.75–1.5 l/tonne of grain		n/a	
Cereal grain	EU South Zone	NEU & SEU	Stored grain pests (Coleoptera, Lepidoptera, Acari)	EC	225	Structural treatment	Pre-storage use	1	0.45 - 0.9 kg as/hl	1hl/1000 m^2		n/a	
Asparagus	EU Central Zone	NEU	Asparagus beetle	EC	225	Broadcast foliar	BBCH 61 - 89	1	n/a	400	0.608	n/a	
Brassicas (Broccoli, Brussels sprouts, cabbage, cauliflower)	EU Central Zone	NEU & SEU	Aphids, Lepidoptera	EC	225	Broadcast foliar	BBCH 11 - 49	1	n/a	400	0.9	21	
Globe artichoke	EU Central Zone	NEU & SEU	Artichoke aphid (DACTTO)	EC	225	Broadcast foliar	BBCH 11 - 49	1	n/a	400	0.608	14	

1	2		3	4	5	6			7			8	9
Crop and / or situation	State	NEU SEU G	Pest or group of pests controlled	Formulation		Application			Application rate per treatment			PHI (days)	Remarks:
				Type	Conc. of a.i.	method, kind	growth stage BBCH	number (range)	Kg a.i./hl	water l/ha	Kg a.i./ha		
(a)	(b)		(c)	(d - f)	(i)	(f - h)	(j)					(k)	(l)
Raspberry	EU Central Zone	NEU	Cane midge (THOMTE), raspberry beetle (BYTUTO)	EC	225	Broadcast foliar	BBCH 11 - 89	1	n/a	400	0.5	21	
Sugar beet	EU Central Zone	NEU & SEU	Pygmy mangold beetle	EC	225	Broadcast foliar	BBCH 11 - 39	1	n/a	400	0.9	60	
Pomegranate	EU South Zone	SEU	Scales, Aphids, Diptera, Trips, Coleoptera, Lepidoptera, Whyte fly	EC	225	Broadcast foliar	BBCH 11-89	2 (60)	0.09	800-1200	0.72 - 0.9	15	400 ml product/hl Do not apply at flowering of the crop (BBCH 60-69)
Persimmon	EU South Zone	SEU	Scales, Aphids, Diptera, Trips, Coleoptera, Lepidoptera, Whyte fly	EC	225	Broadcast foliar	BBCH 11-89	2 (60)	0.09	1250-1500	1.125 - 1.35	15	400 ml product/hl Do not apply at flowering of the crop (BBCH 60-69)
Banana	EU South Zone	SEU		EC	225	Broadcast foliar	BBCH11-89	1	0.125	1800	2.25	15	No applications during flowering (BBCH 60-69)
Lettuce	EU South Zone	SEU	Aphids, Lepidoptera	EC	225	Broadcast foliar	BBCH 11-49	1	n/a	1000	0.675	21	

Remarks:
(a) In case of group of crops the Codex classification should be used
(b) NEU: outdoor field use in Northern EU, SEU: outdoor field use in Southern EU, State: Member state (MS) or country for Import tolerance, G: glasshouse or indoor application
(c) e.g. biting and sucking insects, soil born insects, foliar fungi
(d) e.g. wettable powder (WP), emulsifiable concentration (EC), granule (GR)
(e) Use CIPAC/FAO Codes where appropriate

(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants
(i) g/kg or g/l
(j) Growth stage at last treatment
(k) PHI = Pre-harvest interval
(l) Remarks may include: Extent of use/economic importance/restrictions (e.g. feeding, grazing)/minimal intervals between applications

1.5.5. Overview on authorisations in EU Member States

Authorised uses and actual uses

Country	Product	Product Material / Formulation	Conc'n	Crop	Main pests	Use Rate	PHI
Austria	Reldan 2E	no DAS Formulation	225 G/L	pome fruit, peach, strawberries	Aphids, Capua reticulana	0.20%	21
Austria	Reldan 2E	no DAS Formulation	225 G/L	grapes	Sparganothis pilleriana, Eupoecilia ambiguella, Lobesia botrana, cicada	0.20%	28
Austria	Reldan 2E	no DAS Formulation	225 G/L	pome fruit, peach	Quadraspidiotus perniciosus, Cydia pomonella, mining moths	0.30%	21
Austria	Reldan 2E	no DAS Formulation	225 G/L	grapes	Eriophyes vitis	0.30%	28
Austria	Reldan 2E	no DAS Formulation	225 G/L	empty storage rooms	Calandra granaria, Tribolium castaneum	0,2 - 0,4 L/100m2	
Austria	Reldan 2E	no DAS Formulation	225 G/L	pome fruit, peach, strawberries	Tetranychus urticae	0.20%	21
Austria	Reldan 2E	no DAS Formulation	225 G/L	grapes	Tetranychus urticae	0.20%	28
Czech Republic	Reldan 22	GF-1684	225 G/L	chrysanthemum	aphids	1,3 l /ha	AT
Czech Republic	Reldan 22	GF-1684	225 G/L	mustard	pollen beetle	1,5 - 2,0 l/ha	AT
Czech Republic	Reldan 22	GF-1684	225 G/L	empty warehouses, graineries	stored grain insects	1,3 %	AT
Czech Republic	Reldan 22	GF-1684	225 G/L	Oilseed rape	pollen beetle	1,5 - 2,0 l/ha	AT
Czech Republic	Reldan 22	GF-1684	225 G/L	apple	aphids, codling moth, apple sawfly	2,25-2,7 l/ha	21

Country	**Product**	**Product Material / Formulation**	**Conc'n**	**Crop**	**Main pests**	**Use Rate**	**PHI**
Czech Republic	Reldan 22	GF-1684	225 G/L	brassicaceae veggie	cabbage aphid	1,3 l/ha	AT
Czech Republic	Reldan 22	GF-1684	225 G/L	cherry	cherry fruit fly	2,7 l/ha	21
France	EXAQ 2M	GF-1684	225 G/L	clementines, mandarines	scales	2.2 L/HA	21 days
France	EXAQ 2M	GF-1684	225 G/L	lavander	Resseliella lavandulae and scales	1.5 L/HA	na (pre-flow. appl. only)
France	EXAQ 2M	GF-1684	225 G/L	blackcurrant	scales	2.2 L/HA	na- post harvest
France	EXAQ 2M	GF-1684	225 G/L	actinidia (kiwi fruit)	scales	2 L/HA	21 days
France	EXAQ 2M	GF-1684	225 G/L	peach and nectarine	scales	2.2 L/HA	21 days
France	EXAQ 2M	GF-1684	225 G/L	grapes (wine and table)	scales, gbm, leafhopper	1.5 L/HA	21 days
France	EXAQ 2M	GF-1684	225 G/L	oil seed rape	meliae, ceutna	1.5 L/HA	na -pre-flowering
France	RELDAN 2M	GF-1684	225 G/L	grapes (wine and table)	scales, gbm, leafhopper	1.5 L/HA	21 days
France	RELDAN 2M	GF-1684	225 G/L	blackcurrant	scales	2.2 L/HA	na- post harvest
France	RELDAN 2M	GF-1684	225 G/L	oil seed rape	MELIAE, CEUTNA	1.5 L/HA	na -pre-flowering
France	RELDAN 2M	GF-1684	225 G/L	lavander	Resseliella lavandulae and scales	1.5 L/HA	na (pre-flow. appl. only)
France	RELDAN 2M	GF-1684	225 G/L	peach and nectarine	scales	2.2 L/HA	21 days
France	RELDAN 2M	GF-1684	225 G/L	clementines, mandarins	scales	2.2 L/HA	21 days
France	RELDAN 2M	GF-1684	225 G/L	actinidia (kiwi fruit)	scales	2 L/HA	21 days
France	ZERTELL 2M	GF-1684	225 G/L	grapes (wine and table)	scales, gbm, leafhopper	1.5 L/HA	21 days
France	ZERTELL 2M	GF-1684	225 G/L	lavander	Resseliella lavandulae and scales	1.5 L/HA	na (pre-flow. appl. only)

Country	Product	Product Material / Formulation	Conc'n	Crop	Main pests	Use Rate	PHI
France	ZERTELL 2M	GF-1684	225 G/L	oil seed rape	MELIAE, CEUTNA	1.5 L/HA	na -pre-flowering
France	ZERTELL 2M	GF-1684	225 G/L	actinidia (kiwi fruit)	scales	2 L/HA	21 days
France	ZERTELL 2M	GF-1684	225 G/L	clementines, mandarines	scales	2.2 L/HA	21 days
France	ZERTELL 2M	GF-1684	225 G/L	blackcurrant	scales	2.2 L/HA	na- post harvest
France	ZERTELL 2M	GF-1684	225 G/L	peach and nectarine	scales	2.2 L/HA	21 days
France	RELDAN GS	GF-1684	225 G/L	Stored cereals	Grain store pests	10ml/T	none
France	RELDAN GS	GF-1684	225 G/L	grain stores - fabric of building	Grain store pests	250mLs/100 m2	n.a.
Greece	RELDAN 2E	GF-1325	225 G/L	Fruits-Stone Fruits	Scales, Armyworm, fall, Aphids	250 mL/HL	21 DAYS
Greece	RELDAN 2E	GF-1325	225 G/L	Fruits-Citrus Fruits	Scales,Mealybugs, Armyworm, fall, Aphids	250 mL/HL	21 DAYS
Greece	RELDAN 2E	GF-1325	225 G/L	Fruits-Pome Fruits	Scales, Armyworm, fall, Aphids, Pear sucker	250 mL/HL	21 DAYS
Greece	RELDAN 2E	GF-1325	225 G/L	Fruits- Grapes (table,vines,raisins)	Scales,Mealybugs, Armyworm, vine weevil	200 mL/HL	21 DAYS
Greece	RELDAN 2E	GF-1325	225 G/L	Fruits Edible Peel (tomatoes, peppers, aubergines)	Armyworm, weevil, aphids	250-300 ml/hl (max 3 L/HA)	5 DAYS
Greece	RELDAN 2E	GF-1325	225 G/L	Cotton	Armyworm, weevil, aphids	250-300 ml/hl (max 2.4 L/HA)	21 DAYS
Greece	RELDAN 2E	GF-1325	225 G/L	Potatoes	Armyworm, weevil, aphids	250-300 ml/hl (max 3 L/HA)	5 DAYS
Greece	RELDAN 2E	GF-1325	225 G/L	Fruits-Olives	Scales, Armyworm	250-300 ml/hl	60 DAYS

Country	**Product**	**Product Material / Formulation**	**Conc'n**	**Crop**	**Main pests**	**Use Rate**	**PHI**
Hungary	Reldan 22 EC	GF-1684	225 G/L	Cherry	Aphids, scales	2,7 l/ha	21 days
Hungary	Reldan 22 EC	GF-1684	225 G/L	Apple, pear, quince, medlar	Aphids, Cydia pomonella, leafminers	2,7 l/ha	21 days
Hungary	Reldan 22 EC	GF-1684	225 G/L	Grapevines	Grape berry moths, Sparganothis pilleriana, Scaphoideus titanus	2,2 l/ha	14 days
Hungary	Reldan 22 EC	GF-1684	225 G/L	Sour cherry	Aphis, scales	2,7 l/ha	21 days
Hungary	Reldan 22 EC	GF-1684	225 G/L	Empty warehouse	Grain store pests	1,05-1,95 ml/m2	n.a.
Hungary	Reldan 22 EC	GF-1684	225 G/L	Oilseed rape	Ceutorhynchus quadridens, Meligethes aeneus, Ceutorhynchus assimilis, Psylliodes chrysocephala, Athalia rosae	2,0 l/ha	n.a.
Hungary	Reldan 22 EC	GF-1684	225 G/L	Mustard, radish	Ceutorhynchus quadridens, Meligethes aeneus, Ceutorhynchus assimilis, Psylliodes chrysocephala, Athalia rosae	2,0	n.a.
Hungary	Reldan 22 EC	GF-1684	225 G/L	Stored cereals	Grain store pests	7,0-10,5 ml/t	90 days
Ireland	Reldan 22 EC	GF-1684	225 G/L	Stored cereals(admixture treatment)	Grain store pests	10ml/T	90 days

Country	Product	Product Material / Formulation	Conc'n	Crop	Main pests	Use Rate	PHI
Ireland	Reldan 22 EC	GF-1684	225 G/L	grain stores - fabric of building	Grain store pests	200mLs/100 m2	n.a.
Italy	RELDAN 22	GF-1684	225 G/L	peach	scales; moths	200-250 ml/hl	15 days
Italy	RELDAN 22	GF-1684	225 G/L	apple	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	RELDAN 22	GF-1684	225 G/L	pear	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	RELDAN 22	GF-1684	225 G/L	orange	scales	250 ml/hl	15 days
Italy	RELDAN 22	GF-1684	225 G/L	lemon	scales	250 ml/hl	15 days
Italy	RELDAN 22	GF-1684	225 G/L	mandarine	scales	250 ml/hl	15 days
Italy	RELDAN 22	GF-1684	225 G/L	clementine	scales	250 ml/hl	15 days
Italy	RELDAN 22	GF-1684	225 G/L	grapes (wine)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	RELDAN 22	GF-1684	225 G/L	grapes (table)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	RELDAN 22	GF-1684	225 G/L	strawberry	thrips, cutworms	300-400 ml/hl	15 days
Italy	RELDAN 22	GF-1684	225 G/L	tomato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	RELDAN 22	GF-1684	225 G/L	egg plant (aubergine)	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	RELDAN 22	GF-1684	225 G/L	pepper family	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	RELDAN 22	GF-1684	225 G/L	pea	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	RELDAN 22	GF-1684	225 G/L	turnip	cutworms and other lepidoptera	1500-2000 ml/ha	15 days

Country	Product	Product Material / Formulation	Conc'n	Crop	Main pests	Use Rate	PHI
Italy	RELDAN 22	GF-1684	225 G/L	potato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	RELDAN 22	GF-1684	225 G/L	corn/maize	corn borer, cutworms	300 ml/hl	15 days
Italy	RELDAN 22	GF-1684	225 G/L	poplar	criptorrhynchus, saperda	400-500 ml/hl	15 days
Italy	RELDAN 22	GF-1684	225 G/L	ornamentals	scales, lepidoptera	200 ml/hl	15 days
Italy	RELDAN 22	GF-1684	225 G/L	palms	red palm weevil	500 ml/hl	15 days
Italy	CLEANER 22	GF-1684	225 G/L	peach	scales; moths	200-250 ml/hl	15 days
Italy	CLEANER 22	GF-1684	225 G/L	apple	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	CLEANER 22	GF-1684	225 G/L	pear	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	CLEANER 22	GF-1684	225 G/L	orange	scales	250 ml/hl	15 days
Italy	CLEANER 22	GF-1684	225 G/L	lemon	scales	250 ml/hl	15 days
Italy	CLEANER 22	GF-1684	225 G/L	mandarine	scales	250 ml/hl	15 days
Italy	CLEANER 22	GF-1684	225 G/L	clementine	scales	250 ml/hl	15 days
Italy	CLEANER 22	GF-1684	225 G/L	grapes (wine)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	CLEANER 22	GF-1684	225 G/L	grapes (table)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	CLEANER 22	GF-1684	225 G/L	strawberry	thrips, cutworms	300-400 ml/hl	15 days
Italy	CLEANER 22	GF-1684	225 G/L	tomato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	CLEANER 22	GF-1684	225 G/L	egg plant (aubergine)	cutworms and other lepidoptera	1500-2000 ml/ha	15 days

Country	Product	Product Material / Formulation	Conc'n	Crop	Main pests	Use Rate	PHI
Italy	CLEANER 22	GF-1684	225 G/L	pepper family	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	CLEANER 22	GF-1684	225 G/L	pea	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	CLEANER 22	GF-1684	225 G/L	turnip	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	CLEANER 22	GF-1684	225 G/L	potato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	CLEANER 22	GF-1684	225 G/L	corn/maize	corn borer, cutworms	300 ml/hl	15 days
Italy	CLEANER 22	GF-1684	225 G/L	poplar	criptorrhynchus, saperda	400-500 ml/hl	15 days
Italy	CLEANER 22	GF-1684	225 G/L	ornamentals	scales, lepidoptera	200 ml/hl	15 days
Italy	CLORMETIL	GF-1684	225 G/L	peach	scales; moths	200-250 ml/hl	15 days
Italy	CLORMETIL	GF-1684	225 G/L	apple	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	CLORMETIL	GF-1684	225 G/L	pear	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	CLORMETIL	GF-1684	225 G/L	orange	scales	250 ml/hl	15 days
Italy	CLORMETIL	GF-1684	225 G/L	lemon	scales	250 ml/hl	15 days
Italy	CLORMETIL	GF-1684	225 G/L	mandarine	scales	250 ml/hl	15 days
Italy	CLORMETIL	GF-1684	225 G/L	clementine	scales	250 ml/hl	15 days
Italy	CLORMETIL	GF-1684	225 G/L	grapes (wine)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	CLORMETIL	GF-1684	225 G/L	grapes (table)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	CLORMETIL	GF-1684	225 G/L	strawberry	thrips, cutworms	300-400 ml/hl	15 days

Country	**Product**	**Product Material / Formulation**	**Conc'n**	**Crop**	**Main pests**	**Use Rate**	**PHI**
Italy	CLORMETIL	GF-1684	225 G/L	tomato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	CLORMETIL	GF-1684	225 G/L	egg plant (aubergine)	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	CLORMETIL	GF-1684	225 G/L	pepper family	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	CLORMETIL	GF-1684	225 G/L	pea	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	CLORMETIL	GF-1684	225 G/L	turnip	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	CLORMETIL	GF-1684	225 G/L	potato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	CLORMETIL	GF-1684	225 G/L	corn/maize	corn borer, cutworms	300 ml/hl	15 days
Italy	CLORMETIL	GF-1684	225 G/L	poplar	criptorrhynchus, saperda	400-500 ml/hl	15 days
Italy	CLORMETIL	GF-1684	225 G/L	ornamentals	scales, lepidoptera	200 ml/hl	15 days
Italy	CLORPIR CE	GF-1684	225 G/L	peach	scales; moths	200-250 ml/hl	15 days
Italy	CLORPIR CE	GF-1684	225 G/L	apple	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	CLORPIR CE	GF-1684	225 G/L	pear	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	CLORPIR CE	GF-1684	225 G/L	orange	scales	250 ml/hl	15 days
Italy	CLORPIR CE	GF-1684	225 G/L	lemon	scales	250 ml/hl	15 days
Italy	CLORPIR CE	GF-1684	225 G/L	mandarine	scales	250 ml/hl	15 days
Italy	CLORPIR CE	GF-1684	225 G/L	clementine	scales	250 ml/hl	15 days
Italy	CLORPIR CE	GF-1684	225 G/L	grapes (wine)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days

Country	Product	Product Material / Formulation	Conc'n	Crop	Main pests	Use Rate	PHI
Italy	CLORPIR CE	GF-1684	225 G/L	grapes (table)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	CLORPIR CE	GF-1684	225 G/L	strawberry	thrips, cutworms	300-400 ml/hl	15 days
Italy	CLORPIR CE	GF-1684	225 G/L	tomato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	CLORPIR CE	GF-1684	225 G/L	egg plant (aubergine)	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	CLORPIR CE	GF-1684	225 G/L	pepper family	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	CLORPIR CE	GF-1684	225 G/L	pea	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	CLORPIR CE	GF-1684	225 G/L	turnip	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	CLORPIR CE	GF-1684	225 G/L	potato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	CLORPIR CE	GF-1684	225 G/L	corn/maize	corn borer, cutworms	300 ml/hl	15 days
Italy	CLORPIR CE	GF-1684	225 G/L	poplar	criptorrhynchus, saperda	400-500 ml/hl	15 days
Italy	CLORPIR CE	GF-1684	225 G/L	ornamentals	scales, lepidoptera	200 ml/hl	15 days
Italy	CUTIS	GF-1684	225 G/L	peach	scales; moths	200-250 ml/hl	15 days
Italy	CUTIS	GF-1684	225 G/L	apple	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	CUTIS	GF-1684	225 G/L	pear	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	CUTIS	GF-1684	225 G/L	orange	scales	250 ml/hl	15 days
Italy	CUTIS	GF-1684	225 G/L	lemon	scales	250 ml/hl	15 days

Country	**Product**	**Product Material / Formulation**	**Conc'n**	**Crop**	**Main pests**	**Use Rate**	**PHI**
Italy	CUTIS	GF-1684	225 G/L	mandarine	scales	250 ml/hl	15 days
Italy	CUTIS	GF-1684	225 G/L	clementine	scales	250 ml/hl	15 days
Italy	CUTIS	GF-1684	225 G/L	grapes (wine)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	CUTIS	GF-1684	225 G/L	grapes (table)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	CUTIS	GF-1684	225 G/L	strawberry	thrips, cutworms	300-400 ml/hl	15 days
Italy	CUTIS	GF-1684	225 G/L	tomato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	CUTIS	GF-1684	225 G/L	egg plant (aubergine)	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	CUTIS	GF-1684	225 G/L	pepper family	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	CUTIS	GF-1684	225 G/L	pea	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	CUTIS	GF-1684	225 G/L	turnip	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	CUTIS	GF-1684	225 G/L	potato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	CUTIS	GF-1684	225 G/L	corn/maize	corn borer, cutworms	300 ml/hl	15 days
Italy	CUTIS	GF-1684	225 G/L	poplar	criptorrhynchus, saperda	400-500 ml/hl	15 days
Italy	CUTIS	GF-1684	225 G/L	ornamentals	scales, lepidoptera	200 ml/hl	15 days
Italy	DEVOX	GF-1684	225 G/L	peach	scales; moths	200-250 ml/hl	15 days
Italy	DEVOX	GF-1684	225 G/L	apple	scales, leafrollers, codling moth	200-250 ml/hl	15 days

Country	Product	Product Material / Formulation	Conc'n	Crop	Main pests	Use Rate	PHI
Italy	DEVOX	GF-1684	225 G/L	pear	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	DEVOX	GF-1684	225 G/L	orange	scales	250 ml/hl	15 days
Italy	DEVOX	GF-1684	225 G/L	lemon	scales	250 ml/hl	15 days
Italy	DEVOX	GF-1684	225 G/L	mandarine	scales	250 ml/hl	15 days
Italy	DEVOX	GF-1684	225 G/L	clementine	scales	250 ml/hl	15 days
Italy	DEVOX	GF-1684	225 G/L	grapes (wine)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	DEVOX	GF-1684	225 G/L	grapes (table)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	DEVOX	GF-1684	225 G/L	strawberry	thrips, cutworms	300-400 ml/hl	15 days
Italy	DEVOX	GF-1684	225 G/L	tomato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	DEVOX	GF-1684	225 G/L	egg plant (aubergine)	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	DEVOX	GF-1684	225 G/L	pepper family	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	DEVOX	GF-1684	225 G/L	pea	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	DEVOX	GF-1684	225 G/L	turnip	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	DEVOX	GF-1684	225 G/L	potato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	DEVOX	GF-1684	225 G/L	corn/maize	corn borer, cutworms	300 ml/hl	15 days
Italy	DEVOX	GF-1684	225 G/L	poplar	criptorrhynchus, saperda	400-500 ml/hl	15 days
Italy	DEVOX	GF-1684	225 G/L	ornamentals	scales, lepidoptera	200 ml/hl	15 days

Country	**Product**	**Product Material / Formulation**	**Conc'n**	**Crop**	**Main pests**	**Use Rate**	**PHI**
Italy	KUKAR 22	GF-1684	225 G/L	peach	scales; moths	200-250 ml/hl	15 days
Italy	KUKAR 22	GF-1684	225 G/L	apple	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	KUKAR 22	GF-1684	225 G/L	pear	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	KUKAR 22	GF-1684	225 G/L	orange	scales	250 ml/hl	15 days
Italy	KUKAR 22	GF-1684	225 G/L	lemon	scales	250 ml/hl	15 days
Italy	KUKAR 22	GF-1684	225 G/L	mandarine	scales	250 ml/hl	15 days
Italy	KUKAR 22	GF-1684	225 G/L	clementine	scales	250 ml/hl	15 days
Italy	KUKAR 22	GF-1684	225 G/L	grapes (wine)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	KUKAR 22	GF-1684	225 G/L	grapes (table)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	KUKAR 22	GF-1684	225 G/L	strawberry	thrips, cutworms	300-400 ml/hl	15 days
Italy	KUKAR 22	GF-1684	225 G/L	tomato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	KUKAR 22	GF-1684	225 G/L	egg plant (aubergine)	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	KUKAR 22	GF-1684	225 G/L	pepper family	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	KUKAR 22	GF-1684	225 G/L	pea	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	KUKAR 22	GF-1684	225 G/L	turnip	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	KUKAR 22	GF-1684	225 G/L	potato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days

Country	Product	Product Material / Formulation	Conc'n	Crop	Main pests	Use Rate	PHI
Italy	KUKAR 22	GF-1684	225 G/L	corn/maize	corn borer, cutworms	300 ml/hl	15 days
Italy	KUKAR 22	GF-1684	225 G/L	poplar	criptorrhynchus, saperda	400-500 ml/hl	15 days
Italy	KUKAR 22	GF-1684	225 G/L	ornamentals	scales, lepidoptera	200 ml/hl	15 days
Italy	ETIFOS ME	GF-1684	225 G/L	peach	scales; moths	200-250 ml/hl	15 days
Italy	ETIFOS ME	GF-1684	225 G/L	apple	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	ETIFOS ME	GF-1684	225 G/L	pear	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	ETIFOS ME	GF-1684	225 G/L	orange	scales	250 ml/hl	15 days
Italy	ETIFOS ME	GF-1684	225 G/L	lemon	scales	250 ml/hl	15 days
Italy	ETIFOS ME	GF-1684	225 G/L	mandarine	scales	250 ml/hl	15 days
Italy	ETIFOS ME	GF-1684	225 G/L	clementine	scales	250 ml/hl	15 days
Italy	ETIFOS ME	GF-1684	225 G/L	grapes (wine)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	ETIFOS ME	GF-1684	225 G/L	grapes (table)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	ETIFOS ME	GF-1684	225 G/L	strawberry	thrips, cutworms	300-400 ml/hl	15 days
Italy	ETIFOS ME	GF-1684	225 G/L	tomato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	ETIFOS ME	GF-1684	225 G/L	egg plant (aubergine)	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	ETIFOS ME	GF-1684	225 G/L	pepper family	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	ETIFOS ME	GF-1684	225 G/L	pea	cutworms and other lepidoptera	1500-2000 ml/ha	15 days

Country	Product	Product Material / Formulation	Conc'n	Crop	Main pests	Use Rate	PHI
Italy	ETIFOS ME	GF-1684	225 G/L	turnip	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	ETIFOS ME	GF-1684	225 G/L	potato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	ETIFOS ME	GF-1684	225 G/L	corn/maize	corn borer, cutworms	300 ml/hl	15 days
Italy	ETIFOS ME	GF-1684	225 G/L	poplar	criptorrhynchus, saperda	400-500 ml/hl	15 days
Italy	ETIFOS ME	GF-1684	225 G/L	ornamentals	scales, lepidoptera	200 ml/hl	15 days
Italy	METIDANE 22	GF-1684	225 G/L	peach	scales; moths	200-250 ml/hl	15 days
Italy	METIDANE 22	GF-1684	225 G/L	apple	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	METIDANE 22	GF-1684	225 G/L	pear	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	METIDANE 22	GF-1684	225 G/L	orange	scales	250 ml/hl	15 days
Italy	METIDANE 22	GF-1684	225 G/L	lemon	scales	250 ml/hl	15 days
Italy	METIDANE 22	GF-1684	225 G/L	mandarine	scales	250 ml/hl	15 days
Italy	METIDANE 22	GF-1684	225 G/L	clementine	scales	250 ml/hl	15 days
Italy	METIDANE 22	GF-1684	225 G/L	grapes (wine)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	METIDANE 22	GF-1684	225 G/L	grapes (table)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	METIDANE 22	GF-1684	225 G/L	strawberry	thrips, cutworms	300-400 ml/hl	15 days
Italy	METIDANE 22	GF-1684	225 G/L	tomato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	METIDANE 22	GF-1684	225 G/L	egg plant (aubergine)	cutworms and other lepidoptera	1500-2000 ml/ha	15 days

Country	**Product**	**Product Material / Formulation**	**Conc'n**	**Crop**	**Main pests**	**Use Rate**	**PHI**
Italy	METIDANE 22	GF-1684	225 G/L	pepper family	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	METIDANE 22	GF-1684	225 G/L	pea	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	METIDANE 22	GF-1684	225 G/L	turnip	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	METIDANE 22	GF-1684	225 G/L	potato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	METIDANE 22	GF-1684	225 G/L	corn/maize	corn borer, cutworms	300 ml/hl	15 days
Italy	METIDANE 22	GF-1684	225 G/L	poplar	criptorrhynchus, saperda	400-500 ml/hl	15 days
Italy	METIDANE 22	GF-1684	225 G/L	ornamentals	scales, lepidoptera	200 ml/hl	15 days
Italy	PANDAR 22	GF-1684	225 G/L	peach	scales; moths	200-250 ml/hl	15 days
Italy	PANDAR 22	GF-1684	225 G/L	apple	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	PANDAR 22	GF-1684	225 G/L	pear	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	PANDAR 22	GF-1684	225 G/L	orange	scales	250 ml/hl	15 days
Italy	PANDAR 22	GF-1684	225 G/L	lemon	scales	250 ml/hl	15 days
Italy	PANDAR 22	GF-1684	225 G/L	mandarine	scales	250 ml/hl	15 days
Italy	PANDAR 22	GF-1684	225 G/L	clementine	scales	250 ml/hl	15 days
Italy	PANDAR 22	GF-1684	225 G/L	grapes (wine)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	PANDAR 22	GF-1684	225 G/L	grapes (table)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	PANDAR 22	GF-1684	225 G/L	strawberry	thrips, cutworms	300-400 ml/hl	15 days

Country	Product	Product Material / Formulation	Conc'n	Crop	Main pests	Use Rate	PHI
Italy	PANDAR 22	GF-1684	225 G/L	tomato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	PANDAR 22	GF-1684	225 G/L	egg plant (aubergine)	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	PANDAR 22	GF-1684	225 G/L	pepper family	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	PANDAR 22	GF-1684	225 G/L	pea	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	PANDAR 22	GF-1684	225 G/L	turnip	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	PANDAR 22	GF-1684	225 G/L	potato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	PANDAR 22	GF-1684	225 G/L	corn/maize	corn borer, cutworms	300 ml/hl	15 days
Italy	PANDAR 22	GF-1684	225 G/L	poplar	criptorrhynchus, saperda	400-500 ml/hl	15 days
Italy	PANDAR 22	GF-1684	225 G/L	ornamentals	scales, lepidoptera	200 ml/hl	15 days
Italy	RUNNER M	GF-1684	225 G/L	peach	scales; moths	200-250 ml/hl	15 days
Italy	RUNNER M	GF-1684	225 G/L	apple	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	RUNNER M	GF-1684	225 G/L	pear	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	RUNNER M	GF-1684	225 G/L	orange	scales	250 ml/hl	15 days
Italy	RUNNER M	GF-1684	225 G/L	lemon	scales	250 ml/hl	15 days
Italy	RUNNER M	GF-1684	225 G/L	mandarine	scales	250 ml/hl	15 days
Italy	RUNNER M	GF-1684	225 G/L	clementine	scales	250 ml/hl	15 days
Italy	RUNNER M	GF-1684	225 G/L	grapes (wine)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days

Country	**Product**	**Product Material / Formulation**	**Conc'n**	**Crop**	**Main pests**	**Use Rate**	**PHI**
Italy	RUNNER M	GF-1684	225 G/L	grapes (table)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	RUNNER M	GF-1684	225 G/L	strawberry	thrips, cutworms	300-400 ml/hl	15 days
Italy	RUNNER M	GF-1684	225 G/L	tomato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	RUNNER M	GF-1684	225 G/L	egg plant (aubergine)	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	RUNNER M	GF-1684	225 G/L	pepper family	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	RUNNER M	GF-1684	225 G/L	pea	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	RUNNER M	GF-1684	225 G/L	turnip	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	RUNNER M	GF-1684	225 G/L	potato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	RUNNER M	GF-1684	225 G/L	corn/maize	corn borer, cutworms	300 ml/hl	15 days
Italy	RUNNER M	GF-1684	225 G/L	poplar	criptorrhynchus, saperda	400-500 ml/hl	15 days
Italy	RUNNER M	GF-1684	225 G/L	ornamentals	scales, lepidoptera	200 ml/hl	15 days
Italy	RUNNER M 22	GF-1684	225 G/L	peach	scales; moths	200-250 ml/hl	15 days
Italy	RUNNER M 22	GF-1684	225 G/L	apple	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	RUNNER M 22	GF-1684	225 G/L	pear	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	RUNNER M 22	GF-1684	225 G/L	orange	scales	250 ml/hl	15 days
Italy	RUNNER M 22	GF-1684	225 G/L	lemon	scales	250 ml/hl	15 days

Country	Product	Product Material / Formulation	Conc'n	Crop	Main pests	Use Rate	PHI
Italy	RUNNER M 22	GF-1684	225 G/L	mandarine	scales	250 ml/hl	15 days
Italy	RUNNER M 22	GF-1684	225 G/L	clementine	scales	250 ml/hl	15 days
Italy	RUNNER M 22	GF-1684	225 G/L	grapes (wine)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	RUNNER M 22	GF-1684	225 G/L	grapes (table)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	RUNNER M 22	GF-1684	225 G/L	strawberry	thrips, cutworms	300-400 ml/hl	15 days
Italy	RUNNER M 22	GF-1684	225 G/L	tomato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	RUNNER M 22	GF-1684	225 G/L	egg plant (aubergine)	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	RUNNER M 22	GF-1684	225 G/L	pepper family	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	RUNNER M 22	GF-1684	225 G/L	pea	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	RUNNER M 22	GF-1684	225 G/L	turnip	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	RUNNER M 22	GF-1684	225 G/L	potato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	RUNNER M 22	GF-1684	225 G/L	corn/maize	corn borer, cutworms	300 ml/hl	15 days
Italy	RUNNER M 22	GF-1684	225 G/L	poplar	criptorrhynchus, saperda	400-500 ml/hl	15 days
Italy	RUNNER M 22	GF-1684	225 G/L	ornamentals	scales, lepidoptera	200 ml/hl	15 days
Italy	SKORPIO EC	GF-1684	225 G/L	peach	scales; moths	200-250 ml/hl	15 days
Italy	SKORPIO EC	GF-1684	225 G/L	apple	scales, leafrollers, codling moth	200-250 ml/hl	15 days

Country	Product	Product Material / Formulation	Conc'n	Crop	Main pests	Use Rate	PHI
Italy	SKORPIO EC	GF-1684	225 G/L	pear	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	SKORPIO EC	GF-1684	225 G/L	orange	scales	250 ml/hl	15 days
Italy	SKORPIO EC	GF-1684	225 G/L	lemon	scales	250 ml/hl	15 days
Italy	SKORPIO EC	GF-1684	225 G/L	mandarine	scales	250 ml/hl	15 days
Italy	SKORPIO EC	GF-1684	225 G/L	clementine	scales	250 ml/hl	15 days
Italy	SKORPIO EC	GF-1684	225 G/L	grapes (wine)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	SKORPIO EC	GF-1684	225 G/L	grapes (table)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	SKORPIO EC	GF-1684	225 G/L	strawberry	thrips, cutworms	300-400 ml/hl	15 days
Italy	SKORPIO EC	GF-1684	225 G/L	tomato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	SKORPIO EC	GF-1684	225 G/L	egg plant (aubergine)	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	SKORPIO EC	GF-1684	225 G/L	pepper family	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	SKORPIO EC	GF-1684	225 G/L	pea	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	SKORPIO EC	GF-1684	225 G/L	turnip	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	SKORPIO EC	GF-1684	225 G/L	potato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	SKORPIO EC	GF-1684	225 G/L	corn/maize	corn borer, cutworms	300 ml/hl	15 days
Italy	SKORPIO EC	GF-1684	225 G/L	poplar	criptorrhynchus, saperda	400-500 ml/hl	15 days
Italy	SKORPIO EC	GF-1684	225 G/L	ornamentals	scales, lepidoptera	200 ml/hl	15 days

Country	Product	Product Material / Formulation	Conc'n	Crop	Main pests	Use Rate	PHI
Italy	TECNIFOS M 22	GF-1684	225 G/L	peach	scales; moths	200-250 ml/hl	15 days
Italy	TECNIFOS M 22	GF-1684	225 G/L	apple	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	TECNIFOS M 22	GF-1684	225 G/L	pear	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	TECNIFOS M 22	GF-1684	225 G/L	orange	scales	250 ml/hl	15 days
Italy	TECNIFOS M 22	GF-1684	225 G/L	lemon	scales	250 ml/hl	15 days
Italy	TECNIFOS M 22	GF-1684	225 G/L	mandarine	scales	250 ml/hl	15 days
Italy	TECNIFOS M 22	GF-1684	225 G/L	clementine	scales	250 ml/hl	15 days
Italy	TECNIFOS M 22	GF-1684	225 G/L	grapes (wine)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	TECNIFOS M 22	GF-1684	225 G/L	grapes (table)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	TECNIFOS M 22	GF-1684	225 G/L	strawberry	thrips, cutworms	300-400 ml/hl	15 days
Italy	TECNIFOS M 22	GF-1684	225 G/L	tomato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	TECNIFOS M 22	GF-1684	225 G/L	egg plant (aubergine)	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	TECNIFOS M 22	GF-1684	225 G/L	pepper family	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	TECNIFOS M 22	GF-1684	225 G/L	pea	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	TECNIFOS M 22	GF-1684	225 G/L	turnip	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	TECNIFOS M 22	GF-1684	225 G/L	potato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days

Country	Product	Product Material / Formulation	Conc'n	Crop	Main pests	Use Rate	PHI
Italy	TECNIFOS M 22	GF-1684	225 G/L	corn/maize	corn borer, cutworms	300 ml/hl	15 days
Italy	TECNIFOS M 22	GF-1684	225 G/L	poplar	criptorrhynchus, saperda	400-500 ml/hl	15 days
Italy	TECNIFOS M 22	GF-1684	225 G/L	ornamentals	scales, lepidoptera	200 ml/hl	15 days
Italy	TERIAL 22	GF-1684	225 G/L	peach	scales; moths	200-250 ml/hl	15 days
Italy	TERIAL 22	GF-1684	225 G/L	apple	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	TERIAL 22	GF-1684	225 G/L	pear	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	TERIAL 22	GF-1684	225 G/L	orange	scales	250 ml/hl	15 days
Italy	TERIAL 22	GF-1684	225 G/L	lemon	scales	250 ml/hl	15 days
Italy	TERIAL 22	GF-1684	225 G/L	mandarine	scales	250 ml/hl	15 days
Italy	TERIAL 22	GF-1684	225 G/L	clementine	scales	250 ml/hl	15 days
Italy	TERIAL 22	GF-1684	225 G/L	grapes (wine)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	TERIAL 22	GF-1684	225 G/L	grapes (table)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	TERIAL 22	GF-1684	225 G/L	strawberry	thrips, cutworms	300-400 ml/hl	15 days
Italy	TERIAL 22	GF-1684	225 G/L	tomato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	TERIAL 22	GF-1684	225 G/L	egg plant (aubergine)	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	TERIAL 22	GF-1684	225 G/L	pepper family	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	TERIAL 22	GF-1684	225 G/L	pea	cutworms and other lepidoptera	1500-2000 ml/ha	15 days

Country	**Product**	**Product Material / Formulation**	**Conc'n**	**Crop**	**Main pests**	**Use Rate**	**PHI**
Italy	TERIAL 22	GF-1684	225 G/L	turnip	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	TERIAL 22	GF-1684	225 G/L	potato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	TERIAL 22	GF-1684	225 G/L	corn/maize	corn borer, cutworms	300 ml/hl	15 days
Italy	TERIAL 22	GF-1684	225 G/L	poplar	criptorrhynchus, saperda	400-500 ml/hl	15 days
Italy	TERIAL 22	GF-1684	225 G/L	ornamentals	scales, lepidoptera	200 ml/hl	15 days
Italy	VITADOR	GF-1684	225 G/L	peach	scales; moths	200-250 ml/hl	15 days
Italy	VITADOR	GF-1684	225 G/L	apple	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	VITADOR	GF-1684	225 G/L	pear	scales, leafrollers, codling moth	200-250 ml/hl	15 days
Italy	VITADOR	GF-1684	225 G/L	orange	scales	250 ml/hl	15 days
Italy	VITADOR	GF-1684	225 G/L	lemon	scales	250 ml/hl	15 days
Italy	VITADOR	GF-1684	225 G/L	mandarine	scales	250 ml/hl	15 days
Italy	VITADOR	GF-1684	225 G/L	clementine	scales	250 ml/hl	15 days
Italy	VITADOR	GF-1684	225 G/L	grapes (wine)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	VITADOR	GF-1684	225 G/L	grapes (table)	moths, leafhoppers, scaphoideus, scales	100-200 ml/hl	15 days
Italy	VITADOR	GF-1684	225 G/L	strawberry	thrips, cutworms	300-400 ml/hl	15 days
Italy	VITADOR	GF-1684	225 G/L	tomato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	VITADOR	GF-1684	225 G/L	egg plant (aubergine)	cutworms and other lepidoptera	1500-2000 ml/ha	15 days

Country	Product	Product Material / Formulation	Conc'n	Crop	Main pests	Use Rate	PHI
Italy	VITADOR	GF-1684	225 G/L	pepper family	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	VITADOR	GF-1684	225 G/L	pea	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	VITADOR	GF-1684	225 G/L	turnip	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	VITADOR	GF-1684	225 G/L	potato	cutworms and other lepidoptera	1500-2000 ml/ha	15 days
Italy	VITADOR	GF-1684	225 G/L	corn/maize	corn borer, cutworms	300 ml/hl	15 days
Italy	VITADOR	GF-1684	225 G/L	poplar	criptorrhynchus, saperda	400-500 ml/hl	15 days
Italy	VITADOR	GF-1684	225 G/L	ornamentals	scales, lepidoptera	200 ml/hl	15 days
Poland	Reldan 225 EC	GF-1684	225 G/L	Apple	Leaf rollers	2.7 l/ha	21 days
Poland	Reldan 225 EC	GF-1684	225 G/L	Apple	Aphids (APHISP)	2.25 l/ha	21 days
Poland	Reldan 225 EC	GF-1684	225 G/L	Apple	Codling moth, Fruit fly, Psylla	2.25- 2.7 l/ha	21 days
Romania	RELDAN 22EC	GF-1684	225 G/L	stored cereals/grains	Codling moth (Sitophyllus, Rhizoperta)	stored cereal grains: 22 ml/T (Sitophyllus, Rhizoperta)	between 5 and 21 days
Romania	RELDAN 22EC	GF-1684	225 G/L	vines	Grape berry moth (POLYBO)	2.2 l/ha (in 1000 l water/ha) - Lobesia botrana	between 5 and 21 days
Romania	RELDAN 22EC	GF-1684	225 G/L	oilseed rape	Meligethes aeneus	2.0 l/ha (in 200-300 l water/ha) - Meligethes	between 5 and 21 days

Country	Product	Product Material / Formulation	Conc'n	Crop	Main pests	Use Rate	PHI
Romania	RELDAN 22EC	GF-1684	225 G/L	mustard	Meligethes aeneus	2.0 l/ha (in 200-300 l water/ha) - Meligethes	between 5 and 21 days
Romania	RELDAN 22EC	GF-1684	225 G/L	apple	Blossom beetles (Cydia pomonela, LITHBL)	2.0-2.2 l/ha (in 1500 l water/ha)	between 5 and 21 days
Serbia	RELDAN 22	GF-1684	225 G/L	Non-Crop Plants	Powdery mildew: rose	0,05%	5 days
Serbia	RELDAN 22	GF-1684	225 G/L	Fruits-Pome Fruits	Codling moth	0,2 - 0,25%	21 days
Slovakia	Reldan 22	GF-1684	225 G/L	oilseed rape, mustard	Melighetes aeneus	2,0 l/ha	N/A
Slovakia	Reldan 22	GF-1684	225 G/L	stored cereals	Grain store pests	8,88 - 22,22 ml/t of grain	90
Slovakia	Reldan 22	GF-1684	225 G/L	empty warehouses, graineries	Stored grain insects	0,2 l/100 m2	30
Slovakia	Reldan 22	GF-1684	225 G/L	apple	Hyplocampa testudinea, Aphidula phomi, Sappaphis mali, ydia pomonella	2,25 l/ha	21
Slovenia	RELDAN 22 EC	GF-1684	225 G/L	wine grapes	Leafhoppers (Torticidae, Scaphoideus sp.)	1 lt/ha	21 days
Slovenia	RELDAN 22 EC	GF-1684	225 G/L	wine grapes	Grape Berry Moth (CLYSAM)	1 lt/ha	21 days
Slovenia	RELDAN 22 EC	GF-1684	225 G/L	wine grapes	Frogfly, green (Empoasca vitis)	1 lt/ha	21 days
Slovenia	RELDAN 22 EC	GF-1684	225 G/L	wine grapes	Grape berry, moth (POLYBO)	1 lt/ha	21 days
Spain	RELDAN-E	GF-1684	225 G/L	lemon	Scales, ceratitis, prays, aphids, trips	300-400 ml/hl	15 days
Spain	RELDAN-E	GF-1684	225 G/L	mandarin	Scales, ceratitis, prays, aphids, trips	300-400 ml/hl	15 days
Spain	RELDAN-E	GF-1684	225 G/L	sweet orange	Scales, ceratitis, prays, aphids, trips	300-400 ml/hl	15 days

Country	Product	Product Material / Formulation	Conc'n	Crop	Main pests	Use Rate	PHI
Spain	RELDAN-E	GF-1684	225 G/L	peach, nectarine	Ceratitis, QUADPE, aphids, trips	300-400 ml/hl	15 days
Spain	RELDAN-E	GF-1684	225 G/L	pomme fruits	QUADPE, Carpocapsa, capua, aphids	300-400 ml/hl	15 days
Spain	RELDAN-E	GF-1684	225 G/L	pear	Psila	300-400 ml/hl	15 days
Spain	RELDAN-E	GF-1684	225 G/L	cotton	Earias, Heliothis, aphids, trips, Agrotis spp.	300-400 ml/hl	15 days
Spain	RELDAN-E	GF-1684	225 G/L	tomato, pepper, aubergine	Spodoptera, catterpillar, trips	300-400 ml/hl	5 days
Spain	RELDAN-E	GF-1684	225 G/L	strawberry	Spodoptera, catterpillar, trips, aphids	300-400 ml/hl	5 days
Spain	RELDAN-E	GF-1684	225 G/L	lettuce	Spodoptera, catterpillar, trips, aphids	300-400 ml/hl	15 days
Spain	RELDAN-E	GF-1684	225 G/L	wheat and barley grains	Ephestia, oryzaephilues, rizopherta, tribolium	10 cc/Tm	NA
Spain	RELDAN-E	GF-1684	225 G/L	maize	Agrotis, Heliothis, Taladro	300-400 ml/hl	15 days
Spain	RELDAN-E	GF-1684	225 G/L	olive	Prays (antophage generation)	200 ml/hl	NA
Spain	RELDAN-E	GF-1684	225 G/L	potato	Potato weevil, aphids	300-400 ml/hl	15 days
Spain	RELDAN-E	GF-1684	225 G/L	wines	Castañeta, melazo, piral, Lobesia and other berry moths, trips	300-400 ml/hl	15 days
Spain	RELDAN-E	GF-1684	225 G/L	only empty places. direct spray to walls, roofs and ground	insects	1%	NA

Country	Product	Product Material / Formulation	Conc'n	Crop	Main pests	Use Rate	PHI
United Kingdom	Reldan 22 EC	GF-1684	225 G/L	Stored cereals(admixture treatment)	Grain store pests	10ml/T	90 days
United Kingdom	Reldan 22 EC	GF-1684	225 G/L	grain stores - fabric of building	Grain store pests	200mLs/100 m2	n.a.

LIST OF CURRENTLY AUTHORIZED USES AND EXTENT OF USE

Supported Representative uses for Maize, Oilseedrape for solo-products containing Chlorpyrifos-methyl and their current authorisation status in South EU

	Representative Uses (for application details see **table 5)**				Existing Authorisations								
Crop	Target	Situation of use (e.g. indoor…)	AI content & Formulation Type	Application method	Country	Zone	Since	Reg. No.	Product	Product Application rate per treatment Min and Max	Active Substance Application rate per treatment Min and Max	Number of treatments per Season Min and Max	Active Substance Max total dose/ ha Min and Max
Grape	Leafhopper, scale, grape berry moth	outdoor	225 g/l, EC	Spraying	France	S-EU	2012	2120086	Exaq 2M	1.5 L/ha	337.5 g a.s./ha	1	337.5 g a.s./ha
Grape	Leafhopper, scale, grape berry moth	outdoor	225 g/l, EC	Spraying	France	S-EU	2015	2150083	Garvine	1.5 L/ha	337.5 g a.s./ha	1	337.5 g a.s./ha
Grape	Leafhopper, scale, grape berry moth	outdoor	225 g/l, EC	Spraying	France	S-EU	2012	2120086	Reldan 2M	1.5 L/ha	337.5 g a.s./ha	1	337.5 g a.s./ha
Grape	Leafhopper, scale, grape berry moth	outdoor	225 g/l, EC	Spraying	France	S-EU	2014	2140229	Reldan Cazo	1.5 L/ha	337.5 g a.s./ha	1	337.5 g a.s./ha
Grape	Leafhopper, scale, grape berry moth	outdoor	225 g/l, EC	Spraying	France	S-EU	2008	2080127	Retumba	1.5 L/ha	337.5 g a.s./ha	1	337.5 g a.s./ha
Grape	Leafhopper, scale, grape berry moth	outdoor	224 g/l, EC	Spraying	Spain	S-EU	1976	12211	Reldan-E	300-400 ml/hl 1.5-4 L/Ha*	336-896 g/Ha	1	336-896 g/Ha
Grape	Leafhopper, scale, grape berry moth, Trips, *Noctua* spp.	outdoor	223 g/l, EC	Spraying	Italy	S-EU	1992	8156	Devox	100-200 ml/hl 0.5-2 L/Ha*	111.5-446 g/Ha	2	223-892 g/Ha
Grape	Leafhopper, scale, grape berry moth	outdoor	223 g/l, EC	Spraying	Italy	S-EU	1980	4012	Reldan 22	100-200 ml/hl 0.5-2 L/Ha*	111.5-446 g/Ha	2	223-892 g/Ha
Grape	Leafhopper, scale, grape berry moth	outdoor	223 g/l, EC	Spraying	Italy	S-EU	1999	9963	Metidane 22	100-200 ml/hl 0.5-2 L/Ha*	111.5-446 g/Ha	2	223-892 g/Ha
Grape	Leafhopper, scale, grape berry moth	outdoor	223 g/l, EC	Spraying	Italy	S-EU	2000	10493	Runner M22	100-200 ml/hl 0.5-2 L/Ha*	111.5-446 g/Ha	2	223-892 g/Ha
Grape	grape berry moth	outdoor	217.8 g/l, EC	Spraying	Italy	S-EU	2000	10507	Clormetil	100-150 ml/hl 0.5-1.5 L/Ha*	108.9-326.7 g/Ha	2	217.8-653.4 g/Ha
Grape	grape berry moth	outdoor	217.8 g/l, EC	Spraying	Italy	S-EU	2002	11186	Cutis	100-150 ml/hl 0.5-1.5 L/Ha*	108.9-326.7 g/Ha	2	217.8-653.4 g/Ha
Grape	Leafhopper, scale, grape berry moth, Trips, *Noctua* spp.	outdoor	223 g/l, EC	Spraying	Italy	S-EU	2003	11849	Skorpio EC	100-200 ml/hl 0.5-2 L/Ha*	111.5-446 g/Ha	2	223-892 g/Ha

	Representative Uses (for application details see **table 5)**				Existing Authorisations								
Crop	Target	Situation of use (e.g. indoor…)	AI content & Formulation Type	Application method	Country	Zone	Since	Reg. No.	Product	Product Application rate per treatment Min and Max	Active Substance Application rate per treatment Min and Max	Number of treatments per Season Min and Max	Active Substance Max total dose/ ha Min and Max
Grape	Leafhopper, scale, grape berry moth	outdoor	223 g/l, EC	Spraying	Italy	S-EU	2007	13622	Tecnifos M22	100-200 ml/hl 0.5-2 L/Ha*	111.5-446 g/Ha	2	223-892 g/Ha
Grape	Leafhopper, scale, grape berry moth	outdoor	223 g/l, EC	Spraying	Italy	S-EU	2007	13743	Kukar 22	100-200 ml/hl 0.5-2 L/Ha*	111.5-446 g/Ha	2	223-892 g/Ha
Grape	Leafhopper, scale, grape berry moth	outdoor	223 g/l, EC	Spraying	Italy	S-EU	2007	13793	Runner M	100-200 ml/hl 0.5-2 L/Ha*	111.5-446 g/Ha	2	223-892 g/Ha
Grape	Leafhopper, scale, grape berry moth	outdoor	223 g/l, EC	Spraying	Italy	S-EU	2007	13808	Etifos ME	100-200 ml/hl 0.5-2 L/Ha*	111.5-446 g/Ha	2	223-892 g/Ha
Grape	Leafhopper, scale, grape berry moth	outdoor	223 g/l, EC	Spraying	Italy	S-EU	2001	11029	Pandar 22	100-200 ml/hl 0.5-2 L/Ha*	111.5-446 g/Ha	2	223-892 g/Ha
Grape	Leafhopper, scale, grape berry moth, Trips	outdoor	223 g/l, EC	Spraying	Italy	S-EU	2003	11603	Cleaner 22	100-200 ml/hl 0.5-2 L/Ha*	111.5-446 g/Ha	2	223-892 g/Ha
Grape	Leafhopper, scale, grape berry moth	outdoor	223 g/l, EC	Spraying	Italy	S-EU	2008	14208	Clorpir CE	100-200 ml/hl 0.5-2 L/Ha*	111.5-446 g/Ha	2	223-892 g/Ha
Oilseedrape	Plant-eating beetles	outdoor	225 g/l, EC	Spraying	France	S-EU	2012	2120086	Exaq 2M	1.5 L/ha	337.5 g a.s./ha	1	337.5 g a.s./ha
Oilseedrape	Plant-eating beetles	outdoor	225 g/l, EC	Spraying	France	S-EU	2012	2120086	Reldan 2M	1.5 L/ha	337.5 g a.s./ha	1	337.5 g a.s./ha

* dose rate based on a spray volume of 500-1000 L/Ha

Level 2

Summary of active substance hazard and of product risk assessment

CHLORPYRIFOS-METHYL

2. SUMMARY OF ACTIVE SUBSTANCE HAZARD AND OF PRODUCT RISK ASSESSMENT

2.1. IDENTITY

ISO: Chlorpyrifos-methyl

IUPAC: O,O-dimethyl-O-3,5,6-trichloro-2-pyridyl phosphorothioate

CAS No.: 5598-13-0

EU: The existing specification for pure active substance in technical material is minimum 960 g/kg, relevant impurities sulfotemp < 5 g/Kg and sulfotemp-ester < 5 g/Kg (SANCO/3061/99 - rev. 1.6 from 03 June 2005 and SANCO/3061/99 - rev. 2 from 20 March 2015).

FAO: No FAO Specifications

Specification of purity:

DOW: 960 g/kg
SAPEC: 985 g/kg

Relevant impurities:

DOW:
Sulfotemp: maximum level of 0.5% (5 g/kg)
Sulfotemp Ester: maximum level of 0.3% (3 g/kg)

SAPEC:
Not specified

2.2. PHYSICAL AND CHEMICAL PROPERTIES

2.2.1. Summary of physical and chemical properties of the active substance

Chlorpyrifos-methyl is a low melting point solid, which did not boil, was not flammable, was devoid of explosive or oxidising properties but was subject to auto-ignition at 272 ± 5°C.
It is of moderately high vapour pressure and may show some tendency to volatilise from water. It is of low solubility in water across the environmental pH range but highly soluble in a range of organic solvents. It is moderately unstable in aqueous media with an increasing degradation at higher values of pH.
It has a relative density of 1.642, a high n-octanol/water partition coefficient and shows little absorbance to UV-Visible light above 290 nm, however it is photodegraded in the presence of water with a quantum yield of 2.6 x 10^{-3}. Its surface tension (71.3 mN/m) classifies it as a non-surface active material.

2.2.2. Summary of physical and chemical properties of the plant protection product

DOW: The appearance of the plant protection product GF-1684 is an orange liquid at 24.0°C, with a gasoline-like odor. The pH of an approximately 1% wt/wt aqueous solution was 4.74 at 23.1 °C.

GF-1684 formulation is not explosive and has no oxidizing properties. GF-1684 was found not to have an auto-ignition temperature below 400ºC, and the flash point is 82.5°C. The formulation is a Newtonian substance with a viscosity of 5.22 mm^2/s at 20.0°C and 3.11 mm^2/s at 40.0°C. The density of the formulation is 1.0504 g/mL at 20.0°C. GF-1684 is stable when stored for 14 days at 54°C, and 24 months at ambient temperature, in PET commercial packaging. Its technical characteristics are acceptable for an EC formulation.

SAP: The appearance of the product is that of an off-white liquid, with characteristic odour. It is not explosive, has no oxidising properties. It has a self-ignition temperature > 397°C. In aqueous solution, it has a pH value around 4.9. The stability data after two weeks storage at high temperature (54ºC; HT) and when exposed to high and low temperature cycles indicate a shelf life of at least 2 years at ambient temperature but **the results after 24 months at ambient temperature are required (final report is scheduled by December 2016).** Its technical characteristics are acceptable for capsule suspension formulation.

2.3. DATA ON APPLICATION AND EFFICACY

2.3.1. Summary of effectiveness

Chlorpyrifos-methyl is an insecticide used in agriculture to control a wide range of chewing and sucking pests in a range of crops such as grape, citrus, top fruit, vegetable crops, cereals, oilseed rape, corn, cotton, potato, soybean and strawberry. In cereals, stored grain pests are controlled in storehouses, while in the other crops open field broadcast applications are registered. Chlorpyrifos is effective by contact, ingestion and vapour phase to control insect pests.
Chlorpyrifos-methyl is a well known contact and ingested insecticide that has demonstrated effective control of key sucking and chewing pests, representatives of the classes *Coleoptera, Diptera, Homoptera* and *Lepidoptera* in a wide range of crops and situations. It has been long established as an effective broad spectrum insect management tool for growers across Europe for use in both major and minor crops. Chlorpyrifos-methyl also control some mite pests in store houses.

2.3.2. Summary of information on the development of resistance

Where there is a general resistance in the pest population to organophosphates there could be cross resistance to chlorpyrifos-methyl. One specific case of resistance to this molecule have been reported in Europe (Czech Republic) on *Phorodon humuli* as agricultural pest species according to the Arthropod Pesticide Resistance Database of Michigan University and IRAC (Insecticide Resistance Action Committee).
It is recommended that chlorpyrifos-methyl should be applied according to basic IRAC principles and used in programmes alternating with products that have different modes of action. As in most uses chlorpyrifos-methyl can be applied only once per year and very few other IRAC Group 1B insecticides are used in the practice, the chance to develop resistance is low.

2.3.3. Summary of adverse effects on treated crops

Chlorpyrifos-methyl does not have any adverse effect on treated crops when applied according to label recommendations.

2.3.4. Summary of observations on other undesirable or unintended side-effects

No other undesirable or unintended side-effects have been observed for chlorpyrifos-methyl when applied according to label recommendations.

2.4. FURTHER INFORMATION

2.4.1. Summary of methods and precautions concerning handling, storage, transport or fire

Handling: During normal handling of either technical substance or formulated product, respiratory protection, goggles or safety glasses, gloves and apron or other covering clothing are recommended.
Storage: Bothe active substance and product should be stored in the original container in dry and well ventilated places and protected from sunlight, heat and humidity

Transport

	Chlorpyrifos-methyl	**Chlorpyrifos-methyl 200CS**
UN number:	3077	3082
ADR Class:	9	9
OMI/IMDG Class:	III	III
Packaging group:	Dangerous for the environment.	Dangerous for the

		environment
Marine Pollutant	UN 3077; Environmentally hazardous substance, solid, N.O.S. (contains: Chlorpyrifos); 9; III; (E).	UN 3082; Environmentally hazardous substance, liquid, N.O.S. (contains: Chlorpyrifos-methyl), 9, III; (E)
UN proper shipping name:	3077	UN 3082

Fire: During a fire, irritating and possibly toxic gases may be generated by thermal decomposition or combustion: carbon, nitrogen and sulphur oxides; chlorine compounds: HCl and possibly $CSCl_2$

2.4.2. Summary of procedures for destruction or decontamination

No neutralization procedure (e.g. reaction with alkali to form less toxic compounds) is suitable. All waste products should be packaged and labelled as waste chemical material. Product and packaging should be disposed of in a suitable waste incineration or disposal plant in accordance with local/national regulations.

2.4.3. Summary of emergency measures in case of an accident

First aid measures:

Inhalation: Move the victim to fresh air. Control the breathing, and if necessary provide oxygen therapy. Seek medical advice if symptoms develop.

Skin contact: Wash the skin with plenty of water and soap for 15-20 minutes. Seek medical advice if symptoms develop.

Eye contact: In the case of contact with eyes, separate eyelids and rinse immediately with plenty of water for several minutes. Do not forget to remove contact lens. Seek medical advice, if symptoms develop.

Ingestion: Wash mouth with water provided the victim is conscious. Seek medical advice, if symptoms develop. Do not give anything by mouth to an unconscious person. Do not induce vomiting unless told so by a doctor or poison control centre.

General measures: Take the person away from the contaminated area.
Remove the contaminated clothing immediately.
Keep the affected person stable.
Maintain the body temperature.
If the person is unconscious, lay him/her down on one side, with the head lower than the rest of the body, and the knees half-bended.
Never leave the victim alone.

Note to physician: **Chlorpyrifos-methyl is an acetylcholinesterase inhibitor**. Provide supportive care and symptomatic treatment. If swallowed induce vomiting or provide a gastric wash, avoiding aspiration; administrate activated charcoal or saline laxative (type: sodium or magnesium sulphate or similar). Control vital functions (respiratory, cardio and central nervous systems) and electrolytic equilibrium. Antidotes: atropine sulphate and oximes. Administrate atropine sulphate until symptoms of atropinization appears; provide blood analysis to check cholinesterase level, before administration of oxime (pralidoxime chloride or obidoxime chloride). Keep the treatment with oximes during the administration of atropine sulphate. In case of seizures administrate diazepam. At first signs of pulmonary oedema provide oxygen therapy and symptomatic treatment.

Do not administrate morphine, aminophiline, anti-histaminics, barbiturates, phenothiazines and other respiratory depressants, catecolamines, physostigmine, neostigmine or other anticholinesterase, fats including milk, and alcohol. Keep the patient under observation depending on the severity of poisoning, but at least during 48 hours.

Accidental release measures:

For non-emergency personnel:
Avoid contact or inhalation of product.

For emergency responders:
Isolate the spill area and limit the access to essential personnel. Use adequate protective clothes, gloves and protective mask with dust filter (as described under point CA 3.8). Eliminate any possible ignition source. Avoid contact or inhalation of product. Ventilate confined space before entry.

Containment of spillages:
Keep spill and cleaning runoff, out of municipal sewers and open bodies of water. Prevent dispersion of spill. Block the leakage, if this operation doesn't implicate risks. If product has contaminated bodies of water or soil or vegetation, alert the local authorities.
Cover entire spill with absorbing material or sand, collect it, avoiding producing dust, and place it in a container appropriate for later disposal. Avoid use of water for cleaning up.

Decontamination of areas, vehicles and buildings
Absorbed spillage or contaminated soil has to be collected, for small quantities best by an industrial vacuum cleaner, alternatively with broom and shovel. Solid surfaces may be further cleaned by washing with detergents. Pack absorbed material into tightly closed disposable containers.
Water contaminated by a spillage and recovered by containment must be collected and burned in a commercial incinerator or treated in a waste water treatment plant.

Disposal of damaged packaging, adsorbents and other materials:
Damaged packaging and collected material from spillage have to be burned in a commercial incinerator.

2.4.4 Possible occurrence of pesticide degradates from drinking water treatments.

DOW: Data Required.

SAPEC: brief literature review to investigate the fate of chlorpyrifos-methyl during water treatment with chlorine or ozone. Results found for chlorpyrifos can be extrapolated to chlorpyrifos-methyl. Possible occurrence of pesticide degradates by hydrolysis or oxidation include 3,5,6- trichloro- 2- pyridinol (TCP), chlorpyrifos-methyl-oxon, O,O- dimethylphosphorothioate, O,O-dimethylthiophosphate, and O,O-dimethylphosphonate.

2.5. METHODS OF ANALYSIS

2.5.1. Methods used for the generation of pre-authorisation data

2.5.1.1 Analysis of the active substance as manufactured

Active substance:

DOW: Gas Chromatography with FID detection using a HP Ultra 2 Column, 25 m x 0.32 mm x 0.52 µm

SAP: HPLC UV method

Relevant impurities:

DOW: Sulfotemp and Sulfotemp ester in technical chlorpyrifos-methyl can be quantified by GC- FID method

SAP: Sulfotemp and Sulfotemp ester in technical chlorpyrifos-methyl were preliminary screened by LC-MS. **Accurately validated method is required.**

2.5.1.2 Formulation analysis

Active substance:

DOW: Gas Chromatography with FID detection using a DB-5 Column, 10 m x 0.1 mm x 0.17 µm
SAP: HPLC/UV method. The active substance, chlorpyrifos-methyl, in the formulated product is determined by high-performance liquid chromatography (HPLC), using a column Purospher STAR RP-18e (250x2mm, 5µm particle size), acetonitrile/water/acetic acid (82.0/17.5/0.5) as mobile phase and UV detection at 300 nm. **Free chlorpyrifos-methyl in the preparation SAP200CHLORI (Chlorpyrifos-methyl 200 g/L CS) is quantified using a GLC-FID method that cannot be considered accurately validated according to SANC0/3030/99 rev. 4 (Accuracy of the method should be provided).**

Relevant impurities:

DOW: Sulfotemp in the formulation can be quantified by GC- FID method. V**alidation of the method for the determination of Sulfotemp ester is required.**

SAP: Analytical method for the determination of Sulfotemp and Sulfotemp ester in the formulation would be required if a specification for these impurities in technical material is set.

Methods for Risk Assessment

<u>Plants and plant products</u>

DOW:
Chlorpyrifos-methyl; high water, acidic, dry and oily commodities; LC-MS/MS; LOQ: 0.01 mg/kg
TCP ; high water, acidic, dry and oily commodities and in foodstuff of animal origin LC-MS/MS LOQ: 0.01 mg/kg
Des-methyl Chlorpyrifos-methyl; crops and processed fractions; LC-MS/MS; LOQ: 0.01 mg/kg

SAP:
Chlorpyrifos-methyl; Grapes, rapeseed; LC-ESI-MS-MS; LOQ: 0.01 mg/kg
Chlorpyrifos-methyl, TCP-glucoside, TCP as TCP; Grapes, rapeseed ; LC-ESI-MS-MS; LOQ: 0.01 mg/kg
Chlorpyrifos-methyl, desmethyl-chlopyrifos-methyl; Grapes processed commodities; LC-ESI-MS-MS; LOQ: 0.01 mg/kg
Chlorpyrifos-methyl; Grapes and its processed commodities; GC-MS/MS; LOQ: 0.01 mg/kg

<u>Food of animal origin</u>

DOW:
Chlorpyrifos-methyl; animal matrices; LC-MS/MS; LOQ: 0.01 mg/kg
Des-methyl Chlorpyrifos-methyl; Animal Matrices; LC-MS/MS; LOQ: 0.01 mg/kg
TCP (free and conjugates) ; animal matrices; LC-MS/MS LOQ: 0.01 mg/kg

SAP:
Chlorpyrifos-methyl; Milk, Eggs, Meat, Fat, Liver/Kidney; LC-MS/MS; LOQ: 0.01 mg/kg
Chlorpyrifos-methyl (as TCP), TCP and TCP-glucuronide (as TCP); Milk, Eggs, Meat, Fat, Liver/Kidney; LC-MS/MS; LOQ: 0.01 mg/kg

Soil

DOW:
3,6-dichloro-2-pyridinol (3,6-DCP); soil (sandy loam, silt loam and clay loam); LC-MS/MS.; LOQ: 0.05 mg/kg

SAP:
chlorpyrifos-methyl and its metabolites in soil degradation studies; LC-MS/MS; LOQ = 0.01 mg/kg.

Water

DOW:
Chlorpyrifos-methyl, 3,5,6-trichloro-2-pyridinol (TCP) and 3,6-dichloro-2-pyridinol (3,6-DCP) in Ground, Surface and Drinking Water; LC-MS/MS; LOQ: 0.01 µg/L
Des-methyl Chlorpyrifos-methyl, X143491 (chlorpyrifos-methyl-oxon) and X131419 (3,5,6-trichloro-1-methylpyridin-2(1H)-one) in Ground, Surface and Drinking Water ; LC-MS/MS; LOQ: 0.1 µg/L

SAP:

TMP (metabolite); water (Test medium for *Daphnia magna*); HPLC-UV-Vis; LOQ: 0.02 mg test item/L
Desmethyl-chlorpyrifos-methyl (metabolite); water (Test medium for *Daphnia magna*); HPLC-UV-Vis; LOQ: 2 mg/l
Desmethyl-chlorpyrifos-methyl (metabolite); water (Test medium for green algae); HPLC-UV-Vis; LOQ: 7 mg/l

Air

No new toxicological, operator or ecotoxicological study has been submitted requiring the analysis of chlorpyrifos in air.

Body fluids and tissues

DOW:
Chlorpyrifos-methyl; Body Fluid(s) (blood, urine); LC-MS/MS; LOQ of 0.05 µg/L
Chlorpyrifos-methyl; animal matrices; LC-MS/MS; LOQ: 0.01 mg/kg
Des-methyl Chlorpyrifos-methyl; Animal Matrices; LC-MS/MS; LOQ: 0.01 mg/kg
TCP (free and conjugates) ; animal matrices; LC-MS/MS LOQ: 0.01 mg/kg

SAP:
Chlorpyrifos-methyl; Milk, Eggs, Meat, Fat, Liver/Kidney; LC-MS/MS; LOQ: 0.01 mg/kg
Chlorpyrifos-methyl (as TCP), TCP and TCP-glucuronide (as TCP); Milk, Eggs, Meat, Fat, Liver/Kidney; LC-MS/MS; LOQ: 0.01 mg/kg

2.5.2. Methods for post control and monitoring purposes

Plants and plant products

DOW:
Chlorpyrifos-methyl ; high water, acidic, dry and oily commodities and in foodstuff of animal origin LC-MS/MS (multiresidue analytical method is based on the QuEChERS); LOQ of 0.01 mg/kg; ILV
Chlorpyrifos-methyl; high water, acidic, dry and oily commodities; LC/MS; LOQ: 0.01 mg/kg; ILV

SAP:
Chlorpyrifos-methyl; apple grape potato; LC-ESI-MS-MS; LOQ: 0.01 mg/kg; ILV
Chlorpyrifos-methyl, Oilseed Rape; LC-ESI-MS-MS; LOQ: 0.01 mg/kg; ILV
Chlorpyrifos-methyl; LC-MS/MS; Nectar, LOQ: 0.001 mg/kg; Pollen, LOQ: 0.005mg/kg

Food of animal origin

DOW:
Chlorpyrifos-methyl ; high water, acidic, dry and oily commodities and in foodstuff of animal origin LC-MS/MS (multiresidue analytical method is based on the QuEChERS); LOQ of 0.01 mg/kg; ILV
Chlorpyrifos-methyl; animal matrices; LC-MS/MS; LOQ: 0.01 mg/kg; ILV

SAP:
Chlorpyrifos-methyl; Milk, Eggs, Meat, Fat, Liver/Kidney; LC-MS/MS; LOQ: 0.01 mg/kg; ILV

Soil

DOW:
Chlorpyrifos-methyl; soil; LC-MS/MS; LOQ: 0.01 mg/kg

SAP:
Chlorpyrifos-methyl and TCP; soil; LOQ: LC-MS/MS; 0.01 mg/kg.

Water

DOW:
Chlorpyrifos-methyl, 3,5,6-trichloro-2-pyridinol and 3,6-dichloro-2-pyridinol, Ground, Surface and Drinking Water; LC-MS/MS; LOQ: 0.01 µg/l; ILV for drinking water
X143491 (chlorpyrifos-methyl-oxon), Des-methyl Chlorpyrifos-methyl, and X131419 (3,5,6-trichloro-1-methylpyridin-2(1H)-one) in Water; LC-MS/MS; LOQ: 0.01 µg/l; ILV for drinking water

SAP:
Chlorpyrifos-methyl, TCP and TMP; drinking and surface water; LC-MS/MS; LOQ: 0.01 µg/l. ILV for drinking water

Air

DOW:
Chlorpyrifos-methyl, Chlorpyrifos-methyl-oxon, TCP and TMP in Air (ambient and warm/humid). GC-MS/MS For Chlorpyrifos-methyl and Chlorpyrifos-methyl-oxon the analytical method was validated with a LOQ of 0.3 µg/m3 and for TCP and TMP the validated LOQ was 0.90 µg/m3

SAP:
Chlropyrifos-methyl; air; GC-ECD;
TCP; air; LC-MS/MS; LOQ: 15.0 µg/m^3

Body fluids and tissues

DOW:
Chlorpyrifos-methyl in body fluid(s) (blood, urine); LC-MS/MS; LOQ of 0.05 µg/L
chlorpyrifos-methyl in tissues: LC-MS/MS (multiresidue analytical method is based on the QuEChERS); LOQ of 0.01 mg/kg

SAP:
A method has been validated for the Determination of Chlorpyrifos-Methyl in tissues with a LOQ of 0.01 mg/kg
Analytical method is required for the monitoring of active substance and relevant metabolites in body fluids according with Regulation 283/2013.

2.6. Effects on human and animal health

2.6.1. Summary of absorption, distribution and excretion in mammals

Four studies of ADME in mammals were submitted, three of them were previously evaluated under 91/414/EEC. Table 2.6.1-1 summarizes the content of each one.

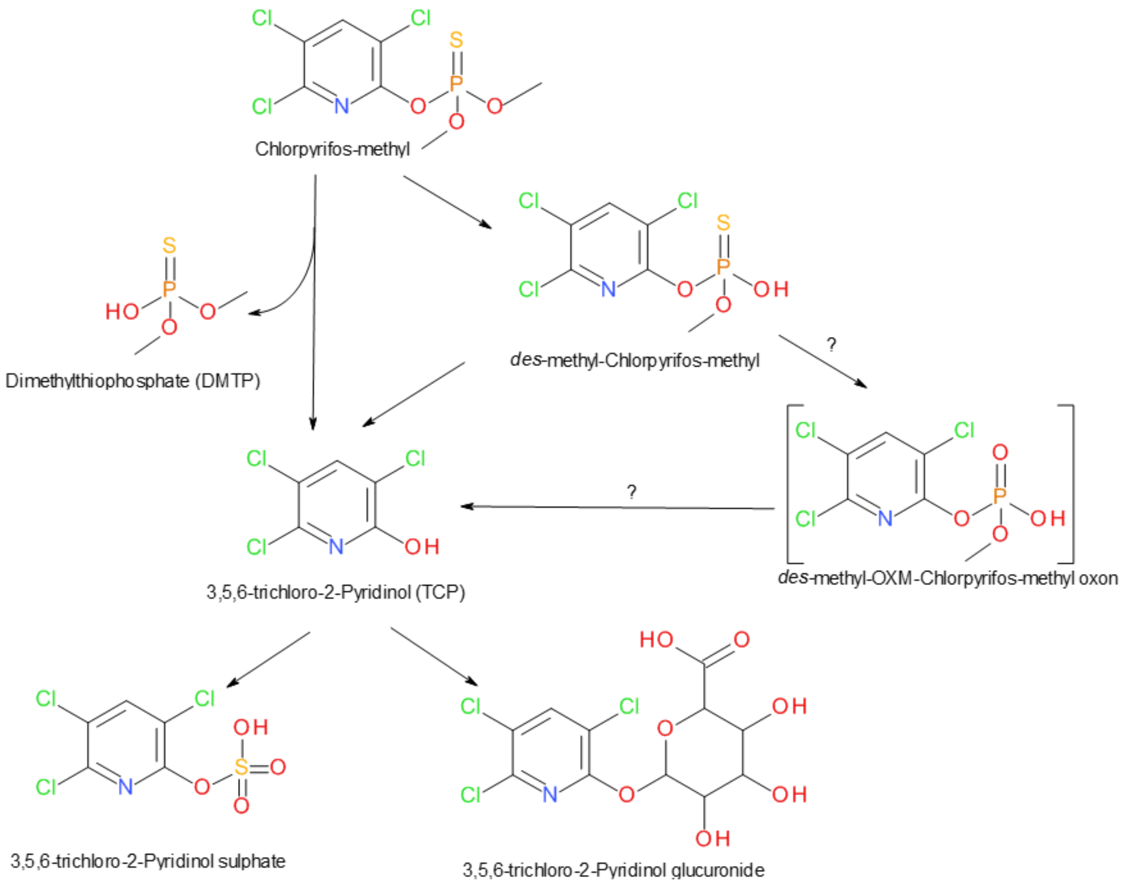
Single dose administration. Both, the works of [redacted] (1971) as well as that of [redacted] (1976) were conducted prior to the formal implementation of GLP, *i.e.*, they are not GLP compliant, neither followed any Guideline. On top of that, other serious deficiencies were found. Otherwise, the comparison of the results obtained in rats (the only species comparable between both studies) pointed out different radioactivity within 24 hours via the urine (80% vs 64% absorption rate), and only small amounts were added after 72 hours (reaching 85%) and 48 hours (<3%), in the studies of [redacted], respectively. Radioactivity collected after 72 hours in faeces ranged 7-9% for [redacted], 2.8% after 48 hours in the case of [redacted]. Total recovery reached 95% in the oldest study, an overall recovery of 74% in the recent one.

Repeated dose administration. The study of [redacted] (1987) was performed with chlorpyrifos-ethyl; it was already evaluated and already formerly rejected as valuable information for chlorpyrifos-methyl.
Newly supplementary submitted information underlines the differences between those two molecules, despite their structural similarity. Chlorpyrifos-ethyl is hydrolytically more stable and more lipophilic than Chlorpyrifos-methyl. In another study of [redacted] (dated 1970) on the comparative kinetics of chlorpyrifos-ethyl and chlorpyrifos-methyl in rats showed different Tmax (3 h and 5 h, respectively); additionally, chlorpyrifos-ethyl was excreted more rapidly than chlorpyrifos-methyl.
A repeat dose ADME study ([redacted] 2015) was conducted because a data gap had been identified in the previous European review and was a data requirement as outlined in Commission Regulation (EU) No 283/2013.
From the [^{14}C]-labeled metabolites and parent compound present in urine (0-48 h) and faeces (8-24 h), the major metabolites (present as >5% dosed amount) identified were DEM (6.7% in males, 15.6% in females), TCP (57.7% in males, 50.3% females) and its conjugate TCP-glucuronide (17.8% in males, 5.9% in females) and the parent compound itself (3.8% in faeces in males and 6.5% in faeces in females, 8-24 h period). Total [^{14}C]-labeled metabolites and parent compound present in urine and faeces reach 91.3% and 82.6% in males and females, respectively, of the given dose. A different metabolism pathway is proposed; this revised and updated version is considered the appropriate one.

Table 2.6.1-1 Summary of the ADME in mammals, oral studies.

Substance	Species – Number, strain, sex	Study type, Doses (mg/kg)	Purity (%), batch, vehicle	Reference	Guideline OECD/GLP
Chlorpyrifos-methyl	Rat – 2, Sprague-Dawley, M	Single dose, 16	>99%, ?, corn oil	[redacted] [redacted] [redacted], 1971	No / No
Chlorpyrifos-methyl	Rat - 10, ?, M	Single dose; 30 (rat) and 100 (sheep)	>99%, ?, ethanol	[redacted] 1976	No / No
	Sheep - 1, ?, F		>99%, ?, Gelatine capsule		
^{14}C-3,5,6-trichloro-2-pyridinol	Sheep - 1, ?, F		?, ?, Gelatine capsule		
Chlorpyrifos-methyl	Rat, 4/sex , Sprague-Dawley, M+F	Repeat dose, 2.5	Purity: 98%. Batch ZK08272001; Radiolabelled test item, purity: >99%. Batch: XX3-139481-6; corn oil	[redacted] 2015	#417 / Yes
Chlorpyrifos-ethyl	Rat, 5/sex , CDF Fischer 344, M+F	Single (0.5 or 25) and repeated (0.5)	>99%, AGR 200391, corn oil	[redacted] 1987	Meets #417 /Yes

Proposed metabolic pathway



DMPT and *des*-methyl-OXM-Chlorpyrifos-methyl oxon were only detected by LC-MS analysis
? indicates theoretical pathway

In vivo

Oral route. Despite the fact that the toxicokinetics and metabolism of chlorpyrifos-methyl were studied in rats, in sheep and also in the lactating goat (the latest excluded in the renewal report) by administration of single doses no conclusions can be attained from all those studies given that the maximum number of animals employed per study was two, together with many other observed deficiencies.

Rat:

Only one study in male rats on toxicokinetics and metabolism of chlorpyrifos-methyl after administration of a single dose ([redacted], 1976) employed a significant number of animals (n=10); leaving out the deficiencies, and considered as information only, results showed that urinary radioactivity accounted for 64% of the administered dose within 24 hours and an additional 2.7% in the next 24 - 48 hour collections while cage rinsings contributed with <5% of the dose. Levels in faeces for the first and second 24-hour periods reached 2.4 and 0.4%, respectively. Overall recovery of radioactivity was 74.4%. After 96 hours, radioactivity was present in visceral fat (11.8), eviscerated carcass (2.65) and heart (2.11) measured as ppm of equivalents of chlorpyrifos-methyl.

In a recent study ([redacted] 2015), rats of both sexes (n=4) received a daily oral dose for 14 consecutive days (repeated dose); the first 13 days non-radiolabeled chlorpyrifos-methyl, followed on day 14 by a single oral ^{14}C-dose (2.5 mg/kg). The total recovery of the dosed radioactivity was 94.8% and 92.4% in males and females, respectively. The absorbed radioactivity was predominantly excreted with the urine (87 and 77% for males and females, respectively) during the 0-72 h period while recovered radioactivity in faeces for the same time interval was 6 and 9.8% for males and females respectively. On turn, cage wash accounted for 1.6% in males and 4.13% in females and the major part of the retained radioactivity was present in the residual carcass, i.e. 0.2% in males and 0.7% in females. Kinetic parameters: For males and females, C_{max} values of 1.12

µg/mL and 1.39 µg/mL were found after 6h and 4h, respectively. Volume of distribution was 1719 mL/kg in males and 1608 mL/kg in females. [^{14}C]-Chlorpyrifos-methyl´ half-life value in blood was 6.6 hours for males and 7.8 hours in females. The calculated AUC_{last} for males and females was 13.9 h*µg/ml and 17.4 h*µg/ml, respectively.

Metabolite profiling. The profile proposed by [redacted] (2015) was considered: It was conducted in pooled urine (0-48 h) and faecal (8-24 h) samples. The percentage of the total dosed radioactivity of the [^{14}C]-labeled metabolites and parent compound was 91.3% and 82.6% in males and females, respectively. In urine, five metabolites were found. In males, the most abundant metabolite found was TCP followed by TCP-glucuronide and des-methyl chlorpyrifos-methyl (DEM). In females, the most abundant metabolite found was TCP as well, but followed by DEM and TCP-glucuronide. Parent compound was not detectable in urine. In faeces, the major compound found in both genders was the parent compound (chlorpyrifos-methyl, 3.8% and 6.5% in males and females respectively), followed by TCP and DEM, both at levels below 1.5% (see B.6.1.1.3).
Other routes. Data on absorption, distribution, metabolism and excretion (ADME) following exposure by the dermal route shall be provided where toxicity following dermal exposure is of concern compared to that following oral exposure. From the acute data package it can be concluded that this is not the case for chlorpyrifos methyl. Otherwise, before investigating ADME *in vivo* following dermal exposure, an *in vitro* dermal penetration study shall be conducted to assess the likely magnitude and rate of dermal bioavailability. The study of [redacted] (1981) is the only study included in this section. It was already rejected in the original DAR, and is not valuable for the above mentioned purpose.

In vitro
Phase I NADPH-dependent metabolism of Chlorpyrifos-methyl in human liver microsomes (HLM) and rat liver microsomes (RLM) were compared. Recovery ranged roughly between 90 and 100%. Results showed that Chlorpyrifos-methyl metabolism is mainly NADPH-dependent. In HLM and RLM, the percentage of remaining parent compound decreased with incubation time. After 120 minutes of incubation, remaining parent compound accounted for 63.7 % and 46.9 % of Chlorpyrifos-methyl dose in HLM and RLM incubates, respectively. In HLM and RLM incubates, up to 8 radio-HPLC peaks were detected, but only three of them were over 5% of the administered dose (other radio-HPLC peaks corresponded to minor metabolic products accounting for less than 1% of Chlorpyrifos-methyl dose). Peak 4 was assigned to 3,5,6-trichloro-2-pyridinol (TCP): It was the main metabolic product in both HLM and RLM incubates (after 120 minutes of incubation, TCP reached 26.6% and 43.4% of Chlorpyrifos-methyl dose, respectively). At the same time-point, peak 6 represented 5.1% and 5.7% of Chlorpyrifos-methyl dose and peak 5, assigned to desmethyl chlorpyrifos-methyl (DEM), accounted for 1.3% and 2.2% of Chlorpyrifos-methyl dose in HLM and RLM, respectively.
Metabolic profiles and kinetics observed in HLM and RLM incubated with 10 µM Chlorpyrifos-methyl were similar qualitatively, but constantly different in quantitatively terms regarding parent compound, TCP, Peak 6 and DEM. Chlorpyrifos-methyl metabolism rate in human *in vitro* is lower compared to the rat.

Conclusion
Following single and repeated oral doses of ^{14}C-chlorpyrifos-methyl, absorption and elimination were rapid. The extent of absorption in the rat was 77% and almost all radioactivity was excreted within 72h (primarily via urine). Chlorpyrifos-methyl was extensively metabolised primarily via demethylation, hydrolysis and conjugation. The major metabolites included TCP and desmethyl chlorpyrifos-methyl and TCP-glucuronide. Parent compound only to be found in faeces. Although potential for accumulation seems to be low, data from the study of [redacted] (1976) might suggest certain degree of retention in fatty tissues Excretion reaches 94.6% and 91.6% in males and females respectively (repeat dose) comprising urine (0-72 h), faeces (8-72 h) and cage wash.

2.6.2. Summary of acute toxicity

Chlorpyrifos-methyl was already tested for the whole acute toxicity package. Four new studies were recently added.
From the initial acute oral toxicity studies it was concluded that acute oral median LD_{50} was determined to be 2814 mg/kg bw for rats (both sexes) with a similar value for the mouse (2843 mg/kg bw). Data have been generated from a new acute oral toxicity study in rats ([redacted] 2015: Toxic class method) in order to show equivalency of new technical material (Dow). As long the outcome of that work was a LD_{50} of 2500 mg/kg bw.
The acute dermal study produced no deaths at the tested dose and therefore the LD_{50} is > of 2000 mg/kg bw.
Chlorpyrifos-methyl was also applied to rats for acute inhalation toxicity (whole body) at the maximum attainable concentration of 0.67 mg/L. Rats showed clear signs of toxicity (salivation, lachrymation and other

signs of irritation) during the treatment, but no deaths were recorded. It is concluded that the inhalation LC_{50} is > 0.67 mg/L.

Chlorpyrifos-methyl was a slight transient irritant to rabbit skin ([redacted] 1984b) and eyes ([redacted] 1985c) that were not enough to warrant classification according to EC criteria.
In a guinea-pig skin sensitization study using a Buehler protocol, chlorpyrifos-methyl was not a skin sensitizer ([redacted] 1985d), but positive results were seen when a Magnusson & Kligman maximization protocol was used ([redacted] 2000). Consequently, it classification as a skin sensitiser, Cat 1 (H317) is proposed according to Regulation EC/1272/2008.

Two GLP and guideline compliant fototoxicity test were presented. According the studies results, Chlorpyrifos-methyl technical, was predicted to not have phototoxic potential using Balb/c 3T3 mouse fibroblasts (i.e., PIF <2.0 and MPE < 0.100) and to not have phototoxic potential in the presence and absence of exposure to a non-cytotoxic dose of UVA/VIS light.

According to EC Regulation 1272/2008, Chlorpyrifos methyl only requires classification for acute toxicity as skin sensitiser Cat.1, H317

Table 2.6.2-1 Summary of the acute toxicity of chlorpyrifos-methyl in mammals.

Test substance	Species, strain, number, sex	Route, dose (mg/kg bw)	Result/ Classification	Purity (%); batch Vehicle	Guideline/GLP	Reference
Reldan F (Tech. gr. chlorpyrifos methyl)	Rat, Sprague-Dawley, 5/sex; M & F	Oral, 5000	LD_{50} (mg/kg/bw)> 5000 Not classified	95.5; EK-840929097 Polyethylene glycol	#401/Yes	[redacted] (1984)
OP2 (Tech. gr. chlorpyrifos methyl)	Rat, Sprague-Dawley, 5/sex; M & F	Oral, 2000, 2860, 4000, 5600	LD_{50} (mg/kg/bw): 2814 Not classified	95.5; EK-840929097 Corn oil	#401/Yes	[redacted] (1985)
Reldan F TG 002 (Tech. gr. chlorpyrifos methyl)	Mouse, OF1 ICO, 5/sex; M & F	Oral, 2000, 2600, 3200, 4000, 5600	LD_{50} (mg/kg/bw): 2843 Not classified	96.9; EK900512002/RMM 1710 0.5% CMC	#401/Yes	[redacted] (1992)
Chlorpyrifos-Methyl TGAI.	Rat, Wistar, 7; F	Oral, 2000, 5000	LD_{50} (mg/kg/bw): 2500 Not classified	97.9; 2J04272001	#423/Yes	[redacted] (2015)
Reldan F (Tech. gr. chlorpyrifos methyl)	Rat, Sprague-Dawley-derived; 5/sex; M+F	Dermal, 2000	LD_{50} (mg/kg/bw)> 2000 Not classified	95.5; EK-840929097 Polyethylene glycol	#402/Yes	[redacted] (1985d)
Reldan Technical (Tech. gr. chlorpyrifos methyl)	Rat, Wistar-derived; 5/sex; M+F	Inhalation, 0.67 g/m^3	LC_{50} > 0.67 g/m^3 (0.67 mg/l) Not classified	?; EK 82092 8086	#403/Yes	[redacted] (1984)
Reldan F (Tech. gr. chlorpyrifos methyl)	Rabbit, NZ, 3 F	Topical (skin irritation), 0.5 g	Not irritant Not classified	95.5; EK-840929097	#404/Yes	[redacted] (1984a)
Reldan F	Rabbit,	Topical (eye	Not irritant	95.5; EK-	#405/Yes	[redacted]

Test substance	**Species, strain, number, sex**	**Route, dose (mg/kg bw)**	**Result/ Classification**	**Purity (%); batch Vehicle**	**Guideline/GLP**	**Reference**
(Tech. gr. chlorpyrifos methyl)	NZ, 3 F	irritation), 0.1 g	Not classified	840929097		(1984b)
Chlorpyrifos methyl	Rabbit, Albino, 6 M	Topical (eye irritation), 0.1 g	Not irritant Not classified	?; ?	No/No	[redacted] (1974)
Reldan F (Tech. gr. chlorpyrifos methyl)	Guinea pig, Dunkin-Hartley, 6M+6F	Topical (skin sensitisation)	Not sensitizer Not classified	95.5; EK-840929097	#406/Yes	[redacted] (1985)
Technical Grade Chlorpyrifos -methyl	Guinea pig, Dunkin-Hartley, 10M+10 F	Topical (skin sensiti) GMPT	Sensitiser Cat.1, H317	96.8; NB05272036	#406/Yes	[redacted] (2000)
Chlorpyrifos methyl	BALB/c 3T3 Mouse Fibroblast	In vitro test	No phototoxic potential. Not classified	99.9%, ZK08272001, DMSO	#432/Yes	[redacted] (20049
Chlorpyrifos methyl	BALB/c 3T3 Mouse Fibroblast	In vitro test	No phototoxic potential. Not classified	98.5%, BH-MUA DMSO	#432/Yes	[redacted] 2014

2.6.3. Summary of short-term toxicity

Seven short term repeat dose studies ranging from 28 to 180 days in duration have been conducted in a number of species (rat, mouse, dog and monkey). The two oral studies of [redacted] (1975) in rat and monkey were already rejected in the original report. On the other hand, two new studies in rat are presented (a 4-week dermal study and 2-week inhalation study, those from [redacted] both dated 2000)
In general the studies revealed that inhibition of plasma cholinesterase activity is the most sensitive indicator of treatment, followed by erythrocyte/brain cholinesterase. At higher, effects on organ weights and histpathoplogical changes in the adrenal gland, liver and kidney were observed in rodents. Partial recovery was observed over a 28-day recovery period.

In the 28-day oral study in mice, reduction in RBC cholinesterase was reported at at 1.27 mg/kg bw/day.
Dietary administration of chlorpyrifos-methyl (dose levels of 0.1, 1, 10 and 250 mg/kg bw/day), to rats for 13 weeks affected primarily cholinesterase activity and the adrenal glands. RCB and brain ChE was inhibited at 10 and 250 mg/kg bw/day. Adrenal gland weights were increased and microscopic examination revealed changes (varying degrees of hypertrophy and vacuolation of the cells of the zona fasciculate) in both sexes fed at 10 and 250 mg/kg bw/day. The NOAEL was 1 mg/Kg bw/day.
Decreses in RCB and brain ChE activity were seen also at 10 mg/kg bw/day in 13-week dietary study in dog (dose levels of 0.1, 10 and 50 mg/kg bw/day). The NOAEL was 0.1mg/kg bw/day

In a 28 day dermal toxicity study in F-344 rats the lowest relevant LOAEL was 10 mg/kg bw/day based on dose-related very slight vacuolation of the adrenals at 10 mg/kg bw/day.

In a 2-week vapour inhalation study in the rat there were no treatment related effects noted in any of the parameters evaluated and the NOAEC was determined to be 18 ppb, which is the highest practically attainable concentration.

Oral NOAEL does not need to be modified and is maintained at 1 mg/kg bw/d (rats, 13-weeks).
Dermal NOAEL is 10 mg/kg bw/day and NOAEC was 18 ppb (0.1 mg/m^3).

Table 2.6.3-1 Summary of short-term toxicity studies.

Substance	**Species – Number, sex, strain**	**Study type, Doses (mg/kg bw/day)**	**Purity (%), batch, vehicle**	**Reference**	**Guideline OECD/GLP**	**Outcome, effect**	**Aceptability**
Chlorpyrifos -methyl	Mouse, 12/sex/dose , ICR (Crj:CD-1)	28 days, Concentrations : 0, 1, 5, 10, 1000, 10000 ppm M = 0, 0.125, 0.651, 1.27, 122.0, 523.0 F = 0, 0.141, 0.745, 1.45 , 139.0, 318.0	91.8, AGR 209075, diet	[redacted] 1985	Yes / Yes	NOAEL= 5 ppm (0.651 mg/kg bw) Reduction in RBC cholinesterase activity at 1.27 mg/kg bw/day	Y
Chlorpyrifos -methyl DOWCO 214	Rat, 5/sex/dose, Sprague-Dawley,	42 days, oral (6 days/week) 0, 0.2, 1, 5	?, ?, gum tragacanth	[redacted] 1975	No / No	None due to deficiencies	N
Chlorpyrifos -methyl RELDAN	Rat, 10/sex/dose Fischer 344	13 weeks + 4 weeks recovery 0, 0.1, 1.0, 10 and 250	95.2±0.4, AGR-219561, diet	[redacted] 1990	Yes / Yes	LOAEL: 10 mg/kg bw/day NOAEL= 1 mg/kg bw both sexes Significantly reduction in RBC ChE and adrenal pathology (hypertrophy and vacuolation of cells of the zone fasciculata) at 10 mg/kg bw/day.	Y
Chlorpyrifos -ethyl RELDAN	Dog, 4/sex/dose, Beagle	13 weeks 0, 0.1, 10, 50 and 250	95.2±0.4, AGR-219561, diet	[redacted] 1990	Yes / Yes	LOAEL: 10 mg/kg bw/day NOAEL = 0.1 mg/kg bw both sexes Reductions in RBC and brain ChE at 10 mg/kg bw/day	Y
Chlorpyrifos -methyl DOWCO 214	Monkey, 3/sex/dose, Rhesus,	180 days, oral (6 days/week) 0, 0.2, 1, 5	?, ?, gum tragacanth	[redacted] 1975	No / No	None due to deficiencies	N
Reldan F	Rat, 10/sex/dose Fischer 344	28 days, dermal 6 h/day, 7 days/week, 0, 10, 100, 300	96.8%; NB05272036 , 0,5% methyl cellulose	[redacted] 2000	Yes / Yes	LOAEL 10 mg/kg bw/day, based on very slight vacuolation adrenals at 10 mg/kg bw /day	Y

Substance	Species – Number, sex, strain	Study type, Doses (mg/kg bw/day)	Purity (%), batch, vehicle	Reference	Guideline OECD/GLP	Outcome, effect	Aceptability
Reldan F	Rat, 10/sex/dose Fischer 344	2 weeks inhalation nose-only 6 h/day, 5 days/week 0, 0.49, 3.7 or 18 (ppb)	96.8%; NB05272036	[redacted] 2000	Yes / Yes	NOAEC 18 ppb Not detected signs at any dose level	Y

2.6.4. Summary of genotoxicity

Five new studies have been conducted to demonstrate equivalence of the new technical material.
Chlorpyrifos was tested *in vitro* for gene mutation, clastogenic effects and DNA effects. All the tests were negative. The substance was also tested *in vivo* for clastogenic effects. This test was also negative.
A summary of genotoxicity studies is included in table below.

Table 2.6.4-1: Summary of genotoxicity studies

Test	Test system	Concentration and test substance	EU Agreed endpoint[1]	Proposed new endpoint	Reference
In vitro genotoxicity tests					
In vitro bacterial reverse mutation	*S. typhimurium*, TA 98, TA 100, TA 102, TA 1535, TA 1537	1, 10, 500, 500, 100, 2500, 5000, 10 000 µg/plate, ±S9 Chlorpyrifos-methyl	Negative	Not relevant	20988, DeGraff, W.G., 1983 (E03)
***In vitro* bacterial reverse mutation**	***S. typhimurium*, TA 98, TA 100, TA 102, TA 1535, TA 1537**	**Trial I: 39.06, 78.13, 156.25, 312.5, 625 and 1250 µg/plate ±S9 Trial II: 12.8, 32, 80, 200, 500 and 1250 µg/plate ±S9 chlorpyrifos-methyl**	**New data Negative**		**140862 Tendulkar, K.E., 2015**
***In vitro* bacterial reverse mutation**	***Salmonella typhimurium* TA 98, TA 100, TA 102, TA 1535, TA 1537**	**31 .6, 100, 316, 1000., 2500 and 5000 µg/plate, ±S9**	**New data Negative**		**Wallner, 2010**
In vitro mammalian cytogenetics	Chinese hamster ovary cells	4, 12, 40 µg/ml, −S9 5, 15, 50 µg/ml, +S9 Chlorpyrifos-methyl	Negative –S9 Positive + S9	Not relevant	K-046193-023 [redacted] 1985 (E07)
***In vitro* mammalian cytogenetics**	**Rat lymphocytes**	**Trial I: 10, 20, 40, 60, 80 and 110 µg/mL ± 1% S9 Trial II: 10, 20, 40, 60, 80 and 110 µg/mL ± 2% S9**	**New data Negative**		**140864 [redacted] 2015**
In vitro mammalian forward mutation	Chinese hamster ovary cells (CHO/HGPRT)	5, 20, 40, 60, 80, 100 µmol/l, ±S9 Chlorpyrifos-methyl	Negative	Not relevant	K−046193−022 [redacted] 1985 (E06)
***In vitro* mammalian forward mutation**	**Chinese hamster ovary cells (CHO/HGPRT)**	**Trial I: 10, 20, 40, 60, 80 and 100 µg/ml ± S9 Trial II: 10, 20, 40, 60, 80 and 100 µg/mL ± S9 chlorpyrifos-methyl**	**New data Negative**		**140865 [redacted] 2015**
DNA damage	Unscheduled DNA synthesis in rat primary hepatocytes	1, 3.16, 10, 31.6, 100 µM	No UDS synthesis	Not relevant	[redacted] 1985
In vivo genotoxicity tests – Somatic cells					
In vivo micronucleus	Rat bone marrow polychromatic erythrocytes	0, 146, 460, 1460 mg/kg bw, chlorpyrifos-methyl	Negative	Not relevant	K‑046193‑020 [redacted] 1985 (E05)
***In vivo* micronucleus**	**Rat bone marrow polychromatic erythrocytes**	**50, 150 and 400 mg/kg bw chlorpyrifos-methyl**	**New data Negative**		**140863 [redacted] 2015**
In vivo mammalian UDS	Cultured primary rat hepatocytes	0, 600, 2000 mg/kg bw, chlorpyrifos-methyl	Negative	Not relevant	DWC 696/931261 [redacted] 1994 (E08)

[1] SANCO/3061/99; June 2005

Studies highlighted in **bold** are new studies since Annex I inclusion

2.6.5. Summary of long-term toxicity and carcinogenicity

The chronic toxicity and/or carcinogenicity of Chlorpyrifos-Methyl were evaluated in rats, mice and dogs. These studies were already available in the first DAR. A summary is presented in Table 2.6.5-1.

Table 2.6.5-1: Chlorpyrifos-methyl – Summary of long-term toxicity and carcinogenicity studies

Data point	Study	Species/ strain	Dosages (mg/kg bw/day)	NOAEL	Target organ/ principal effects at LOAEL	Reference
CA 5.5/1	2-year combined toxicity and carcinogenicity dietary	Rat/F344	0, 0.05, 0.1, 1.0, 50	1	Adrenal, RBC and Brain ChE	K-046193-031. [redacted] 1991 (I02)
CA 5.5/2	Pathology Peer Review – Adrenocortical Vacuolar Change.	Rat/F344			Adrenal vacuolation at 1 mg/kg bw/day and below were consistent with background findings and that the only dose producing clear effects was the top dose of 50 mg/kg bw/day	K-046193-031S [redacted] 2000 (I04)
CA 5.5/3	18 month combined toxicity and carcinogenicity	Mouse/CD-1	0, 0.08, 0.4, 4.0, 40.0	0.4	RBC and Brain ChE	GHF-R 166. [redacted] 1988 (I01)
CA 5.5/4	2- year chronic toxicity study	Dog/Beagle	0, 0.03, 0.1, 1.0, 3.0	1	RBC ChE	Lab study number DWC 94/74207 [redacted] 1974

Chlorpyrifos-Methyl did not elicit an oncogenic response in rats or mice at any dose level tested

The cholinesterase activity inhibition, in plasma, red blood cells and brain, was the most sensitive effect observed in all studies.

In rats, effects at 50 mg/kg bw/day comprised decreased plasma, RBC and brain cholinesterase activity, and in-life body weight, in male and female rats. Decreased food consumption was seen in male rat at 50 mg/kg bw/day

Increased adrenal gland weights and histopathologic alteration of the adrenal gland cortex were observed in males and females of the top dose group (50 mg/kg bw/day) and an incidence of slight diffuse vacuolation of the *zona fasciculata* in the adrenal gland of males was seen at 1.0 mg/kg bw/day. The adrenal vacuolation was extensively discussed during the first inclusion process and concluded that "vacuolar changes observed in all animals assigned to the control, low or intermediate dose groups were considered to represent manifestations of mild physiologic stress or systemic disease".

The NOAEL of this study is set at 1.0 mg/kg bw/day and based on reductions in brain and RBC cholinesterase.

In mice, inhibition of cholinesterase activity with a clear dose-effect relationship was found in the plasma, RBC and brain in both sexes at 50 ppm (4.40 mg/kg bw/day in males, 3.94 mg/kg/day in females) and 500 ppm (44.0 mg/kg bw/day in males, 41.5 mg/kg/day in females). Decreased body weights, food efficiency, water and food consumption were observed from 500 ppm in males. In females, lower body weights and water consumption were also observed.

Histopathological data revealed in increased overall incidence of the centrilobular hepatocellular fatty change in both sexes at 500 ppm. Increased incidence of adrenal cortical cell swelling renal tubular atrophy and renal cortical cyst was seen in males of the 500 ppm group. Increased overall incidence of renal tubular atrophy in males was also observed at 50 ppm. There were no treatment-related abnormalities in the data of clinical sign, mortality, hematology, autopsy, and organ weight in both sexes of the treated groups. No substance-related effects were seen at 5 ppm and 1 ppm.

The NOAEL of this study is set at 5 ppm for both sexes (around 0.4 mg/kg bw/day).

In dogs, there were no test substance-related changes in bodyweight gain, food consumption, water consumption, haematology, urinalysis, histopathology or ophthalmoscopy. Plasma and red blood cells chlonesterase was reduced at the two highest dose levels. The NOAEL is established in 1.0 mg/kg bw/day based on RBC cholinesterase inhibition.

2.6.6. Summary of reproductive toxicity

The potential for chlorpyrifos methyl on mammalian reproduction was assessed in a two-generation study in the rat, teratology studies in the rat and rabbit and a developmental neurotoxicity study. A published study was also taken into account for risk assessment. A summary of the findings is shown in Table 2.6.6-1. All studies were performed according to specific test guidelines. GLPs were applied in all cases.

In the two generation reproductive toxicity study, chlorpyrifos methyl was administered at 0, 1, 3, 10 mg/kg bw/day. Chlorpyrifos methyl did not produce reproductive adverse effects up to the dose of 10 mg/kg bw/day. Parental systemic effects were observed at 10 mg/kg bw/day, with decreased food consumption and increased adrenal glands weight accompanied with vacuolization of the cytoplasmatic cells in the zona fasciculata. The same effects with less intensity were also observed at 3 mg /kg bw/day. The critical effect was depression of the AChE activity in red blood cells at ≥ 3 mg/kg bw/day. The offspring was affected at the highest dose (10 mg/kg bw/day), with RBC AChE depression. Therefore, the parental NOAEL was set at 1 mg/kg bw/day, the offspring NOAEL was 3 mg/kg bw/day and the reproductive NOAEL was 10 mg/kg bw/day. The 1-generation reproductive study published in literature (Jeong et al., 2006) showed that CPM can be regarded as an anti-androgenic chemical and induced hypothyroidism, probably acting directly on thyroid hormonal system. CPM induced histopathological alterations in thyroid (>1 mg/kg bw/day) and adrenal glands (>10 mg/kg bw/day) with changes in the serum levels of T4 (decrease), testosterone (decrease) and TSH (increase). Therefore, the NOAEL could be 1 mg/kg bw.

In the rat developmental study, the females were dosed with 0, 1, 12.5 and 50 mg/kg bw/day. The critical effect was inhibition of the AchE activity in RBC (>12.5 mg/kg bw/day), also observable in brain at the higher dose (50 mg/kg bw/day). Developmental or teratogenic adverse effects were not observed. The maternal NOAEL was 1 mg/kg bw/day and the developmental NOAEL was 50 mg/kg bw/day. In the rabbit developmental study, the dams were dosed with 0, 4, 8 and 16 mg/kg bw/day, and no adverse effects were observed either in females or in the foetuses. Therefore, the maternal/developmental NOAEL for Chlorpyrifos-methyl was 16 mg/kg bw/day, with no potential to produce teratogenicity.

In the developmental neurotoxicity study with 0, 2, 10 and 50 mg/kg bw/day chlorpyrifos methyl, maternal effects were observed at > 10 mg/kg bw/day, with decreased brain and RBC cholinesterase activity. The offspring showed no signs of toxicity at the highest dose tested (50 mg/kg bw/day). Developmental neurotoxicity was manifested by RBC AChE inhibition at PND 21. The maternal NOAEL was 2 mg/kg bw/day, while the pup NOAEL was 50 mg/kg bw/day, and developmental neurotoxicity NOAEL could be set at 10 mg/kg bw/day. Nonetheless, we find more appropriate to select a developmental neurotoxicity NOAEL of 1 mg/kg bw/day based on histopathological effects in the thyroid, accompanied with changes in thyroid hormones than can represent neurodevelopmenta effects.

Table 2.6.6-1: Table summary of acceptable reproductive toxicity studies with Chlorpyrifos methyl

Study	Dosage mg/kg bw/ day	NOAEL mg/kg bw/day	LOAEL mg/kg bw/day	Main Adverse effect	References
Multigeneration studies					
Chlorpyrifos-methyl: two generation dietary reproduction toxicity study in CD rats	M & F: 0, 1, 3, 10	Parental: 1 developmental: 3 Reproductive: 10	Parental: 3 developmental: 3 Reproductive: -	Parental: Increased food consumption Increased adrenal gland weight, accompanied with histopathological effects (vacuolation cytoplasmatic cells in the zona fasciculata). RBC AchE inhibition Developmental: RBC AchE inhibition Reproductive: No effects	[redacted] **(2002). (KCA5.6.1)**
1-generation reproductive study in rat Published study	0, 1, 10, 100	1	10	↑adrenal gland weight (histopathology) Thyroid histopathology ↑ cholesterol ↓serum T4 (M) ↑serum TSH (M) ↓testosterone (M) ↓no. implantations	[redacted] 2006. Literature review
Developmental studies					
A Study of the Effect of Technical Reldan on Pregnancy of the Rat	0, 1, 12.5 and 50.	Maternal: 1 Developmental: 50	Maternal: 12.5 Developmental: -	Main maternal adverse effect: RBC AchE inhibition Main fetal adverse effect: No effects No teratogenicity observed.	[redacted] **1991**. **(KCA5.6.2)**
Study of the effects of chlorpyrifos-methyl on rabbits embryonal and fetal development.	0, 4, 8 and 16.	Maternal: 16 Developmental: 16	Maternal: - Developmental: -	Main maternal adverse effect: No effects Main fetal adverse effect: none. No teratogenicity observed.	[redacted] **1976 (KCA5.6.2)**
A Dietary Developmental Neurotoxicity Study of Chlorpyrifos-Methyl in Rats	0, 2, 10, 50.	Maternal: 2 pup: 50 Neurodevelopmental: 10	Maternal: 10 pup: - Neurodevelopmental: 50	Maternal adverse effect: RBC/Brain AchE inhibition pup systemic: No effects Osspring Neurodevelopmental: RBC AchE inhibition PND 21 Other sporious effects: decreased forelimb grip strength PND 45, decreased S1 brain measurement.	[redacted] **2015 (CA 5.6.2/3)**

2.6.7. Summary of neurotoxicity

Chlorpyrifos-methyl was tested for acute and subchronic neurotoxicity in rat and for its potential to produce delayed neurotoxicity in hen (acute, subchronic studies).
After acute administration of chlorpyrifos methyl, the critical neurotoxic effect was the inhibition of the RBC cholinesterase. The acute neurotoxicity study contained additional substudies in order to evaluate toxicological parameters regarding cholinesterase inhibition and the chlorpyrifos-methyl itself. After the administration of 30 mg/kg bw chlorpyrifos methyl, the Cmax measured was 0.485 µg/g, Tmax was 2h, half-life of 4.95h, and depression of the RBC cholinesterase activity was observed. Brain AChE inhibition was observed after acute administration of 150 mg/kg bw, but not at 75 mg/kg bw. Therefore, the critical effect was the RBC cholinesterase inhibition achieved after administration of 30 mg/kg bw, with a NOAEL of 10 mg/kg bw.

The 90-day neurotoxicity study in rats (0, 0.1, 1, 10 and 250 mg/kg bw/day) showed that chlorpyrifos methyl produced adverse effects, consistent with RBC and Brain AChE depression, at 10 mg/kg bw/day. At 250 mg/kg bw/day the animals showed clinical signs, cholinesterase inhibition, decreased bodyweight gain and food consumption, and histopathological effects in liver (hypertrophy), kidney (degeneration) and adrenal glands (cell vacuolation). The 90-d neurotoxicity NOAEL was 1 mg/kg bw/day.

Chlorpyrifos methyl did not show evidences of delayed neurotoxicity after both acute and subchronic administration to hen.

Table 2.6.7-1: Table summary of acceptable neurotoxicity studies with Chlorpyrifos methyl

Study	Dosage	NOAEL		LOAEL		Main Adverse effect	References
		Ppm	mg/kgbw/day	ppm	mg/kgbw/day		
Chlorpyrifos-methyl: acute oral neurobehavioral and cholinesterase inhibition study in female Crl (SD) rats	Pilot 1: 0, 30 mg/kg Toxicokinetic parameters Rat, females Pilot 2 : 0, 75 or 150 mg/Kg RBC/brain Cholinesterase Rat, females Definitive : 0, 5, 10 or 75 mg/kg Acute neurotoxicity study Rat, females		Pilot 1: - Pilot 2: - Definitive: 10		Pilot 1: 30 Pilot 2: 75 Definitive: 75	Pilot 1: Cmax = 0.485 µg/g Tmax = 2h Half-life = 4.95h AUC (0-24h) = 3.11 µg-h/g RBC AChE depression at 2, 4, 8, 24h Brain AChE OK Pilot 2: RBC AChE depression at 3, 6, 9, 12h Brain AChE inhibition (150 mg/kg bw) Definitive: RBC AChE depression	[redacted] **2013 (CA 5.7.1/1)**
Chlorpyrifos-methyl (RELDAN): Rat Subchronic Dietary Toxicity and Recovery	mg/kg bw/day: 0, 0.1, 1, 10 and 250.		1		10	Decreased RBC cholinesterase (week 6) Decreased brain AChE (week 13)	[redacted] **1990 (CA 5.7.1/2)**
Acute delayed neurotoxicity evaluation in chlorpyrifos-methyl in White Leghorn hens	mg/kg bw: 0, 2500, 5000 C+ (TCP) = 250 mg/kg bw		2500		5000	Neurological signs Histopathology sciatic nerve No delayed neurotoxicity C+: histopathology, delayed neurotoxicity	[redacted] **1979 (KCA 5.7.2)**
Chlorpyrifos-methyl insecticide: sub-chronic (3	mg/kg bw/day: 0, 50, 500		50		500	Decreased egg production Decreased bodyweight No delayed neurotoxicity	[redacted] **1984 (KCA**

Study	Dosage	NOAEL		LOAEL		Main Adverse effect	References
		Ppm	mg/kgbw/day	ppm	mg/kgbw/day		
month) delayed neurotoxicity study in laying chicken hens	C+ (TCP) = 10, 30 mg/kg bw					C+: histopathology, delayed neurotoxicity	**5.7.3)**

2.6.8. Summary of further toxicicological studies on the active substance

Endocrine disrupting properties

This is a new data requirement under Regulation 1107/2009 therefore no data have previously been considered.
There are currently no studies available that directly assesses the endocrine potential for chlorpyrifos-methyl. However, the data available for chlorpyrifos-ethyl are believed to be suitable in bridging to chlorpyrifos-methyl and are detailed below.

Chlorpyrifos was one of 67 chemicals selected for EPA's Endocrine Disruptor Screening Program (EDSP) based on the exposure potential to humans and environment. The purpose of the program is to screen pesticide chemicals for their potential to interact with the estrogen, androgen, or thyroid systems. A battery of 11 EDSP assays (Table 2.6.8-1) covering the scope of the program was completed for chlorpyrifos based on the EDSP data call-in and in accordance with test guidelines developed for EDSP Tier 1 screening. Data from Tier I endocrine disruptor screening assays are not valid for risk assessment purposes but will be used in a "weight of evidence" assessment of the potential endocrine activity of test substance.

To assist with scientific interpretation of the EDSP screening results for chlorpyrifos and within the context of existing data from regulatory guideline studies and published literature, a weight-of-evidence (WoE) evaluation was completed. This WoE approach was based on the OECD conceptual framework for testing and assessment of potential endocrine-disrupting chemicals that focused on estrogen/androgen and thyroid pathways. However, other endocrine and neuro-endocrine pathways may also have adverse outcomes, such as symptoms of metabolic syndrome, reproductive dysfunction, altered fetal development. OECD conceptual framework consisted of a systematic evaluation of data, progressing from simple to complex across multiple levels of biological organization. Five levels of information were considered including (Level 1) non-test information; (Level 2) in vitro assay results; (Level 3) in vivo assays that inform on endocrine pathways; (Level 4) in vivo assays that evaluate specific endocrine endpoints; and (Level 5) in vivo assays that provide comprehensive data on potential adverse effects over multiple life stages of an organism. In addition to the newly developed data under this screening, review of multiple study types conducted under Good Laboratory Practices (GLP) for registration purposes, and which collectively span a host of endpoints that inform on endocrine disruption potential was undertaken, along with an extensive literature review for identification of other published literature related to this WoE evaluation.

Table 2.6.8-1: Chlorpyrifos - Endocrine disrupting properties

Data point	Study type	Species/strain (sex)	Route/ method	Dose levels* and test substance	NOAEL*	Effects at lowest observed acceptable effect level (LOAEL)	Report reference
CA 5.8.3/1	Estrogen Receptor Binding Assay	Rat cytosol; *in vitro*	*In vitro*	10^{-10} M to 10^{-3} M / Chlorpyrifos	N/A	Provisional conclusion Chlorpyrifos was negative (not interactive) for estrogen receptor binding at concentrations up to 10^{-3} M.	[redacted] 2012 (111122)
CA 5.8.3/2	Estrogen Receptor Transcriptional Activation	hERa-HeLa-9903	*In vitro*	10^{-10} M to 10^{-4} M / Chlorpyrifos	N/A	Provisional conclusion Chlorpyrifos slightly increased estrogen receptor-mediated transactivation.	[redacted] 2011 (101190)
CA 5.8.3/3	Androgen Receptor Binding Assay	Rat cytosol; *In vitro*	*In vitro*	10^{-10} M to 10^{-3} M / Chlorpyrifos	N/A	Provisional conclusion Chlorpyrifos was equivocal for AR binding	[redacted] 2012 (111099)
CA 5.8.3/4	Aromatase Assay	*In vitro*	*In vitro*	10^{-10} to 10^{-3} M / Chlorpyrifos	N/A	Provisional conclusion Chlorpyrifos did not inhibit aromatase activity	Coady, K.K., Sosinski, L.K., 2011 (101142)
CA 5.8.3/5	Steroidogenesis Assay	H295R cell line; *In vitro*	*In vitro*	$10-^{10}$ M to 10^{-4} M / Chlorpyrifos	N/A	Provisional conclusion Chlorpyrifos altered steroidogenesis,	[redacted] 2011 (101189)
CA 5.8.3/6	Uterotrophic Assay in the Immature Female Crl:CD(SD) Rat	Rat/Crl:CD(SD); ♀	Gavage	0, 0.5, 1.5, 4 mg/kg bw/day / Chlorpyrifos	4 mg/kg bw/day	Provisional conclusion Under the conditions of this study, there was no indication of estrogenicity from chlorpyrifos at doses from 0.5 to 4 mg/kg bw/day, the highest dose level tested in female immature rats.	[redacted] 2011 (111008)
CA 5.8.3/7	Hershberger Assay in Castrated Adult Male Crl:CD(SD) Rats	Rats / Crl:CD(SD) (Male)	Gavage	0, 1, 6, 12 mg/kg bw/day / Chlorpyrifos	≥ 12 mg/kg bw/day	Based on the lack of statistically significant, treatment-related changes in two AST organ weights, chlorpyrifos at doses from 1 to 6 mg/kg/day was deemed negative for both androgenic and antiandrogenic activity in the Hershberger assay. ChE activity was significantly inhibited in RBCs at ≥ 1 mg/kg/day	[redacted], 2011 (101152)

Data point	**Study type**	**Species/strain (sex)**	**Route/ method**	**Dose levels* and test substance**	**NOAEL***	**Effects at lowest observed acceptable effect level (LOAEL)**	**Report reference**
CA 5.8.3/8	Female Pubertal Assay	Rats / Crl:CD(SD) (Female)	Gavage	0, 0.5, 1, 2 mg/kg/day / Chlorpyrifos	2	There was no evidence of endocrine activity for chlorpyrifos in the female pubertal assay at doses from 0.5 to 2.0 mg/kg/	[redacted] 2011 (111076)
CA 5.8.3/9	Male Pubertal Assay	Rats / Crl:CD(SD) (Male)	Gavage	0, 0.5, 1, 2 Chlorpyrifos	2	Provisional conclusion Based on the lack of treatment-related changes in puberty onset, endocrine-sensitive organ weights, serum testosterone, T4 and TSH levels, and testicular, epididymal and thyroid histopathology, there was no evidence of endocrine activity for chlorpyrifos in the male pubertal assay at doses from 0.5 to 2.0 mg/kg/day.	[redacted] 2011 (111077)
CA 5.8.3/10 Also CA 5.8.3/11 (publication)	Weight of Evidence of Potential Estrogen, Androgen, or Thyroid Effects	N/A	N/A	N/A/ Chlorpyrifos	N/A	The conclusion of the weight of evidence evaluation is that chlorpyrifos demonstrates no potential to interact with the endocrine system, including estrogen, androgen, or thyroid pathways.	Juberg, D.R., Gehen, S.C., Kramer, V.J., Lu, H., Marty, M.S., Coady, K.K., 2011 (110687)
CA 5.8.3/12	US EPA EDSP: WEIGHT OF EVIDENCE ANALYSIS OF POTENTIAL INTERACTION WITH THE ESTROGEN, ANDROGEN OR THYROID PATHWAYS	N/A	N/A	N/A/ Chlorpyrifos	N/A	Based on weight of evidence considerations, EDSP Tier 2 testing is not recommended for chlorpyrifos since there was no evidence of potential interaction with the estrogen, androgen and thyroid pathways.	US EPA, 2015

* mg/kg bw/day, unless otherwise stated
Bolded studies are new studies since Annex I inclusion
N/A = not applicable

Estrogen (E), androgen (A) or thyroid (T) signalling pathways (AET)

A battery of 11 *in vitro* and *in vivo* assays were presented to evaluate the potential of Chlorpyrifos to interact with the estrogen (E), androgen (A) or thyroid (T) signalling pathways (OECD Conceptual Framework (CF) for testing and assessment for potential endocrine-disrupting chemicals), also in this framework, review of multiple study types conducted for registration purposes, along with an extensive literature review for

identification of other published literature pertinent were considered to perform a Weight of Evidence evaluation of potential interaction with the EAT signalling pathways.
The conclusions of the *in vitro* mammalian assays indicate positive responses in the ER transactivation assay and equivocal results in the AR binding assay. In the ER binding assay no interactive (negative responses) were found. In the steroidogenesis assay, the production of testosterone decreased while the production of estradiol were increased at the high test concentrations. Aromatasa was not inhibited.
From literature review, in the study Medjakovic S., 2014 study, evaluated as Klimisch cat 2, Aryl hydrocarbon Receptor agonist activity and weak Androgen Receptor binding activity were reported. Chlorpyrifos-methyl also showed an ability to inhibit the growth of two human prostate and two human breast cancer cell lines, although the toxicological significance of this result was not clear.

From *in vivo* studies, the uterotrophic assay showed no indication of estrogenicity in immature females treated at doses from 0.5 to 4 mg/kg bw/day and female pubertal assay does not show evidence of endocrine activity (regarding to estrogen pathway and thyroid parameters) at doses from 0.5 to 2 mg/kg bw/d. The Hershberger assay was negative for both androgenic and antiandrogenic activity at doses from 1 to 6 mg/kg bw/d. There were no treatment-related changes in any of the thyroid parameters or androgenic pathway in the male pubertal assays at doses from 0.5 to 2 mg/kg bw/day, which caused significant cholinesterase inhibition.

It should be highlighted that it remains concerns regarding adverse effects that can occurs at dose levels of chlorpyrifos below those that produces cholinesterase inhibition (See Addedum III, 2013), therefore it would be useful that dose levels below 0.5 mg/kg bw/day were also tested in the *in vivo* studies in OECD conceptual framework for testing and assessment for potential endocrine-disrupting chemicals.

Regarding to published studies, one of them (Meeker el al, 2006a) (allocated in Klimisch criteria 2) assessed TCPY urine metabolite and testosterone levels in man and concluded that the presence of TCPY in urine of masculine population tested is associated in a dose dependent manner to decreases in testosterone levels. Similar studies published in 2004 and 2006b by Meeker *et al* (and also allocated in Klimisch criteria 2) concluded that the urinary TCPY concentration in masculine population tested was associated with a dose-dependent decrease in T4 and increase in TSH levels while an inverse association between urinary TCPY concentration and serum estradiol levels was found.

In spite of the deficiencies observed in the studies it should be highlighted that TCPY is the main metabolite of CPF and CPFmethyl, for this reason these conclusions were considered in the WoE evaluation.

On the other hand the rat study in F0 and F1 generations regarding effects of Chlorpyrifos methyl on steroid and thyroid hormones (Jeong et als., 2006) (Klimish criteria 2) showed histopathological findings in the thyroid gland and adrenal glands and decreases in content of estradiol and T4 in serum with increment of cholesterol at each dose level of F1 rats. Results suggest that long term exposure to Chlorpyrifos methyl from prenatal to adulthood induce hypothyroidism and anti-androgenic effect in male rats with morphologically altered adrenal gland and thyroid gland and reduced sperm count and prostate gland weight, while similar effects were not apparent when exposed at adulthood. In the same way the study to assess the antiandrogenic effect and uterine cell proliferation of chlorpyrifos methyl in castrate male and immature female rats respectively (Kang et al , 2014) showed that in males the weights of the androgen-dependent accessory sex organs were unaffected by treatment with chlorpyrifos-methyl, nevertheless increases in the weights of accessory sex organs, and of blood testosterone and thyroxine concentrations induced by Testosterone propionate(TP) were ameliorated by concomitant chlorpyrifos-methyl treatment, as was a TP-related decrease in adrenal weight indicating some degree of androgen-antagonism and hipotiroidism effect of Chlorpyrifos methyl in females, uterine cell proliferation was unaffected by chlorpyrifos-methyl treatment, as were body weight gain and relative ovary, vagina and uterus weights

In conclusion, provisional results of *in vitro* test indicated possible antiandrogenic activity, not confirmed by the provisional results of *in vivo* test, with the observation that it would be useful that dose levels below 0.5 mg/kg bw/day were also included in these tests.
Some potentially relevant studies identified in literature search (Section 9 Literature data of DAS) pertain to endocrine disruptor potential of Chlorpyrifos in mammals, evaluated as Category 2 and not included in the WoE (Juberg, 2013) are considered by RMS and included in the WoE of potential interaction with the estrogen, androgen, or thyroid pathways.

Scientific literature data relating to endocrine effects of Chlorpyrifos/Chlorpyrifos methyl indicate weak androgen receptor binding activity, hypothyroidism and anti-androgenic effect in male rats and dose dependent decreases in testosterone levels, decrease in T4 and increases in TSH levels associates with urinary TCPY concentration in masculine population tested, while not apparent effect were seen in estrogen pathway

Non-EAT pathways, atypical EAT pathways and neuroendocrine pathways
In addition to the receptors involved in (Estrogen, Androgen and Thyroid) EAT signalling, hormone-activated nuclear receptors in vertebrates include the corticosteroid receptors (e.g., mineralocorticoid, glucocorticoid), retinoic acid receptor (RAR), retinoid X receptor (RXR), vitamin D receptor (VDR), and peroxisome proliferator activated receptor (PPAR). Ligands to some of these receptors (e.g., vitamin D binding to the VDR, retinoids binding to the RAR, fatty acids binding to PPAR) may not fit the conventional view of a hormone. Therefore, endocrine disruption is no longer limited to oestrogenic, androgenic and thyroid pathways and a better understanding of the endocrine systems is therefore needed.
Moreover, testing protocols should cover aspects such as sensitive windows of exposure across the lifespan, low dose effects and the non-monotonic dose response curves.

Hormones, among other factors, are important for the correct development of organs and tissues to take place. Disruption at critical points during such development can result in irreversible changes of the organ/tissue.
In mammals, critical periods of development have been identified at conception, during pregnancy, infancy, childhood and puberty. Also in other vertebrates such as fish, disturbances at critical periods of development can result in dysfunction and/or disease across the entire lifespan.

It is widely accepted that, in relation to potential effects from exposure during critical periods of susceptibility, testing *in vivo* is required. This is to encompass sufficiently sensitive endpoints of toxicological relevance during the sensitive life stages that allow judgement of adversity. To avoid the possibility that relevant effects are overlooked, the administration of test compounds needs to address recognised periods of sensitivity and endpoint assessment has to cover all life stages. In the OECD CF for testing and assessment of endocrine disrupting substances, some Level 4 and 5 tests do cover critical periods of development *in utero* and in later life stages. However, several recent review reports concluded that current mammalian tests do not cover certain endpoints that might be induced by exposure during foetal or pubertal development but emerge later in life like certain cancers (breast, prostate, testis, ovarian and endometrial) and effects on reproductive senescence (EFSA, 2010; [redacted] 2011; EEA, 2012; OECD, 2012b).

In relation to mammals, a limitation of the current suite of test methods available for the identification of EDs is the lack of a single study involving exposure through the complete life cycle of a mammal, from conception to old age or a single study involving developmental exposure with follow-up into old age. The first study could be similar to the one that was suggested to perform to be submitted for the current renewal of approval of CPF (See Conclusions Addendum III of Chlorpyrifos). This study, still not realized, involving exposure through the complete life cycle of a mammal, from conception to old age, covering a wide range of doses from 0.1 to 5 mg/kg bw/day, administered by diet (adults) and through maternal milk (pups), measuring RCB Che inhibition in dams and in pups at all dose levels and registering neurodevelopmental and endocrine endpoints might clarify some aspect about chlorpyrifos toxicity.

With the available information it can be concluded that chlorpyrifos seems to be no potential to interact with the estrogen pathway, while hipotiroidism and antiandrogenic effects cannot be discarded.
Effects on Non-EAT pathways, atypical EAT pathways and neuroendocrine pathways were not assessed.

2.6.9. Summary of toxicological data on impurities and metabolites

Toxicological data is available for four Chlorpyrifos-methyl metabolites. A summary of the toxicology studies for the metabolites of chlorpyrifos is presented in Tables 2.6.9 1 to 2.6.9-4.

Metabolite 3,5,6-trichloropyridinol (TCP)
TCP was assessed using Quantitative Structure-Activity Relationship (QSAR). It is expected that TCP to be less toxic than the parent chlorpyrifos-methyl.
Acute oral toxicity (LD50 Up And Down) of TCP was estimated to be 3.129 mg/kg of body weight in female rats ([redacted] 2015). In one-year dietary in Beagle dogs study ([redacted] 1987) NOAEL was established at 12 mg/kg bw based on dose-related and significant increases in alkaline phosphatase activity and in alanine aminotransferase activity observed at 48 mg/kg bw/day. With studies submitted for genotoxicity it can be concluded that metabolite TCP is negative for genotoxicity (complete package).
TCP was tested for its developmental toxicity (table 2.6.9-1). In rats, TCP was not teratogenic, but produced an increased incidence of total malformations recorded at the highest dose tested (150 mg/kg bw/day), which was

maternally toxic (decreased bodyweight, increased relative liver weight and vaginal bleeding). The critical effect for dams was the the reduced bodyweight gain at 100 mg/kg bw/day. Therefore, the maternal NOAEL was 50 mg/kg bw/day, while the developmental NOAEL was 100 mg/kg bw/day. On the contrary, TCP showed to be teratogenic to rabbits. While the adverse effect in the dam was a decrease in the overall bodyweight gain for the dosing period at >250 mg/kg bw/day, malformations in the central nervous tissue (dilation of the cerebral ventricles and hydrocephaly) were observed at >100 mg/kg bw/day. Therefore, the maternal NOAEL was 100 mg/kg bw/day and the developmental NOAEL was 25 mg/kg bw/day.

Reference doses of TCP:

No long-term studies performed on TCP were presented, therefore the ADI is derived of the one-year dietary study in dog, for which a NOAEL of 12 mg/kg/bw was established An additional safety factor of 2 was considered for extrapolation from subchronic to chronic study duration (EFSA Journal 2012;10 (3):2579. [32 pp.]). Therefore, the ADI is calculated as (12 mg/kg bw/day) /200= 0.06 mg/kg bw/day

An ARfD value of 0.25 mg/kg bw/day is proposed by TCP derived of the NOAEL from the rabbit teratogenicity study and applying a safety factor of 100. The NOAEL was based on increased incidences of CNS malformations at 100 mg/kg bw/day.

<u>Metabolite 2,3,5-trichloro-6-methoxypyridine (TMP)</u>

Acute oral toxicity (LD50 Acute toxic class) of TMP in female rats was found to be greater than 2000 mg/kg bw.The three *in vitro* genotoxicity studies with TMP were negative with and without S9.

<u>Metabolite 3,6-dichloro-2-pyridinol (DCP)</u>

Acute oral toxicity (LD50 Acute toxic class) of DCP in female rats ranged between 2000 and 5000 mg/kg bw. Ames test conducted on 3,6-DCP was negative.

<u>Metabolite Desmethyl-chlorpyrifos-methyl (DEM)</u>

A QSAR assessment is provided for desmethyl-chlorpyrifos-methyl. DEM presents less alerts than the parent chlorpyrifos-methyl.

Acute oral toxicity (LD_{50} Acute toxic class) in female Crl:CD(SD) rats was 500 mg/kg bw ([redacted] 2015)

Table 2.6.9-1: Chlorpyrifos- Toxicology studies for the metabolite 3,5,6-trichloro-2-pyridinol (TCP)

Data point	Test	Test system	Concentration and test substance	EU Agreed endpoint[1]	Proposed new endpoint	Reference
Acute Toxicity						
CA 5.8.1/1	Oral/gavage (Up Down method)	Rat/F	175, 550, 1750, 5000 mg/kg bw TCP	New data	LD_{50} = 3129 mg/kg bw	050254, [redacted] 2005
In vitro & *in vivo* genotoxicity tests						
CA 5.8.1/2	*In vitro* bacterial reverse mutation	*S. typhimurium*, TA 98, TA 100, TA 102, TA 1535, TA 1537	3.16, 10, 31.6, 100 or 316 µg/plate in DMSO TCP	Negative	Not relevant	K-038278-010 Zempel, J.A. & Bruce, R.J., 1986, E03
CA 5.8.1/3	*in vitro* Unscheduled DNA Synthesis (UDS) Assay	Rat hepatocyte	1 – 100 µg/ml in DMSO TCP	Negative	Not relevant	K-038278-012 [redacted] 1987
CA 5.8.1/4	*In vitro* mammalian forward mutation	Chinese hamster ovary cells (CHO/HGPRT)	62.5, 125, 250, 500 or 750 µg/mL TCP	Negative	Not relevant	K-038278-013 [redacted] 1986
CA 5.8.1/5	*In vivo* micronucleus	Mouse bone marrow cells	0, 1000 mg/kg bw, p.o. in corn oil (250–3000 mg/kg bw in range-finding test) TCP	Negative	Not relevant	K-038278-008A [redacted] 1989
CA 5.8.1/6	*In vivo* micronucleus	Mouse bone marrow cells	0, 24, 76 or 240 mg/kg bw, p.o. in corn oil TCP	Negative	Not relevant	K-038278-008 [redacted] 1985
Sub-chronic						

Data point	Test	Test system	Concentration and test substance	EU Agreed endpoint[1]	Proposed new endpoint	Reference
CA 5.8.1/7	Oral/diet (90-day)	Rat/F344	0, 10, 30 and 100 mg/kg bw/day TCP	NOAEL = 30 mg/kg bw/day based on ↑ liver and kidney weight in both sexes at 100 mg/kg bw/day	Not relevant	K-065999-009 [redacted] 1985; D06 TCP
Long term toxicity						
CA 5.8.1/8	Oral/diet (1-year)	Dog/beagle	0, 3, 12 and 48 mg/kg bw/day TCP	NOAEL = 12 mg/kg bw/day based on ↓ body weight & haematological effects in ♀, clinical chemistry effects in both sexes at 48 mg/kg bw/day	Not relevant	K-038278-009 [redacted] 1987; I01 TCP
Developmental toxicity						
CA 5.8.1/9	Oral/gavage	Rabbit/NZW	0, 25, 100, 250 mg/kg bw/day TCP	Maternal NOAEL = 100 mg/kg bw/day based on reduced maternal body weight gain at 250 mg/kg bw/day Developmental NOAEL = 25 mg/kg bw/day based on dose-dependent increases in the incidence of foetal and litter CNS malformations at 100 and 250 mg/kg bw/day compared to concurrent control.	Not relevant	K-038278-015, [redacted] 1987
CA 5.8.1/10	Oral/gavage	Rat/F344	0, 50, 100, 150 mg/kg bw/day TCP	Maternal NOAEL = 50 mg/kg bw/day based on reduction in body weight gain at 100 mg/kg bw/day Developmental NOAEL = 150 mg/kg bw/day (highest dose tested)	Not relevant	K-038278-011, [redacted] 1987

[1] EFSA Scientific Report (Triclopyr), 2005: 56, 1-103

Studies highlighted in **bold** are new studies since Annex I inclusion

Table 2.6.9-2: Chlorpyrifos- Toxicology studies for the metabolite 2,3,5-trichloro-6-methoxypyridine (TMP)

Data point	Test	Test system	Concentration and test substance	EU Agreed endpoint	Proposed new endpoint	Reference
Acute Toxicity						
CA 5.8.1/11	Oral/gavage Acute toxic class method	Rat/Wistar	2000 mg/kg bw TMP	New data	LD_{50} > 2000 mg/kg bw	130506 [redacted] 2013
In vitro genotoxicity tests						
CA 5.8.1/12	*In vitro* bacterial reverse mutation	*S. typhimurium*, TA 98, TA 100, TA 102, TA 1535, TA 1537	Trial I : 19.53, 39.06, 78.13, 156.25, 312.5 and 625 µg/plate ± 5% v/v S9 Trial II : 6.4, 16, 40, 100, 250 and 625 µg/plate ± 5% v/v S9 TMP	New data	Negative	101720 Nagane, R.M., 2011
CA 5.8.1/13	*In vitro* mammalian cytogenetics	Human peripheral blood lymphocytes (HLCAT)	15, 30, 60, 120, 160, 200 and 240 µg/mL ± S9 TMP	New data	Negative	101721 [redacted] 2011
CA 5.8.1/14	*In vitro* mammalian forward mutation	Chinese hamster ovary cells (CHO/HGPRT)	Trial I: 5, 10, 20, 40, 60 &80 µg/mL ± S9 Trial II: 3.75, 7.5, 15, 30 & 60 µg/mL ± S9 TMP	New data	Negative	101722 [redacted] 2011

Studies highlighted in **bold** are new studies since Annex I inclusion

Table 2.6.9-3: Chlorpyrifos - Toxicology studies for the metabolite 3,6-dichloro-2-pyridinol (3,6-DCP)

Data point	Test	Test system	Concentration and test substance	EU Agreed endpoint	Proposed new endpoint	Reference
Acute Toxicity						
CA 5.8.1/15	Oral/gavage Acute toxic class method	Rat/Wistar	2000, 5000 mg/kg bw 3,6-DCP	New data	2000 > LD_{50} < 5000 mg/kg bw	150278 [redacted] 2015
***In vitro* genotoxicity tests**						

Data point	Test	Test system	Concentration and test substance	EU Agreed endpoint	Proposed new endpoint	Reference
CA 5.8.1/16	*In vitro* bacterial reverse mutation	*S. typhimurium*, TA 98, TA 100, TA 102, TA 1535, TA 1537	Trial 1: 78.13, 156.25, 312.5, 625, 1250, 2500 µg/plate ± 5% v/v S9 Trial II : 25.6, 64, 160, 400, 1000, 2500 µg/plate ± 5% v/v S9 3,6-DCP	New data	Negative	150279 Tendulkar, K.E., 2015

Studies highlighted in **bold** are new studies since Annex I inclusion

Table 2.6.9-4: Chlorpyrifos - Toxicology studies for the metabolite Des-methyl chlorpyrifos methyl (DEM)

Data point	Test	Test system	Concentration and test substance	EU Agreed endpoint	Proposed new endpoint	Reference
Acute Toxicity						
CA 5.8.1/17	**Oral/gavage: Acute Toxic Class Method**	**Rat/ Crl:CD(SD)**	**300, 2000 mg/kg bw Des-methyl chlorpyrifos methyl**	**New data**	**LD_{50} = 500 mg/kg bw**	**140705** [redacted] **2015**
KCA 5.8.1/01	**QSAR approach**	**Derek Nexus and OECD (Q)SAR toolbox**	**- / TCP and DEM**	**New data**	**Less alerts than the parent chlorpyrifos-methyl.**	**CSA/46/15** **Paulino A, Pereira M. ; 2015**

Studies highlighted in **bold** are new studies since Annex I inclusion

2.6.10. Summary of medical data and information

Medical surveillance program on manufacturing plant personnel and monitoring studies (of personnel involved in the development of the compound) did not reveal any symptom/s or disease/s that might be related to the production of and exposure to chlorpyrifos-methyl or the starting materials. The site ceased manufacturing chlorpyrifos in 2009, but there is still some formulation activity involving this agent.
There are data available from chlorpyrifos methyl studies on humans.

Data from reported human exposure incidents (or alleged exposure) from the general public, industry and medical facilities revealed only few cases in which reported symptoms were mild. Additionally, a review of the available scientific literature, turned up no documented reports in the refereed scientific journals etc of human cases of chlorpyrifos-methyl poisoning in humans (no data collected in humans, no direct observations recorded).

It was underlined that there have been no observations undertaken on the exposure of the general population and no published epidemiological studies, ie, since then, no new epidemiology studies on the product chlorpyrifos-methyl, are known to have been undertaken.
Nevertheless, different epidemiological studies tried mainly by means of the measure of biological makers to determine whether environmental exposures to nonpersistent pesticides such organophosphates have the ability of modifying physiology -in a broad sense- in both children and adults, even at low-levels of exposure. Certain references simply taken from the LRR that were judged as not reliable in all cases seem to show or at least suggest, that there is a body of evidence that underlines the influence of early exposures to organophosphates, chlorpyrifos-methyl in this case.

2.6.11. Toxicological end point for assessment of risk following long-term dietary exposure - ADI

The experts at the Pesticides Peer Review Meeting 106 that discussed the active substance Chlorpyrifos agreed the use of RBC cholinesterase inhibition (>20% decrease), that decreases earlier and to a greater extent that brain ChE, to derive reference values. RMS proposes to apply the same argument for Chlorpyrifos methyl.

The calculation of an ADI should take account of the total toxicology data base for a compound and is usually derived from results in chronic dietary studies, including a multigeneration reproduction test, and use of an appropriate uncertainty factor. No new studies have been submitted, which would alter the existing ADI.
It is proposed that the ADI should be maintained at 0.01 mg/kg bw/day. This value is derived from the NOAEL of 1 mg/kg bw per day, identified on the basis of inhibition of RCB and brain acetylcholinesterase activity and adrenal vacuolation in the 2-year study of toxicity and carcinogenicity in rats and applying a safety factor of 100 (accounting for inter- and intra-species variation). This ADI value was also supported by the NOAEL of 1mg/kg bw/day of the 2-year toxicity study in dog in which of inhibition of RCB and brain acetylcholinesterase activity were reported at 3 mg/kg bw/day. Therefore:

ADI = (1 mg/kg bw/day) /100= 0.01 mg/kg bw/day

2.6.12. Toxicological end point for assessment of risk following acute dietary exposure - ARfD (acute reference dose)

The experts at the Pesticides Peer Review Meeting 106 that discussed the active substance Chlorpyrifos agreed the use of RBC cholinesterase inhibition (>20% decrease), that decreases earlier and to a greater extent that brain ChE, to derive reference values. RMS proposes to apply the same argument for Chlorpyrifos methyl.

For the assessment of the acute oral exposure, data from the new study of acute oral neurobehavioral and cholinesterase inhibition study ([redacted] 2013) is considered to provide appropriate information for the establishment of ARfD based on data obtained with
Chlorpyrifos methyl (and thus removes the need to subrogate the existing Chlorpyrifos information) (See CPF methyl Addendum III Nov 2013).
In this case, the NOAEL for RBC AChE inhibition of 10 mg/Kg bw provides the most sensitive data for deriving an acute reference dose. An overall default uncertainty factor of 100 is proposed for acute oral exposure to Chlorpyrifos-methyl. Therefore, the ARfD is calculated as follows:

ARfD = (10 mg/kg bw/day) /100= 0.1 mg/kg bw/day

2.6.13. Toxicological end point for assessment of occupational, bystander and residents risks – AOEL

An AOEL value of 0.01 mg/kg bw/day had been previously derived at the EU level from a 90-day rat study with a NOAEL of 1 mg/kg bw/day based on statistically significant reductions in erythrocyte and brain cholinesterase activity and adrenal microscopic findings at 10 mg/kg bw/day. A safety factor of 100 was considered for inter- and intra-species variation. Based on the absorption data from the repeat dose ADME study (approximately 80%) a correction factor for oral absorption need not be applied.
AOEL = (1 mg/kg bw/day) /100= 0.01 mg/kg bw/day

2.6.14. Summary of product exposure and risk assessment

GF-1684
The Plant Protection Product GF-1684, an insecticidal formulation, contains a nominal 225 g/L chlorpyrifos-methyl. The intended uses are to target a range of insect pests on a range of cereals, vegetables, fruit, cotton and cereal grains (direct treatment and structural treatment) using field boom sprayers (2D crops), airblast sprayers (3D crops) or handheld applications (cereal grains).
GF-1684 is an emulsifiable concentrate (EC) formulation. Water is the intended diluent/carrier.
A dermal absorption value of 2% for concentrate and 13% for dilutions are considered in estimations of exposure.

Operator:
Based on the worst-case exposures predicted by the German Model (mean) GF-1684 does not present a risk to human health when the appropriate PPE is worn for all supported crops except orchards.
Predicted exposures derived from the UK POEM and German model (75th percentile) are all above the AOEL even when PPE (gloves) and RPE are assumed.
Predicted exposures from EFSA model, show safe use for low crops when PPE (gloves) is assumed, and for high crops when PPE (gloves), RPE and closure cab are assumed.
According to *Thouvenin, (2009)* study, the supported grain treatment and structural treatment to cereal stores use is considered to present no risk to human health when the appropriate PPE (coverall, gloves, hood and visor) and RPE are used.

Bystander and resident:
On the basis of exposure estimates performed according to [redacted] (2008, bystander and resident) and PSD model, the estimated exposure for bystanders to chlorpyrifos-methyl from GF-1684 does not present a risk to human health (all predicted bystander exposures are below the proposed AOEL) when it is considered 10 m distance between bystanders and the application machinery for 2D crops and 20 m distance for 3D crops.
The applicant should make sure the representativeness and it should be mentioned on the label that no bystanders are present in the area to < 20 m.
On the basis of exposure estimates performed according to [redacted] (2008, bystander and resident), the resident assessments shows that predicted systemic exposures are less than the AOEL for chlorpyrifos-methyl.

Worker:
On the basis of exposure estimates performed according to EUROPOEM, the estimated exposure for workers to chlorpyrifos-methyl, for all uses present a risk to human health.
Derived from BfR May 2012 calculator and based on the use of theoretical foliar deposits and assuming immediate re-entry after an application of GF-1684, the predicted exposures do not represent an unacceptable risk to human health when normal workwear is worn (for cotton, oilseed rape, soybean maize/corn and potato re-entry activities) and for certain crops (vegetables, strawberry, table and wine grapes, pome and stone fruit and citrus) appropriate PPE is worn (gloves).
The DFR studies show that the dissipation of chlorpyrifos-methyl is very rapid. Refined assessments based on DFR field data show that predicted re-entry workers will be low or negligible shortly after application and will be negligible at harvest. All re-entry scenarios for all supported uses of GF-1684 are below the AOEL for chlorpyrifos-methyl. Refined assessments assume normal workwear is worn but no additional PPE is required.
Taking into account the toxicological properties of the preparation, the recommendation of wearing gloves and protective clothing in case of re-entry in the field shortly after spraying, should be included in the label.

SAP200CHLORI

The Plant Protection Product SAP200CHLORI containing 200 g/L chlorpyrifos-methyl is intended to be used on grapes and oilseed rape as an insecticide. The formulation is a capsuled suspension (CS) commercialized in 1L, 5L, 10L and 20L containers.
A dermal absorption value of 1% is considered by notifier in estimations of exposure.

The 2014 EFSA Conclusion for chlorpyrifos gives a dermal absorption value of 1%, based on human data. The Conclusion does note, however, that dermal absorption may vary for other formulations of chlorpyrifos. For encapsulated formulations, the concern is that dermal absorption of the active substance will be greater when released from the capsules, and that this may occur following spraying or when the product dries on the leaf surface.
It was requested a new absorption study. According to the applicant, *the results of the pre-test on Chlorpyrifos-methyl 200 CS are available, but they are in no way suitable to support a formal risk assessment. The main study to derive a dermal penetration endpoint is starting, but again it will take some months until the final report is available.*
Exposure data for operator, bystander and worker will be carried out with appropriate absorption data. Risk assessment cannot be finished.

2.7. RESIDUE

2.7.1. Summary of storage stability of residues

(DAS)

Chlorpyrifos-methyl showed acceptable stability of residues during frozen storage for up to 734 days (24 months) in tomatoes, tomato juice, wheat grain and wheat straw. Chlorpyrifos-methyl residues were found to be stable in whole oranges, grapes and grape wine for at least 12 months (in a first study).

In another study, Chlorpyrifos-methyl and 3,5,6-trichloro-2-pyridinol showed acceptable stability of residues during frozen storage for up to 18 months in apple, peach, cabbage, tomato, grape, oilseed rape, potato, orange peel and orange pulp and up to 24 months in wheat grain and wheat straw.

As a conclusion, Chlorpyrifos-methyl is stable under deep-freezer conditions in the following group of commodities and during the following storage periods:

Plant products (Category)	**Commodity**	**T** (°C)	**Stability** (Months)
High water content	Tomato/juice	-18	24
High oil content	Oilseed rape	-18	18
High starch content	Wheat grain	-18	24
High acid content	Oranges/grapes	-18	18
Others	Wheat straw	-18	24
	Grape wine	-18	12

For **TCP,** the storage stability of the residues has been demonstrated up to:

Plant products (Category)	**Commodity**	**T** (°C)	**Stability** (Months)
High water content	Tomato	-18	18
High oil content	Oilseed rape	-18	18
High starch content	Wheat grain	-18	24
High acid content	Oranges/grapes	-18	18
Others	Wheat straw	-18	24

Des-methyl chlorpyrifos-methyl showed acceptable stability of residues during frozen storage for up to 22 months in wheat grain, barley grain and processed fractions.
The freezer storage stability of des-methyl Chlorpyrifos Methyl was also demonstrated in the following commodities and processed fractions for up to 20 months: apple juice, dried apple, grape juice, raisins, wine, orange fruits, orange pulp, marmalade, tomato, tomato puree, tomato ketchup, raspberry, raspberry jam and canned raspberry.

Furthermore, the levels of des-methyl Chlorpyrifos Methyl declined in the following commodities : apple fruits (stable up to 3 months), grapes (6 months), orange peel (9 months) and orange oil (< 1 month).

The freezer storage stability of chlorpyrifos-methyl was demonstrated in animal matrices (beef muscle, liver, kidney, fat and dairy milk) for up to 735 days (24 months) in freezer storage conditions.
For chicken eggs, the stability was demonstrated up to 27 days.

(SAP)

Chlorpyrifos-methyl and **TCP** showed acceptable stability of residues during frozen storage for up to 180 days (6 months) in both, grapes (high acid) and oilseed rape (high oil content commodity).

One additional study investigating the storage stablity of **Des-methyl chlorpyrifos-methyl** in wine is currently being performed, and an interim report was provided, showing an acceptable storage stability at -18ºC up to 179 days (6 months).

A study investigating the freezer storage stability of chlorpyrifos-methyl and TCP in animal matrices has been provided. CP-Me showed acceptable stability in freezer storage conditions in meat, liver, milk and eggs for up to 372 days and TCP for up to 373 days in the same commodities.

2.7.2. Summary of metabolism, distribution and expression of residues in plants, poultry, lactating ruminants, pigs and fish

(DAS)

Plants

Metabolism studies have been conducted in a range of crops using chlorpyrifos–methyl and the structurally related active substance chlorpyrifos.

Part of these studies were already presented in the DAR and Addenda of chlorpyrifos-methyl. Some of them are considered as supportive data, only the studies performed in tomatoes, oranges (fruit crops) and cabbage (leafy crops) after foliar application are considered fully valid.

Moreover, two additional studies conducted on peas and radishes were presented in the context of the MRL modification evaluated by EFSA (EFSA Journal 2011;9(6):2219) and were considered relevant. The results of these two studies were consistent with the results from previous chlorpyrifos and chlorpyrifos–methyl plant metabolism studies. They demonstrated that the parent compound is a good marker for monitoring and confirmed that the polar metabolites represent a major component of the residue at harvest.

Applications were done as foliar application reflecting the representative application method with following application rates:

Crop Group	Crop	Labeled Test Material [a]	Application and Sampling Details				
			Type (F) [b]	Rate (GAP) [c]	No. of Apps.	Sampling (DAT)	Remarks
Fruit crops	Oranges	^{14}C CHP	Foliar (F)	3.97 kg/ha (1.3 X)	1	Fruit: 0, 6 and 21 DAT Leaves: 0, 6 and 21 DAT	Whole fruit was rinsed with organic solvent and then separated to give samples of peel and pulp.
	Tomatoes	^{14}C CHP-Me	Foliar (F)	0.99 kg/ha (0.33-1.97 X)	1	Fruit: 0, 5, 13, 26 and 42 DAT Vines: 5 and 13 DAT	Fruit samples were extracted and analyzed. Vine samples were available as a source of metabolites if needed.
Leafy crops	Cabbage	^{14}C CHP	Foliar (F)	1.43 kg/ha (0.75-2 X)	1	All Samples: 0, 7, 14, 21 and 42 DAT	At each time point, whole plants were collected and separated to give samples of heads, wrapper leaves and flat leaves.
Cereals	Wheat and maize grains	^{14}C CHP-Me	Direct	32.4 mg a.s/kg grain	1	30, 90, 180 DAT	Samples stored at 25ºC
Root Crops	Radishes	^{14}C CHP	Foliar (F)	6.64 kg/ha (3.3 X)	1	0, 7, 14, 21 and 35 DAT	Roots and tops were analyzed separately at each time point.
Pulses and Oilseeds	Peas	^{14}C CHP	Foliar (F)	1.9 kg/ha (3.2 X)	1	All Samples: 0, 7, 14, 21 and 28 DAT	At all time points, peas with pods were collected and then the remainder of the whole plant.

The metabolic pattern after foliar application in the four different crop groups (fruit, leafy, root crops and pulses) was similar and included the hydroxilation of the phosphate ester to form TCP and polar residues, mainly TCP conjugates. Based on the results from these studies, the metabolism of chlorpyrifos and chlorpyrifos-methyl appears to be the same in all crops. From these studies, the residue of greatest toxicological significance is the unchanged parent test material (chlorpyrifos or chlorpyrifos-methyl), while the only other residue of significance is TCP (free and conjugated).

The main metabolites found in the stored grain metabolism study (post-harvest application) are TCP and the DEM, although parent chlorpyrifos methyl predominated in stored grain, especially at earlier time intervals where less degradation had occurred.

The representative uses are covered by available studies. Based on the available data the residue definition for risk assessment and monitoring purposes in plants is proposed below.

Animal products

The overall pattern of absorption and elimination was similar among the species investigated. Chlorpyrifos-methyl was rapidly absorbed and excreted mainly via the urine. The highest levels were present in fatty tissues and consisted almost exclusively of parent compound. In the remaining tissues, the residues were mainly identified as parent compound and 3,5,6-trichloro-2-pyridinol (TCP), in either free or conjugated form and a compound formed by demethylation, desmethyl chlorpyrifos-methyl (DEM). Residues in whole milk, comprising mainly of parent compound and TCP, were low and reached the plateau within two days; levels in milk fat were correspondingly higher and were constituted mainly of parent compound. In hens, tissue residues were generally low and comprised TCP and DEM, except fat in which the parent compound was the main residue.

Based on the results from the metabolism studies in poultry and lactating ruminants, there appeared to be only one metabolic process involved in the metabolism of chlorpyrifos-methyl. This process resulted in the hydrolysis of either one of the methoxy side chains to give desmethyl chlorpyrifos-methyl or of the thiophosphate ester to give TCP which in turn can then be conjugated with glucuronic acid or sulphate prior to elimination via the urine.

Given these results, a similar residue profile will be seen in the meat, milk and eggs from livestock following oral exposure to residues of chlorpyrifos-methyl.

2.7.3. Definition of the residue

The proposed residue definition in **crops** is the parent compound, Chlorpyrifos-methyl, for monitoring purposes, and Chlorpyrifos-methyl plus TCP and its conjugates, expressed as chlorpyrifos methyl, for risk assessment purposes.

These residue definitions are in line with the conclusions in the EFSA Reasoned Opinion on Modification of the existing MRLs for chlorpyrifos-methyl in various crops (EFSA Journal 2011;9(6):2219).

	Monitoring	**Risk assessment**
Plant residue definition	Chlorpyrifos-methyl	**Crops:** Chlorpyrifos-methyl + 3,5,6-trichloropyridinol (TCP) and its conjugates, expressed as chlorpyrifos-methyl **Post-harvest use in stored grain:** Chlorpyrifos-methyl + des-methyl chlorpyrifos-methyl, expressed as chlorpyrifos-methyl
Animal residue definition	Chlorpyrifos-methyl	Chlorpyrifos-methyl + 3,5,6-trichloropyridinol (TCP), expressed as chlorpyrifos-methyl

2.7.4. Summary of residue trials in plants and identification of critical GAP

2.7.4.1: Representative uses

The use pattern for evaluation for renewal of approval of chlorpyrifos-methyl is summarised below (Table **2.7.4.1-A**). The representative uses included in this submission are for citrus, pome fruit, peach/nectarine, cherry, plum grape, strawberry, potato, tomato, aubergine, pepper, oilseed rape, soybean, cotton, stored cereal grain and corn/maize.

RMS DISCLAIMER

At the end of the evaluation period, Dow AgroScience has proposed to split out the GAP table. RMS has kept the range of the initial doses.

If EFSA considers the need of to conduct a risk assessment of the new GAP table, then the applicant must to submit the risk assessment for each of the proposed alternative use which are specified below:

Central zone
Wine Grape: reduction the number of applications to one

Pome fruits: reduction of the dose to 0.45 kg as/ha Solanaceae: reduction of the dose to 0.338 kg as/ha Stone fruit (cherry): reduction of the dose to 0.75 kg as/ha **Southern Zone** Table grape: reduction of the dose to 0.338 kg as /ha Wine Grape: reduction the number of applications to one Solanaceae: reduction of the dose to 0.338 kg as/ha Strawberry reduction of the dose to 0.338 kg as/ha

Table 2.7.4.1-A. Summary of the critical GAP

(DAS)

Crop (Zone)	**Maximum Rate**			**Number of applications (minimum interval in days)**	**PHI (days)**	**Growth stage at latest application (BBCH)**
	g as/ha	**g as/hL**	**Water (L/ha)**			
Representative uses						
Citrus (S)	1283	67.5	1900	1	21	BBCH 89
Pome fruit (S/C/N)	900	90	1000	1	21	BBCH 87
Stone fruit, apricot, peach, nectarine (S)	1020	68	1500	1	21	BBCH 87
Stone fruit, cherry, plum (C/N)	750-1000	100	750-1000	1	21	BBCH 87
Grape, Table (S)	608	67.5	900	1	14	BBCH 89
Grape, Wine (S/C/N)	338	67.5	500	2 (14)	14	BBCH 89
Strawberry (S/C/N)	540	-	-	1	5	BBCH 95
Potato (S/C/N)	540	-	750	1	21	BBCH 59
Solanaceous Vegetables, eggplant, pepper, tomato (S/C/N)	675	-	1000	1	5	BBCH 89
Oilseed rape (S/C/N)	450	-	600	1	N/A	BBCH 59
Soybean (S)	450	-	600	1	N/A	BBCH 59
Cotton (S)	680	-	800	1	14	BBCH 89
Stored cereal grain	5 mg/kg grain	-	1.5 L/ tonne grain	1	N/A	
Stored cereal grain (structural treatment)	900 mg as/m^2	-	-	1	N/A	Pre-storage use
Corn/Maize (S)	900	-	400	1	N/A	BBCH 59

(SAP)

Crop (Zone)	Maximum Rate			Number of applications (minimum interval in days)	PHI (days)	Growth stage at latest application (BBCH)
	g as/ha	g as/hL	Water (L/ha)			
Representative uses						
Grape (S)	340	-	600	1	14	BBCH 89
Oilseed rape (S)	340	-	500	1	N/A	BBCH 59

Citrus (S)

(DAS)

30 residue trials conducted on oranges (17) and mandarins (13) in Southern European Zone during 2004-2006 were already included in the Evaluation Report of July 2010 for the chlorpyrifos-methyl evaluated by Rapporteur Member State (RMS), Spain, and concluded by EFSA in his Reasoned Opinion (EFSA 2011, 9(6);2219). In the context of the present submission, the proposed GAPs are different (less critical) than those of the Evaluation report of 2010 concerning the application rate.

Among these, only 8 trials (4 on oranges and 4 on mandarins) fully fitted the intended GAPs. The remaining trials were conducted at more critical application rate. In addition, four trials conducted on oranges during 2013 and four trials during 2014 are presented, also overdosed.

Oranges and mandarins are major crops in S-EU. **8 trials on oranges and 8 on mandarins are necessary to extrapolate to the whole group of citrus fruits** (SANCO 7525/VI/95, rev. 10.1). There is no enough data to extrapolate to the whole group and to derive a common MRL.

The data set on mandarins can be completed using the overdosed trials, as a worst case, to support the use, since the current MRL (1 mg/kg) is covered. For oranges, the complete data set leads to a MRL exceedance.

The current EU MRLs for chlorpyrifos-methyl in grapefruit /lime /citron, lemons, oranges and mandarins are 0.05, 0.3, 0.5 and 1.0 mg/kg respectively.

In the period of comments the Applicant proposed to apply the proportionality approach to calculate the expected residue levels at the proposed GAPs, leading to the following values for oranges and mandarins (see table 2.7.4.1-2). This approach has been applied to the entire data set for oranges and mandarins (including the trials conducted at dose rates within the ±25% tolerance rule). The scaled residue values can be used to derive a common MRL for the whole group of citrus. The conversion factor has been calculated to perform the risk assessment (see table 2.7.4.1-3).

Table 2.7.4.1-1: Residue data for chlorpyrifos-methyl in citrus evaluated in Evaluation Report of July 2010 and new residue data from trials conducted in 2013 and 2014 (non-scaled residues)

Commodity	Region (a)	Outdoor/ Indoor	Individual trial results (mg/kg) *	Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Comments
Oranges	SEU	Outdoor	0.37, 0.49, 0.47, 0.47, 0.37, 0.45, 0.305, 0.19, 0.20, 0.18, 0.13, 0.12, 0.21, 0.06, 0.16, 0.022, 0.21, 0.06, 0.21, 0.11, 0.58, 0.24, 0.56	0.21	0.58	-	-
Mandarins	SEU	Outdoor	0.38, 0.31, 0.32, 0.46, 0.07, 0.21, 0.20, 0.11, 0.17, 0.19, 0.33, 0.31	0.26	0.46	-	-

Table 2.7.4.1-2: Residue data for chlorpyrifos-methyl in citrus evaluated in Evaluation Report of July 2010 and new residue data from trials conducted in 2013 and 2014 (scaled residues)

Commodity	Region (a)	Outdoor/ Indoor	Individual trial results (mg/kg) *	Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Comments
Oranges	SEU	Outdoor	0.22, 0.28, 0.27, 0.267, 0.214, 0.264, 0.178, 0.106, 0.094, 0.086, 0.064, 0.060, 0.096, 0.097, 0.056, 0.142, 0.020, 0.194, 0.03, 0.086, 0.05, 0.29, 0.11, 0.29	0.11	0.3	0.6	
Mandarins	SEU	Outdoor	0.18, 0.15, 0.22, 0.06, 0.18, 0.18, 0.10, 0.07, 0.07, 0.14, 0.13	0.14	0.22	0.4	
Oranges + mandarins	SEU	Outdoor	0.22, 0.28, 0.27, 0.267, 0.214, 0.264, 0.178, 0.106, 0.094, 0.086, 0.064, 0.060, 0.096, 0.097, 0.056, 0.142, 0.020, 0.194, 0.03, 0.086, 0.05, 0.29, 0.11, 0.29, 0.18, 0.15, 0.22, 0.06, 0.18, 0.18, 0.10, 0.07, 0.07, 0.14, 0.13	**0.13**	**0.3**	**0.5**	Data set combined to derive a common MRL for citrus fruits**

(a): SEU = Southern Europe
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
*Scaled residues
**According to the Mann-Whitney-U test results, populations in oranges and mandarins are similar; therefore, both data set are combined to propose a common MRL for citrus fruits

Table 2.7.4.1-3: Residue trials for Citrus (chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl) evaluated in Evaluation report of July 2010 and new residue data from trials conducted in 2013 and 2014 –used for risk assessment (non-scaled residues)

Commodity	Region	Outdoor/ Indoor	Individual trial results (mg/kg)	Median residue (mg/kg)	Highest residue (mg/kg)	Comments
Oranges	SEU	Outdoor	0.69, 0.96, 0.7, 0.53, 0.64, 0.85, 0.91, 0.43, 0.34, 0.29, 0.24, 0.33, 0.42, 0.23, 0.28, 0.24, 0.16, 0.33, 0.44, 0.35, 0.59, 0.58, 0.38, 0.62	0.43	0.96	
Mandarins	SEU	Outdoor	0.80, 0.55, 0.62, 0.88, 0.26, 0.45, 0.35, 0.28, 0.62, 0.34, 1.10, 0.62	0.58	1.10	
Oranges + mandarins	SEU	Outdoor	0.69, 0.96, 0.7, 0.53, 0.64, 0.85, 0.91, 0.43, 0.34, 0.29, 0.24, 0.33, 0.42, 0.23, 0.28, 0.24, 0.16, 0.33, 0.44, 0.35, 0.59, 0.58, 0.38, 0.62 0.80, 0.55, 0.62, 0.88, 0.26, 0.45, 0.35, 0.28, 0.62, 0.34, 1.10, 0.62	0.445	0.58	Median CF calculated = **1.89***

SEU = Southern Europe

<0 = Immediately before final application, CHP-M = Chlorpyrifos-methyl
CHP-M equiv. = Residues of total TCP x 1.6257 = Chlorpyrifos-methyl + free/conjugated TCP expressed as chlorpyrifos-methyl
*for risk assessment purposes the scaled residue values (according to the monitoring residue definition) x CF are used.

Pome fruit (S/C/N)

(DAS)

NEU: In total 7 residue trials on apple (6 new trials conducted in 2013-2014, 1 already evaluated in EFSA Journal 9(6);2219, (2011)) and 3 on pears comply with the proposed GAPs.

In the context of the present submission, the proposed GAPs are similar than those evaluated by EFSA.

Among these trials, some were slightly underdosed concerning the application rate in g/ha, but complied with cGAP in g/hl, one of these trials was considered to complete the data package for apple (with the highest residue).

Apple and pear are major crops in Southern and Northern Europe. A minimum of eight trials (minimum of 4 apple trials) are required to extrapolate for the whole pome fruit group (SANCO 7525/VI/95, rev. 10.1).

There are sufficient data to extrapolate to the whole group of pome fruits.

SEU: In total 17 trials on apples and 8 trials on pears can be used to support the S-EU use in apple and pears and there is enough data to extrapolate to the whole group of pome fruits (SANCO 7525/VI/95, rev. 10.1).

The residue data from these trials have been used to estimate maximum residue levels (MRL) of chlorpyrifos-methyl in Europe. The data sets for apple and pears have not similar distribution according to the Mann-Whitney tests, and they were not pooled to derive a MRL.

As a result a new MRL of 0.30 and 0.05 mg/kg has been estimated and proposed for chlorpyrifos-methyl in apple and pear respectively (for pears values from S and N-EU are pooled to derive a MRL). The current EU MRL for chlorpyrifos-methyl in apple and pear is 0.5 mg/kg.

Table* 2.7.4.1-3*: Residue trials for apple and pear (chlorpyrifos-methyl) evaluated in Evaluation report of July 2010 and new residue data from trials conducted in 2013 and 2014

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**	**MRL proposal (mg/kg)**
Apples + **new data from 2013 and 2014 trials**	NEU	Outdoor	0.04, ND, **0.05, <0.01, 0.05, 0.02, 0.03, 0.05**	0.03	0.05	0.15
Pear	NEU	Outdoor	ND, 0.01, 0.02, 0.02	**0.019**	0.02	----
Apples + **new data from 2013 and 2014 trials**	SEU	Outdoor	0.13, 0.10, 0.02, 0.08, 0.15, 0.07, 0.10, 0.07, 0.02, 0.03, 0.03, 0.06 **0.029, 0.082, 0.03, 0.043, 0.032**	**0.06**	**0.15**	**0.30**
Pear	SEU	Outdoor	0.01, 0.01, 0.03, 0.01, 0.01, 0.01, 0.01, 0.01	0.01	**0.03**	0.04
Pear	N+SEU	Outdoor	ND, 0.01, 0.02, 0.02, 0.01, 0.01, 0.03, 0.01, 0.01, 0.01, 0.01, 0.01	0.01	0.03	**0.05**

(a): SEU = Southern Europe, NEU = Northern Europe
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the MRL calculation; <0.01 mg/kg = less than limit of quantification (<LOQ)

Table* 2.7.4.1-4*: Residue trials for apple and pear (chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl) evaluated in Evaluation report of July 2010 and new residue data from trials conducted in 2013 and 2014–used for risk assessment

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**
Apples and **new data from 2013 and 2014 trials**	NEU	Outdoor	0.09, ND **0.06, 0.020, 0.11, 0.02, 0.06, 0.10**	0.06	0.11
Pear	NEU	Outdoor	0.06, 0.13, 0.08, 0.06	0.07	0.13
Apples and **new data from 2013 and 2014 trials**	SEU	Outdoor	0.16, 0.15, 0.03, 0.18, 0.20, 0.12, 0.15, 0.14, 0.05, 0.08, 0.11, 0.08, **0.06, 0.03, 0.06, 0.07, 0.106**	**0.11**	**0.20**
Pear	SEU	Outdoor	0.08, 0.10, 0.05, 0.08, 0.15, 0.11, 0.09, 0.09	**0.09**	**0.15**

Stone fruit: apricot, peach, nectarine (S)

(DAS)

In total 16 trials on peach and 11 on apricots can support the proposed GAPs in S-EU. Apricot and peach/nectarine are major crops in Southern Europe and a minimum of eight trials (minimum of 4 peach trials) are generally required to extrapolate for apricot, peach and nectarine. Peach and nectarine are minor crops in the Northern Europe and a minimum of 4 trials are generally required (only the S-EU use is proposed).

Available data are enough to support the use on peach, apricot and nectarine. The residue data from these trials can been used to estimate maximum residue levels (MRL) of chlorpyrifos-methyl in Europe. As a result a new MRL of 0.04 mg/kg has been estimated and proposed for chlorpyrifos-methyl in apricots and peaches/nectarines. The current EU MRL for chlorpyrifos-methyl are 0.05* and 0.5 mg/kg respectively, for apricots and peaches/nectarines.

Table* 2.7.4.1-5*: Residue trials for peach and apricot (chlorpyrifos-methyl) evaluated in Evaluation report of July 2010 and new residue data from trials on GF-1684 conducted in 2014

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**	**MRL proposal (mg/kg)**
Apricot	SEU	Outdoor	6 x ND, 4 x <0.01, 0.028	**0.01**	**0.028**	**0.04**
Peach + **New data on from 2014 trials**	SEU	Outdoor	8x<0.01, 0.01, 0.014, 0.019, 0.02, 0.03, **<0.01, 0.013, 0.028**	**0.01**	**0.028**	**0.04**
Peach **New data from 2014 trials**	NEU	Outdoor	**ND, <0.01, <0.01, <0.01**	0.01	0.01	0.03

(a): SEU = Southern Europe , NEU = Northern Europe
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the MRL calculation.
<0.01 mg/kg = less than limit of quantification (<LOQ)

Table** 2.7.4.1-6**: Residue trials for peach and apricot (chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl) evaluated in Evaluation report of July 2010 and new residue data from trials on GF-1684 conducted in 2013 and 2014 –used for risk assessment

Commodity	**Region**	**Outdoor/ Indoor**	**Individual trial results (mg/kg)**	**Median residue (mg/kg)**	**Highest residue (mg/kg)**
Apricot	SEU	Outdoor	0.05, 0.06, 0.07, 0.08, 2 x 0.13, 0.15, 0.18, 0.19, 0.28, 0.60	**0.13**	**0.60**
Peach + N**ew data from 2014 trials**	SEU	Outdoor	0.02, 2 x 0.03, **0.04, 0.06,** 0.06, 0.07, 0.08, 0.11, 0.13, 0.14, 2 x 0.15, 0.16, **0.17,** 0.18	**0.095**	**0.18**
Peach New data from 2014 trials	NEU	Outdoor	**2 x 0.02, 0.03, 0.06**	0.024	0.06

Stone fruit: cherry, plum (C/N)

(DAS)

Cherry: 4 field trials (4 South) on sweet cherries conducted in 2014 are available.

The representative uses only include C/N-EU uses for cherry. The trials presented in the Evaluation Report of July 2010 for the chlorpyrifos-methyl in cherries evaluated by Rapporteur Member State (RMS), Spain, and concluded by EFSA in his Reasoned Opinion (EFSA 2011, 9(6);2219) comply witht the GAPs (±25%) proposed by the Applicant during the period of comments (0.75 kg/ha, 100 kg/hl) and are considered suitable for this purpose (10 trials).

Plum: in total 8 trials are available to support the proposed GAPs. These can be used to support the C/N-EU use on plum.

Cherry is a major crop in N-EU and minor in S-EU and plum is major in N- and S-EU. 8 trials are necessary to support the N-EU uses.

The residue data from these trials have been used to estimate maximum residue levels (MRL) of chlorpyrifos-methyl in Europe. As a result a new MRL of 0.01 mg/kg and 0.20 mg/kg has been estimated and proposed for chlorpyrifos-methyl in cherry and plums, respectively. The current EU MRL for chlorpyrifos-methyl in cherries and plums is 0.05* mg/kg.

Table** 2.7.4.1-7**: Residue trials for cherry and plum (chlorpyrifos-methyl) evaluated in Evaluation Report of July 2010 and new residue data from trials conducted in 2014

Commodity	**Region** (a)	**Outdoor/ Indoor**	**Individual trial results (mg/kg)**	**Median residue (mg/kg)** (b)	**Highest residue (mg/kg)** (c)	**MRL proposal (mg/kg)**	**Comments**
Cherry	NEU	Outdoor	9 x ND, < 0.01	0.003	<0.01	**0.01**	
Cherry*	SEU	Outdoor	ND, ND, ND, ND	0.003	0.003	0.01	
Plum*	NEU	Outdoor	0.13, 0.05, <0.01, ND, 0.04, ND, 0.03, 0.04	**0.032**	**0.133**	**0.20**	
Plum*	SEU	Outdoor	ND, ND, ND, ND, ND, ND, ND, <0.01	0.003	0.010	0.015	

(a): SEU = Southern Europe , NEU = Northern Europe
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
*New trials conducted in 2014
ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the MRL calculation.
<0.01 mg/kg = less than limit of quantification (<LOQ)

Table** 2.7.4.1-8 **: Residue trials for cherry and plum (chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl) evaluated in Evaluation Report of July 2010 and new residue data from trials conducted in 2014 –used for risk assessment

Commodity	**Region**	**Outdoor/ Indoor**	**Individual trial results (mg/kg)**	**Median residue (mg/kg)**	**Highest residue (mg/kg)**	**Comments**
Cherry	NEU	Outdoor	0.09, 0.13, 0.04, 0.02, 0.29, 0.07, 0.02, 0.08, 0.10, 0.10	0.09	0.29	
Cherry*	SEU	Outdoor	0.23, 0.31, 0.47, 0.17	**0.27**	**0.47**	
Plum*	NEU	Outdoor	0.23, 0.06, 0.04, <0.01, 0.10, 0.02, 0.08, 0.11	**0.07**	**0.23**	
Plum*	SEU	Outdoor	0.03, 0.06, 0.03, 0.02, <0.01, 0.02, 0.02, 0.05	0.03	0.06	

*New trials conducted in 2014

Grapes

(DAS)

Different cGAPs for wine and table grapes are intended in Southern Europe. In Northern Europe, only wine grape is an intended use. Both types of crop (wine and table grapes) are major crops in Southern Europe, but only wine grape is a major crop in Northern Europe. Therefore, a minimum of eight trials are required for both crops in Southern Europe, and eight trials are required for wine grape in Northern Europe too.

For table grapes 8 trials are available to support the use in S-EU.

For wine grapes, 12 trials are available to support the N-EU use (among these, 6 new trials performed in 2013-2014). For wine grapes, 7 trials fully complied the intended S-EU GAPs. However, 1 trial slightly overdosed can be used to complete the data set necessary to support the use, since the residue figures were below the current MRL.

Results from wine grapes should not be extrapolated to table grapes since the cGAPs are not comparable.
The trials in the North and in the South showed values clearly below the current grapes EU MRL of 0.2 mg/kg

The residue data from these trials have been used to estimate maximum residue levels (MRL) of chlorpyrifos-methyl in Europe. As a result of estimation no changes to the current MRL of 0.2 mg/kg in wine grapes proposed for chlorpyrifos-methyl. For table grapes a MRL of 0,15 is proposed.

Table** 2.7.4.1-9**: Residue trials for grapes (chlorpyrifos-methyl) evaluated in Evaluation report of July 2010 and new residue data from trials conducted in 2013 and 2014

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**	**MRL proposal (mg/kg)**
Table grapes	SEU	Outdoor	Table grapes: <0.01, ND, ND, ND, 0.07, ND, <0.01, 0.011	0.01	0.07	**0.15**
Wine grapes and **new data on grapes from 2013 and 2014 trials**	NEU	Outdoor	Wine grapes: <0.01, <0.01, 0.02, 0.01, 0.03, 0.03 **<0.01, <0.01** **0.014, 0.135, 0.051, 0.023**	**0.017**	**0.135**	**0.20**
	SEU	Outdoor	Wine grapes: <0.01, 0.03, ND **0.04, 0.021, <0.01, 0.026, 0.036**	0.02	0.04	0.08

SEU = Southern Europe , NEU = Northern Europe

ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the MRL calculation.
<0.01 mg/kg = less than limit of quantification (<LOQ), value of 0.01 mg/kg was used in the MRL calculation.

Table B.7.3.5-10: Residue trials for Grapes (chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl) evaluated in Evaluation report of July 2010 and new residue data from trials conducted in 2013 and 2014 –used for risk assessment

Commodity	**Region**	**Outdoor/ Indoor**	**Individual trial results (mg/kg)**	**Median residue (mg/kg)**	**Highest residue (mg/kg)**
Table grapes	SEU	Outdoor	Table grapes: 0.098, 0.033, 0.150, 0.016, 0.276, 0.367, 0.091, 0.130	0.114	**0.37**
Wine grapes and **new data on grapes from 2013 and 2014 trials**	NEU	Outdoor	Wine grapes: 0.091, 0.044, 0.130, 0.228, 0.195, 0.130 **0.054, 0.086, 0.064, 0.244, 0.258, 0.093**	0.11	0.26
	SEU	Outdoor	Wine grapes: 0.081, 0.260, 0.049 **0.223, 0.083, 0.072, 0.087, 0.105**	0.08	0.26

SEU = Southern Europe , NEU = Northern Europe

(SAP)

16 independent field trials (8 in N-EU, 8 in S-EU) on grapes conducted in 2014, complied with the proposed GAPs and can support the proposed use.

NEU and SEU datasets are not significantly different (U-test; 5 %). The MRL is therefore derived from the merged data.
In order to perform the further risk assessments, STMR and HR have been calculated with the total chlorpyrifos-methyl data (Table 2.7.4.1-12). For total chlorpyrifos-methyl, NEU and SEU datasets are not significantly different according the Mann-Witney test (U-test; 5 %). Therefore, the NEU and SEU are also merged for total chlorpyrifos methyl.

Table 2.7.4.1-11*: Overview of the available residue data of chlorpyrifos-methyl in grapes*

Commodity	**Residue region**	**Residue data***	**Median residue (mg/kg)**	**Highest residue (mg/kg)**	**MRL proposal (mg/kg)**
Grapes	N-EU	3 x < LOQ, 0.012, 0.016, 0.019, 0.022, 0.028	0.01	0.028	0.04
	S-EU	7 x < LOQ, 0.021			

*Residues expressed as requested for monitoring –chlorpyrifos –methyl

Table 2.7.4.1-12*: Overview of the available residue data of total chlorpyrifos-methyl in grapes*

Commodity	**Residue region**	**Residue data***	**Median residue (mg/kg)**	**Highest residue (mg/kg)**
Grapes	N-EU	0.11, 0.073, 0.055, 0.088, 0.086, 0.076, 0.01, 0.016	0.05	0.11
	S-EU	0.032, 0.01, 0.024, 0.01, 0.05, 0.068, 0.01, 0.072		

*Residues expressed as requested for risk assessment – sum of chlorpyrifos –methyl, TCP and its conjugates expressed as chlorpyrifos-methyl.

Strawberries (S/C/N)

(DAS)

16 trials performed in 2007 (8 in N-EU and 8 in S-EU) complied with the cGAPs (±25%) and are acceptable to support the proposed GAPs. These were presented in the Evaluation Report of July 2010 for the chlorpyrifos-methyl in strawberries and evaluated by Rapporteur Member State (RMS), Spain, and concluded by EFSA in his Reasoned Opinion (EFSA 2011, 9(6);2219). Moreover, 4 N-EU and 3 S-EU trials conducted in 2006 at more critical conditions (2 applications instead of 1) are available and can be considered as supportive data. Strawberry is a major crop in Southern and Northern Europe. A minimum of eight trials in each area are required to support the use.

The residue data from these trials have been used to estimate maximum residue levels (MRL) of chlorpyrifos-methyl in Europe. As a result a new MRL of 0.10 mg/kg has been estimated and proposed for chlorpyrifos-methyl in outdoor strawberries. The current EU MRL for chlorpyrifos-methyl in strawberries is 0.5 mg/kg.

Table* 2.7.4.1-12*: Residue trials for strawberry (chlorpyrifos-methyl) evaluated in Evaluation report of July 2010

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**	**MRL proposal (mg/kg)**
Strawberry	NEU	Outdoor	0.05, 0.05, 0.02, 0.02, 0.03, <0.01, 0.01, ND	**0.02**	**0.05**	**0.10**
Strawberry	SEU	Outdoor	0.02, <0.01, ND, 0.01, <0.01, 0.02, <0.01, 0.02	0.01	0.02	0.04

(a): SEU = Southern Europe , NEU = Northern Europe
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the MRL calculation.
<0.01 mg/kg = less than limit of quantification (<LOQ)

Table* 2.7.4.1-13*: Residue trials for strawberry (chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl) evaluated in Evaluation report of July 2010 – used for risk assessment

Commodity	**Region**	**Outdoor/ Indoor**	**Individual trial results (mg/kg)**	**Median residue (mg/kg)**	**Highest residue (mg/kg)**
Strawberry	NEU	Outdoor	0.16, 0.25, 0.13, 0.08, 0.22, 0.08, 0.12, 0.08	0.125	0.25
Strawberry	SEU	Outdoor	0.17, 0.10, 0.07, 0.27, 0.16, 0.18, 0.09, 0.22	0.165	0.27

Potatoes (S/C/N)

(DAS)

Eight trials conducted on potatoes in Southern Europe and eight in Northern Europe during 2006-2007 are available to support the proposed GAPs. Potato is a major crop in Southern and Northern Europe. A minimum of eight trials in each area are required to support the use.

Some of these trials were carried out using two applications (a worst case). Residue levels of chlorpyrifos-methyl were not detected.

The trials included were already presented in the Evaluation Report of July 2010 for the chlorpyrifos-methyl in strawberries and evaluated by Rapporteur Member State (RMS), Spain, and concluded by EFSA in his Reasoned Opinion (EFSA 2011, 9(6);2219).

The residue data from these trials have been used to estimate maximum residue levels (MRL) of chlorpyrifos-methyl in Europe. Since a new limit of quantification has been established for potatoes (0.01 mg/kg), and according to the submitted residue trials, a new EU MRL of 0.01 mg/kg could be proposed for potatoes. The current EU MRL for chlorpyrifos-methyl in potatoes is 0.05* mg/kg.

Table* 2.7.4.1-14*: Residue trials for potatoes (chlorpyrifos-methyl) evaluated in Evaluation report of July 2010

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**	**MRL proposal (mg/kg)**
Potatoes	NEU	Outdoor	ND, ND, ND, ND, ND, ND, ND, ND	0.003	0.003	0.01
Potatoes	SEU	Outdoor	ND, ND, ND, ND, ND, ND, ND, ND	0.003	0.003	0.01

ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the MRL calculation.
<0.01 mg/kg = less than limit of quantification (<LOQ), value of 0.01 mg/kg was used in the MRL calculation.

Table 2.7.4.1-15**: Residue trials for potatoes (chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl) evaluated in Evaluation report of July 2010**

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results* (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**
Potatoes	NEU	Outdoor	0.016, 0.005, 0.016, 0.033, 0.005, 0.016, 0.016, 0.016	0.016	0.033
Potatoes	SEU	Outdoor	0.023, 0.062, 0.033, 0.098, 0.016, 0.005, 0.016, 0.016	0.020	0.098

*Chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl = Residues of total TCP x 1.6257

Tomatoes and eggplants (S/C/N)

(DAS)

In total 15 trials are included in the current Dossier on tomatoes in S-EU field conditions in different growing seasons: 3 S-EU trials were acceptable and fully reflecting the proposed GAPs. This data set was completed with 6 trials conducted with 2 applications instead of 1, since no residues of chlorpyrifos-methyl were detected just before the second application. In total 9 SEU trials fitted the intended GAPs. These trials were already presented in the Evaluation Report of July 2010 for the chlorpyrifos-methyl and evaluated by Rapporteur Member State (RMS), Spain, and concluded by EFSA in his Reasoned Opinion (EFSA 2011, 9(6);2219).

Moreover, 8 outdoor trials on tomato were also conducted in the Northern Europe during 2014, complying with the proposed GAPs and considered acceptable.

Tomatoes are major crops and a minimum of eight trials are generally required to extrapolate to eggplants. Available data are enough to support the use on tomatoes/eggplants.

The residue data from these trials have been used to estimate maximum residue levels (MRL) of chlorpyrifos-methyl in Europe. As a result a new MRL of 0.30 mg/kg has been estimated and proposed for chlorpyrifos-methyl in outdoor tomatoes and eggplants. The current EU MRL for chlorpyrifos-methyl in outdoor tomatoes and eggplants is 0.5 mg/kg.

Table* 2.7.4.1-16*: Residue trials for tomato (chlorpyrifos-methyl) evaluated in Evaluation Report of July 2010 and new residue data from trials conducted in Northern Europe during 2014

Commodity	Region (a)	Outdoor/ Indoor	Individual trial results (mg/kg)	Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)
Tomato	NEU**	Outdoor	0.04, 0.17, 0.07, 0.17, 0.08, 0.10, 0.06, 0.03	0.08	**0.17**	**0.30**
Tomato	SEU	Outdoor	0.02, 0.92*, 0.03, 0.07, 0.02, 0.07, 0.06, 0.06, 0.07	0.06	0.07	0.15

(a): SEU = Southern Europe , NEU = Northern Europe
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
* Detected as potential outlier using Dixon's Q-test (FAO, 2009a) and discarded from the data set.
**New trials conducted in 2014
ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the MRL calculation.
<0.01 mg/kg = less than limit of quantification (<LOQ)

Table* 2.7.4.1-17*: Residue trials for tomato (chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl) evaluated in Evaluation Report of July 2010 and new residue data from trials conducted in Northern Europe during 2014 –used for risk assessment

Commodity	Region	Outdoor/ Indoor	Individual trial results (mg/kg)	Median residue (mg/kg)	Highest residue (mg/kg)
Tomato	NEU**	Outdoor	0.07, 0.19, 0.10, 0.16, 0.11, 0.14, 0.10, 0.03	**0.11**	**0.19**
Tomato	SEU	Outdoor	0.03, 0.41*, 0.09, 0.17, 0.10, 0.14, 0.09, 0.13, 0.09	0.11	0.17

* Detected as potential outlier using Dixon's Q-test (FAO, 2009a)
**New trials conducted in 2014

Peppers (S/C/N)

(DAS)

16 trials according to the intended cGAP were conducted on outdoor peppers in Southern and Northern Europe during 2014. In total, 6 N-EU and 8 S-EU independent trials were considered to support the proposed GAPs. Peppers are major crops in Northern and Southern Europe and a minimum of eight trials are generally required.

The residue data from these trials have been used to estimate maximum residue levels (MRL) of chlorpyrifos-methyl in southern Europe. As a result of estimation no changes to the current MRL of 0.5 mg/kg in peppers proposed for chlorpyrifos-methyl.

2 additional N-EU trials are necessary to support the use.

Table* 2.7.4.1-18*: Residue trials for pepper (chlorpyrifos-methyl) conducted in Northern and Southern Europe during 2014

Commodity	Region (a)	Outdoor/ Indoor	Individual trial results (mg/kg)	Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)
Pepper	NEU	Outdoor	0.036, 0.056, 0.066, 0.054, 0.023, 0.103	0.055	0.103	0.20
	SEU	Outdoor	0.013, 0.023, 0.049, 0.046, 0.066, 0.033, 0.112, 0.329	0.048	0.329	0.50

(a): SEU = Southern Europe , NEU = Northern Europe
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the MRL calculation.

<0.01 mg/kg = less than limit of quantification (<LOQ)

Table* 2.7.4.1-19*: Residue trials for pepper (chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl) conducted in Northern and Southern Europe during 2014 –used for risk assessment

Commodity	Region	Outdoor/ Indoor	Individual trial results (mg/kg)	Median residue (mg/kg)	Highest residue (mg/kg)
Pepper	NEU	Outdoor	0.068, 0.145, 0.163, 0.114, 0.119, 0.192,	0.132	0.19
	SEU	Outdoor	0.018, 0.098, 0.122, 0.229, 0.107, 0.067, 0.247, 1.099	0.115	1.099

Oilseed rape and Soybean (S/C/N)

(DAS)

In total 16 trials fitting the intended GAPs were available on oilseed rape (8 in N and 8 in S-EU field conditions) in two different growing seasons. These trials were included in the Evaluation Report of July 2010 for the chlorpyrifos-methyl, evaluated by Rapporteur Member State (RMS), Spain, and concluded by EFSA in his Reasoned Opinion (EFSA 2011, 9(6);2219)

Oilseed rape is major crops and a minimum of eight trials are generally required to extrapolate to the whole group Oilseeds, except peanuts (SANCO 7525/VI/95, rev. 10.1). All residue values were not detected or below the LOQ, therefore a reduced data set is sufficient (OECD, 2009).

Considering the period of time between application and harvest (PHI is not applicable), extrapolation could be carried out from oilseed rape to soybean, sunflower, linseed and mustard seed. These residue figures cannot be extrapolated to cotton, because the intended use for cotton is different than the intended use for oilseed rape.

The residue data from these trials have been used to estimate maximum residue levels (MRL) of chlorpyrifos-methyl in Europe. As a result a new MRL of 0.02 mg/kg has been estimated and proposed for chlorpyrifos-methyl in oilseed rape and soybean seeds. The current EU MRL for chlorpyrifos-methyl in oilseed rape and soybean seeds is 0.05* mg/kg.

Table* 2.7.4.1-20*: Residue trials for oilseed rape (chlorpyrifos-methyl) evaluated in Evaluation report of July 2010

Commodity	Region (a)	Outdoor/ Indoor	Individual trial results (mg/kg)	Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)
Oilseed rape seeds	NEU	Outdoor	<0.01, ND, ND, ND, ND, <0.01, 0.015[1], ND	**0.003**	**0.01**	**0.02**
Oilseed rape straw	NEU	Outdoor	ND, ND, ND, ND, ND, 0.02, 0.02, ND	0.003	0.02	0.05
Oilseed rape seeds	SEU	Outdoor	ND, ND, ND, ND, ND, ND, ND	0.003	0.003	0.01
Oilseed rape straw	SEU	Outdoor	ND, ND, 0.04, 0.02, ND, ND, ND	0.003	0.04	0.07

ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the MRL calculation.
<0.01 mg/kg = less than limit of quantification (<LOQ), value of 0.01 mg/kg was used in the MRL calculation.
[1] This value has been considered as not valid. It seems inconsistent that the value of total TCP expressed as chlorpyrifos-methyl (<0.003) is lower than the value of chlorpyrifos-methyl alone (0.015 mg/kg). Moreover, all the other 14 values in Southern and Northern Europe were below LOQ (0.01 mg/kg), and 12 of these 14 values were ND (<0.003 mg/kg)

Table 2.7.4.1-21: Residue trials for oilseed rape (chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl) evaluated in Evaluation report of July 2010

Commodity	Region (a)	Outdoor/ Indoor	Individual trial results* (mg/kg)	Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)
Oilseed rape seeds	NEU	Outdoor	0.02, 0.02, 0.05, 0.03, ND, 0.02, ND, ND	0.02	0.05
Oilseed rape straw	NEU	Outdoor	0.13, 0.07, 0.09, 0.18, 0.60, 0.24, 0.50, 0.32	0.21	0.60
Oilseed rape seeds	SEU	Outdoor	0.02, 0.02, ND, 0.17, 0.04, ND, 0.04	**0.02**	**0.17**
Oilseed rape straw	SEU	Outdoor	0.04, 0.04, 0.21, 0.74, 0.03, 0.25, 0.14	0.14	0.74

*Chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl = Residues of total TCP x 1.6257
ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the MRL calculation.
<0.01 mg/kg = less than limit of quantification (<LOQ), value of 0.01 mg/kg was used in the MRL calculation.

(SAP)

A total of eight trials (4 NEU and 4 SEU) are available to support the use on oilseed rape in conditions according the critical GAP. According the OECD guideline (OECD, 2009), this reduced data package is sufficient to defend the proposed use since all residues at harvest have been found to be below the LOQ (most of them are below the LOD).

Calculations have been performed to determine the proposed MRL value according to the chlorpyrifos-methyl residue definition for monitoring (Table 2.7.4.1-22). As all the results are below the LOQ, the MRL is therefore derived from the merged data.

For later risk assessments, according the risk assessment definition of the residue, the values of 0.01 mg/kg for STMR and 0.01 mg/kg for HR will be applied (residues according to the risk assessment residue definition were not detected in all trials).

Table 2.7.4.1-22 Residues in rapeseed (chlorpyrifos-methyl) and MRL proposal

Commodity	Region (a)	Outdoor/ Indoor	Individual trial results (mg/kg)	Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)
Oilseed rape seeds	NEU	Outdoor	ND, ND, ND, ND	0.003	0.003	0.01
	SEU	Outdoor	ND, ND, ND, ND	0.003	0.003	0.01

Cotton (S)

(DAS)

In total 12 trials are available conducted on cotton seed in S-EU field conditions in two different growing seasons. 4 trials conducted in 2006 didn’t reflect the proposed GAPs. 8 trials fitted the intended GAPs and are acceptable to support the proposed use. These trials were included in the Evaluation Report of July 2010 for the chlorpyrifos-methyl, evaluated by Rapporteur Member State (RMS), Spain, and concluded by EFSA in his Reasoned Opinion (EFSA 2011, 9(6);2219). Cotton seed is major crop in S-EU and a minimum of eight trials are required.

The residue data from these trials have been used to estimate maximum residue levels (MRL) of chlorpyrifos-methyl in southern Europe. As a result a new MRL of 0.04 mg/kg has been estimated and proposed for chlorpyrifos-methyl in cotton seeds. The current EU MRL for chlorpyrifos-methyl in oilseed rape and soybean seeds is 0.05* mg/kg.

Table 2.7.4.1-23: ***Residue trials for cotton seeds (chlorpyrifos-methyl) evaluated in Evaluation report of July 2010***

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**	**MRL proposal (mg/kg)**
Cotton seeds	SEU	Outdoor	ND, <0.01, <0.01, ND, <0.01, 0.02, 0.02, <0.01	0.01	0.02	0.04

ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the MRL calculation

. <0.01 mg/kg = less than limit of quantification (<LOQ), value of 0.01 mg/kg was used in the MRL calculation.

Table 2.7.4.1-24: Residue trials for cotton seeds (chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl) evaluated in Evaluation report of July 2010

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results* (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**
Cotton seeds	SEU	Outdoor	0.005, 0.037, 0.057, 0.036, 0.021, 0.085, 0.093, 0.034	0.037	0.093

*Chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl = Residues of total TCP x 1.6257

Stored cereal grain

(DAS)

Sixteen residue trials on barley (8) and wheat grain (8) storage, conducted in Central, Northern and Southern Europe during 2004-2006 complied with the proposed GAPs. Only the samples from 2006 trials were analysed for des-methyl chlorpyrifos-methyl. Available data are sufficient to support the post-harvest use on barley and wheat and to extrapolate to rye and oat (Guidance Document SANCO 7525/VI/95, rev.10), post-harvest treatment). The residue data from these trials have been used to estimate maximum residue levels (MRL) of chlorpyrifos-methyl in Europe. As a result a new MRL of 5.0 mg/kg has been estimated in wheat, rye, oat and barley (equivalent to the proposed application rate). However, a potential chronic consumer risk concern cannot be excluded, being rye and wheat the main contributors (see point 2.7.9.). The RMS proposes a refined scenario rejecting this MRL proposal and using the median residue value obtained with a rate of 3 mg/kg (based on data from the first Peer Review (2004) and scenario 3 of EFSA 2011, 9(6):2219). Furthermore, in order to support this fall-back GAP and the current MRL (3 mg/kg) **the Applicant is requested to provide residue data complying with the dose rate of 3 mg/kg on stored cereals.** During the period of comments the Applicant proposed to use 3 mg/kg for STMR, HR and MRL**.**

Table 2.7.4.1-25: Residue trials for stored wheat or barley grain (chlorpyrifos-methyl) evaluated in Evaluation report of July 2010

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**	**MRL proposal (mg/kg)**
Grain	N/S EU	Indoor (Immediately after treatment and storage)	3.05, 3.94, 3.58, 3.35, 3.25, 3.56, 3.92, 3.18, 2.60, 2.95, 3.59, **6.23***, 3.05, 3.04, 3.81, 4.88	**3.35**	**4.88**	**5.0**
Grain	N/S EU	Indoor (6 months after treatment and storage)	2.46, 2.08, 3.05, 3.19, 2.85, 2.43, 2.91, 2.36, 3.22, 1.59, 3.14, **6.69***, 2.66, 1.86, 3.03, 4.70	2.85	4.70	5.0

(a): SEU = Southern Europe , NEU = Northern Europe

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

*Outlier; not included in the MRL calculation (residue level well above the range of observed values)

Table 2.7.4.1-26: Residue trials for stored wheat or barley grain (chlorpyrifos-methyl + des-methyl chlorpyrifos-methyl expressed as chlorpyrifos-methyl) evaluated in Evaluation report of July 2010 – used for risk assessment

Commodity	**Region**	**Outdoor/ Indoor**	**Individual trial results (mg/kg) ***	**Median residue (mg/kg)**	**Highest residue (mg/kg)**
Grain	N/S EU	Indoor (Immediately after treatment and storage)	2.63, 3.01, 3.66, **6.34****, 3.08, 3.09, 3.88, 4.93	3.094	4.93
Grain	N/S EU	Indoor (6 months after treatment and storage)	3.76, 2.34, 3.69, **8.19****, 3.01, 2.38, 3.77, 5.24	**3.693**	**5.24**

* Chlorpyrifos-methyl + (des-methyl chlorpyrifos-methyl x 1.045)
** Outlier; not included in the MRL calculation (residue level well above the range of observed values)

Corn/Maize (S)

(DAS)

Eight residue trials were conducted in Southern Europe during 2007 fitting the intended GAPs. The application was made at BBCH 59 or BBCH 83 (as a worst case). The residue data from these trials have been used to estimate maximum residue levels (MRL) of chlorpyrifos-methyl in southern Europe. As a result a new MRL of 0.01* mg/kg has been estimated and proposed for chlorpyrifos-methyl in maize grain. The current EU MRL for chlorpyrifos-methyl in maize is 3.0 mg/kg.

Table 2.7.4.1-27: Residue trials for Corn/Maize (chlorpyrifos-methyl) evaluated in Evaluation report of July 2010

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**	**MRL proposal (mg/kg)**
Maize grain	SEU	Outdoor	ND, ND, ND, ND, ND, ND, ND, ND	0.003	0.003	0.01
Maize stover	SEU	Outdoor	0.01, ND, <0.01, 0.02, ND	0.01	0.02	0.04

(a): SEU = Southern Europe
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the MRL calculation.
<0.01 mg/kg = less than limit of quantification (<LOQ), value of 0.01 mg/kg was used in the MRL calculation.

Table 2.7.4.1-28: Residue trials for Corn/Maize (chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl) evaluated in Evaluation report of July 2010

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results* (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**
Corn/Maize grain	SEU	Outdoor	0.016, 0.018, 0.016, 0.005, 0.016, 0.005, 0.005, 0.005	0.011	0.018
Corn/Maize stover	SEU	Outdoor	1.536, 0.171, 0.930, 1.157, 0.098	0.930	1.536

*Chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl = Residues of total TCP x 1.6257
ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the MRL calculation.
<0.01 mg/kg = less than limit of quantification (<LOQ), value of 0.01 mg/kg was used in the MRL calculation.

2.7.4.2: MRL Applications

(DAS)

Uses on asparagus, banana, broccoli, Brussels sprout, cabbage, cauliflower, cherry, globe artichoke, lettuce, persimmon, plum, pomegranate, raspberry, and sugar beet are not included in the GAP being used to support Annex I renewal. The studies on these crops have however been produced since Annex I listing and they are presented for completeness and MRL assessment.

Summary of the critical GAP

Crop (Zone)	Maximum Rate			Number of applications (minimum interval in days)	PHI (days)	Growth stage at latest application (BBCH)
	g as/ha	g as/hL	Water (L/ha)			
Crops for MRL assessment						
Pomegranate (S)	1.08	90	1200	2 (60)	15	BBCH 89
Persimmon (S)	1.35	90	1500	2 (60)	15	BBCH 89
Banana (S)	2250	125	1800	1	21	
Lettuce (S)	675	-	1000	1	15	BBCH 48
Cabbage (S/C/N)	900	-	400	1	21	BBCH 49
Cauliflower (S/C/N)	900	-	400	1	21	
Broccoli (S/C/N)	900	-	400	1	21	
Brussels sprout (S/C/N)	900	-	400	1	21	
Globe artichokes (S/C/N)	608	-	400	1	14	
Asparagus (C/N)	608	-	400	1	N/A	Summer/Autumn
Raspberry (C/N)	500	-	400	1	21	
Sugar beet (S/C/N)	900	-	400	1	60	BBCH 49

A summary of the residue trials conducted is presented in the following table.

Summary of the number of new residue trials with chlorpyrifos-methyl

Year	Crop	Zone	Study Type		Total Number of Trials
			Decline	At-Harvest	
2011	Pomegranate	Southern EU	0	2	2
2012	Pomegranate	Southern EU	0	2	2
2012	Persimmon	Southern EU	0	2	2
2013	Persimmon	Southern EU	0	2	2
2013	Banana	Southern EU	4	4	8
2011	Lettuce	Southern EU	4	0	4
2013	Lettuce	Southern EU	0	4	4
2013	Cabbage	Northern EU	4	4	8
2013	Cabbage	Southern EU	2	2	4
2013	Cauliflower	Northern EU	2	2	4

Year	Crop	Zone	Study Type		Total Number of Trials
			Decline	At-Harvest	
2013	Cauliflower	Southern EU	2	2	4
2013	Broccoli	Northern EU	2	2	4
2013	Broccoli	Southern EU	2	2	4
2013	Brussels sprout	Northern EU	2	2	4
2013	Brussels sprout	Southern EU	2	2	4
2013	Globe artichokes	Northern EU	2	2	4
2013	Globe artichokes	Southern EU	2	2	4
2013	Asparagus	Northern EU	2	2	4
2013	Raspberry	Northern EU	3	1	4
2014	Raspberry	Northern EU	0	2	2
2013	Sugar beet	Northern EU	4	4	8
2013	Sugar beet	Southern EU	4	4	8

The MRL, STMR and HR values for chlorpyrifos-methyl and chlorpyrifos-methyl + free/conjugated TCP expressed as chlorpyrifos-methyl (risk assessment) are given in summaries included below.

Pomegranate (S)

Four residue trials on pomegranate were already be presented in the Evaluation Report of December 2015 prepared by ES as Rapporteur Member State (*Setting of MRLs for chlorpyrifos-methyl in Persimmons and Pomegranates*), not yet concluded by EFSA. 4 trials performed in 2011-2012 complied with the cGAPs (±25%) and are acceptable. Pomegranate is a minor crop in Southern Europe. A minimum of four trials are required.

The residue data from these trials have been used to estimate maximum residue levels (MRL) of chlorpyrifos-methyl in southern Europe. As a result a new MRL of 0.30 mg/kg has been estimated and proposed for chlorpyrifos-methyl in pomegranate. The current EU MRL for chlorpyrifos-methyl in pomegranate is 0.05* mg/kg.

Table* 2.7.4.2-1*: Residue trials for Pomegranate (chlorpyrifos-methyl)

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**	**MRL proposal (mg/kg)**
Pomegranate	SEU	Outdoor	0.042, 0.049, 0.094, 0.122	0.072	0.122	0.30

(a): SEU = Southern Europe
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition

Table* 2.7.4.2-2*: Residue trials for Pomegranate (chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl)

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results* (mg/kg)**	**Median residue (mg/kg)**	**Highest residue (mg/kg)**
Pomegranate	SEU	Outdoor	0.217, 0.256, 0.328, 0.769	0.29	0.77

*Chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl = Residues of total TCP x 1.6257

Persimmon (S)

Four residue trials on persimmon were already be presented in the Evaluation Report of December 2015 prepared by ES as Rapporteur Member State (*Setting of MRLs for chlorpyrifos-methyl in Persimmons and Pomegranates*), not yet concluded by EFSA. 4 trials performed in 2012-2013 complied with the cGAPs (±25%) and are considered acceptable. Persimmon is a minor crop in Southern Europe. A minimum of four trials are required.
The residue data from these trials have been used to estimate maximum residue levels (MRL) of chlorpyrifos-methyl in southern Europe. As a result a new MRL of 0.50 mg/kg has been estimated and proposed for chlorpyrifos-methyl in persimmon.

Table* 2.7.4.2-3*: Residue trials for Persimmon (chlorpyrifos-methyl)

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**	**MRL proposal (mg/kg)**
Persimmon	SEU	Outdoor	0.077, 0.093, 0.113, 0.250	0.103	0.25	0.5

(a): SEU = Southern Europe
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition

Table* 2.7.4.2-4*: Residue trials for Persimmon (chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl)

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results* (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**
Persimmon	SEU	Outdoor	0.389, 0.517, 0.697, 0.712	0.607	0.712

*Chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl = Residues of total TCP x 1.6257

<u>Banana</u>

Seven residue trials are available to support the use on banana, conducted in Southern Europe during 2013. Banana is a major crop in world productions (SANCO 7525/VI/95, rev. 10.1 (dec. 2015), but not in S- and N-EU. Therefore, a minimum of four trials are required. The residue data from these trials have been used to estimate maximum residue levels (MRL) of chlorpyrifos-methyl in southern Europe. As a result a new MRL of 0.15 mg/kg has been estimated and proposed for chlorpyrifos-methyl in banana. The current EU MRL for chlorpyrifos-methyl is 0.05* mg/kg.

Table* 2.7.4.2-5 *: Residue trials for banana (chlorpyrifos-methyl)

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**	**MRL proposal (mg/kg)**
Banana (whole)	SEU	Outdoor	0.022, 0.045, 0.047, 0.048, 0.052, 0.055, 0.084	0.050	0.08	0.15

(a): SEU = Southern Europe
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.

Table* 2.7.4.2-6*: Residue trials for Banana (chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl)

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results* (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**
Banana (whole)	SEU	Outdoor	0.062, 0.088, 0.104. 0.11, 0.12, 0.13, 0.24,	0.11	0.24

*Chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl = Residues of total TCP x 1.6257

Lettuce

8 trials were performed on lettuce in 2011 and 2013 compliant with the cGAPs (±25%) and are considered relevant. Lettuce is a major crop in S-EU. Therefore, a minimum of 8 trials are required. The residue data from these trials have been used to estimate maximum residue levels (MRL) of chlorpyrifos-methyl in southern Europe. As a result a new MRL of 0.15 mg/kg has been estimated and proposed for chlorpyrifos-methyl in lettuce. The current EU MRL for chlorpyrifos-methyl in lettuce is 0.05* mg/kg.

Table* 2.7.4.2-7*: Residue trials for Lettuce (chlorpyrifos-methyl)

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**	**MRL proposal (mg/kg)**
Lettuce	SEU	Outdoor	3 x ND, 0.01, 0.021, 0.022, 0.033, 0.082	0.022	0.082	0.15

(a): SEU = Southern Europe
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the MRL calculation.

Table* 2.7.4.2-8*: Residue trials for Lettuce (chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl)

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results* (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**
Lettuce	SEU	Outdoor	0.03, 0.072, 0.076, 0.28, 0.45, 0.53, 0.58, 0.62	0.366	0.616

*Chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl = Residues of total TCP x 1.6257.

Head cabbage (S/C/N)

Seven residue trials fitting the proposed GAPs are available in Northern Europe and 4 trials in Southern Europe. Head cabbage is a major and a minor crop in N-EU and S-EU, respectively. Therefore, a minimum of 8 N-EU and 4 S-EU trials are required. **1 additional N-EU trial would be necessary**. The residue data from these trials have been used to estimate maximum residue levels (MRL) of chlorpyrifos-methyl in Europe. As a result a new MRL of 0.03 mg/kg has been estimated and proposed for chlorpyrifos-methyl in head cabbage. The current EU MRL for chlorpyrifos-methyl in head cabbage is 0.05* mg/kg.

Table* 2.7.4.2-9*: Residue trials for Head Cabbage (chlorpyrifos-methyl)

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**	**MRL proposal (mg/kg)**
Head Cabbage	NEU	Outdoor	6 x ND, 0.019	0.003	0.019	0.03
	SEU	Outdoor	3 x ND, <0.01	0.003	0.010	0.02

(a): SEU = Southern Europe
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results 0.003 mg/kg was used in the MRL calculation.
<0.01 mg/kg = less than limit of quantification (<LOQ), value of 0.01 mg/kg was used in the MRL calculation.

Table** 2.7.4.2-10**: Residue trials for Head Cabbage (chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl)

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results* (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**
Head Cabbage	NEU	Outdoor	0.008, 0.015, 0.024, 0.026, 0.036, 0.078, 0.27	0.025	0.268
	SEU	Outdoor	0.01, 0.013, 0.024, 0.138	0.019	0.138

*Chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl = Residues of total TCP x 1.6257

Flowering brassicae (cauliflower and broccoli) (S/C/N)

Sixteen residue trials were conducted on cauliflower (4 NEU, 4 SEU) and broccoli (4 NEU, 4 SEU) in Northern and Southern Europe during 2013 complying with the proposed GAps. Cauliflower is a major crop in N-EU and S-EU and broccoli is a minor one, 4 trials on each are enough to extrapolate to the whole group of flowering Brassica (SANCO 7525/VI/95, rev. 10.1).

The residue data from these trials have been used to estimate maximum residue levels (MRL) of chlorpyrifos-methyl in Europe. As a result a new MRL of 0.05 mg/kg has been estimated and proposed for chlorpyrifos-methyl in flowering brassica (cauliflower and broccoli). The current EU MRL for chlorpyrifos-methyl in cauliflower and broccoli is 0.05* mg/kg.

Table** 2.7.4.2-11**: Residue trials for Cauliflower and Broccoli (chlorpyrifos-methyl)

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**	**MRL proposal (mg/kg)**
Cauliflower	SEU	Outdoor	ND, ND, ND, <0.01	0.003	0.01	0.015
Broccoli			ND, ND, ND, ND			
Cauliflower	NEU	Outdoor	ND, ND, ND, <0.01	0.003	0.028	0.05
Broccoli			0.028, <0.01, ND, ND			

(a): NEU/SEU = Northern/Southern Europe
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the MRL calculation.
<0.01 mg/kg = less than limit of quantification (<LOQ), value of 0.01 mg/kg was used in the MRL calculation.

Table** 2.7.4.2-12 **Residue trials for Cauliflower and Broccoli (chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl)

Commodity	**Region (a)**	**Outdoor / Indoor**	**Individual trial results* (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**
Cauliflower	SEU	Outdoor	0.044, 0.125, 0.015, 0.007	0.042	0.125
Broccoli			0.091, 0.039, 0.021, 0.101		
Cauliflower	NEU	Outdoor	0.070, 0.080, 0.031, 0.049	0.113	0.639
Broccoli			0.639, 0.467, 0.337, 0.145		

*Chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl = Residues of total TCP x 1.6257

Brussels sprout (S/C/N)

8 trials on Brusels sprout (4 NEU, 4 SEU) conducted in 2013 complied with the cGAPs (±25%) and are acceptable.

The residue data from these trials have been used to estimate maximum residue levels (MRL) of chlorpyrifos-methyl in Europe. As a result a new MRL of 0.4 mg/kg has been estimated and proposed for chlorpyrifos-methyl in brussels sprout. The current EU MRL for chlorpyrifos-methyl in brussels sprout is 0.05* mg/kg.

Table* 2.7.4.2-13 : *Residue trials for brussel sprout (chlorpyrifos-methyl)

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**	**MRL proposal (mg/kg)**
Brussel sprout	SEU	Outdoor	2 x ND, 0.011, 0.167	0.007	0.167	0.40
	NEU	Outdoor	0.010, 0.019, 0.029, 0.039	0.024	0.039	0.08

(a): NEU = Northern Europe, SEU = Southern Europe
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the MRL calculation.
<0.01 mg/kg = less than limit of quantification (<LOQ), value of 0.01 mg/kg was used in the MRL calculation.

Table* 2.7.4.2-14*: Residue trials for brussel sprout (chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl)

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results* (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**
Brussel sprout	SEU	Outdoor	0.153, 0.179, 0.189, 0.606	0.184	0.606
	NEU	Outdoor	0.096, 0.696, 0.163, 0.314	0.239	0.696

*Chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl = Residues of total TCP x 1.6257

Globe artichokes (S/C/N)

Eight residue trials (4 NEU and 4 SEU) fitting the proposed GAPs were conducted on globe artichokes during 2013. Globe artichoke is a minor crop in N-EU and S-EU, 4 trials on each are sufficient to this use. The residue data from these trials have been used to estimate maximum residue levels (MRL) of chlorpyrifos-methyl in Europe. As a result a new MRL of 0.03 mg/kg has been estimated and proposed for chlorpyrifos-methyl in globe artichokes. The current EU MRL for chlorpyrifos-methyl in globe artichokes is 0.05* mg/kg.

Table* 2.7.4.2-15 *Residue trials for globe artichoke (chlorpyrifos-methyl)

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**	**MRL proposal (mg/kg)**
Globe Artichoke	NEU	Outdoor	ND, <0.01, <0.01, <0.01	0.008	0.01	0.03
	SEU	Outdoor	ND, <0.01, ND, <0.01	0.007	0.01	0.03

(a): NEU = Northern Europe,
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the MRL calculation.
<0.01 mg/kg = less than limit of quantification (<LOQ), value of 0.01 mg/kg was used in the MRL calculation.

Table** 2.7.4.2-16**: Residue trials for globe artichoke (chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl)

Commodity	Region (a)	Outdoor/ Indoor	Individual trial results* (mg/kg)	Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)
Globe Artichoke	NEU	Outdoor	0.03, 0.02, 0.06, 0.12	0.045	0.12
	SEU	Outdoor	0.03, 0.11, ND, 0.01	0.020	0.11

*Chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl = Residues of total TCP x 1.6257
ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the MRL calculation.

Asparagus (C/N)

4 trials on asparagus (NEU) conducted in 2013 complied with the cGAPs (±25%) and are aceptable. Asparagus is a minor crop in N-EU, 4 trials are sufficient to this use.

The residue data from these trials have been used to estimate maximum residue levels (MRL) of chlorpyrifos-methyl in Northern and central Europe. As a result a new MRL of 0.01 mg/kg has been estimated and proposed for chlorpyrifos-methyl in asparagus. The current EU MRL for chlorpyrifos-methyl in asparagus is 0.05* mg/kg.

Table** 2.7.4.2-17**: Residue trials for asparagus (chlorpyrifos-methyl)

Commodity	Region (a)	Outdoor/ Indoor	Individual trial results (mg/kg)	Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)
Asparagus	NEU	Outdoor	ND, ND, ND, ND	0.003	0.003	0.01

(a): NEU = Northern Europe,
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the MRL calculation.
<0.01 mg/kg = less than limit of quantification (<LOQ), value of 0.01 mg/kg was used in the MRL calculation.

Table** 2.7.4.2-19**: Residue trials for asparagus (chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl)

Commodity	Region (a)	Outdoor/ Indoor	Individual trial results* (mg/kg)	Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)
Asparagus	NEU	Outdoor	ND, ND, ND, ND	0.003	0.003

*Chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl = Residues of total TCP x 1.6257
ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the MRL calculation.
<0.01 mg/kg = less than limit of quantification (<LOQ), value of 0.01 mg/kg was used in the MRL calculation.

Raspberries (C/N)

8 trials on raspberry (NEU) conducted in 2013-2014 complied with the cGAPs (±25%) and are acceptable. Raspberry is a minor crop in N-EU, 4 trials are sufficient to this use. The residue data from these trials have been used to estimate maximum residue levels (MRL) of chlorpyrifos-methyl in Northern and central Europe. As a result a new MRL of 0.15 mg/kg has been estimated and proposed for chlorpyrifos-methyl in raspberries. The current EU MRL for chlorpyrifos-methyl in raspberries is 0.05* mg/kg.

Table** 2.7.4.2-20**: Residue trials for raspberry (chlorpyrifos-methyl)

Commodity	Region (a)	Outdoor/ Indoor	Individual trial results (mg/kg)	Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)
Raspberry	NEU	Outdoor	0.01, 0.02, 0.09, 0.01, <0.01, 0.01, 0.06, 0.04	0.02	0.09	0.15

(a): NEU = Northern Europe,

(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the MRL calculation.
<0.01 mg/kg = less than limit of quantification (<LOQ), value of 0.01 mg/kg was used in the MRL calculation.

Table* 2.7.4.2-21*: Residue trials for raspberry (chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl)

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results* (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**
Raspberry	NEU	Outdoor	0.09, 0.13, 0.25, 0.07, 0.04, 0.07, 0.17, 0.14	0.11	0.25

*Chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl = Residues of total TCP x 1.6257

Sugar beet (S/C/N)

Eight residue trials were conducted on sugar beet in Northern Europe and eight trials in Southern Europe during 2013. These complied with the cGAPs (±25%).

The residue data from these trials have been used to estimate maximum residue levels (MRL) of chlorpyrifos-methyl in Europe. As a result a new MRL of 0.01 mg/kg has been estimated and proposed for chlorpyrifos-methyl in sugar beet roots. The current EU MRL for chlorpyrifos-methyl in sugar beet roots is 0.05* mg/kg.

Table* 2.7.4.2-22*: Residue trials for sugar beet (chlorpyrifos-methyl)

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**	**MRL proposal (mg/kg)**
Sugar beet roots	NEU	Outdoor	ND, ND, ND, ND, ND, ND, ND, ND	**0.003**	**0.003**	**0.01**
Sugar beet tops/leaves			0.019, 0.009, ND, ND, 0.009, ND, ND, 0.008	**0.006**	0.019	0.03
Sugar beet roots	SEU	Outdoor	0.01, ND, ND, ND, ND, ND, ND, ND	0.003	0.01	0.01
Sugar beet tops/leaves			0.004, ND, ND, 0.032, 0.005, 0.015, ND, 0.003	0.004	**0.032**	**0.05**

(a): SEU = Southern Europe, NEU = Northern Europe
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the MRL calculation.
<0.01 mg/kg = less than limit of quantification (<LOQ), value of 0.01 mg/kg was used in the MRL calculation.

Table* 2.7.4.2-23*: Residue trials for sugar beet (chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl)

Commodity	**Region (a)**	**Outdoor/ Indoor**	**Individual trial results* (mg/kg)**	**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**
Sugar beet roots	NEU	Outdoor	0.008, 0.072, 0.018, 0.020, 0.010, 0.015, 0.010, 0.005	0.013	**0.072**
Sugar beet tops/leaves			0.312, 0.265, 1.406, 0.184, 0.441, 0.450, 0.621, 0.005	**0.377**	**1.406**
Sugar beet roots	SEU	Outdoor	0.031, 0.016, 0.039, 0.031 0.024, 0.018, 0.020, 0.008	**0.022**	0.039
Sugar beet tops/leaves			0.857, 0.340, 0.288, 0.182, 0.125, 0.361, 0.075, 0.078	0.235	0.857

*Chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl = Residues of total TCP x 1.6257
ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the MRL calculation.
<0.01 mg/kg = less than limit of quantification (<LOQ), value of 0.01 mg/kg was used in the MRL calculation.

2.7.5. Summary of feeding studies in poultry, ruminants, pigs and fish

The crops intended for the renewal assessment of chlorpyrifos-methyl might be fed to livestock. The median and maximum dietary burdens were therefore calculated for different groups of livestock.

Dietary burden calculations were performed by EFSA in a recent EFSA Reasoned Opinion on modification of the existing MRLs for chlorpyrifos-methyl in various crops (EFSA Journal 2011;9(6):2219). For all the crops in this submission which contribute to the EU model for animal diets, the calculated MRLs are the same as, or lower than, those proposed by EFSA in that context. No increases to MRLs, or the corresponding HR or STMR values are proposed in this submission. However, in order to accommodate feed commodities sugar beet leaves, a new dietary burden calculation has been performed (table 2.7.5-1).

Table *2.7.5-1* **Summary of dietary burden of chlorpyrifos-methyl**

Animal	**Median burden** (mg/kg bw/d)	**Maximum burden** (mg/kg bw/d)	**>0.004** mg/kg bw/d (Y/N)	**Highest contributing commodity**[(a)]
Beef cattle	0.067	0.089	Yes	Sugar beet tops
Dairy cattle	0.075	0.131	Yes	Sugar beet tops
Ram/Ewe	0.060	0.095	Yes	Sugar beet tops
Lamb	0.105	0.145	Yes	Sugar beet tops
Pig (breeding)	0.068	0.078	Yes	Sugar beet tops
Pig (finishing)	0.082	0.085	Yes	Barley grain
Poultry broiler	0.170	0.172	Yes	Barley grain
Poultry layer	0.233	0.243	Yes	Sugar beet tops
Turkey	0.148	0.154	Yes	Rye grain

An exceedance of the trigger value of 0.004 mg/kg bw/day is expected for poultry, ruminants and swine. Therefore, studies on the nature and magnitude of residues in commodities of animal origin are required regarding the uses representatives of DAS and these were provided. The available feeding study was therefore presented and was used to calculate the expected STMR, HR and MRL values in animal matrices (Table 2.7.5-2, 3 and 4).

The feeding studies were already evaluated and considered acceptable (EFSA Journal 9 (6):2219, 2011). Samples of meat, fat, liver, kidneys, milk, cream and eggs were taken from dosed animals and analysed for chlorpyrifos-methyl and 3,5,6-trichloropyridinol (free and conjugated) concentrations.

The results showed that, at the calculated maximum livestock exposure to chlorpyrifos-methyl residues, no measurable residues of chlorpyrifos-methyl and TCP occurred in animal products, such as milk, poultry tissues and eggs, except in fat (chlorpyrifos-methyl) and in kidney and liver (TCP) of bovine and swine.

The results of the feeding studies in livestock and the estimated residues of chlorpyrifos-methyl associated to the dietary burden based on all the intended uses of chlorpyrifos-methyl on potential feed items for which a MRL is proposed, including the use on wheat, barley, oats and rye at 3 mg a.s./kg grains and highest residues of 1.41 mg/kg in sugar beet leaves are summarized in Tables 2.7.5-2 and 2.7.5-3.

Table 2.7.5-2: Overview of the values derived from the livestock feeding studies corresponding to the dietary burden and MRL proposals

Animal	**Residues at closet feeding level** (mg/kg)		**Estimated value at 1N level**		**MRL proposal** (mg/kg)
	Mean	Highest	STMR[(b)] (mg/kg)	HR (mg/kg)	
Bovine	Closest feeding level[(a)]:		0,12	mg/kg bw	
	0,9	N Dairy c.	1,3	N Beef c.	
Meat	-	-	0,010	0,010	-
Muscle	0,010	0,010	0,010	0,010	**0,01***
Fat	0,010	0,010	0,010	0,012	**0,02**
Liver	0,010	0,010	0,010	0,010	**0,01***
Kidney	0,010	0,010	0,010	0,010	**0,01***
Milk[(c)]	0,010	0,010	0,010	0,010	**0,01***
Sheep	Closest feeding level[(a)]:		0,12	mg/kg bw	
	0,8	N Lamb	1,3	N Ram/Ewe	
Meat	-	-	0,010	0,011	-
Muscle	0,010	0,010	0,010	0,010	**0,01***
Fat	0,010	0,010	0,010	0,013	**0,02**
Liver	0,010	0,010	0,010	0,010	**0,01***
Kidney	0,010	0,010	0,010	0,010	**0,01***
Milk[(c)]	0,010	0,010	0,010	0,010	**0,01***
Swine	Closest feeding level[(a)]:		0,12	mg/kg bw	
	1,4	N Finishing	1,5	N Breeding	
Meat	-	-			-
Muscle	0,010	0,010	0.01	0.01	**0,01***
Fat	0,010	0,010	0,010	0,010	**0,01***
Liver	0,010	0,010	0,010	0,010	**0,01***
Kidney	0,010	0,010	0,010	0,010	**0,01***
Poultry	Closest feeding level[(a)]:		0,19	mg/kg bw	
	0,8	N Layer	1,1	N Broiler	
Meat	-	-	0,010	0,010	-
Muscle	0,010	0,010	0,010	0,010	**0,01**
Fat	0,010	0,010	0,010	0,010	**0,01**
Liver	0,010	0,010	0,010	0,010	**0,01**
Kidney					
Eggs[(c)]	0,010	0,010	0,010	0,010	**0,01**

Table 2.7.5-3: MRL proposals derived from the livestock feeding studies (RD-Mo ≠ RD-RA)

Animals & Commodities	Residues at closet feeding level (mg/kg)		Estimated value at 1N level		MRL proposal (mg/kg)	CF	STMR (mg/kg)	HR (mg/kg)
	Mean	Highest	$STMR_{Mo}$ (mg/kg)	HR_{Mo} (mg/kg)				
Bovine	Closest feeding level[(a)]:			0,12	mg/kg bw			
	0,9	N Dairy cattle		1,3	N Beef cattle			
Meat	-	-	-	-	-	-		
Muscle	0,010	0,010	0,01	0,01	**0,01***			
Fat	0,010	0,010	0,01	0,01	**0,02**	1,0	0,01	0,01
Liver	0,010	0,010	0,01	0,01	**0,01***	24,0	0,24	0,24
Kidney	0,010	0,010	0,01	0,01	**0,01***	100	1,00	1,00
Milk[(c)]	0,010	0,010	0,01	0,01	**0,01***	3,0	0,03	0,03
Sheep	Closest feeding level[(a)]:			0,12	mg/kg bw			
	0,8	N Lamb		1,3	N Ram/Ewe			
Meat	-	-	-	-	-	-		
Muscle	0,010	0,010	0,01	0,01	**0,01***	n.c.		
Fat	0,010	0,010	0,01	0,01	**0,02**	1,0	0,01	0,01
Liver	0,010	0,010	0,01	0,01	**0,01***	24,0	0,24	0,24
Kidney	0,010	0,010	0,01	0,01	**0,01***	100	1,00	1,00
Milk[(c)]	0,010	0,010	0,01	0,01	**0,01***	3,0	0,03	0,03
Swine	Closest feeding level[(a)]:			0,12	mg/kg bw			
	1,4	N Finishing		1,5	N Breeding			
Meat	-	-	-	-	-	-		
Muscle	0,010	0,010	0,010	0,010	**0,01***	n.c.		
Fat	0,010	0,010	0,010	0,010	**0,01***	1,0	0,01	0,01
Liver	0,010	0,010	0,010	0,010	**0,01***	24,0	0,24	0,24
Kidney	0,010	0,010	0,010	0,010	**0,01***	100	1,00	1,00
Poultry	Closest feeding level[(a)]:			0,19	mg/kg bw			
	0,8	N Layer		1,1	N Broiler			
Meat	-	-	-	-	-	-		
Muscle	0,010	0,010	0,010	0,010	**0,01**			
Fat	0,010	0,010	0,010	0,010	**0,01**	1,0	0,01	0,01
Liver	0,010	0,010	0,010	0,010	**0,01**			
Kidney								
Eggs[(c)]	0,010	0,010	0,010	0,010	**0,01**			

(SAP)

In the present application, registration is sought for application in grapes and oilseed rape. Of these, only oilseed rape may be fed to livestock. The calculations performed demonstrate that Chlorpyrifos-methyl uptake of livestock will not exceed 0.004 mg/kg bw/day.
Input values used in the calculations are included in table Table 2.7.5-4

Table 2.7.5-4 Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition:sum of chlorpyrifos-methyl, TCP and its conjugates expressed as chlorpyrifos-methyl				
Rape seed meal	0.02	STMR x pf (2)[1]	0.02	STMR x pf (2)[1]

[1] Default processing factor established by EFSA (EFSA, 2011)

Calculations have been performed using the Excel sheet provided by EFSA (EFSA, 2015b). Results of the calculations are included in table Table 2.7.5-5.

Table 2.7.5-4 **Results of the dietary burden calculations**

Animals	**Median burden** (mg/kg bw)	**Maximum burden** (mg/kg bw)	**Above 0.004 mg /kg bw**	**Maximum burden** (mg/kg DM)	**Highest contributing commodities**
Beef cattle	0.000	0.000	No	0.00	Rape meal
Dairy cattle	0.000	0.000	No	0.00	Rape meal
Ram/Ewe	0.000	0.000	No	0.00	Rape meal
Lamb	0.000	0.000	No	0.00	Rape meal
Pig (breeding)	0.000	0.000	No	0.00	Rape meal
Pig (finishing)	0.000	0.000	No	0.00	Rape meal
Poultry broiler	-	-	-	-	-
Poultry layer	0.000	0.000	No	0.00	Rape meal
Turkey	0.000	0.000	No	0.00	Rape meal

According to OECD Guideline Series on Pesticides Nº. 73 (ENV/JM/MONO(2013)8 04/09/2013) rapeseed meal can be fed to layers and turkeys, beef and dairy cattle, ram/ewes and lambs, breeding and finishing swine. According to the guideline, in Europe, broilers are not fed with oilseed rape. Calculation of dietary burden intakes has been made following the methodology described by the OECD Guidance document on residues in livestock.

No exceedance of the trigger value of 0.004 mg/kg bw/day is expected for poultry, ruminants and swine. Therefore, studies on the nature and magnitude of residues in commodities of animal origin are not required regarding the uses representatives of SAP.

No fish feeding study is required since grapes are not usually included in fish feed and no residues have been found in rape seeds.

2.7.6. Summary of effects of processing

(DAS)

A new study, investigating the hydrolytic stability of [14C] chlorpyrifos-methyl in aqueous buffer solutions at three pH values and temperatures, in order to simulate processing practices, showed that chlorpyrifos-methyl is only moderately stable to the conditions under which pasteurization will occur and even less stable to those simulating baking/brewing/boiling and sterilization. The principle degradate formed under these conditions is desmethyl chlorpyrifos-methyl (DEM) along with lesser amounts of TCP. No other hydrolysis products were observed in any of the three hydrolysis scenarios used.

For processed commodities and taking into account these results, the following **residue definitions** are proposed (RMS proposal):

Monitoring: Chlorpyrifos-methyl

Risk assessment : Chlorpyrifos-methyl + 3,5,6-trichloropyridinol (TCP) and its conjugates + des-methyl chlorpyrifos-methyl, expressed as chlorpyrifos-methyl.

Of the crops supported in this document, **distribution of the residues in peel and pulp** is only relevant for citrus and banana (non representative use). In the Evaluation Report prepared by ES and evaluated by EFSA (EFSA Journal 2011;9(6):2219), it was proposed to include processing factor of <0.06 for chlorpyrifos-methyl in peeled citrus. Chlorpyrifos-methyl and TCP residues were found almost exclusively in the citrus peel. After the EFSA opinion, new studies have been conducted on oranges and banana (table 2.7.6-1 and 2.7.6-2). The studies were considered acceptable to derive a reliable peeling factor of 0.06 for banana and 0.05 for citrus.

Since the EFSA Reasoned Opinion [2219] in 2011, new processing studies conducted on apple, grape, orange and tomato, were considered to derive reliable processing factors for a wide range of commodities. Residue results of desmethyl chlorpyrifos-methyl have been included in the calculation of processing factors for risk assessment and the calculation of conversion factors (tables 2.7.6-3-2.7.6.-8).

Furthermore, results of studies previously presented and considered acceptable by EFSA (EFSA Journal 2011;9(6):2219) have been included in the calculation of median processing factors for monitoring (tables 2.7.6-4, 2.7.6-6 and 2.7.6-8). Reliable processing factors and conversion factors are derived from these results.

During the period of comments the Applicant provided the results of a new study in which frozen storage of des-methyl chlorpyrifos-methyl was determined in apple juice, dried apple, grape juice, raisins, wine, orange fruits, orange pulp, marmalade, tomato, tomato puree, tomato ketchup, raspberry, raspberry jam and canned raspberry for up to 20 months. The levels of des-methyl Chlorpyrifos Methyl declined in the following processed commodities : orange peel (9 months) and orange oil (< 1 month).

Table 2.7.6.-1 ***Chlorpyrifos-methyl residues in banana peel, pulp and whole fruit and processing factors***

Commodity	Individual Trial Results (mg/kg)	Median Residue (mg/kg)	Median Processing Factor
Banana (whole)	0.022, 0.048, 0.047, 0.084, 0.052, 0.055, 0.045	0.050	----
Peel	0.042, 0.084, 0.093, 0.181, 0.109, 0.108, 0.099	0.104	1.98
Pulp	ND, 0.007, ND, ND, ND, 0.005, ND	0.003	0.07

ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the calculation.

Table 2.7.6.-2 ***Total TCP expressed as chlorpyrifos-methyl residues in banana peel, pulp and whole fruit and processing factors***

Commodity	Individual Trial Results* (mg/kg)	Median Residue (mg/kg)	Median Processing Factor
Banana (whole)	0.062, 0.104, 0.122, 0.242, 0.111, 0.135, 0.088	0.117	-----
Peel	0.114, 0.197, 0.236, 0.517, 0.231 0.275, 0.192	0.21	2.00
Pulp	0.007, ND, 0.007, 0.005, ND, ND, ND	0.005	0.06

*Chlorpyrifos-methyl + free/conjugated-TCP expressed as chlorpyrifos-methyl = Residues of total TCP x 1.6257

ND = Not Detected (<0.003 mg/kg), value of 0.003 mg/kg was used in the calculation.

Table 2.7.6-3: **Summary of processing factors for orange**

Crop	**Portion Analysed**	**Processing Factors**			**Median or Mean Processing Factor**			**CF**
		CHP-M	**CHP-M***	**CHP-M* + DES***	**CHP-M**	**CHP-M***	**CHP-M* + DES***	
Orange	Juice	<0.01, <0.01, 0.08, <0.01,	<0.01<0.01, 0.07, <0.01	<0.01, <0.01	0.01	0.01	**0.01**	1
Orange/Mandarin	Pulp (peeled citrus)	0.2, <0.02, <0.08, <0.07, <0.02, <0.02, <0.04, <0.02, <0.02, <0.05, 0.07, 0.12	<0.05, <0.06, <0.07, <0.05, <0.04, <0.02, <0.03, <0.05, <0.02, <005, <0.01, <0.01	-	0.03	0.05	---	---
Orange	Dried pulp	0.15, 0.25	0.25, 0.27	0.28, 0.29	0.20	0.26	**0.28**	1.4
Orange	Canned	<0.01, <0.01	<0.01, <0.01	<0.01, <0.01	0.01	0.01	**0.01**	1
Orange	Marmalade	0.01, 0.05	0.03, 0.03	0.02, 0.06	0.03	0.03	**0.04**	1.66
Orange	Essential Oil	54.0, 106.5, 40.1, 40.4	131.7, 133.8, 50.6, 35.91	129.7, 131.4	47.1	83.8	**130.6**	1.56

CHP-M = Chlorpyrifos-methyl;
CHP-M* = Chlorpyrifos-methyl + free/ conjugated TCP expressed as chlorpyrifos-methyl = Residues of total TCP x 1.6257
DES* = Residues of des-methyl Chlorpyrifos-methyl expressed as chlorpyrifos-methyl = Residues of Des-methyl x 1.045
Processing Factor (PF) = (residues in processed fraction)/(residues in fruit before processing)
CF : from monitoring to risk assessment (for processed products)

Table 2.7.6-4**: Summary of processing factors for apple**

Crop	**Portion Analysed**	**Processing Factors**			**Mean Processing Factor of new studies**			**CF**
		CHP-M[a]	**CHP-M***	**CHP-M* + DES***	**CHP-M**	**CHP-M***	**CHP-M* + DES***	
Apple	Sauce	0.03, 0.05, ***<0.04, <0.15, <0.25***	0.15, 0.31	0.15, 0.31	0.04	0.23	0.23	5.75
	Wet pomace	1.42, 5.49	0.70, 6.43	0.70, 6.50	3.46	3.56	3.60	1.04
	Dry pomace	4.16, 19.43, ***2.29, 4.0***	2.93, 19.59	3.02, 20.15	7.47	11.26	11.58	1.55
	Juice	0.01, 0.01, ***<0.04, <0.05, <0.15***	0.04, 0.09	0.04, 0.09	0.01	0.06	0.06	6
	Canned	0.01, 0.07	0.03, 0.10	0.03, 0.10	0.04	0.06	0.06	1.5
	Dried	0.38, 1.70	0.64, 2.69	0.67, 2.88	1.04	1.66	1.78	1.7

CHP-M = Chlorpyrifos-methyl
CHP-M* = Chlorpyrifos-methyl + free/conjugated TCP expressed as chlorpyrifos-methyl = Residues of total TCP x 1.6257
DES* = Residues of des-methyl Chlorpyrifos-methyl expressed as chlorpyrifos-methyl = Residues of Des-methyl x 1.045
[a] *Italic and bold values are from EFSA Reasoned Opinion (EFSA Journal 2011;9(6):2219- not included in the calculation of mean processing factor and the conversion factor.*

Table 2.7.6-5 **Summary of new processing factors for grape**

Crop	**Portion Analysed**	**Processing Factors**			**Median Processing Factor**			**CF**
		CHP-M	**CHP-M***	**CHP-M* + DES***	**CHP-M**	**CHP-M***	**CHP-M* + DES***	
Wine Grape	Raisins	2.65, 1.88, 1.01, 3.43, 2.24, 0.31	2.46, 4.40, 0.94, 4.75, 2.28, 1.20	2.65, 5.08, 1.05, 4.86, 2.40, 1.34	2.06	2.37	2.50	1.2

Crop	Portion Analysed	Processing Factors			Median Processing Factor			CF
		CHP-M	CHP-M*	CHP-M* + DES*	CHP-M	CHP-M*	CHP-M* + DES*	
	Juice	0.03, 0.05, 0.03, 0.07, 0.00, 0.01	0.33, 0.49, 0.22, 0.60, 0.38, 0.44	0.408, 0.63, 0.23, 0.66, 0.41, 0.44	0.03	0.41	0.42	14
	Wet Pomace	3.56, 4.91, 5.79, 12.2, 21.6, 0.81	3.14, 5.19, 2.20, 6.81, 11.6, 0.92	3.09, 5.19, 2.18, 6.07, 10.97, 0.97	5.35	4.16	4.14	0.77
	Wine	0.03, 0.05, 0.03, 0.07, 0.00, 0.01	0.17, 0.15, 0.21, 0.90, 0.34, 0.08	0.204, 0.19, 0.23, 0.923, 0.45, 0.09	0.03	0.19	0.21	**7**

CHP-M = Chlorpyrifos-methyl
CHP-M* = Chlorpyrifos-methyl + free/conjugated TCP expressed as chlorpyrifos-methyl = Residues of total TCP x 1.6257
DES* = Residues of des-methyl Chlorpyrifos-methyl expressed as chlorpyrifos-methyl = Residues of Des-methyl x 1.045

Table 2.7.6-6 **Summary of processing factors for tomato**

Crop	Portion Analysed	Processing Factors			Mean Processing Factor			CF
		CHP-M[a]	CHP-M*	CHP-M* + DES*	CHP-M	CHP-M*	CHP-M* + DES*	
Tomato	Juice	0.005, 0.009, ***<0.01, <0.04, <0.05***	0.046, 0.065	0.053, 0.067	0.007	0.06	0.06	8.5
Tomato	Peeled	0.05, 0.008	0.112, 0.032	0.115, 0.034	0.029	0.07	0.07	2.4
Tomato	Canned	0.014, 0.005, ***<0.01, <0.04***	0.044, 0.079	0.049, 0.081	0.01	0.06	0.06	6
Tomato	Ketchup	0.162, 0.127	0.461, 0.295	0.672, 0.425	0.14	0.38	0.55	3.92
Tomato	Puree	0.277, 0.147, ***0.12, 0.46***	0.717, 0.346	0.996, 0.492	0.21	0.53	0.74	3.5
Tomato	Paste	0.143, 0.135	1.227, 0.602	1.802, 1.027	0.14	0.91	1.41	10.1
Tomato	dried	3.66, 3.20	3.93, 3.54	4.165, 3.595	3.43	3.74	3.88	1.3

CHP-M* = Chlorpyrifos-methyl + free/ conjugated TCP expressed as chlorpyrifos-methyl = Residues of total TCP x 1.6257
DES* = Residues of des-methyl Chlorpyrifos-methyl expressed as chlorpyrifos-methyl = Residues of Des-methyl x 1.045
[a] *Italic and bold values are from EFSA Reasoned Opinion (EFSA Journal 2011;9(6):2219- not included in the calculation of mean processing factor and the conversion factor*

Table 2.7.6-7**: Summary of processing factors for raspberry**

Crop	Portion Analysed	Processing Factors	Median Processing Factor	CF

		CHP-M	CHP-M*	CHP-M* + DES*	CHP-M	CHP-M*	CHP-M* + DES*	
Raspberry	Juice	0.38, 0.07, 0.14	0.64, 1.83, 0.87	0.64, 1.68, 0.97	0.14	0.87	0.97	6.9
Raspberry	Canned	0.38, 0.34, 0.18	0.10, 0.43, 0.50	0.12, 0.42, 0.50	0.34	0.43	0.42	1.23
Raspberry	Jam	0.38, 0.61, 0.36	0.04, 0.88, 1.06	0.07, 0.83, 1.05	0.38	0.88	0.83	2.18

Table 2.7.6-8**: Summary of processing factors for cereals**

Crop / processed crop	**Number of studies**[a]	**Mean processing factor**				
		CHP-M	TCP	CHP-M*	DES*	CHP-M +DES*
Barley / beer	3	None	0.05	0.05	0.53	0.01
Barley / brewers yeast	3	None	0.19	0.19	0.71	0.01
Barley / malt sprouts	3	0.08	0.48	0.48	3.21	0.14
Barley / spent grains	3	0.07	0.15	0.15	0.57	0.08
Wheat / bran	3	2.98	3.05	3.05	4.61	3.02
Wheat / germ	3	1.90	2.38	2.38	31.59	1.95
Wheat / wholemeal flour	3	1.02	0.89	0.89	1.42	1.13
Wheat / wholemeal bread	3	0.48	0.49	0.49	7.97	0.68
Wheat / white flour	3	0.23	0.19	0.19	0.45	0.23
Wheat / white bread	3	0.08	0.10	0.10	3.15	0.14

[a] Only 2 studies were analyzed for DES*
CHP-M = Chlorpyrifos-methyl; TCP = Total TCP
CHP-M* = Chlorpyrifos-methyl + free/conjugated TCP expressed as chlorpyrifos-methyl;
DES* = Des-methyl chlorpyrifos-methyl expressed as chlorpyrifos-methyl = Residues of des-methyl chlorpyrifos-methyl x 1.045
CHP-M + DES* = Chlorpyrifos-methyl + Residues of des-methyl chlorpyrifos-methyl expressed as chlorpyrifos-methyl

(SAP)

A study investigated the hydrolytic stability of [14C] chlorpyrifos-methyl in aqueous buffer solutions at three pH values and temperatures, in order to simulate processing practices, show that chlorpyrifos-methyl is hydrolytically unstable under conditions simulating pasteurisation (pH 4, 90°C), baking, brewing and boiling (pH 5, 100°C), and sterilisation (pH 6, 120°C).

The principle degradate formed under these conditions is desmethyl chlorpyrifos-methyl (DEM). Chlorpyrifos-methyl and desmethyl chlorpyrifos-methyl were the major components detected under conditions representative of pasteurization, with TCP present as a minor degradate. For conditions representative of baking, brewing and boiling, and sterilization, desmethyl-chlorpyrifos-methyl and TCP were the major components detected.

The following residue definitions for processed commodities is proposed by this Applicant, and the processing factors calculated are summarized below (table 2.7.6-9):

- Monitoring: *Chlorpyrifos-methyl + Desmethyl chlorpyrifos-methyl expressed as chlorpyrifos-methyl.*
- Risk assessment: *Chlorpyrifos-methyl plus TCP and its conjugates expressed as chlorpyrifos methyl*

Table 2.7.6-9: Overview of the available processing studies

Processed commodities	**Number of studies**	**Median PF[a]**	**Median CF[b]**
Residue definition for monitoring: chlorpyrifos-methyl plus desmethyl chlorpyrifos-methyl Residue definition for risk assessment: *chlorpyrifos-methyl plus TCP and its conjugates expressed as chlorpyrifos methyl*			
Wine grapes, Raisins	2	0.29	**1.25**
Wine grapes, Wet pomace (juice)	2	0.81	**2.64**
Wine grapes, Pasteurized juice	2	0.03	**2.08**
Wine grapes, Must (red wine)	2	1.18	**1[c]**
Wine grapes, Wet pomace (red wine)	2	4.76	**1.06**
Wine grapes, Wine (red)	2	0.07	**1.65**
Wine grapes, Must (White wine)	2	0.69	**1.00**
Wine grapes, Wet pomace (White wine)	2	0.87	**1.25**
Wine grapes, Wine (White)	2	0.02	**1.67**

[a] The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
[b] The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.
[c] calculated value <1 rounded up to one.

2.7.7. Summary of residues in rotational crops

The nature and potential magnitude of chlorpyrifos-methyl related residues in rotational crops has been examined in three studies using the surrogate compound chlorpyrifos. These studies were presented in the DAR of chlorpyrifos-methyl and Adenda and were deemed acceptable following evaluation and peer review at the EU level.

Given the structural similarities between chlorpyrifos and chlorpyrifos-methyl and the fact that they are metabolized in a similar manner in both soil and plants, results from rotational crop studies with chlorpyrifos-methyl would be expected to be the same as with chlorpyrifos. Thus it would be expected that while some residues of TCP and TMP could be present in rotational crops, the residues would be low. There would likely be no residues of chlorpyrifos-methyl itself found in any crops. Results from these studies also confirmed that the nature of any residues found in rotational crops will not differ from those observed in primary crops. Thus any residue definitions adopted for primary crops will also be adequate for rotational crops.

Based on so far available data, it can be concluded that relevant residue of chlorpyrifos-methyl and it metabolites are unlikely to occur in rotational crops according to the proposed patterns.

A further study investigating the residues of chlorpyrifos-methyl and TCP in radish, leaf lettuce, oilseed rape and wheat grown as rotational crops is still ongoing. This is considered as supportive information.

2.7.8. Summary of other studies

Effect on the residue level in pollen and bee products

DAS: A study is provided for determination of residues of chlorpyrifos-methyl and TCP in nectar, pollen and flowers from Phacelia tanacetifolia and in honey bee products (honey and wax) after one treatment of GF-1684 with two treatment rates under confined semi-field conditions. During the 2014 growing season three separate field trials were conducted in Germany and Spain.

In flower, pollen and nectar samples a clear decline of residues for chlorpyrifos-methyl and TCP was observed in all trials until the end of the sampling period. For honey, residues of chlorpyrifos-methyl and TCP were not detected or were below the limit of quantification.

SAP: A clear decline of residues for chlorpyrifos-methyl in nectar samples was observed until the end of the sampling period in 3 trials conducted in FR, following one application of Chlorpyrifos-methyl 224 g/l EC (SAP224I) on phacelia at dose rates of 302.4 g a.i/ha and 80.44 g ai/ha.

2.7.9. Estimation of the potential and actual exposure through diet and other sources

2.7.9.1. Representative uses

(DAS)

The Acceptable Daily Intake (ADI) and the Acute Reference Dose (ARfD) for chlorpyrifos-methyl is used to perform the calculations of the potential and actual exposure through diet and other sources is included in table 2.7.9.1-1.

Table 2.7.9.1-1 Overview of the toxicological reference values

End-Point	Value	Study	Safety Factor	Reference
Acceptable Daily Intake (ADI)	0.01 mg/kg bw/d	Chronic Dietary Toxicity/Oncogenicity Study in Rats	100	[redacted] (1991) Report number: K-046193-031
Acute Reference Dose (ARfD)	0.1 mg/kg bw/d*	CCA study in rats after a single dose exposure	100	[redacted] (2013) Study ID: 121202

** The Applicant proposed a ARfD of 0.75 mg/kg bw in this Dossier.*

The consumer risk assessment was performed using revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model). For the chronic and acute intake assessment the proposed MRL, STMR and HR derived from residue trials were considered for plant and animal commodities.

Table 2.7.9.1-2: Summary of the endpoints used in the dietary exposure calculations

Commodity	**Chronic exposure assessment**		**Acute exposure assessment**	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Risk assessment residue definition: chlorpyrifos-methyl +TCP and its conjugates, expressed as chlorpyrifos-methyl; post-harvest (grains): chlorpyrifos-methyl+ desmethyl chlorpyrifos-methyl, expressed as chlorpyrifos-methyl				
Citrus fruits	0.012 (0.24*0.05)	Median residue *CF (1.89) *PF (peeling factor)	0.028 (0.57*0.05)	High residue *CF(1.89) *PF (peeling factor)
Orange juice	0.0024 (0.24*0.01)	Median residue *CF (1.89) *PF (STMR-p)	0.0024 (0.24*0.01)	Median residue *CF (1.89) *PF (STMR-p)
Apples	0.11	Median residue RA (apple, SEU)	0.2	High residue RA
Pears	0.09	Median residue RA (pear, SEU)	0.15	High residue RA
Pome fruit juice	0.0066 (0.11*0.06)	Median residue RA*PF (STMR-p)	0.0066 (0.11*0.06)	Median residue RA*PF (STMR-p)
Quince	0.11	Median residue RA (apple, SEU)	0.2	High residue RA
Quince jelly	0.11	Median residue RA (for crop)	0.11	Median residue RA (for crop)
Apricots	0.13	Median residue RA	0.60	High residue RA
Cherries	0.27	Median residue RA	0.47	High residue RA
Peaches	0.10	Median residue RA	0.18	High residue RA
Plums	0.07	Median residue RA	0.23	High residue RA

Commodity	**Chronic exposure assessment**		**Acute exposure assessment**	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Risk assessment residue definition: chlorpyrifos-methyl +TCP and its conjugates, expressed as chlorpyrifos-methyl; post-harvest (grains): chlorpyrifos-methyl+ desmethyl chlorpyrifos-methyl, expressed as chlorpyrifos-methyl				
Table Grapes	0.11	Median residue RA	0.37	High residue RA
Wine Grapes	0.11	Median residue RA	0.26	High residue RA
Wine	0.02 (0.11*0.21)	Median residue RA*PF (STMR-p)	0.02 (0.11*0.21)	Median residue RA*PF (STMR-p)
Grape juice	0.04 (0.11*0.42)	Median residue RA*PF (STMR-p)	0.04 (0.11*0.42)	Median residue RA*PF (STMR-p)
Grape raisins	0.27 (0.11*2.5)	Median residue*PF (STMR-p)	0.27 (0.11*2.5)	Median residue*PF (STMR-p)
Strawberries	0.17	Median residue RA	0.27	High residue RA
Potatoes	0.02	Median residue RA	0.1	High residue RA
Tomatoes and aubergines	0.11	Median residue RA	0.19	High residue RA
Tomato juice	0.0066 (0.11*0.06)	Median residue*PF (STMR-p)	0.0066 (0.11*0.06)	Median residue*PF (STMR-p)
Tomato puree	0.08 (0.11*0.73)	Median residue*PF (STMR-p)	0.08 (0.11*0.73)	Median residue*PF (STMR-p)
Pepper	0.12	Median residue RA	1.1	High residue RA
Rapeseeds	0.02	Median residue RA	0.17	High residue RA
Soya bean	0.02	Median residue RA	0.17	High residue RA
Cotton seeds	0.04	Median residue RA	0.093	High residue RA
Stored cereal grain (wheat)	0.0217 [a]	Mean residue values [EFSA Journal 2013;11(3):3130][1]	5.0	MRL**
Stored cereal grain (Barley)	0.0217[a]	As wheat input value	5.0	MRL**
Stored cereal grain (oats)	0.0340 [a]	Mean residue values [EFSA Journal 2013;11(3):3130][1]	5.0	MRL**
Stored cereal grain (rye)	0.0141[a]	Mean residue values [EFSA Journal 2013;11(3):3130][1]	5.0	MRL**
Wheat white flour	0.85 (3.69*0.23)	Median residue*PF (STMR-p)	0.85 (3.69*0.23)	Median residue*PF (STMR-p)
Wheat wholemeal bread/pizza	1.77 (3.69*0.48)	Median residue*PF (STMR-p)	1.77 (3.69*0.48)	Median residue*PF (STMR-p)
Corn/Maize	0.01	Median residue RA	0.018	High residue RA
Honey	0.005	Proposed MRL (LOQ)	0.005	Proposed MRL (LOQ)
Swine: Meat	0.01	Proposed MRL	0.01	Proposed MRL
Swine: Fat	0.01	Proposed MRL	0.01	Proposed MRL
Swine: Liver	0.01	Proposed MRL	0.01	Proposed MRL
Swine: Kidney	0.01	Proposed MRL	0.01	Proposed MRL
Bovine, sheep, goat, horse: Meat	0.01	Proposed MRL	0.01	Proposed MRL
Bovine, sheep, goat, horse: Fat	0.02	Proposed MRL	0.02	Proposed MRL
Bovine, sheep, goat and horse: Liver	0.01	Proposed MRL	0.01	Proposed MRL
Poultry: Meat, fat, liver, kidney	0.01	Proposed MRL	0.01	Proposed MRL
Milk and cream	0.01	Proposed MRL	0.01	Proposed MRL
Birds eggs	0.01	Proposed MRL	0.01	Proposed MRL
Fish	0.03	Proposed MRL	0.03	Proposed MRL

[1]EFSA Journal 2013;11(3):3130 – The EU Report on Pesticide Residues in Food, European Food Safety Authority (EFSA), Parma, Italy, 2013. Applicant proposal (see below Chronic Dietary Exposure).

[a]Applicant proposal (see below Chronic Dietary Exposure).

Chronic Dietary Exposure Calculations

TMDI calculations

The Theoretical Maximum Daily Intake (TMDI) calculations have been performed using the EFSA Pesticide Residue Intake Model version 2 (PRIMo). The detailed input values for the TMDI calculation are given in Table 2.7.9.1-2. It is assumed that 100% of crops with established and proposed uses will contain residues at the STMR or STMR-p. The Proposed MRL for honey, fish and animal products.

According to the Applicant (DAS), for a more realistic chronic dietary exposure calculations, monitoring data from the EU Report on Pesticide Residues in Food, European Food Safety Authority (EFSA), Parma, Italy, 2013 (EFSA Journal 2013;11(3):3130) were used for cereals. The results indicate that the estimated TMDI, based on input values given in Table 2.7.9.1-2 (including the monitoring data mentioned), were below the ADI. The total calculated intake values ranged from 2.7% to 22.9% of the ADI (Table 2.7.9.1-3).

However, in the context of the Reasoned Opnion on Modification of the existing MRLs for chlorpyrifos-methyl in varios crops (EFSA Journal 2011, 9 (6) :2219) this approach was not deemed aceptable.

Therefore, the same approach used by EFSA in his RO (EFSA Journal 2011, 9 (6) :2219) is proposed by the RMS, using as a refinement the available processing factors for wheat to white bread, whole meal bread, bran and flour and for barley to beer and detailed consumption data for processed barley and wheat products collected by EFSA for 15 european diets (EFSA Journal 2011;9(6):2219, Scenario 2).

In this scenario 2, results indicate that the estimated TMDI, based on input values given in Table 2.7.9.1-2, except wheat, barley, oat and rye, were above 100% of ADI for 1 diet (DK child). The total calculated intake values ranged from 5.1% to 110.5% of the ADI (Table 2.7.9.1-4).

A further dietary exposure assessment is performed, based on scenario 3 from EFSA, in which the proposed MRL for cereals is rejected and the current MRL is maintained (3 mg/kg) and the median value of 2.2 mg/kg from supervised residue trials performed on barley and wheat at a rate of 3 mg/kg (Spain, 2004) is used as input value. Furthermore, in order to support this fall-back GAP and the current MRL (3 mg/kg) **the Applicant is requested to provide residue data complying with the dose rate of 3 mg/kg on stored cereals.**

In this scenario 3, results indicate that the estimated TMDI were below 100% of ADI for all diets The total calculated intake values ranged from 5.1% to 82.4% of the ADI, the maximum for DK child, being the main contributors rye and rye products (Table 2.7.9.1-5).

Acute Dietary Exposure Calculations

The International/National Estimated Short-Term Intakes (I/NESTIs) for chlorpyrifos-methyl have been calculated using the EFSA PRIMo (version 2) because there is an acute reference dose proposed for chlorpyrifos-methyl. The RMS proposal of 0.1 mg/kg bw/day for the ARfD was used to estimate the acute risk.

For this conservative acute dietary exposure assessment, residues in commodities were assumed to be at HR or STMR-p values based on risk assessment residue definition or a the proposed MRL for cereals commodities. This is a highly conservative approach, especially when considering composite commodities. The values entered into the EFSA PRIMo are shown in table 2.7.9.1-2.

Calculation of the International/National Estimated Short Term Intake (NESTI) showed the highest acute intakes, for unprocessed and processed commodities, were 72.2% and 10% of the ARfD for unprocessed wheat and processed wheat flour commodity, respectively (Table 2.7.9.1-6).

The results indicate that there is no unacceptable acute risk to human health from the consumption of commodities treated with chlorpyrifos-methyl according to the uses considered.

Table 2.7.9.1-3: Chlorpyrifos-methyl: Representative uses (DAS) – *Theoretical Maximum Daily Intake Calculation (PRIMo version 2)* (DAS refinement proposal)

chlorpyrifos-methyl

Status of the active substance:	included	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,01**	ARfD (mg/kg bw):	**0,1**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2011**	Year of evaluation:	**2011**

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI
minimum - maximum
3 23

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
22,9	DE child	13,3	Apples	1,4	Milk and cream,	1,4	Table grapes	
16,6	NL child	7,0	Apples	2,9	Milk and cream,	1,2	Potatoes	
13,5	WHO Cluster diet B	3,4	Tomatoes	2,0	Wine grapes	1,9	Wheat	
11,5	FR toddler	4,0	Milk and cream,	2,9	Apples	1,1	Strawberries	
8,6	UK Infant	3,9	Milk and cream,	1,7	Apples	0,7	Potatoes	
8,4	DK child	2,6	Apples	1,3	Milk and cream,	1,2	Wheat	
8,4	PT General population	2,7	Wine grapes	1,2	Apples	1,1	Potatoes	
8,0	FR infant	2,8	Apples	2,6	Milk and cream,	0,8	Strawberries	
7,9	IE adult	1,4	Wine grapes	0,9	Apples	0,6	Pears	
7,8	FR all population	4,4	Wine grapes	0,7	Wheat	0,5	Apples	
7,6	WHO cluster diet E	1,8	Wine grapes	0,9	Apples	0,9	Wheat	
7,3	UK Toddler	2,1	Milk and cream,	1,9	Apples	0,9	Wheat	
7,3	ES child	1,3	Apples	1,3	Milk and cream,	1,1	Tomatoes	
6,7	WHO regional European diet	1,2	Tomatoes	0,8	Potatoes	0,7	Apples	
6,6	WHO cluster diet D	1,4	Wheat	1,1	Tomatoes	0,8	Potatoes	
6,2	SE general population 90th percentile	1,2	Milk and cream,	1,2	Apples	0,8	Tomatoes	
6,1	WHO Cluster diet F	0,8	Wheat	0,7	Tomatoes	0,7	Apples	
5,8	IT kids/toddler	1,6	Tomatoes	1,4	Wheat	1,0	Apples	
5,8	NL general	1,3	Apples	0,7	Wine grapes	0,7	Milk and cream,	
5,2	ES adult	0,9	Tomatoes	0,8	Apples	0,5	Wheat	
5,2	LT adult	2,1	Apples	0,7	Tomatoes	0,6	Potatoes	
5,1	PL general population	2,2	Apples	1,0	Tomatoes	0,7	Potatoes	
5,0	DK adult	1,5	Wine grapes	0,9	Apples	0,5	Milk and cream,	
4,6	IT adult	1,3	Tomatoes	0,9	Wheat	0,9	Apples	
3,9	UK vegetarian	0,9	Wine grapes	0,7	Tomatoes	0,7	Apples	
3,5	UK Adult	1,2	Wine grapes	0,5	Tomatoes	0,5	Apples	
2,7	FI adult	0,6	Milk and cream,	0,5	Tomatoes	0,4	Apples	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of chlorpyrifos-methyl is unlikely to present a public health concern.

Table 2.7.9.1-4: Chlorpyrifos-methyl: Representative uses (DAS) – *Theoretical Maximum Daily Intake Calculation (PRIMo version 2)* (refinement based on scenario 2, EFSA 2011)

Scenario 2

Chlorpyrifos-methyl

Status of the active substance:	**included**	Code no.	
LOQ (mg/kg bw):	0,01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,01**	ARfD (mg/kg bw):	**0,1**
Source of ADI:	**efsa**	Source of ARfD:	**efsa**
Year of evaluation:	**2011**	Year of evaluation:	**2011**

Prepare workbook for refined calculations

Undo refined calculations

The calculation is based on the detailed food consumption data available for processed cereal grain, taking into account the processing factors based on the information reported in the ER (Spain, 2010) and the JMPR report (FAO, 2009b).
The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum: 5 – 111

No of diets exceeding ADI: 1

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
110,5	DK child	69,6	Rye and rye products	21,2	Wheat and wheat products	13,2	Oats and oat products	1,4
69,2	UK Infant	52,8	Wheat and wheat products	8,5	Oats and oat products	3,9	Milk and cream,	4,1
63,9	DE child	21,4	Wheat and wheat products	13,3	Apples	12,5	Rye and rye products	1,7
50,1	WHO Cluster diet B	37,5	Wheat and wheat products	3,4	Tomatoes	1,4	Wine grapes	0,8
49,2	NL child	24,7	Wheat and wheat products	7,0	Apples	3,6	Oats and oat products	3,2
45,3	WHO cluster diet D	26,3	Wheat and wheat products	6,4	Rye and rye products	2,6	Barley and barley products	0,7
45,3	WHO Cluster diet F	15,4	Wheat and wheat products	12,0	Rye and rye products	8,0	Barley and barley products	0,6
42,9	IE adult	13,3	Oats and oat products	12,0	Wheat and wheat products	6,1	Buckwheat	0,7
36,9	LT adult	17,0	Rye and rye products	5,5	Wheat and wheat products	4,7	Buckwheat	0,5
34,5	WHO cluster diet E	16,3	Wheat and wheat products	6,8	Rye and rye products	3,2	Oats and oat products	0,6
33,9	WHO regional European diet	15,5	Wheat and wheat products	11,1	Barley and barley products	1,2	Tomatoes	0,8
33,5	IT kids/toddler	20,8	Wheat and wheat products	7,9	Other cereal and its products	1,6	Tomatoes	0,0
31,3	PT General population	20,4	Wheat and wheat products	2,2	Rye and rye products	1,9	Wine grapes	0,0
30,8	NL general	12,5	Barley and barley products	10,8	Wheat and wheat products	1,3	Apples	0,8
27,8	UK Toddler	19,2	Wheat and wheat products	2,1	Milk and cream,	1,9	Apples	2,2
27,4	DK adult	10,7	Rye and rye products	8,8	Wheat and wheat products	3,8	Oats and oat products	0,6
26,8	SE general population 90th percentile	16,7	Wheat and wheat products	4,6	Rye and rye products	1,2	Milk and cream,	1,3
24,5	FR toddler	13,7	Wheat and wheat products	4,0	Milk and cream,	2,9	Apples	4,3
23,1	FR all population	17,1	Wheat and wheat products	3,1	Wine grapes	0,5	Apples	0,4
22,3	UK vegetarian	16,6	Wheat and wheat products	1,6	Oats and oat products	0,7	Tomatoes	0,4
21,8	FI adult	10,7	Rye and rye products	5,1	Wheat and wheat products	2,9	Oats and oat products	0,6
19,7	IT adult	11,9	Wheat and wheat products	3,7	Other cereal and its products	1,3	Tomatoes	0,0
18,5	ES child	12,1	Wheat and wheat products	1,3	Apples	1,3	Milk and cream,	1,7
13,4	UK Adult	9,1	Wheat and wheat products	0,9	Barley and barley products	0,8	Wine grapes	0,3
12,2	FR infant	4,4	Wheat and wheat products	2,8	Apples	2,6	Milk and cream,	2,7
10,8	ES adult	6,3	Wheat and wheat products	0,9	Tomatoes	0,8	Apples	0,7
5,1	PL general population	2,2	Apples	1,0	Tomatoes	0,7	Potatoes	0,0

Conclusion:
The estimated Theoretical Maximum Daily Intakes based on MS and WHO diets and pTMRLs were in the range of 5,1 % to 111 % of the ADI.
For 1 diets the ADI is exceeded. Further refinements of the dietary intake estimates have not been performed. A public health risk can not be excluded at the moment.

Table 2.7.9.1-5: Chlorpyrifos-methyl: Representative uses (DAS) – *Theoretical Maximum Daily Intake Calculation (PRIMo version 2)* (refinement based on scenario 3, EFSA 2011)

Chlorpyrifos-methyl

Status of the active substance:	**included**	Code no.	
LOQ (mg/kg bw):	0,01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,01**	ARfD (mg/kg bw):	**0,1**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2011**	Year of evaluation:	**2011**

The calculation is based on the detailed food consumption data for processed cereal grains, taking into account the processing factors based on the information reported in the ER (Spain, 2010) and the JMPR report . (FAO, 2009b). Refer also to refinement scenario 3 in EFSA Journal 2011:9 (6): 2219).

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
5	82
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
82,4	DK child	45,7	Rye and rye products	21,5	Wheat and wheat products	8,7	Oats and oat products	1,4
67,0	UK Infant	53,5	Wheat and wheat products	5,6	Oats and oat products	3,9	Milk and cream,	4,1
56,4	DE child	21,7	Wheat and wheat products	13,3	Apples	8,2	Rye and rye products	1,7
48,8	WHO Cluster diet B	38,0	Wheat and wheat products	3,4	Tomatoes	1,1	Apples	0,8
45,3	NL child	25,0	Wheat and wheat products	7,0	Apples	2,9	Milk and cream,	3,2
38,9	WHO cluster diet D	26,7	Wheat and wheat products	4,2	Rye and rye products	1,7	Barley and barley products	0,7
36,4	WHO Cluster diet F	15,6	Wheat and wheat products	7,9	Rye and rye products	5,3	Barley and barley products	0,6
33,7	IT kids/toddler	21,1	Wheat and wheat products	7,9	Other cereal and their products	1,6	Tomatoes	0,0
29,8	IE adult	12,1	Wheat and wheat products	8,8	Oats and oat products	1,7	Barley and barley products	0,7
29,7	WHO regional European diet	15,7	Wheat and wheat products	7,3	Barley and barley products	1,2	Tomatoes	0,8
29,0	WHO cluster diet E	16,5	Wheat and wheat products	4,4	Rye and rye products	2,1	Oats and oat products	0,6
28,4	PT General population	20,7	Wheat and wheat products	1,4	Rye and rye products	1,2	Apples	0,0
27,3	UK Toddler	19,4	Wheat and wheat products	2,1	Milk and cream,	1,9	Apples	2,2
25,4	SE general population 90th percentile	16,9	Wheat and wheat products	3,1	Rye and rye products	1,2	Milk and cream,	1,3
25,2	NL general	10,9	Wheat and wheat products	8,2	Barley and barley products	1,3	Apples	0,8
24,8	LT adult	11,1	Rye and rye products	5,6	Wheat and wheat products	2,1	Apples	0,5
24,7	FR toddler	13,8	Wheat and wheat products	4,0	Milk and cream,	2,9	Apples	4,3
21,5	DK adult	9,0	Wheat and wheat products	7,0	Rye and rye products	2,5	Oats and oat products	0,6
21,1	UK vegetarian	16,9	Wheat and wheat products	1,1	Oats and oat products	0,7	Tomatoes	0,4
20,4	FR all population	17,4	Wheat and wheat products	0,5	Apples	0,5	Tomatoes	0,4
19,8	IT adult	12,1	Wheat and wheat products	3,7	Other cereal and their products	1,3	Tomatoes	0,0
18,6	ES child	12,3	Wheat and wheat products	1,3	Apples	1,3	Milk and cream,	1,7
16,7	FI adult	7,1	Rye and rye products	5,2	Wheat and wheat products	1,9	Oats and oat products	0,6
12,3	FR infant	4,4	Wheat and wheat products	2,8	Apples	2,6	Milk and cream,	2,7
12,2	UK Adult	9,2	Wheat and wheat products	0,6	Barley and barley products	0,5	Tomatoes	0,3
10,5	ES adult	6,3	Wheat and wheat products	0,9	Tomatoes	0,8	Apples	0,7
5,1	PL general population	2,2	Apples	1,0	Tomatoes	0,7	Potatoes	0,0

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Chlorpyrifos-methyl is unlikely to present a public health concern.

SCENARIO 3 - Refined intake for cereals

The calculation is based on the detailed food consumption data for processed cereals, taking into account the processing factors based on the information reported in the ER (Spain, 2010) and the JMPR report (FAO, 2009b).

level	Code no.	Groups of crops and examples of individual products within the groups to which the MRLs apply	STMR (mg/kg)	input values for refined calculations	PF	Description PF	DK adult	ES adult	FI adult	FR all population	IE adult	IT adult	LT adult	NL general	PL general population	PT General population	SE general population 90th percentile	UK Adult	UK vegetarian	WHO regional European diet	WHO Cluster diet B	WHO cluster European D	WHO cluster diet E	WHO Cluster diet F	DE child	DK child	ES child	FR infant	FR toddler	IT kids/toddler	NL child	UK Toddler	UK Infant
							daily intake (% of ADI)																										
1	500000	CEREALS																															
4	500010	Barley	2.20																														
		Barley from breakfast cereals		2.20	1.000	Barley pearl					1.4300																						
		Barley from lager		0.00	0.001	Barley - beer		0.0108			0.0909																						
		Barley from stout		0.00	0.001	Barley - beer					0.1642																						
		Barley from malt		0.00	0.001	Barley - beer					0.0056																						
		Pot barley		2.20	1.00	Barley pearl																1.4667	0.7333	4.5833									
		Barley, pearled		2.20	1.00	Barley pearl															0.1467	0.1467	0.1467	0.3300									
		Barley flour and grits		2.20	1.00	Barley pearl															0.1100	0.1100	0.1833	0.3300									
		Barley beer		0.00	0.001	Barley - beer															0.0062	0.0048	0.0178	0.0118									
		Barley grain		2.20	1.00	Barley pearl																								0.0370			
		Other barley products		2.20	1.00	Barley pearl			0.5181	0.1467		0.2051	1.3169	8.2413		0.6600		0.5789	0.4288	7.2600					0.2724		0.0462			0.1956	0.5661	0.3014	
4	500020	Buckwheat	2.20	2.20	1.00				0.0273		6.1144		4.6986	0.2444							0.0367	0.5867	0.5500	0.0367	0.1362						1.1322		
4	500030	Maize	0.02	0.02	1.00			0.0165	0.0052		0.4590	0.0036	0.0015	0.0095	0.0002	0.0950		0.0005	0.0016	0.0293	0.4947	0.1060	0.1110	0.0250	0.0297		0.0575			0.0053	0.0292	0.0024	0.2052
4	500040	Millet	2.20	2.20	1.00									0.0279								2.0533	0.0733		0.4087						0.5275		
4	500050	Oats	2.20																														
		Oats in porredge		2.20	1.00	Rolled oats					3.8940																						
		Oats from breakfast cereal		2.20	1.00	Rolled oats					4.6860																						
		Oats from oatscakes		0.11	0.05	Wheat white bread					0.1738																						
		Oats rolled		2.20	1.00	Rolled oats															0.1100	0.8067	1.1000	1.7233									
		Other oats products		2.20	1.00	Rolled oats	2.5270		1.8744			0.0033	1.9957	0.6949		0.6600		0.3763	1.0555	0.7333	0.0733	0.7333	0.9900	1.5400	4.4954	8.7000				0.0106	2.3544	1.0548	5.5632
4	500060	Rice	2.20	2.20	1.00		1.9027	5.3218	2.3980	2.4933	3.7447	3.9363	4.7080	3.5200		17.2700	8.8367	8.0474	8.4108	4.3267	11.5867	12.1733	4.6200	4.6200	5.8576	2.3000	10.6282	2.0000	7.8868	4.2298	7.7579	12.6575	13.9080
4	500070	Rye	2.20	1.03	0.47	whole meal bread (wheat)	7.0424		7.0596		1.5125		11.1332	0.7238		1.4131	3.0503	0.0680	0.2015	0.2585	0.6376	4.1877	4.4462	7.8929	8.1952	45.6840					1.8503	0.0708	
4	500080	Sorghum	2.20	2.20	1.00									0.0349											0.4087						0.1287		
4	500090	Wheat	2.20																														
		White bread		0.11	0.05	Wheat white bread	0.728378	1.3596										0.9987	1.0131							1.9000	2.4456					2.4034	1.2391
		Whole meal bread		1.03	0.47	Wheat wholemeal bread	2.235676	0.8184										2.0680	9.5231							4.7000	0.2999					15.7933	8.4384
		Pasta		0.53	0.24	Wheat flour	0.998919	1.3054																		4.0800	2.7074						
		Cakes including cookies		0.53	0.24	Wheat flour	2.782703	1.8944																		7.9200	4.1407						
		Flour as ingredient		0.53	0.24	Wheat flour		0.2699			1.4362																0.4808						
		Flour from biscuits		0.53	0.24	Wheat flour					0.7181																						
		Flour from bread		0.53	0.24	Wheat flour					5.1691																						
		Flour from breakfast cereal		0.53	0.24	Wheat flour					1.0613																1.3077						
		Flour from cakes and buns		0.53	0.24	Wheat flour					0.6864																						
		Flour from pastry and pastry pies		0.53	0.24	Wheat flour					0.7075																						
		Flour from pasta and noodels		0.53	0.24	Wheat flour					0.8395																						
		Flour from pizza		0.53	0.24	Wheat flour					0.7445																						
		Flour from packet/jarred sauce/soups etc		0.53	0.24	Wheat flour					0.1267																						
		Flour from crumb(batter coating		0.53	0.24	Wheat flour					0.4013																						
		Wheat bran		5.61	2.55	Wheat Bran												3.4693	5.7783													1.2398	43.8483
		Cereals - sweet products		0.53	0.24	Wheat flour						3.5412																		7.6281			
		Bread/pizza (with veg, with other		0.11	0.05	Wheat white bread						2.5632																		3.5438			
		Bread substitute		0.11	0.05	Wheat white bread																								0.1761			
		Pasta (durum whet, egg noodles, filled)		0.53	0.24	Wheat flour						5.8112																		9.7858			
		Churros		0.53	0.24	Wheat flour		0.1056																			0.1929						
		Bread roll		0.11	0.05	Wheat white bread		0.3397																			0.7022						
		Triticale flour		0.53	0.24	Wheat flour															7.8408		0.0176										
		Wheat bulgur wholemeal		2.31	1.05	Wheat wholemeal flour															3.9270	0.0770	0.0385										
		Wheat flour		0.53	0.24	Wheat flour															26.0744	26.4000	15.9808	14.6256									
		Wheat macaroni		0.53	0.24	Wheat flour															0.0968	0.1584	0.4048	0.6688									
		Wheat pastry		0.11	0.05	Wheat white bread															0.0202	0.0477	0.0312	0.0990									
		White bread		0.11	0.05	Wheat white bread															0.0018	0.0018	0.0018	0.0183									
		Whole meal bread		1.03	0.47	Wheat wholemeal bread															0.0172	0.0172	0.0172	0.1723									
		Wheat germ																															
		Other wheat products (not specified)		0.53	0.24	Wheat flour	2.2119	0.2471	5.1960	17.3624	0.2282	0.1793	5.5538	10.9455		20.6888	16.9048	2.6747	0.5437	15.6640					21.7085	2.9040		4.4400	13.8475		25.0352		
4	500990	Other cereal	2.20	0.53	0.24	Wheat flour						3.7335																		7.9308			
					-																												
1		TMDI (%of ADI)					20.430	11.689	17.079	20.002	34.394	19.977	29.408	24.442	0.000	40.787	28.792	18.282	26.956	28.272	51.180	49.077	29.464	36.677	41.512	78.188	23.009	6.440	21.734	33.543	39.381	33.523	73.202

Table 2.7.9.1-6: Chlorpyrifos-methyl: Representative uses (DAS) – International/National Estimated Short Term Intake Calculation (PRIMo version

Acute risk assessment /children - refined calculations	Acute risk assessment / adults / general population - refined calculations

The acute risk assessment is based on the ARfD.

For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1):		**---**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		**---**	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		**---**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		**---**
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	**)**
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
72,2	Wheat	5 / -	72,2	Wheat	5 / -	39,1	Wheat	5 / -	39,1	Wheat	5 / -
69,3	Peppers	1,1 / -	49,5	Peppers	1,1 / -	36,2	Barley	5 / -	36,2	Barley	5 / -
31,6	Rye	5 / -	31,6	Rye	5 / -	24,3	Rye	5 / -	24,3	Rye	5 / -
24,2	Table grapes	0,37 / -	24,2	Table grapes	0,37 / -	18,0	Peppers	1,1 / -	12,8	Peppers	1,1 / -
19,9	Oats	5 / -	19,9	Oats	5 / -	11,7	Table grapes	0,37 / -	11,7	Table grapes	0,37 / -
19,6	Apples	0,2 / -	14,9	Apricots	0,6 / -	7,1	Oats	5 / -	7,1	Oats	5 / -
2,0	Wine grapes	0,26 / -	2,0	Wine grapes	0,26 / -	1,4	Strawberries	0,27 / -	1,3	Quinces	0,2 / -
0,4	Swine: Meat	0,05 / -	0,4	Swine: Meat	0,05 / -	0,3	Swine: Meat	0,05 / -	0,3	Swine: Meat	0,05 / -
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

No of commodities for which ARfD/ADI is exceeded:		**---**	**No of commodities for which ARfD/ADI is exceeded:**		**---**
		****)**			****)**
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
10,0	Wheat flour	0,85 / -	7,8	Bread/pizza	1,77 / -
1,3	Grape juice	0,04 / -	0,1	Quince jelly	0,11 / -
0,3	Apple juice	0,0066 / -	0,1	Raisins	0,27 / -

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
**) pTMRL: provisional temporary MRL
***) pTMRL: provisional temporary MRL for unprocessed commodity

Conclusion:

For Chlorpyrifos-methyl IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

SAP

Table 2.7.9.1-7: Chlorpyrifos-methyl – Endpoints used for dietary exposure calculations

	Source	Year	Values	Study relied upon	Safety factor
Chlorpyrifos-methyl					
ADI	EC	2005	0.01 mg/kg bw/d	Rat, 2 year study	100
ARfD	EC	2005	0.1 mg/kg bw	Rat, acute and delayed neurotoxicity studies	

TMDI calculations- chronic risk assessment

The calculation of the chronic risk assessment has been performed using the EFSA PRIMo model rev. 2 and taking into account the crops to which chlorpyrifos-methyl can be applied (representative uses).

In order to do this assessment, calculated HR values for grapes and oilseed rape, according to residue trials submitted, have been used (as a worst scenario). Input data used in the assessment are included in table 2.7.9.1-8.

Table 2.7.9.1-8 Input values for the chronic risk assessment of chlorpyrifos methyl

Commodity	Chronic risk assessment	
	Input value (mg/kg)	**Comment**
Risk assessment residue definition: chlorpyrifos-methyl+TCP and its conjugates, expressed as chlorpyrifos-methyl; *Post harvest (grains):chlorpyrifos-methyl + desmethyl chlorpyrifos-methyl, expressed as chlorpyrifos-methyl.*		
Table grapes	0.11	HR
Wine grapes	0.0154 (0.11x0.2[1]x0.7[2])	HRxPF[1]xYF[2]
Oilseed rape	0.01	HR

[1] Processing factor established by EFSA, 2011.
[2] Yield factor from grapes to wine.

Based on the HR values, the contribution of grapes and oilseed rape to the TMDI have also been calculated. For wine grapes processing and yield factors have been applied. Results are shown in table 2.7.9.1-9 and 2.7.9.1-11

Table 2.7.9.1-9 Contribution of grapes and oilseed rape to the TMDI calculated using the EFSA PRIMo v.2 model. Please also refer to table 2.7.9.1-11

Commodities	HR [mg/kg]	% of TMDI (maximum value)
Table grapes	0.11	1.4
Wine grapes	0.0154 (0.11x0.2[1]x0.7[2])	0.6
Oilseed rape	0.01	0.001

[1] Processing factor established by EFSA, 2011.
[2] Yield factor from grapes to wine.

NESTI calculations - acute risk assessment

The acute risk assessment is based on the ARfD. The values for EU population groups have been calculated using the EFSA Excel calculations sheet (rev.2)[1] applying the HRs for table (0.11 mg/kg) and wine grapes (0.0154 mg/kg, calculated applying both processing and yield factors) and oilseed rape (0.01 mg/kg). The results demonstrate that the acute exposure of EU population groups from plant products is below the ARfD of 0.1 mg/kg bw (table 2.7.9.1-10 and table 2.7.9.1-12). They indicate that no unacceptable short-term exposure of children or adults from residues on these crops is to be expected.

Table 2.7.9.1-10 Acute risk assessment calculations for application of chlorpyrifos-methyl.

Children	**IESTI 1**	**IESTI 2**
Commodities	**% of ARfD**	**% of ARfD**
Table grapes	7.2	7.2
Wine grapes	0.1	0.1
Oilseed rape	0.01	0.01

Adults	**IESTI 1**	**IESTI 2**
Commodities	**% of ARfD**	**% of ARfD**
Table grapes	3.5	3.5
Wine grapes	0.4	0.4
Oilseed rape	-	-

Applying the highest measured residue values from residue trials, IESTI-calculations demonstrate that an unacceptable short-term exposure for small children or adults eating grapes and oilseed rape which would contain the active ingredient is unlikely.

2.7.9.1-11 EFSA-PRIMO v.2 chronic exposure consumer risk assessment for chlorpyrifos-methyl based on HR values from intended GAP (SAP)

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities
1.4	DE child	1.4	Table grapes	0.00095	Rape seed		FRUIT (FRESH OR FROZEN)
0.8	NL child	0.8	Table grapes	0.0	Rape seed	0.0	Wine grapes
0.7	FR all population	0.6	Wine grapes	0.1	Table grapes	0.0	Rape seed
0.7	PT General population	0.4	Wine grapes	0.3	Table grapes		FRUIT (FRESH OR FROZEN)
0.7	WHO Cluster diet B	0.4	Table grapes	0.3	Wine grapes	0.0	Rape seed
0.5	WHO cluster diet E	0.2	Wine grapes	0.2	Table grapes	0.1	Rape seed
0.5	IE adult	0.3	Table grapes	0.2	Wine grapes		FRUIT (FRESH OR FROZEN)
0.4	PL general population	0.4	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)
0.3	NL general	0.3	Table grapes	0.1	Wine grapes	0.0	Rape seed
0.3	DK adult	0.2	Wine grapes	0.1	Table grapes	0.0	Rape seed
0.3	UK Toddler	0.3	Table grapes	0.0	Wine grapes		FRUIT (FRESH OR FROZEN)
0.3	WHO cluster diet D	0.2	Table grapes	0.1	Wine grapes	0.0	Rape seed
0.3	WHO Cluster diet F	0.1	Table grapes	0.1	Wine grapes	0.0	Rape seed
0.2	FR toddler	0.2	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)
0.2	WHO regional European diet	0.2	Table grapes	0.0	Wine grapes	0.0	Rape seed
0.2	UK Adult	0.2	Wine grapes	0.1	Table grapes		FRUIT (FRESH OR FROZEN)
0.2	UK vegetarian	0.1	Wine grapes	0.1	Table grapes		FRUIT (FRESH OR FROZEN)
0.2	DK child	0.2	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)
0.1	IT adult	0.1	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)
0.1	IT kids/toddler	0.1	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)
0.1	ES adult	0.1	Wine grapes	0.0	Table grapes		FRUIT (FRESH OR FROZEN)
0.1	FR infant	0.1	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)
0.1	FI adult	0.0	Wine grapes	0.0	Table grapes		FRUIT (FRESH OR FROZEN)
0.0	ES child	0.0	Table grapes	0.0	Wine grapes		FRUIT (FRESH OR FROZEN)
0.0	UK Infant	0.0	Table grapes	0.0	Wine grapes		FRUIT (FRESH OR FROZEN)
0.0	LT adult	0.0	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)

2.7.9.1-12 Acute risk assessment for consumers (NESTI calculations) (SAP)

Acute risk assessment /children - refined calculations | **Acute risk assessment / adults / general population - refined calculations**

The acute risk assessment is based on the ARfD.

For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.

Children

No of commodities for which ARfD/ADI is exceeded (IESTI 1):		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
7.2	Table grapes	0.11 / -	7.2	Table grapes	0.11 / -
0.1	Wine grapes	0.0154 / -	0.1	Wine grapes	0.0154 / -
0.0	Rape seed	0.01 / -	0.0	Rape seed	0.01 / -
No of critical MRLs (IESTI 1)			---		

Adults / general population

No of commodities for which ARfD/ADI is exceeded (IESTI 1):		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
3.5	Table grapes	0.11 / -	3.5	Table grapes	0.11 / -
0.4	Wine grapes	0.0154 / -	0.4	Wine grapes	0.0154 / -
No of critical MRLs (IESTI 2)			---		

Processed commodities – children

No of commodities for which ARfD/ADI is exceeded:		---
		*****)**
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
0.5	Grape juice	0.0154 / -
0.0	Wine	0.0154 / -
0.0	Grapes (raisins)	0.0154 / -

Processed commodities – adults / general population

No of commodities for which ARfD/ADI is exceeded:		---
		*****)**
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
0.1	Wine	0.0154 / -
0.0	Raisins	0.0154 / -

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
**) pTMRL: provisional temporary MRL
***) pTMRL: provisional temporary MRL for unprocessed commodity

Conclusion:

For Chlorpyrifos-methyl IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

2.7.9.2: Representative uses + MRL Applications

(DAS)

Table 2.7.9.2-1: Summary of the endpoints used in the dietary exposure calculations

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: chlorpyrifos-methyl +TCP and its conjugates, expressed as chlorpyrifos-methyl; post-harvest (grains): chlorpyrifos-methyl+ desmethyl chlorpyrifos-methyl, expressed as chlorpyrifos-methyl				
Pomegranate	0.014 (0.29 *0.05)	Median residue*PF (peeling factor)	0.038 (0.77*0.05)	HR RA*PF (peeling factor)
Persimmon	0.61	Median residue RA	0.71	HR RA
Banana pulp	0.007 (0.11*0.06)	Median residue RA*PF	0.014 (0.24*0.06)	HR RA*PF
Lettuce	0.37	Median residue RA	0.62	HR RA
Head Cabbage	0.03	Median residue RA	0.27	HR RA
Cauliflower	0.11	Median residue RA	0.64	HR RA
Broccoli	0.11	Median residue RA	0.64	HR RA
Brussels sprouts	0.24	Median residue RA	0.7	HR RA
Globe artichokes	0.05	Median residue RA	0.12	HR RA
Asparagus	0.003	Median residue RA	0.003	HR RA
Raspberries	0.11	Median residue RA	0.25	HR RA
Raspberry juice	0.106 (0.11*0.97)	Median residue*PF (STMR-p)	0.106 (0.11*0.97)	Median residue*PF (STMR-p)
Sugar beet roots	0.02	Median residue RA	0.07	HR RA

Chronic Dietary Exposure Calculations

For the calculation of the Theoretical Maximum Daily Intake (TMDI) from the representative uses + MRL applications, the EFSA Pesticide Residue Intake Model version 2 (PRIMo) and the input values given in Table 2.7.9.1-2 have been used (except for cereals, for which the refinement according to the Scenario 3 proposed by EFSA was used), along with input data include in table above (table 2.7.9.2-1).

In this scenario 3, results indicate that the estimated TMDI were below 100% of ADI for all diets The total calculated intake values ranged from 5.4% to 83.1% of the ADI for DK child, being the main contributor rye and rye products (Table 2.7.9.2-2).

Acute Dietary Exposure Calculations

The International/National Estimated Short-Term Intakes (I/NESTIs) for chlorpyrifos-methyl have been calculated using the EFSA PRIMo (version 2), only for commodities included in this Dossier as MRL applications. The values entered are shown in table 2.7.9.2-1. Calculation of the International/National Estimated Short Term Intake (NESTI) showed the highest acute intakes, 42.3% and 37.3% of the ARfD for cauliflower and broccoli, respectively (table 2.7.9.2-3).

The results indicate that there is no unacceptable acute risk to human health from the consumption of commodities treated with chlorpyrifos-methyl according to the uses considered.

Table 2.7.9.2-2: Chlorpyrifos-methyl: Representative uses+MRL applications– ***Theoretical Maximum Daily Intake Calculation (PRIMo version 2)*** **(refinement based on scenario 3, EFSA 2011)**

Chlorpyrifos-methyl

Status of the active substance:	**included**	Code no.	
LOQ (mg/kg bw):	0,01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,01**	ARfD (mg/kg bw):	**0,1**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2011**	Year of evaluation:	**2011**

The calculation is based on the detailed food consumption data for processed cereal grains, taking into account the processing factors based on the information reported in the ER (Spain, 2010) and the JMPR report . (FAO, 2009b). Refer also to refinement scenario 3 in EFSA Journal 2011:9 (6): 2219).

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum: 5 – 83

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
83,1	DK child	45,7	Rye and rye products	21,5	Wheat and wheat products	8,7	Oats and oat products	1,4
69,9	UK Infant	53,5	Wheat and wheat products	5,6	Oats and oat products	3,9	Milk and cream,	4,2
57,3	DE child	21,7	Wheat and wheat products	13,3	Apples	8,2	Rye and rye products	1,8
50,7	WHO Cluster diet B	38,0	Wheat and wheat products	3,4	Tomatoes	1,3	Lettuce	0,9
46,9	NL child	25,0	Wheat and wheat products	7,0	Apples	2,9	Milk and cream,	3,3
39,2	WHO cluster diet D	26,7	Wheat and wheat products	4,2	Rye and rye products	1,7	Barley and barley products	0,7
37,8	WHO Cluster diet F	15,6	Wheat and wheat products	7,9	Rye and rye products	5,3	Barley and barley products	0,6
34,9	IT kids/toddler	21,1	Wheat and wheat products	7,9	Other cereal and their products	1,6	Tomatoes	0,0
32,4	UK Toddler	19,4	Wheat and wheat products	4,6	Sugar beet (root)	2,1	Milk and cream,	2,2
31,7	WHO regional European diet	15,7	Wheat and wheat products	7,3	Barley and barley products	1,4	Lettuce	0,8
31,1	IE adult	12,1	Wheat and wheat products	8,8	Oats and oat products	1,7	Barley and barley products	0,7
29,6	WHO cluster diet E	16,5	Wheat and wheat products	4,4	Rye and rye products	2,1	Oats and oat products	0,6
28,4	PT General population	20,7	Wheat and wheat products	1,4	Rye and rye products	1,2	Apples	0,1
26,3	NL general	10,9	Wheat and wheat products	8,2	Barley and barley products	1,3	Apples	0,8
26,0	SE general population 90th percentile	16,9	Wheat and wheat products	3,1	Rye and rye products	1,2	Milk and cream,	1,5
25,8	FR toddler	13,8	Wheat and wheat products	4,0	Milk and cream,	2,9	Apples	4,4
25,1	LT adult	11,1	Rye and rye products	5,6	Wheat and wheat products	2,1	Apples	0,5
22,7	UK vegetarian	16,9	Wheat and wheat products	1,1	Oats and oat products	0,8	Sugar beet (root)	0,4
21,6	DK adult	9,0	Wheat and wheat products	7,0	Rye and rye products	2,5	Oats and oat products	0,7
21,3	IT adult	12,1	Wheat and wheat products	3,7	Other cereal and their products	1,4	Lettuce	0,0
21,0	FR all population	17,4	Wheat and wheat products	0,5	Apples	0,5	Tomatoes	0,4
20,4	ES child	12,3	Wheat and wheat products	1,5	Lettuce	1,3	Apples	1,7
17,1	FI adult	7,1	Rye and rye products	5,2	Wheat and wheat products	1,9	Oats and oat products	0,6
13,7	UK Adult	9,2	Wheat and wheat products	0,8	Sugar beet (root)	0,6	Barley and barley products	0,4
12,8	FR infant	4,4	Wheat and wheat products	2,8	Apples	2,6	Milk and cream,	2,8
12,7	ES adult	6,3	Wheat and wheat products	2,0	Lettuce	0,9	Tomatoes	0,7
5,4	PL general population	2,2	Apples	1,0	Tomatoes	0,7	Potatoes	0,0

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.

A long-term intake of residues of Chlorpyrifos-methyl is unlikely to present a public health concern.

Table 2.7.9.2-3: Chlorpyrifos-methyl: Representative uses + MRL application (DAS) – International/National Estimated Short Term Intake Calculation (PRIMo version

Acute risk assessment /children - refined calculations | **Acute risk assessment / adults / general population - refined calculations**

The acute risk assessment is based on the ARfD.

For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities – children

No of commodities for which ARfD/ADI is exceeded (IESTI 1):		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
42,3	Cauliflower	0,64 / -	42,3	Cauliflower	0,64 / -
37,3	Broccoli	0,64 / -	26,6	Broccoli	0,64 / -
28,3	Persimmon	0,71 / -	20,2	Persimmon	0,71 / -
16,7	Lettuce	0,62 / -	10,0	Lettuce	0,62 / -
14,2	Head cabbage	0,27 / -	8,5	Head cabbage	0,27 / -
6,1	Brussels sprouts	0,7 / -	6,1	Brussels sprouts	0,7 / -
No of critical MRLs (IESTI 1)			---		

Unprocessed commodities – adults / general population

No of commodities for which ARfD/ADI is exceeded (IESTI 1):		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
20,3	Cauliflower	0,64 / -	20,3	Cauliflower	0,64 / -
13,6	Broccoli	0,64 / -	13,6	Broccoli	0,64 / -
10,1	Persimmon	0,71 / -	7,3	Persimmon	0,71 / -
8,6	Head cabbage	0,27 / -	5,1	Head cabbage	0,27 / -
6,8	Lettuce	0,62 / -	4,1	Lettuce	0,62 / -
3,6	Brussels sprouts	0,7 / -	3,6	Brussels sprouts	0,7 / -
No of critical MRLs (IESTI 2)			---		

Processed commodities

No of commodities for which ARfD/ADI is exceeded: (children)		---	**No of commodities for which ARfD/ADI is exceeded:** (adults)		---
		*****)**			*****)**
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
1,3	Raspberries juice	0,11 / -	7,8	Bread/pizza	1,77 / -
			0,1	Quince jelly	0,11 / -
			0,1	Raisins	0,27 / -

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
**) pTMRL: provisional temporary MRL
***) pTMRL: provisional temporary MRL for unprocessed commodity

Conclusion:

For Chlorpyrifos-methyl IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

2.7.10. Proposed MRLs and compliance with existing MRLs

2.7.10.1: Representative uses

(DAS)

Code	Commodity/Group	MRL (mg/kg) and Comments	MRL according Reg. EU No 149/2008
Plant commodities			
Representative uses			
110010	Grapefruit	0.5 Combined data set for oranges and mandarins (scaled residues obtained applying the proportionality approach)	0.05
110020	Oranges		0.5
110030	Lemons		0.3
110040	Limes		0.05
110050	Mandarins		1
130000	Apple	0.3	0.5
130020	Pear	0.04	0.5
130030	Quinces	0.3	0.5
130040	Medlar	0.3	0.5
130050	Loquat	0.3	0.5
140010	Apricots	0.04	0.05
140030	Peaches (Nectarines	0.04	0.5
140020	Cherries (sweet cherries, sour cherries)	0.01*	0.05*
140040	Plums	0.2	0.05*
151010	Table grapes	0.15	0.2
151020	Wine grapes	0.20	0.2
152000	Strawberries	0.10	0.5
211000	Potatoes	0.01*	0.05*
231010	Tomatoes	0.3	0.5
231030	Aubergines (egg plants)	0.3	0.5
231020	Peppers	0.5	0.5
401060	Rape seed	0.02	0.05*
401070	Soya bean	0.02	0.05*
401060	Cotton seed	0.04	0.05*
500000	Stored cereal grain	The proposed GAPs is sufficiently supported by data but for the intended use a potential long-term consumer risk cannot be excluded. The MRL should be maintained at 3 mg/kg.[a]	3.00
500030	Maize	0.01	3.00

[a] Regarding the highest proposed dose rate (5 mg/kg of grains), although the MRL of 5 mg/kg could not be supported, the use could be authorized if this active substance/plant product combination would be included in Annex VII of the Regulation (EC) No.396/2005, as referred to in Article 18(3) of Regulation (EC)No. 396/2005 of 23 February 2005. Moreover according to this Article 18(3), Member States should guarantee that the products are not intended for immediate consumption and appropriate controls are in place to ensure that the products will not be available to the end user or consumer, until the residues no longer exceed the established EU MRL (3 mg/kg). These measures should be informed to the other Member States and the Commission.

(SAP)

Code	**Commodity/Group**	**MRL** (mg/kg) **and Comments**	**MRL according Reg. EU No 149/2008**
Plant commodities			
Representative uses			
151010	Table grapes	0.04	0.2
151020	Wine grapes	0.04	0.2
401060	Rape seed	0.01	0.05*

Residues in grapes and MRL proposal (SAP)

Country, year	Application per treatment			Portion analysed	Residues Chlorpyrifos-methyl mg/kg			Report (Doc. No.)
	Form. type	No	g a.i./ha		BBCH at last treatment	DAT	Residues, mg/kg	
Germany, 2014	CS	1	346.8	bunches	BBCH85	14	0.022	**KCA 6.3.1/01,** TRC14-140
Germany, 2014	CS	1	333.2	bunches	BBCH85	14	0.016	
Germany, 2014	CS	1	312.8	bunches	BBCH85	14	< 0.01	
Germany, 2014	CS	1	323	bunches	BBCH85	14	0.028	
France North, 2014	CS	1	338.16	bunches	BBCH85	14	0.019	
France North, 2014	CS	1	362.75	bunches	BBCH85	14	0.012	
France North, 2014	CS	1	355.34	bunches	BBCH83	14	< 0.01	
France North, 2014	CS	1	326.65	bunches	BBCH83	14	<0.01	
France South, 2014	CS	1	337.52	bunches	BBCH85	14	<0.01	
France South, 2014	CS	1	353.58	bunches	BBCH85	14	<0.01	
Italy, 2014	CS	1	349.02	bunches	BBCH85	14	<0.01	
Italy, 2014	CS	1	338.23	bunches	BBCH83	14	<0.01	
Portugal, 2014	CS	1	340.05	bunches	BBCH81-83	14	<0.01	
Spain, 2014	CS	1	313.72	bunches	BBCH81	14	<0.01	
Spain, 2014	CS	1	333.26	bunches	BBCH83	14	<0.01	
Spain, 2014	CS	1	348.51	bunches	BBCH81-83	14	0.021	
No of trials							16	
Mean							0.014	
Standard deviation							0.006	
Correction factor for censoring							0.583	
Highest residue							0.028	
Mean + 4 STD							0.037	
CF x 3 Mean							0.024	
OECD unrounded MRL proposal							0.037	
OECD rounded MRL proposal							**0.04**	
Existing MRL							**0.2**	

Residues in rapeseed and MRL proposal (SAP)

Country, year	Application per treatment			Portion analysed	Residues Chlorpyrifos-methyl, mg/kg			Report (Doc. No.)
	Form. type	No	g a.i./ha		BBCH at last treatment	DAT	Residues, mg/kg	
Poland, 2014	CS	1	336.3	seeds	55	98	<0.003	**KCA 6.3.2/01** TRC14-062
Poland, 2014	CS	1	342	seeds	53	98	<0.003	
North France, 2014	CS	1	341.9	seeds	57	113	<0.003	
North France, 2014	CS	1	332.5	seeds	57	101	<0.003	
Italy, 2014	CS	1	347.5	seeds	57-59	90	<0.003	
South France, 2014	CS	1	346	seeds	61	104	<0.003	
Spain, 2014	CS	1	353.6	seeds	55-57	103	<0.003	
Spain, 2014	CS	1	326.4	seeds	51-53	98	<0.003	
No of trials							8	
Mean							0.010	
Standard deviation							0.000	
Correction factor for censoring							0.333	
Highest residue							0.003	
Mean + 4 STD							0.003	
CF x 3 Mean							0.003	
OECD unrounded MRL proposal							0.01	
OECD rounded MRL proposal							0.01	
Existing MRL							**0.05**	

2.7.10.2: MRL Applications

(DAS)

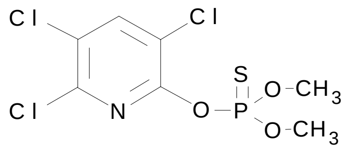
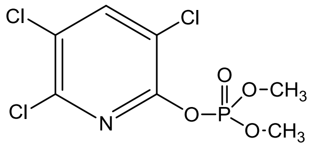
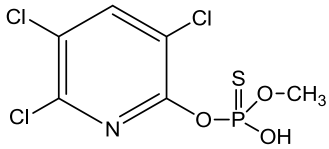
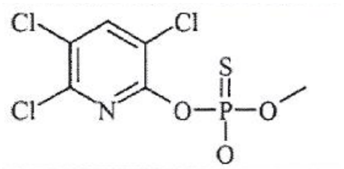
Code	**Commodity/Group**	**MRL** (mg/kg) **and Comments**	**MRL according Reg. EU No 149/2008**
MRLs application			
163050	Pomegranate	0.3	0.05*
161060	Persimmon	0.5	0.05*
163020	Banana	0.15	0.05*
251020	Lettuce	0.15	0.05*
242020	Head Cabbage	0.03	0.05*
241020	Cauliflower	0.05	0.05*
241010	Broccoli	0.05	0.05*
242010	Brussels sprouts	0.4	0.05*
270050	Globe artichokes	0.03	0.05*
270010	Asparagus	0.01*	0.05*
153030	Raspberry	0.15	0.05*
900010	Sugarbeet root	0.01	0.05*

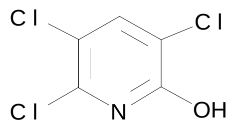
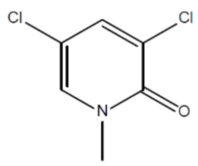
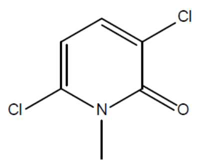
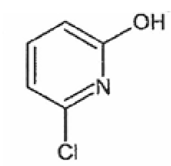
2.7.11. Proposed import tolerances and compliance with existing import tolerances

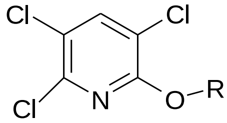
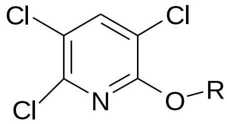
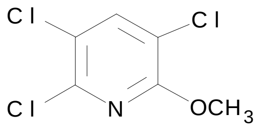
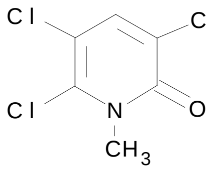
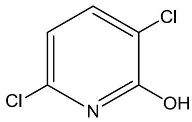
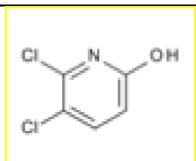
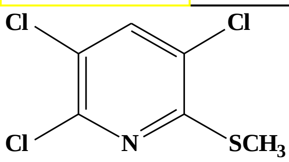
No MRLs for imported commodities are proposed in this submission.

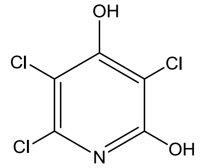
2.8. FATE AND BEHAVIOUR IN THE ENVIRONMENT

Table 2.8-1: Substances and metabolites; structures, codes, synonyms

Code Number (Synonyms)	**Description**	**Compound found in:**	**Structure**
Chlorpyrifos-methyl (E-ISO, BSI, ANSI, ESA), Chlorpyriphos-methyl, (F-ISO, JMAF) CLP-Me CLPM DOWCO 214, ENT 27 520, OMS 1155 EC 227-011-5, CAS 5598-13-0, CIPAC 486 (221.A), CODEX 090	O,O-Dimethyl-O-(3,5,6-trichloro-2-pyridyl)phosphorothioate [IUPAC] O,O-Dimethyl-O-(3,5,6-trichloro-2-pyridinyl)phosphorothioate [CAS]	Crop (Tomato) Stored grain Livestock (goat, laying hen)	 $C_7H_7Cl_3NO_3PS$
Chlorpyrifos-methyl oxon, X143491 CAS 5598-52-7	O,O-Dimethyl-O-(3,5,6-trichloro-2-pyridinyl)phosphate	Air photolysis	 $C_7H_7Cl_3NO_4P$
Des-methyl chlorpyrifos-methyl, Des-methyl Reldan (DEM)	O-methyl-O-(3,5,6-trichloro-2-pyridinyl) O-sodium phosphorothioate (O-methyl-O-(3,5,6-trichloro-2-pyridinyl) phosphorothoic acid	Metabolism of mammals Rat, Livestock (goat, laying hen) Stored grain Process hydrolysis Water: hydrolysis, water/sediment systems, mineralization	  $C_6H_5Cl_3NO_3PS$

Code Number (Synonyms)	**Description**	**Compound found in:**	**Structure**
Trichloropyridinol (TCP), (TCPy) EC 229-405-2 CAS 6515-38-4	3,5,6-trichloro-2-pyridinol [IUPAC and CAS], 3,5,6-trichloro-2-pyridone, 3,5,6-trichloro-2(1H)-pyridone, 3,5,6-trichloro-2(1H)-pyridinone, 3,5,6-trichloropyridin-2-ol	Plants metabolism: Crop (Citrus, Tomato, Cabbage, Peas, Radish, rotated crop) Stored grain Metabolism of mammals: Rat, Livestock (goat, laying hen) Fish Soil (sterile, aerobic, anaerobic, and photolysis) Water (hydrolysis, pseudo processing (high pH / temp hydrolysis), photolysis, and surface water mineralization) Water/sediment systems	 $C_5H_2Cl_3NO$
3,5-dichloro-1-methylpyridin-2(1H)-one (3,5 DCMP)	3,5-dichloro-1-methylpyridin-2(1H)-one	Soil (aerobic)	
3,6-dichloro-1-methylpyridin-2(1H)-one (3,6 DCMP)	3,6-dichloro-1-methylpyridin-2(1H)-one	Soil (aerobic)	
6-chloro-2-pyridinol (MCP) CAS No.: 6515-38-4	6-chloro-2-pyridinol	Soil (anaerobic)	 C_5H_4ClNO

Code Number (Synonyms)	**Description**	**Compound found in:**	**Structure**
*	Sugar conjugates of TCP (no chemical names were established for any of these metabolites)	Crop (Citrus, Cabbage, Tomato,Peas, Rashish)	 (Where R represents sugar conjugates (e.g., glucose and/or glucose plus other natural products).)
*	Conjugates of TCP (no chemical names were established for any of these metabolites)	Rat, Livestock (goat, laying hen) Fish	 (Where R represents conjugates (probably glucuronic acid and sulphate)
Trichloromethoxypyridine (3,5,6-trichloro-6-methoxypyridine) (TMP) CAS 31557-34-3	3,5,6-trichloro-2-methoxypyridine [IUPAC and CAS]	Crop (rotated crop) Soil (aerobic and anaerobic)	 $C_6H_4Cl_3NO$
N-methyl pyridinone, N-methyl, N-methyl-3,5,6-trichloro-2(1H)-pyridinone (MTCP), 3,5,6-trichloro-1-methylpyridin-2(1H)-one (N-methyl-TCP) X131419 CAS None	3,5,6-Trichloro-2(N-methyl)-pyridone [IUPAC] 3,5,6-Trichloro-2(N-methyl)-pyridinone [CAS]	Soil (aerobic, anaerobic, photolysis)	 $C_6H_4Cl_3NO$
3,6-dichloro-2-pyridinol (3,6-DCP)	3,6-dichloro-2-pyridinol	Soil (anaerobic) Water sediment system	 $C_5H_3Cl_2NO$
5,6-dichloropyridin-2-ol (5,6-DCP)	5,6-dichloropyridin-2-ol	Soil (anaerobic)	
2,3,5-trichloro-6-(methylsulfanyl)pyridine (TSP)	2,3,5-trichloro-6-(methylsulfanyl) pyridine	Fish	 $C_6H_4Cl_3NS$

Code Number (Synonyms)	**Description**	**Compound found in:**	**Structure**
Hydroxy-TCP	3,5,6-trichloro-4-hydroxy-2-pyridinol	Crop (Peas, observed as conjugate)	 $C_5H_3Cl_3NO_2$

*Numerous sugar/malonic acid conjugates of TCP were identified in plant NOR studies.

2.8.1. Summary of fate and behaviour in soil

2.8.1.1. Route of degradation in soil

2.8.1.1.1. Aerobic degradation in soil

A total of 14 studies were evaluated in order to stablish the route of degradation of Chlorpyrifos-methyl. Their summaries can be found in the Chlorpyrifos-methyl DRAR Vol.3 B8, under point B.8.1.1.1.

During the first EU review of Chlorpyrifos methyl (2005), three aerobic soil degradation studies under lab conditions were considered and were assessed as “acceptable” (Reeves 1994; Reeves 1999 and Jackson 2000).

Reeves (1994) determined the degradation route of chlorpyrifos-methyl in four European soils.The design of the study is considered valid by RMS and, despite some deviations from OCDE 307 guidelines, it was considered to provide scientifically correct information on the route of degradation in soil of chlorpyrifos-methyl. A total of 10 metabolites were detected, but only two of them were identified, 3,5,6-trichloro-2-pyridinol (TCP) and 2-methoxy-3,5,6-trichloropyridine (TMP). The predominant metabolite in soil was TCP with maximum amounts formed in soil, ranging from 26.49-64.9 %AR. Other two major soil metabolites/degradation products named Met 6 and Met 5 (>10% AR and > 5% AR in two sequential samples, respectively) were seen, but they were not fully characterized or identified in the study. Attempts of characterization of the unknowns were submitted: Reeves G. (1999) and Jackson, R. (2000).

Reeves (1999) was considered as supplementary information. It confirmed Met 5 values from the original study, but Met 6 was not detected while the amounts of parent increased in the re-analysis. Moreover, the identity of Met 5 and 6 could not be determined. However, further information is not required taking into account the results of Jackson and Portwood (2000) where soil metabolites were generated by applying 14C-CPM to two agricultural soils and incubating them under aerobic conditions at 30°C for up to 120 days. The unknown components were generated using procedures similar to the original study (Reeves, 1994). Met 5 and Met 6 seen at ≥10% of applied in Reeves (1994), were identified as isomers of N-methyl-dichloro-2-pyridinone (Met 5; DCMP) and N-methyl-TCP (Met 6; N-Methyl-TCP), respectively. Since the levels of Met 5 and Met 6 could not be reproduced in the incubations of the identification works, the % AR detected in Reeves (1994) were considered to be an artefact.

Two new aerobic soil route studies (Oddy, 2015 and Clark, 2013b) with chlorpyrifos-methyl were submitted for the purpose of the renewal. They were conducted according to the requirements of the current OECD 307 guideline (2002). These studies confirmed the formation of TCP (87.9% AR), TMP (4.93% AR), N-methyl-TCP (5.2% AR), isomers of DCMP (2.1%AR) and several unknowns as degradation products of chlorpyrifos-methyl.

Additionally, seven laboratory soil studies to address the degradation of Chlorpyrifos-methyl metabolites TCP and TMP (De Vette, 2001b; Brüll, 2002a; De Vette, 2001a; Bidlack, 1977, 1979a and 1980; Laskowsky, 1977) have been included in chapter B-8 CA. They were Peer Reviewed for the Annex I inclusion of Chlorpyrifos-methyl, Chlorpyrifos and Triclopyr and have been re-assessed by RMS.

Finally, two studies submitted for renewal purposes were taken into account for the degradation route of TCP and 3,6-DCP (anaerobic metabolite): Clark, 2013a – chlorpyrifos applied- and Ross, 2015 -3,6- DCP applied. The results of the new studies are consistent with the conclusions of the first EU review of chlorpyrifos-methyl (2005). Mineralisation was extensive under aerobic conditions ranged from 23.24 to 68.9 %AR and the non-extractable residues were low, representing 17.9-26.44 %AR. Data indicate that chlorpyrifos-methyl will degrade in a microbially viable soil to TCP and other minor metabolites by both biotic and abiotic processes. TCP, in turn is mainly biologically degraded by a series of unknown reaction to CO2 and some soil organic matter. It can also be methylated to form 3,5,6-trichloro-2-methoxypyridine (TMP), which is reversible to 3,5,6-trichloro-2-pyridinol (TCP). The maximum amount of TCP detected from all studies ranged from 43.56 to 87.89 %AR. TMP and N-methyl-TCP were also considered relevant metabolites in soil with maximum amounts formed in soil of 13 and 5.2 %AR, respectively. The rest of detected unknowns which were formed during the aerobic laboratory studies were considered as not relevant in soil since they did not individually account for more than 5% AR.

Table 2.8.1.1-1 summarizes the guidelines, laboratory conditions, soil characteristics and acceptability of all route of degradation studies that were included in the renewal of chlorpyrifos-methyl review (old studies from the first review of chlorpyrifos-methyl+ newly submitted studies for renewal).

Table 2.8.1.1-2 summarizes the main results of the route studies that were considered acceptable by the RMS and of the route studies that were considered supplementary information.

Table 2.8.1.1-1: Overview of the chlorpyrifos-methyl, TCP and TMP laboratory aerobic route of degradation.

Reference	Guideline	Test substance	Tmp (ºC)	Appl. rate	Test length	Soil	pH	OC (%)	Moisture	Clay (%)	Accepted
B.8.1.1.1/01 Reeves, 1994 GHE-P-3638 (K13)	BBA Guidelines, Par IV, Section 4-1 (1986)	CLP-M	20ºC	0.5 kg as/ha	100 d	**Speyer 2.2** Loam sand	5.6 H_2O	2.32	40% MWHC	6	Y
						Marcham 1 Sandy loam	6.8 KCl	1.2	40% MWHC	15	Y
						Marcham 2 Sandy clay loam	7.2 KCl	1.5	40% MWHC	26	Y
						Derby Silt loam	5.4 KCl	5.5	40% MWHC	19	Y
B.8.1.1.1/02 Reeves, 1999 GHE-P-7879	Sample re-analysis Reeves, 1994. Supplementary information										
B.8.1.1.1/03 Jackson and Portwood, 2000. GHE-P-9032	Not specified	CLP-M	30ºC	100 µg/50 g soil	120 d	**Marcham** Sandy Clay Loam	8.0 H_2O	1.4	40% MWHC	25	S
						Cuckney Sand	7.2 H_2O	1.5	40% MWHC	7	S
B.8.1.1.1/04 De Vette, H.Q.M. and Schoonmade, J.A.; 2001b GH-C 5204	SETAC-Europe Guideline. Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides. Part 1. Section 1.1 (1995)	TCP	20 ºC	0.25 kg/ha	120 d	**Marcham,** UK Sandy clay loam	8.3 H_2O	1.7	40 % MWHC	21.43	Y
			10 ºC		120 d	**Marcham,** UK Sandy clay loam	8.3 H_2O	1.7	40 % MWHC	21.43	Y
			20 ºC		120 d	**Marcham,** UK Sandy clay loam	8.3 H_2O	1.7	10 % MWHC	21.43	Y
			20 ºC		152 d	**Marcham,** UK Sandy clay loam **Sterile**	8.3 H_2O	1.7	40 % MWHC	21.43	Y
			20 ºC		120 d	**Charentilly** France Sandy clay loam	8.0 H_2O	1.0	40 % MWHC	27.62	Y
			20		120 d	**Cuckney,**	6.8	1.2	40 %	5.86	Y

			ºC			UK Sand	H_2O		MWHC		
			20 ºC		120 d	**Thessaloniki**, Greece Loam	8.2 H_2O	0.8	40 % MWHC	13.06	Y
B.8.1.1.1/05 Brüll *et al*., 2002a V2302/02	Sample re-analysis De Vette, 2001b. Accepted.										
B.8.1.1.1/06 De Vette, H.Q.M. and Schoonmade, J.A.; 2001a V2301/01	SETAC-Europe Guideline. Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides. Part 1. Section 1.1 (1995)	CLP	20 ºC	0.96 kg/ha 1.28 mg/kg	120 d	**Marcham,** UK Sandy clay loam	8.3 H_2O	1.7	40 % MWHC	21.4	A
					152 d	**Marcham,** UK Sandy clay loam **Sterile**	8.3 H_2O	1.7	40 % MWHC	21.43	A
					120 d	**Charentilly** France Sandy clay loam	8.0 H_2O	1.0	40 % MWHC	27.6	A
					120 d	**Cuckney,** UK Sand	6.8 H_2O	1.2	40 % MWHC	5.9	A
					120 d	**Thessaloniki**, Greece Loam	8.2 H_2O	0.8	40 % MWHC	13	A
B.8.1.1.1/07 Bidlack, H.D.; 1977 GH-C 991	US EPA 162-1	TCP	25° C	1 ppm	300 d	**Yolo** Loam	5.9	0.8	75% of 1/3 Bar	22	S
						Flanagan Silty Clay Loam	5.2	2.2		28	S
						Fargo Clay	6.1	2.9		56	S
						Barnes Loam	6.3	3.1		20	S
						Hagerstown Clay Loam	5.3	2.5		28	S
						Palouse Silty Loam	5.5	1.7		24	S
						Walla Walla Silty Loam	6.3	1.0		16	S
						Grant Silty Loam	5.3	0.9		18	S
						Houston Black Clay	6.9	1.5		64	S
						Holdrege Loam	5.4	1.2		18	S
						Keith Clay Loam	6.6	1.0		28	S
						Cecil Sandy Loam	5.9	0.9		16	S
						Norfolk Loamy Sand	6.0	0.5		8	S
						Commerce Silty Loam	6.1	0.8		16	S
						Kawkawlin Sandy Loam	6.8	1.4		8	S
B.8.1.1.1/08 Laskowski, L.B., Cormeaux, L.B. & Bidlack, H.D., 1977	US EPA 162-1	TMP	25° C	1 ppm	300 d	**Commerce-1**	6.6	0.77	1/3 bar	20	S
						Commerce-2	5.5	0.86		22	S
						Flanagan-1	5.5	2.10		28	S
						Flanagan-2	6.8	2		28	S

								.20			
						Yolo-1	5.9	0.69		22	S
						Yolo-2	6.6	0.75		22	S
			25°C	1 ppm	199 d	**Commerce-1**	6.6	0.77	35% of 1/3 bar	20	S
						Commerce-2	5.5	0.86		22	S
						Flanagan-1	5.5	2.10		28	S
						Flanagan-2	6.8	2.20		28	S
						Yolo-1	5.9	0.69		22	S
						Yolo-2	6.6	0.75		22	S
B.8.1.1.1/09 Bidlack, H.D., 1979a	US EPA 162-1	CLP		7.6 kg/ha	360 d	**Commerce**					S
						Stockton					S
						Miami					S
						Barnes					S
						German 2.3					S
						Norfolk					S
						Catlin					S
B.8.1.1.1/10 Bidlack, H.D., 1980	Water solutions of 3,5,6-trichloro-2-pyridinol at 0. 005, 0.05 and 1.0 ppm and an acetone solution at 1.0 ppm were applied to four different soils and incubated in the dark at 25ºC and 75% 1/3 bar moisture level to study the effect of the solvent in TCP degradation. The rate of chemical degradation was determined on the basis of the generation of 14CO2. Supplementary information										
B.8.1.1.1/11 Oddy, A.; 2015.	OECD 307	CLP-M	20ºC	1008 g/ha 4.03 mg/kg	122 d	**Lufa Speyer 2.3** Sandy loam	5.6	0.68	between 0.1 bar (pF2) and 0.33 bar (pF2.5)	11	Y
						Clipstone Sand	5.3	1.22		5	Y
						Kenslow Sandy loam	5.3	4.04		17	Y
						Hareby Clay	7.7	1.46		43	Y
B.8.1.1.1/12 Clark, B., 2013b 120572	OECD 307; US EPA OPPTS 835.4100	CLP-M	20ºC	1000 g/ha	120 d	**Boone**	5.2	1.6	50% at 0 bar	17	Y
						Raymondville	8.0	0.65		23	Y
						MSL-PF	6.4	1.7		20	Y
						Tehama	6.7	1.3		29	Y
B.8.1.1.1/13 Clark, B., 2013a 120571	OECD 307; US EPA OPPTS 835.4100	CLP	20ºC	1000 g/ha	120 d	**Boone** Silt loam	5.2	1.6	50% at 0 bar	17	A
						Raymondville Sandy clay loam	8.0	0.65		23	A
						MSL-PF Sandy loam	6.4	1.7		20	A
						Tehama Clay loam	6.7	1.3		29	A

Y: Yes
N: No
S: Supplementary information
A: Additional information

Table 2.8.1.1-2: Overview of the formation of metabolites, CO2 and bound residues in the chlorpyrifos-methyl, TCP and TMP laboratory aerobic route of degradation studies at 20ºC

Reference	**Soil**	**TCP**	**TMP**	**N-Methyl-TCP**	**Isomers DCMP**	**Largest Unknown**	**Total Unknowns**	**CO2**	**Bound**
B.8.1.1.1/01 Reeves, 1994 GHE-P-3638 (K13)	**Speyer 2.2** Loam sand	43.56 (3 d)	3.87 (0 d)	3.33* (14 d)	9.55* (7 d)	16.23 Met 3 (1 d)	18.09 (1 d)	68.09 (100d)	21.62 (14 d)
	Marcham 1 Sandy loam	64.91 (7 d)	1.0 (7 d)	-	9.51* (100 d)	1.82 Met 4 (3d)	3.01 (3d)	27.25 (100d)	21.05 (59 d)

	Marcham 2 Sandy clay loam	63.68 (7 d)	0.94 (14d)	16.21* (59 d)	6.91* (100 d)	1.51 Met 9 (100 d)	1.51 (100 d)	23.24 (100d)	26.44 (100d)
	Derby Silt loam	26.49 (1 d)	2.33 (7 d)	14.58 (3 d)	1.43 (7 d)	2.11 Met 3 (3 d)	4.01 (14 d)	69.24 (100d)	22.75 (7 d)
B.8.1.1.1/04 De Vette, H.Q.M. and Schoonmade, J.A.; 2001b GH-C 5204	**Marcham** Sandy Clay Loam 20 ºC 40% MWHC	-	13.0 (120d)	-	-	5.5 (21 d)	5.5 (21 d)	18.9 (120d)	23.7 (120d)
	Marcham Sandy Clay Loam 10 ºC 40% MWHC	-	7.3 (120d)	-	-	5.5 (120d)	5.5 (120d)	8.9 (120d)	20.6 (42d)
	Marcham Sandy Clay Loam 20 ºC 10% MWHC	-	1.2 (84 d)	-	-	1.3 (84 d)	9.9 (84 d)	1.4 (120d)	20.1 (84 d)
	Marcham Sandy Clay Loam 20 ºC 40% MWHC **Sterile**	-	-	-	-	-	-	1.3 (152d)	16.6 (21d)
	Charentilly Sandy clay loam 20 ºC 40% MWHC	-	9.1 (63d)	-	-	7.5 (21 d)	7.5 (21 d)	58.2 (120d)	26.6 (84d)
	Cuckney Sand 20 ºC 40% MWHC	-	5.2 (14d)	-	-	4.2 (21 d)	6.6 (120 d)	66.7 (120d)	21.5 (84d)
	Thessaloniki Loam 20 ºC 40% MWHC	-	5.7 (63d)	-	-	4.4 (63d)	4.4 (63d)	31.0 (120d)	35.9 (63d)
B.8.1.1.1/11 Oddy, A.; 2015 SAP	**Lufa Speyer 2.3** Sandy Loam	75.2 (14d)	1.53 (122d)	2.09 (122d)	-	2.06 (122d)	3.56 (122d)	34.16 (122d)	25.34 (122d)
	Clipstone Sandy	59.79 (30d)	4.93 (122d)	5.11 (122d)	-	4.93 (122d)	4.93 (122d)	26.32 (69d)	19.59 (122d)
	Kenslow Sandy Loam	64.66 (14d)	0.39 (122d)	5.18 (122d)	-	0.39 (122d)	0.63 (122d)	42.27 (122d)	24.9 (122d)
	Hareby Clay	87.89 (14d)	2.57 (122d)	2.36 (122d)	-	4.55 (122d)	10.0 (122d)	33.04 (122d)	26.2 (122d)
B.8.1.1.1/12 Clark, B; 2013b DAS	**Boone** Silt Loam	57.0 (14d)	2.5 (60d)	5.2 (91d)	**3,5 DCMP** 1.4(30d) **5,6 DCMP** 0.5(120d)	1.3 (1d)	3.0 (60d)	63.6 (120d)	17.9 (120d)
	Raymondville Sandy Clay Loam	81.3 (3d)	1.0 (30d)	1.0 (14d)	**3,5 DCMP** 2.1(91d) **5,6 DCMP** 0.4(120d)	5.5 (14d)	14.6 (14d)	56.4 (120d)	23.7 (120d)
	MSL-PF Sandy Loam	78.8 (7d)	2.7 (14d)	4.5 (91d)	**3,5 DCMP** 0.6(91d) **5,6 DCMP** 0.3(91d)	2.0 (91d)	4.6 (91d)	60.3 (120d)	21.5 (120d)
	Tehama Clay Loam	65.9 (7d)	4.8 (60d)	2.8 (120d)	**3,5 DCMP** 1.8(91d) **5,6 DCMP** 0.8(91d)	3.7 (120d)	6.1 (60d)	53.6 (91d)	26.3 (120d)
Additional information									
B.8.1.1.1/06 De Vette, H.Q.M. and Schoonmade, J.A.; 2001a	**Marcham** Sandy Clay Loam 20 ºC 40% MWHC	39.1 (23d)	7.5 (63d)	-	-	3.2 (42d)		8.0 (84d)	12.0 (63d)

	Marcham Sandy Clay Loam 20 ºC 40% MWHC **Sterile**	71.8 (161d)	nd	-	-	nd	nd	2.7 (161d)	7.6 (21d)
	Charentilly Sandy clay loam	5.5 (42d)	6.4 (84d)	-	-	1.4 (14, 42d)	1.4 (14, 42d)	23.6 (120d)	11.0 (120d)
	Cuckney Sand	6.5 (21d)	0.9 (42d)	-	-	1.4 (14d)	1.4 (14d)	26.6 (120d)	25.0 (120d)
	Thessaloniki Loam	50 (63d)	8.7 (42d)	-	-	1.8 (63d)	1.8 (63d)	13.6 (84d)	9.9 (63d)
B.8.1.1.1/13 Clark, B; 2013a DAS	**Boone** Silt Loam	18.1 (30d)	1.5 (14d)	3.2 (90d)	**3,5 DCMP** 1.3(120d) **5,6 DCMP** 0.4(120d)	1.1 (120d)	2.2 (120d)	51.7 (120d)	14.4 (120d)
	Raymondville Sandy Clay Loam	60.2 (14d)	1.7 (14d)	1.2 (30d)	**3,5 DCMP** 2.1(120d) **5,6 DCMP** 0.5(120d)	6.3 (90d)	11.1 (90d)	54.2 (120d)	26.9 (120d)
	MSL-PF Sandy Loam	43.5 (14d)	3.3 (59d)	4.0 (90d)	**3,5 DCMP** 0.4(90d) **5,6 DCMP** 0.3(90d)	1.5 (90d)	2.5 (59d)	52.2 (120d)	18.3 (120d)
	Tehama Clay Loam	17.2 (10d)	2.1 (59d)	1.5 (59d)	**3,5 DCMP** 0.8(90d) **5,6 DCMP** 1.1(90d)	2.5 (90d)	4.6 (120d)	43.3 (120d)	23.1 (120d)

Supplementary studies									
Reference	**Soil**	**TCP**	**TMP**	**N-Methyl-TCP**	**Isomers DCMP**	**Largest Unknown**	**Total Unknowns**	**CO2**	**Bound**
B.8.1.1.1/03 Jackson and Portwood, 2000. GHE-P-9032	**Marcham** Sandy Clay Loam	31.0 (30d)	4.4 (60d)	7.8 (90 d)	3.3 (120 d)	-	3.0 (120d)	29 (90 d)	-
	Cuckney Sand	14.8 (30d)	1.0 (30d)	1.4 (30 d)	3.0 (45 d)	1.9 Met 7 (45 d)	1.9 (45 d)	55.9 (60 d)	-
B.8.1.1.1/07 Bidlack, H.D.; 1977 GH-C 991	**Yolo** Loam	-	23.6 (300d)	-	-	-	8.6 (300d)	14.3 (300d)	0.3 (0 d)
	Flanagan Silty Clay Loam	-	5.4 (28d)	-	-	-	9.4 (200d)	70.5 (300d)	6.3 (300d)
	Fargo Clay	-	13.9 (100d)	-	-	-	8.8 (200d)	33.1 (300d)	6.7 (200d)
	Barnes Loam	-	15.6 (200d)	-	-	-	39.9 (100d)	47.8 (300d)	7.2 (100d)
	Hagerstown Clay Loam	-	4.9 (14d)	-	-	-	15.2 (300d)	73.4 (100d)	6.8 (28d)
	Palouse Silty Loam	-	24.1 (300d)	-	-	-	26.2 (300d)	47.8 (200d)	5.0 (100d)
	Walla Walla Silty Loam	-	14.2 (300d)	-	-	-	10.8 (100d)	67.3 (300d)	4.4 (28d)
	Grant Silty Loam	-	1.1 (14d)	-	-	-	10.3 (28d)	83.5 (200d)	4.6 (56d)
	Houston Black Clay	-	2.1 (200d)	-	-	-	10.0 (100d)	53.3 (300d)	8.1 (300d)
	Holdrege Loam	-	3.4 (14d)	-	-	-	11.9 (56d)	80.6 (300d)	5.3 (28d)
	Keith Clay Loam	-	4.6 (200d)	-	-	-	11.9 (100d)	55.5 (300d)	6.8 (200d)
	Cecil Sandy Loam	-	1.9 (28d)	-	-	-	16.6 (56d)	78.2 (300d)	6.6 (56d)
	Norfolk Loamy Sand	-	2.7 (300d)	-	-	-	15.2 (100d)	71.8 (300d)	19 (14d)
	Commerce Silty Loam	-	3.9 (200d)	-	-	-	16.5 (28d)	69.9 (300d)	7.6 (56d)
	Kawkawlin Sandy Loam	-	11.2 (300d)	-	-	-	13.1 (100d)	34.8 (300d)	8.2 (300d)

B.8.1.1.1/08 Laskowski, L.B., Cormeaux, L.B. & Bidlack, H.D., 1977	**Commerce-1** 1/3 bar	5.5 (28d)	-	-	-	-	11.7 (199)	61.2 (300d)	13.2 (100d)
	Commerce-2 1/3 bar	5.7 (56d)	-	-	-	-	4.6 (199d)	65.3 (300d)	6.0 (56d)
	Flanagan-1 1/3 bar	9.6 (56d)	-	-	-	-	7.3 (199d)	76.3 (300d)	9.6 (56d)
	Flanagan-2 1/3 bar	15.1 (28d)	-	-	-	-	9.3 (300d)	68.0 (300d)	12.3 (100d)
	Yolo-1 1/3 bar	11.4 (199d)	-	-	-	-	2.1 (300d)	8.3 (300d)	5.7 (14d)
	Yolo-2 1/3 bar	4.2 (300d)	-	-	-	-	1.1 (199d)	11.4 (199d)	5.3 (14d)
	Commerce-1 35% of 1/3 bar	12.9 (56d)	-	-	-	-	6.3 (300d)	53.2 (300d)	6.0 (300d)
	Commerce-2 35% of 1/3 bar	13.8 (199d)	-	-	-	-	6.8 (199d)	54.3 (199d)	5.8 (56d)
	Flanagan-1 35% of 1/3 bar	19.2 (199d)	-	-	-	-	6.8 (199d)	45.3 (199d)	6.9 (56d)
	Flanagan-2 35% of 1/3 bar	29.3 (199d)	-	-	-	-	7.0 (199d)	42.2 (199d)	6.3 (56d)
	Yolo-1 35% of 1/3 bar	13.6 (199d)	-	-	-	-	1.4 (199d)	9.4 (199d)	3.5 (56d)
	Yolo-2 35% of 1/3 bar	4.8 (199d)	-	-	-	-	1.1 (56d)	9.5 (199d)	2.9 (56d)
B.8.1.1.1/09 Bidlack, H.D.; 1979a	**Commerce**	38 (14d)	1.6 (30d)	-	-	-	6.8 (30d)	88.5 (360d)	4.0 (360d)
	Stockton	21.9 (360d)	4.6 (360d)	-	-	-	11.5 (120d)	26.6 (360d)	12.1 (270d)
	Miami	30.8 (60d)	0.4 (270d)	-	-	-	19.1 (60d)	83.3 (360d)	4.9 (120d)
	Barnes	32.5 (30d)	10.2 (120d)	-	-	-	13.4 (120d)	62.8 (360d)	6.0 (360d)
	German 2.3	6.2 (270d)	0.1 (270d)	-	-	-	16.8 (360d)	52.8 (360d)	5.2 (270d)
	Norfolk	33.7 (270d)	1.5 (360d)	-	-	-	8.5 (270d)	31.1 (360d)	3.2 (360d)
	Catlin	19.4 (30d)	6.0 (120d)	-	-	-	6.5 (30d)	75.0 (360d)	7.9 (270)

*Artefact

2.8.1.1.2. Anaerobic degradation in soil

In the annex I inclusion peer review of chlorpyrifos-methyl no data was provided from anaerobic soil studies. It was considered acceptable that the fate and behavior of chlorpyrifos-methyl was adequately addressed in the water sediment study (Phillips and Hall 1994, K12).

Two new anaerobic degradation studies were submitted with chlorpyrifos-methyl (Oddy, 2015; Kang, 2014b). Oddy (2015) studied the degradation of chlorpyrifos-methyl in one soil which was incubated for 115 days under anaerobic conditions in the dark at 20ºC. The major transformation products detected were TCP and 5,6-DCP (5,6-dichloropyridin-2-ol), with maximum concentrations of 75.98% and 63.33% AR, observed on Day 14 and 118 of incubation, respectively. 5,6DCP did not decline at the end of the study and it was only formed under anaerobic conditions. The minor transformation products was N-Methyl-TCP accounted for a maximum of 0.54 % AR at 7 days. Non identified radioactivity was also detected accounting for up to 8.77 % AR at the end of the study. Since none of the unknowns exceeded 3.9% AR, further information was deemed not necessary. Negligible volatiles were observed and the mineralization at day 100 was low (maximum amount of C02 formed at the end of the study was 4.07% AR).

In Kang (2014b), chlorpyrifos-methyl was first metabolized by hydrolysis to produce TCP which was further degraded to 3,6-DCP by dechlorination (isomer of 5,6-dichloropyridin-2-ol). Maximum amounts reached during the study were 90.27% AR (7d) and 73.57% AR (70d) for TCP and 3,6-DCP respectively. 3,6DCP did not decline at the end of the study in any of the four soils. The minor transformation products were TMP and MCP (6-chloro-2-pyridinol) - accounted for a maximum of 3.31 and 6.20 % AR, respectively. No-identified radioactivity was detected in all soils. However, these peaks represented less than 5% radioactivity. The study also showed low formation of volatiles and low mineralization (maximum amount of C02 formed at the end of the study was 5.33 % AR). Organic volatiles were observed at <1% AR. NER accounted for up to 20% of the applied radioactivity by study termination.

One additional study was included as additional information to further address the anaerobic soil route of chlorpyrifos-methyl metabolites TCP and DCP (Kang, 2014a –chlorpyrifos applied-). It was concluded that CLP and CLP-M showed a common main route of degradation in soil under anaerobic conditions.

Table 2.8.1.2-1: Overview of the chlorpyrifos-methyl laboratory anaerobic degradation studies.

Reference	**Guideline**	**Test substance**	**Tmp (ºC)**	**Appl. rate**	**Test length**	**Soil**	**pH**	**OC (%)**	**Moisture**	**Clay (%)**	**Accepted**
B.8.1.1.2/01 Oddy, A.; 2015 FH/14/015 SAP	OECD Guideline for the Testing of Chemicals no. 307	CLP-M	20ºC	0.956 kg/ha	118 d	**Kenslow E3** Loam	5.3	3.2	Flooded	15	Y
B.8.1.1.2/02 Kang, S.; 2014b 130579 DAS	OECD 307 OCSPP 835.4200	CLP-M	20ºC	1000 g as/ha	100 d	**MSL** Sandy loam	6.8 H_2O	2.0	Flooded	19	Y
						South Witham Loam	7.4 H_2O	4.9	Flooded	27	Y
						Longwoods Sandy loam	7.7 H_2O	2.8	Flooded	8	Y
						Hareby Clay	7.8 H_2O	2.2	Flooded	45	Y
B.8.1.1.2/03 Kang, S.; 2014a 130581 DAS	OECD 307 OCSPP 835.4200	CLP	20ºC	1000 g as/ha	120 d	**MSL** Sandy loam	6.8 H_2O	2.0	Flooded	19	A
						South Witham Loam	7.4 H_2O	4.9	Flooded	27	A
						Longwoods Sandy loam	7.7 H_2O	2.8	Flooded	8	A
						Hareby Clay	7.8 H_2O	2.2	Flooded	45	A

Table 2.8.1.2-2: Overview of the formation of metabolites, CO2 and bound residues in the chlorpyrifos-methyl, TCP and TMP in laboratory anaerobic route of degradation studies at 20ºC

Reference	**Soil**	**TCP**	**TMP**	**3,6-DCP**	**5,6-DCP**	**MCP**	**MTCP**	**Polars**	**Total Unknowns**	**CO2**	**Bound**
B.8.1.1.2/01 Oddy, A.; 2015 FH/14/015 SAP	**Kenslow E3** Loam	75.98 (14d)	-	-	63.33 (118d)	-	0.54 (7d)	-	8.77 (118d)	4.07 (118d)	21.86 (118d)
B.8.1.1.2/02 Kang, S.; 2014b 130579 DAS	**MSL** Sandy loam	78.76 (14d)	3.31 (100d)	73.57 (70d)	-	6.20 (28d)	-	2.18 (70d)	4.75 (45d)	4.18 (100d)	15.44 (100d)
	South Witham Loam	77.23 (7d)	0.99 (100d)	66.77 (70d)	-	-	-	5.12 (3d)	4.34 (45d)	2.24 (100d)	21.0 (70d)

Reference	Soil	TCP	TMP	3,6-DCP	5,6-DCP	MCP	MTCP	Polars	Total Unknowns	CO2	Bound
	Longwoods Sandy loam	90.27 (7d)	1.35 (100d)	63.97 (100d)	-	1.18 (45d)	-	2.93 (28d)	1.59 (28d)	2.52 (100d)	11.71 (100d)
	Hareby Clay	84.33 (14d)	-	50.35 (100d)	-	0.74 (70d)	-	2.33 (100d)	5.19 (45d)	5.33 (100d)	20.13 (100d)
Additional studies (Chlorpyrifos applied)											
B.8.1.1.2/03 Kang, S.; 2014a 130581 DAS	**MSL** Sandy loam	73.45 (28d)	-	58.45 (120d)	-	-	0.56 (7d)	1.1 (120d)	0.02 (80d)	5.52 (120d)	12.85 (120d)
	South Witham Loam	73.31 (14d)	-	57.23 (80d)	-	-	2.21 (28d)	1.58 (80d)	0.56 (80d)	4.36 (120d)	21.96 (80d)
	Longwoods Sandy loam	80.24 (45d)	-	66.78 (120d)	-	-	-	2.84 (80d)	1.31 (80d)	2.66 (45d)	14.14 (80d)
	Hareby Clay	82.08 (28d)	-	25.85 (80d)	-	-	-	2.56 (80d)	3.74 (80d)	5.42 (120d)	21.28 (120d)

Due to the results obtained in anaerobic degradation studies, the aerobic biodegradation of 3,6-dichloro-2-pyridinol (DCP) was studied in four soils in order to obtain modelling endpoints.

2.8.1.1.3. Photodegradation in soil

In the 2005 EU evaluation of chlorpyrifos-methyl, no information was provided on its photolytic degradation. Two new studies were submitted with renewal purposes: McLaughlin (2014) and Simmoms & Colemman (2015).

In Simmond and Colemman (2015), chlorpyrifos-methyl degraded to TCP in both irradiated and dark control systems. The metabolite N-methyl TCP and minor unknown metabolites were also observed at very low levels in both systems. However, the transformation of the parent compound was slower in irradiated than in dark control samples and it was concluded that photodegradation would be expected not to contribute to the degradation of chlorpyrifos-methyl on the aerobic soil surface. Due to a potential reduced soil moisture during the incubation of the irradiated samples, these results were considered not acceptable by RMS.

McLaughlin (2014) studied the phototransformation of chlorpyrifos-methyl in a sandy loam soil incubated under continuous irradiation using a Xenon Arc Lamp for up to 15 d. Test material was applied at the rate of 50 mg a.i./kg soil, equivalent to the target field application rate of 1000 g a.i./ha. The main photodegradation product was TCP accounting for up to 26% AR. Other minor metabolites as Des-methyl reldan sodium salt and polar compound (never accounting for >5%AR) were also observed in irradiated samples. According to this study both biodegradation or photodegradation would be expected to contribute to the degradation of chlorpyrifos-methyl on the aerobic soil surface. The transformation of the parent compound was similar in irradiated and dark control samples, therefore, photodegradation would be a minor route of degradation of chlorpyrifos-methyl. In contrast, TCP showed a significantly faster degradation in the irradiated samples than in the dark control samples, being photodegradation an important route of degradation of TCP in soil. That result is in agreement with Racke et al (1994), an old photolysis study which was submitted during the first EU peer review. In this study the photodegradation rate and the formation of photodegradates of TCP were determined. The major photoproduct of TCP was CO2 (40% AR at 30 days) and small amounts of polar and non-extractable residues also formed. The study author suggested that this polar region may represent transient intermediates to CO2.

The general pathway is chlorpyrifos-methyl is rapidly degraded to TCP, which converted to CO2, NER, and polar degradates (<5% AR). The calculated formation fraction for TCP was lower in irradiated soils than in the dark control (0.47 and 0.88, respectively), indicating that chlorpyrifos-methyl was transformed photolytically to degradation products other than TCP. This is supported by the presence of polar components in the irradiated soil that were not observed in the dark control, and also by the much higher levels of carbon dioxide and non-extractable residues (combined total of approximately 80% in irradiated soils; approximately 10% in dark control soil).

Table 2.8.1.3-1: Overview of the chlorpyrifos-methyl photolysis in soil studies.

Reference	Guideline	Test substance	Tmp (ºC)	Appl. rate	Test length	Soil	pH	OC (%)	Moisture/ Light exposure	Clay (%)	Accepted
B.8.1.1.3/01 Simmonds R. and Coleman M.; 2015 FH/14/002 (SAP)	OECD proposal for soil photolysis; SETAC -soil photolysis	CLP-M	20ºC	1008 g/ha	30.6 d	Loam soil (UK) Irradiated	5.4	3.6	75% pF2/ 30 days natural summer sunlight at 30-50°N latitude	20	N
						Loam soil (UK) Dark control	5.4	3.6	75% pF2/ Dark	20	N
B.8.1.1.3/02 McLaughlin, S.P., 2014 130577 (DAS)	US EPA OCSPP 835.2410; OECD proposal for soil photolysis; SETAC -soil photolysis	CLP-M	25ºC	1000 g /ha 50 mg/kg	15d	**MSL** Sandy loam Irradiated	6.8	2.0	75% field capacity/ 30 days of summer sunlight at 40° N latitude		Y
						MSL Sandy loam Dark control	6.8	2.0	75% field capacity/ Dark		Y
B.8.1.1.3/03 Racke, K.D., Concha, M., Shepler, K. 1994	EPA Subdivision N. Chemistry: Environmental Fate Guideline 161-3 Soil Surface Photolysis	TCP	25.1 ºC	33 ppm 32.8 μg/g	30 d	**Commerce** Silty clay loam Irradiated	7.8	1.1	75% of 0.3 bar/ 37.45°N latitude and 122°W longitude,	31.2	Y
			25.3 ºC	33 ppm	30 d	**Commerce** Silty clay loam Dark control	7.8	1.1	75% of 0.3 bar/ dark	31.2	Y

Table 2.8.1.3-2: Overview of the formation of metabolites, CO2 and bound residues in the chlorpyrifos-methyl, TCP and TMP in laboratory photolysis in soil studies

Reference	Soil	TCP	Des-Methyl reldan Sodium Salt	N-methyl TCP	Polars	Total Unknowns	VOC	CO2	Bound
B.8.1.1.3/01 Simmonds R. and Coleman M.; 2015 FH/14/002 (SAP)	Loam soil (UK) Irradiated	22.15 (13.8d)	-	0.27 (30.6d)	-	2.25 (30.6d)		15.23 (30.6d)	20.69 (30.6d)
	Loam soil (UK) Dark control	60.39 (30.6d)	-	1.95 (30.6d)	-	0.99 (0 d)		7.63 (30.6d)	9.42 (30.6d)
B.8.1.1.3/02 McLaughlin, S.P., 2014 130577 (DAS)	**MSL** Sandy loam Irradiated	26.0 (3d)	2.3 (3d)	-	8.4 (5d)	-	1.2 (3d)	49.1 (15d)	46.4 (15d)
	MSL Sandy loam Dark control	84.3 (15d)	-	-	-	-	12.6 (3d)	2.2 (7d)	10.8 (15d)
B.8.1.1.3/03 Racke, K.D., Concha, M., Shepler, K. 1994	**Commerce** Silty clay loam Irradiated	-	-	-	8.2 (12d)	7.3 (8h)	-	40.4 (30d)	37.2 (2d)
	Commerce Silty clay loam Dark control	-	-	-	0.2 (30d)	0.9 (30d)	-	0.6 (30d)	30.4 (12d)

2.8.1.2. Rate of degradation in soil
2.8.1.2.1. Laboratory conditions

Active substance

Three laboratory soil aerobic degradation studies were considered in the analysis of soil persistence (Reeves, 1994; Oddy, 2015; Clark, 2013b). The study of Reeves (1994) was already evaluated for the original Annex I inclusion. Two new studies were submitted in the context of the renewal process (Oddy, 2015; Clark, 2013b) in order to cover the requirements for route and rate of degradation in soil

Reeves G.L. (1994), investigated the degradation of labelled [2,6-14C]-Chlorpyrifos-methyl in four soils (one standard soil –Speyer 2.2- and three agricultural soils –Marcham sandy loam, Marcham sandy clay loam and Derby silt loam-) incubated in dark at 40% MHC and 20ºC at a rate equivalent to 0.5 kg/ha for 100 days. Little or no organic volatiles were observed. The kinetic analysis according to FOCUS degradation kinetics shows DT50 and DT90 values ranged from 1.41-2.04 days and 5.9-36.5 days, respectively.

Oddy (2015) investigated the rate of degradation of [14C]-Chlorpyrifos-methyl under aerobic conditions at 20 ± 2°C in four soils in the dark: Clipstone (sand), Kenslow (sandy loam), Hareby (clay) and Lufa Speyer 2.3 (sandy loam). The soils were incubated at a selected moisture content between 0.1 bar (pF2) and 0.33 bar (pF2.5). Chlorpyrifos-methyl was applied to the soil surface at an application rate of 4.03 mg/kg (oven dried soil), equivalent to a field application rate of 1008 g/ha. Soil samples were incubated for up to 122 days. Non-CO2 volatiles in all soils were considered to be negligible. The kinetic analysis shows a DT50 values ranging between 0.83-7.64 days (20ºC, not corrected to pF2).

Clark, B. (2013b) studied the biotransformation of radiolabelled chlorpyrifos-methyl in four American soils: Boone silt loam; Raymondville sandy clay loam; MSL-PF sandy loam; and Tehama clay loam. Soil samples were adjusted to 50% of moisture-holding capacity at 0 bar prior to test substance application and incubated for up to 120 days at 20 ± 2°C in the dark. 14C-Chlorpyrifos-metil was applied at a nominal rate of 1.5 µg as/g (equivalent to 1 kg/ha). No volatile metabolites, other than CO2, were observed. DT50 values ranging between 0.94-4.72 days (20ºC, not corrected to pF2, SFO).

The effects of temperature, moisture and biological activity on the route and rate of degradation of Chlorpyrifos-methyl were not investigated in any of the studies submitted for renewal purposes.

In the above laboratory studies performed under aerobic conditions (Reeves, 1994, Oddy, 2015 and Clark, 2013b), Chlorpyrifos-methyl is degraded in soil at a relatively fast rate, with calculated DT50 values ranging from 0.83 to 7.64 days at 20ºC. The geometric mean of normalized values was 2.84 d (20ºC and pF2).

Table 2.8.1.2.1.-1: Rates of aerobic degradation in soil of chlorpyrifos-methyl (RMS proposal). Non-normalized values (Persistence criteria)

Soil type	pH[a)]	T.(ºC) / soil moisture	DT_{50} (d)	DT_{90} (d)	Kinetic parameters Kinetic parameter	St. (χ^2)	Method of calculation
Sandy clay loam (Speyer 2.2)	5.6	20ºC / 40% MWHC	1.77	5.87	k=0.3918	11.3	SFO
Sandy loam (Marcham)	6.8*	20ºC / 40% MWHC	1.41 1.04 (fast phase) 40.43 (slow	36.5	k1= 0.669333 k2= 0.017143 g= 0.813045	4.34	DFOP

			phase)				
Sandy clay loam (Marcham)	7.2*	20ºC / 40% MWHC	1.58 1.19 (fast phase) 37.40 (slow phase)	31.14	k1= 0.582813 k2= 0.018532 g= 0.821906	1.75	DFOP
Silt Loam (Derby)	5.4*	20ºC / 40% MWHC	2.04	6.79	k= 0.3393	12.7	SFO
Sandy loam (Lufa Speyer 2.3)	6.1	20ºC / 20% w/w	3.19	10.59	k= 0.2173	6.71	SFO
Sand (Clipstone)	5.9	20ºC / 9% w/w	7.64 6.09 (fast phase) 37.42 (slow phase)	38.06	k1= 0.113894 k2= 0.018523 g= 0.819332	2.31	DFOP
Sandy loam (Kenslow)	5.6	20ºC / 34% w/w	6.65	22.09	k= 0.10422	3.74	SFO
Clay (Hereby)	8.0	20ºC / 24% w/w	0.83	2.75	k= 0.83640	8.86	SFO
Silt loam (Boone)	5.2	20ºC / 50% MWHC	2.95 4.72 (DT90/3.32)	15.66	α= 1.9389 β= 6.8703	6.40	FOMC
Sandy loam (Raymondville)	8.0	20ºC / 50% MWHC	0.94	3.13	k=0.73667	7.17	SFO
Sandy clay loam (MSL-PF)	6.4	20ºC / 50% MWHC	1.30	4.31	k= 0.53390	8.06	SFO
Clay loam (Tehama)	6.7	20ºC / 50% MWHC	2.46	8.18	k= 0.28148	7.66	SFO
Persistence endpoint (worst-case value)			**7.64**				
pH dependence,					No		

[a] Measured in water
[b] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
[c] DT50 calculated from DT90 for FOMC (DT50 = DT90 / 3.32)
[d] DT50 from slow phase of DFOP model
[e] DT50 from slow phase of HS (Ln2/k2)
* Measured in KCl

Table 2.8.1.2.1.-2: Rates of aerobic degradation in soil of chlorpyrifos-methyl (RMS proposal). Normalized values (20ºC and pF2)

Soil type	pH[a)]	t. ºC / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Sandy clay loam (Speyer 2.2)	5.6	20ºC / 40% MWHC	1.77 / 5.87	1.77	11.3	SFO
Sandy loam (Marcham)	6.8*	20ºC / 40% MWHC	1.28 / 21.04	6.27[c)]	5.75	FOMC
Sandy clay loam (Marcham)	7.2*	20ºC / 40% MWHC	1.48 / 18.3	5.24[c)]	6.26	FOMC
Silt Loam (Derby)	5.4*	20ºC / 40% MWHC	2.04/6.79	2.04	12.7	SFO
Sandy loam (Lufa Speyer 2.3)	6.1	20ºC / 20% w/w	3.19 /10.59	2.95	6.71	SFO
Sand (Clipstone)	5.9	20ºC / 9% w/w	7.59 / 36.57	10.69[c)]	2.75	FOMC
Sandy loam (Kenslow)	5.6	20ºC / 34% w/w	6.65 / 22.09	5.84	3.74	SFO
Clay (Hereby)	8.0	20ºC / 24% w/w	0.83 / 2.75	0.79	8.86	SFO
Silt loam (Boone)	5.2	20ºC / 50% MWHC	2.95 / 15.66	4.72 [c)]	6.40	FOMC
Sandy loam (Raymondville)	8.0	20ºC / 50% MWHC	0.94 / 3.13	0.91	7.17	SFO
Sandy clay loam (MSL-PF)	6.4	20ºC / 50% MWHC	1.30 / 4.31	1.30	8.06	SFO
Clay loam (Tehama)	6.7	20ºC / 50% MWHC	2.46 / 8.18	2.09	7.66	SFO
Geometric mean (if not pH dependent)				**2.77**		
pH dependence,				No		

[a)] Measured in water
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
[c)] DT50 calculated from DT90 for FOMC (DT50 = DT90 / 3.32)
[d)] DT50 from slow phase of DFOP model for fate modelling
[e)] DT50 from slow phase of HS (Ln2/k2)
* Measured in KCl

From the two anaerobic soil degradation studies submitted (Oddy, 2015 and Kang, 2014b), only reliable kinetic paramenters could be derived from Kang, 2014b (re-evaluation according to FOCUS Degradation kinetics guidance in Jackson, 2015a). A clear biphasic pattern was observed for parent chlorpyrifos methyl in all four soils, and the best-fit kinetics model was either FOMC or DFOP. The DT50 values were in the range 1.4 to 1.9 days, and DT90 values were in the range 6.7 to 23 days, indicating rapid degradation of chlorpyrifos methyl under anaerobic conditions.

Table 2.8.1.2.1.-3: Rates of anaerobic degradation in soil of chlorpyrifos-methyl (RMS proposal)

Chlorpyrifos-methyl	Dark anaerobic conditions					
Soil type	pH[a)]	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C[b)]	St. (χ^2)	Method of calculation
MSL Sandy Loam	6.8	20 / Flooded	1.85/15.4	4.64 [c)]	4.08	FOMC
South Witham Loam	7.4	20 / Flooded	1.39/22.7	6.84 [c)]	6.28	FOMC
Longwoods Sandy Loam	7.7	20 / Flooded	1.35/20.4	6.15 [c)]	6.64	FOMC
Hareby Clay	7.8	20 / Flooded	1.44/6.69	29.65 [d)]	3.94	DFOP
Geometric mean (if not pH dependent)				8.33		

[a)] Measured in water
[b)] Normalised using a Q10 of 2.58
[c)] DT50 calculated from DT90 of FOMC (DT50 = DT90 / 3.32)
[d)] DT50 from slow phase of DFOP

A study on photolysis (Simmonds and Coleman, 2015) indicate that Chlorpyrifos-methyl degraded rapidly to its hydrolysis product TCP in both light exposed and dark controls. The DT50 for chlorpyrifos-methyl degradation was calculated to be 21.1 days (irradiated conditions) and 7.9 days (dark). Degrdation DT50 values derived from this study were not considered valid by RMS.

In McLauglin (2014), a second photolysis study which was re-evaluated in Jackson (2015c), chlorpyrifos methyl degraded rapidly in both the irradiated and dark control samples with DT50 values of 1.1 days and 1.9 days, respectively. Data indicate that photolytic degradation was not an important route of degradation for the active substance.

A detailed assessment of the kinetic modelling of each soil can be found in CA section B8 of Vol 3 of the DRAR

Metabolites

The experimental data from two old study (Reeves, 1994 and De Vette, 2001b) and three new studies (Oddy, 2015; Clark, 2013b and Ross, 2015) were used to derive the kinetic parameters of chlorpyrifos-methyl soil metabolites, TCP, TMP and DCP. The aerobic degradation rates under laboratory conditions were recalculated according to FOCUS Degradation kinetics in Reeves (1994), Pérez (2015), Oddy (2015), Terry (2015) and Abu (2015b), respectively.

Non-normalized DT50 values of TCP ranged from 2.59 to 79.83 d, with a geomean from normalized values of 29.36 d (n = 15).

Non-normalized DT50 values of TMP ranged from 9.10 to 1000 days, with a geomean from normalized values of 146.44 d (n= 9) and an arithmetic mean of ff = 0.593.

Both Notifiers, SAPEC and DAS, stated that the use of a default formation fraction value of 1.0 and DT50 of 1000 days for TMP is inappropriate.

According to SAPEC, data from Oddy (2015) report are not suitable for DT50 calculations since the values are too low (TMP did not reach 5% AR at study termination in any of the 4 soils). Additionally, no enough data were available to derive a reliable kinetic for TMP for Marcham and Thessaloniki soils in De Vette (2001b). Therefore, it is the notifier opinion that a default DT50 of 1000 days for the Lufa Speyer 2.3, Clipstone, Hereby, Marcham and Thessaloniki soils should be not considered. Finally, SAPEC propose to use the maximum DT50 for TMP of 103.23 d obtained from dissipation studies. Since only one DT50 was derived for TMP from field dissipation study (Gut, 2015; kinetic re-evaluation in Abu, 2015d), RMS disagrees with this proposal.
In contrast, DAS have re-evaluated the data from Oddy 2015 (B.8.1.2.1.1/02) and De Vette 2001b (B.8.1.2.1.2/02) in order to propose a less extreme set of parameters for TMP. The notifier demonstrated that the default assumptions (DT50=1000 d and ff=1) applied to Clipstone, Hareby, Marcham and Thessaloniki soils grossly over-predicts the behaviour of the TMP metabolite. Moreover, DAS proposed to use the same approach to derive worst-case TMP endpoints for Charentelly and Cuckney soils.

RMS agrees with the DAS refined endpoints, except for the soil Lufa Speyer 2.3. The kinetic derived from this soil was considered as not acceptable by RMS due to the bad visual fit and the scattering of data.

This resulted in a refined geomean DT50 for TMP from normalized values of **88.94** d (n= 10) and an arithmetic mean of ff = 0.203.

DT50 values of DCP ranged from 7.52 to 11.35 days, with a geomean of 9.06 d (n=4).

Additional aerobic soil rates for TCP from two aerobic soil degradation studies for chlorpyrifos (De Vette, 2001a and Clark, 2013a) were included in the DRAR. The normalised DT50 values (20 °C; pF2) of TCP were 10.28-1000 days (n= 8). The normalised DT50 values (20 °C; pF2) of TMP were 12.02-1000 days (n=4).

The tables below show summarized non-normalized and normalized DT50 values obtained for each metabolite.

TCP	Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was chlorpyrifos-methyl						
Soil type	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Sandy clay loam (Speyer 2.2)	5.6	20ºC / 40% MWHC	2.59 / 8.99	1.000	2.59	12.07	From CLPM SFO-SFO
Sandy loam (Marcham)	6.8*	20ºC / 40% MWHC	60.26 / 200.18	0.887	59.66	9.36	From CLPM FOMC-SFO
Sandy clay loam (Marcham)	7.2*	20ºC / 40% MWHC	42.78 / 142.11	0.913	40.64	15.52	From CLPM FOMC-SFO
Sandy loam (Lufa Speyer 2.2)	6.1	20ºC / 20% w/w	59.55 / 197.8	0.878	58.53	6.48	From CLPM SFO-SFO
Sand (Clipstone)	5.9	20ºC / 9% w/w	79.83 / 265.17	0.845	77.43	6.27	From CLPM FOMC-SFO
Sandy loam (Kenslow)	5.6	20ºC / 34% w/w	48.70 / 161.79	0.968	42.80	2.84	From CLPM SFO-SFO
Clay (Hereby)	8.0	20ºC / 24% w/w	71.40 / 237.19	1.000	68.25	5.45	From CLPM SFO-SFO
Silt loam (Boone)	5.2	20ºC / 50% MWHC	23.34 / 77.53	0.839	23.34	5.4	From CLPM FOMC-SFO
Sandy loam (Raymondville)	8.0	20ºC / 50% MWHC	27.52 / 91.41	0.890	26.72	8.34	From CLPM SFO-SFO
Sandy clay loam (MSL-PF)	6.7	20ºC / 50% MWHC	26.80 / 89.04	0.907	26.80	6.91	From CLPM SFO-SFO
Clay loam (Tehama)	7.7	20ºC / 50% MWHC	17.31 / 57.51	0.935	14.80	8.22	From CLPM SFO-SFO
Sandy clay loam (Marcham)	8.3	20ºC / 40% MWHC	49.31 / 368.6	-	121.46	2.83	Applied as parent DFOP
Silty clay loam (Charentelly)	8.0	20ºC / 40% MWHC	10.45 / 34.7	-	7.23	8.46	Applied as parent SFO
Sand (Cuckney)	6.8	20ºC / 40% MWHC	12.16 / 40.39	-	12.16	7.17	Applied as parent SFO
Sandy silt loam (Thessaloniki)	8.2	20ºC / 40% MWHC	61.02 / 202.7	-	47.27	5.53	Applied as parent SFO
Geometric mean (if not pH dependent)					**29.36**		
Arithmetic mean				**0.915**			
pH dependence,					No		

CLPM: Chlorpyrifos-methyl
CLP: Chlorpyrifos
*No decline observed. Default value.

TMP	Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was TCP						
Soil type	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Sandy loam (Lufa Speyer 2.3)	6.1	20ºC / 20% w/w	1000/1000	1.000	1000	-	From CLPM Default value*
Sand (Clipstone)	5.9	20ºC / 9% w/w	1000/1000	1.000	1000	-	From CLPM Default value*
Clay (Hereby)	8.0	20ºC / 24% w/w	1000/1000	1.000	1000	-	From CLPM Default value*
Silt loam (Boone)	5.2	20ºC / 50% MWHC	20.21 / 67.14	0.061	20.21	48.67	From CLPM FOMC-SFO-SFO
Sandy loam (Raymondville)	8.0	20ºC / 50% MWHC	10.79 / 35.86	0.050	10.47	27.27	From CLPM SFO-SFO-SFO

Sandy clay loam (MSL-PF)	6.4	20ºC / 50% MWHC	9.10 / 30.23	0.147	9.10	23.07	From CLPM SFO-SFO-SFO
Clay loam (Tehama)	6.7	20ºC / 50% MWHC	18.91 / 62.83	0.087	16.08	40.72	From CLPM SFO-SFO-SFO
Sandy clay loam (Marcham)	8.3	20ºC / 40% MWHC	1000 / 1000	1.000	1000	-	From TCP Default value*
Sandy silt loam (Thessaloniki)	8.2	20ºC / 40% MWHC	1000 / 1000	1.000	1000	-	From TCP Default value*
Geometric mean (if not pH dependent)					**146.44**		
Arithmetic mean				**0.593**			
pH dependence,					No		

The new defined endpoints for TMP proposed by DAS are summarised below.

TMP	Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was TCP						
Soil type	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Sand (Clipstone)	5.9	20ºC / 9% w/w	1000/1000	0.2^	1000	-	From CLPM Default value*
Clay (Hareby)	8	20ºC / 24% w/w	1000/1000	0.2^	1000	-	From CLPM Default value*
Silt loam (Boone)	5.2	20ºC / 50% MWHC	20.21/67.14	0.061	20.21	48.67	From CLPM FOMC-SFO-SFO
Sandy loam (Raymondville)	8	20ºC / 50% MWHC	10.79/35.86	0.05	10.47	27.27	From CLPM SFO-SFO-SFO
Sandy clay loam (MSL-PF)	6.4	20ºC / 50% MWHC	9.10/30.23	0.147	9.1	23.07	From CLPM SFO-SFO-SFO
Clay loam (Tehama)	6.7	20ºC / 50% MWHC	18.91/62.83	0.087	16.08	40.72	From CLPM SFO-SFO-SFO
Sandy clay loam (Marcham)	8.3	20ºC / 40% MWHC	1000 / 1000	0.32^	1000	-	From TCP Default value*
Sandy silt loam (Thessaloniki)	8.2	20ºC / 40% MWHC	100 / 100	0.32^	100	-	From TCP Default value*
Sandy silt loam (Charentilly)	8	20ºC / 40% MWHC	100 / 100	0.32^	100	-	From TCP Default value*
Sand (Cuckney)	6.8	20ºC / 40% MWHC	100 / 100	0.32^	100	-	From TCP Default value*
Geometric mean (if not pH dependent)					**88.94**		
Arithmetic mean				**0.203**			
pH dependence,					No		

CLPM: Chlorpyrifos-methyl
*No decline observed. Default value.
^Refined values proposed by DAS

DCP	Dark aerobic conditions Metabolite dosed						
Soil type	pH[a)]	t. ºC / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Clay loam (Brierlow)		20ºC / pF2	9.33 / 30.99	-	9.33	4.05	Applied as parent SFO
Sandy loam (Longwoods)		20ºC / pF2	11.35 / 37.70	-	11.35	6.81	Applied as parent SFO
Silt loam (South Witham)		20ºC / pF2	8.47 / 28.14	-	8.47	6.78	Applied as parent SFO
Sandy loam (Hickman)		20ºC / pF2	7.52 / 24.97	-	7.52	12.34	Applied as parent SFO
Geometric mean (if not pH dependent)					**9.06**		
Arithmetic mean				-			
pH dependence,					No		

Under anaerobic conditions (Jackson, 2015a), the DT50 values for TCP were in the range from 19 to 141 days (top-down DT50 values for TCP were sºimilar, 19-150 days). A formation fraction of 1 was determined for TCP in all four soils indicating total and rapid conversion of chlorpyrifos methyl to TCP.

On the soil photolysis study (McLauglin, 2014), a rapid degradation of the TCP metabolite was observed in irradiated soil with a DT50 of 2.1 days (Jackson, 2015b). No significant degradation of TCP was seen in the dark control. It can be concluded that TCP is rapidly photodegraded in soil.

A detailed assessment of the kinetic modelling for each soil can be found in CA section B8 of Vol3 of the DRAR.

2.8.1.2.2. Field dissipation studies

Six soil dissipation trials, previously evaluated in Chlorpyrifos-methyl Addendum December 2002 and Chlorpyrifos DAR 1999, and that were carried out using chlorpyrifos (applied as DURSBAN 4 or Lorsban 4E) as the starting material were included in chlorpyrifos-methyl DRAR Vol.3 B8 (B.8.1.2.2.1/01-04, B.8.1.2.2.1/10-11 and B.8.1.2.2.1/13). A re-evaluation of these field studies according to the new SANCO/1211772014-final (12 December 2014) is presented in B.8.1.2.2.1/15. Moreover, five studies which shown the dissipation rate of TCP metabolite after application of GARLON 4 were also included (B.8.1.2.2.1/05-09). They have been already submitted and evaluated in Triclopyr DAR (2003).

DegT50 from the mentioned field dissipation studies were normalized to the standard temperature and moisture conditions of 20 ºC and pF2 considering the available data summarized in the DAR/Addendums of Chlorpyrifos-ethyl and/or Triclopyr. The calculated TCP DisT50field values ranged between 15. to 166.1 days. Estimated field DisT90 was < 1 year. Normalized DegT50 were 10.3-111.34 d.

Table 2.8.1.2.2-1 Summary of TCP DT50 from field studies considered additional information by RMS (studies where chlorpyrifos and triclopyr were applied as parent).

Report for source of data	**Soil**	**$DisT_{50}$ non-normalized**	**$DegT_{50}$ normalized**	**Model**
Old 2002b	Valtohori, Greece	44.2	42.93	SFO
Old 2002b	Tivenys, Spain	166.1	111.34	SFO
Fontaine 1987	Davis, California	15.6	32.1	SFO
Teaslade 1998a	Crimplesham, UK	63.1	22.4	SFO
Teaslade 1997	St. Nicholas, France	30.24	10.3	SFO
Teaslade 1998b	Mucke, Germany	67.8	15.1	SFO
Teaslade 1999a	Herford, Germany	76.5	18.2	SFO

Other field dissipation studies, published studies and general reviews on the environmental fate of chlorpyrifos-ethyl including TCP which were previously evaluated for chlorpyrifos approval under Directive 91/414/EEC and that now are considered as supplementary information have been also taken into account (B.8.1.2.2.1/12).

The endpoints reported in the above TCP degradation field studies are not appropriate for risk assessment and exposure modelling of the environmental fate of chlorpyrifos-methyl or its metabolites since other active substances were applied. However, they are considered to provide additional information about the fate of TCP in soils under field conditions.

A new field study with chlorpyrifos-methyl has been conducted for the purpose of renewal. The dissipation of chlorpyrifos-methyl and its metabolites TCP and TMP was investigated under field conditions in five European soils (2 in Spain, 2 in Italy and 1 in Greece). This field study was performed in line with NAFTA Guidance Document (OPPTS 835.6100), SETAC (Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides, March 1995) and EFSA Guidance Document (EFSA Journal 2014; 12(5):3662) and it was considered acceptable by RMS. Based on data of this field dissipation study, a kinetic evaluation was conducted (Abu, 2015d) to address persistence and modelling endpoints.

Based on time-step normalization, the overall geomean DegT50 value for chlorpyrifos-methyl and TCP were 1.32 days and 67.27 days, respectively (20 °C; pF2 moisture). DisT50 values for chlorpyrifos-methyl between 0.62-2.17 d and 4.22-78.22 d for TCP were obtained. An unnormalized DT50 for TMP of 115 d could be derived from field dissipations studies.

Table 2.8.1.2.2-2: Summary of non-normalized DT50 values for chlorpyrifos-methyl from field studies (Gut, 2015)

Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	pH[a)]	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	Kinetic parameters	St. (χ^2)	Method of calculation
Sandy loam (Bare soil)	Vélez-Málaga (Spain)	8.27	30	1.26	4.18	k 0.55137	13.18	SFO
Sandy loam (Bare soil)	Maro (Spain)	8.30	30	2.17	7.22	k 0.31914	10.6	SFO
Silty Clay (Bare soil)	Ginosa Marina (Italy)	8.80	30	1.25 1.83[c)]	6.08	α 2.3088 β 3.5582	5.84	FOMC
Loamy sand (Bare soil)	Scanzano Jonico (Italy)	8.82	30	0.90	2.97	k 0.77469	11.7	SFO
Silt loam (Bare soil)	Kostaki Arta (Greece)	7.8	30	0.62	2.07	k 1.11253	16.5	SFO
Persistence endpoint (worst-case value)				**2.17**				
pH dependence, *Yes or No*					No			

a) Measured in water
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix
c) DT50 calculated from DT90 for FOMC (DT50 = DT90 / 3.32)

Table 2.8.1.2.2-3: Summary of non-normalized DT50 values for TCP from field studies (Gut, 2015)

Soil type	Location	pH[a)]	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	Kinetic parameters	St. (χ^2)	f. f. k_f / k_{dp}	Method of calculation
Sandy loam (Bare soil)	Maro (Spain)	8.30	30	78.22	259.8	k 0.008862	17.3	0.6688	SFO/SFO
Silty Clay (Bare soil)	Ginosa Marina (Italy)	8.80	30	10.65 4.22 (fast) 103.4 (slow)[c)]	217.8	k1 0.1642 k2 0.006704 g 0.5694	24.4	1.000	FOMC/DFOP
Loamy sand (Bare soil)	Scanzano Jonico (Italy)	8.82	30	67.26	223.4	k 0.01031	13.1	0.6127	SFO/SFO
Silt loam (Bare soil)	Kostaki Arta (Greece)	7.8	30	6.617 81.13[c)]	167.6	k1 0.2596 k2 8.54E-3 g 0.5813	14.5	0.4199	SFO/DFOP

Soil type	Location	pH[a)]	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	Kinetic parameters	St. (χ^2)	f. f. k_f / k_{dp}	Method of calculation
Persistence endpoint (worst-case value)				**78.22**					
Arithmetic mean								**1.0**	
pH dependence, Yes or No									

a) Measured in [medium to be stated, usually calcium chloride solution or water]

b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7 values are DegT50matrix

c) DT50 calculated from k slow phase for DFOP kinetics (DT50 = ln(2) / k2)

Table 2.8.1.2.2-4: Summary of non-normalized DT50 values for TMP from field studies (Gut, 2015)

TMP	Field conditions The precursor from which the f.f. was derived was TCP								
Soil type	Location	pH[a)]	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	Kinetic parameters	St. (χ^2)	f. f. k_f / k_{dp}	Method of calculation
Silt loam (Bare soil)	Kostaki Arta (Greece)	7.8	30	**114.5**	380.4	k 6.05E-3	14.80	0.0566	SFO/DFOP/SFO
Persistence endpoint (worst-case value)									
Arithmetic mean									
pH dependence, Yes or No									

Normalized DT50 values

Table 2.8.1.2.2-5: Summary of normalized DT50 values for chlorpyrifos-methyl from field studies (Gut, 2015)

Chlorpyrifos-methyl	Field conditions							
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	pH[a)]	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (χ^2)	DT_{50} (d) Norm[b)].	Method of calculation
Sandy loam (Bare soil)	Vélez-Málaga (Spain)	8.27	30	-	-	14.1	2.09	SFO
Sandy loam (Bare soil)	Maro (Spain)	8.30	30	-	-	10.6	3.61	SFO
Silty Clay (Bare soil)	Ginosa Marina (Italy)	8.80	30	-	-	5.84	1.14	SFO
Loamy sand (Bare soil)	Scanzano Jonico (Italy)	8.82	30	-	-	11.7	0.62	SFO
Silt loam (Bare soil)	Kostaki Arta (Greece)	7.8	30	-	-	16.5	0.75	SFO
Geometric mean (if not pH dependent)							**1.32**	
pH dependence, *Yes or No*				No				

d) Measured in water

e) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix

f) DT50 calculated from DT90 for FOMC (DT50 = DT90 / 3.32)

Table 2.8.1.2.2-6: Summary of non-normalized DT50 values for TCP from field studies (Gut, 2015)

TCP	Field conditions The precursor from which the f.f. was derived was chlorpyrifos-methyl									
Soil type	Location	X^8	pH[a)]	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (χ^2)	DT_{50} (d) Norm[b)].	f. f. k_f / k_{dp}	Method of calculation
Sandy loam (Bare soil)	Maro (Spain)		8.30	30	-	-	18.8	96.8	0.6930	SFO/SFO
Silty Clay (Bare soil)	Ginosa Marina (Italy)		8.80	30	-	-	21.9	56.44	0.6506	SFO/SFO
Loamy sand (Bare soil)	Scanzano Jonico (Italy)		8.82	30	-	-	14.55	66.96	0.5967	SFO/SFO
Silt loam (Bare soil)	Kostaki Arta (Greece)		7.8	30	-	-	22.89	62.92	0.2812	SFO/SFO
Geometric mean (if not pH dependent)								**69.27**		
Arithmetic mean									**0.555**	
pH dependence, Yes or No										

[d)] Measured in [medium to be stated, usually calcium chloride solution or water]
[e)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7 values are DegT50matrix
[f)] DT50 calculated from k slow phase for DFOP kinetics (DT50 = ln(2) / k2)

Table 2.8.1.2.2-4: Summary of normalized DT50 values for TMP from field studies (Gut, 2015)

TMP	Field conditions The precursor from which the f.f. was derived was TCP									
Soil type	Location	X^8	pH[a)]	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (χ^2)	DT_{50} (d) Norm[b)].	f. f. k_f / k_{dp}	Method of calculation
Silt loam (Bare soil)	Kostaki Arta (Greece)		7.8	30	-	-	12.4	**103.25**	**0.0763**	SFO/SFO/SFO
Geometric mean (if not pH dependent)										
Arithmetic mean										
pH dependence, Yes or No										

2.8.1.2.3. Assessment of Persistence (P) in soil

The assessment of POP PBT and vPvB criteria has been made following the recommendation of the DG SANCO working document on "Evidence needed to identify POP, PBT and vPvB properties of pesticides" ver 3.0 (here on SANCO guidance document, SANCO GD) and Guidance on Information Requirements and Chemical Safety Assessment . Chapter R.11: PBT/vPvB Assessment

It is assumed that single first order (SFO) kinetics and reference temperature of 20 ºC is implicitly when the criteria were defined (Michael Matthies 2014 pers. Presentation)[2]. However, The velaution was made considering selecting best-fit kinetics as recommended by SANCO GD together with a temperature of 20 ºC. No normalization to moisture conditions was considered.

The rate of aerobic degradation of chlorpyrifos-methyl was investigated in eleven representative soil types (of EU origin) under laboratory conditions at 20ºC (Reeves, 1994; Oddy, 2015; Clark, 2013b). The degradation was also investigated under flooded anaerobic conditions in a total of four soils (Kang, 2014).

The aerobic degradation half-lives of chlorpyrifos-methyl expressed as SFO ranged from 0.83 days to 40.43 days with a geomean of 4.7 days (at 20ºC but not corrected to pF2) according to FOCUS degradation kinetics guidance (2006, 2011, 2014).

[2] http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_type=250&lang=en&item_id=7978

In flooded soil, the degradation half-lives ranged from 4.64 days to 29.65 days with a geomean of 8.33 days when data are expressed as SFO.

The photodegradation of chlorpyrifos-methyl has been assessed and it has been clearly demonstrated that photolysis is not a significant environmental degradation route.

The DT50 and DT90 values of chlorpyrifos-methyl derived from a field dissipation study (Gut 2015) range between 0.62-2.17 days for chlorpyrifos-methyl (geomean of 1.23 d, n= 5) and between 67.26-103.40 days for TCP (geomean of 81.51 d, n=4) when data are expressed as SFO.

Overall, chlorpyrifos-methyl does not fulfill the persistence criterion in soil set out in points 3.7.1.1 (POP criteria), 3.7.2.1 (PBT criteria), 3.7.3.1 (vPvB criteria) of annecx II of the regulation 1107/2009

2.8.1.2.4. DT50 values proposed for modelling

For the use in PECsoil calculations the maximum half-life of unnormalized values from field dissipation studies should be used. DT50 cannot be compared directly ince the persitence field data were based on best-fit kinetics for SFO as well as biphasic models. Therefore, as a conservative approach the worst-case of all data expressed as SFO was selected.

The longest field persistence DT50 of 2.172 days from Maro soil (Gut, 2015) was considered appropriate to calculate PECsoil of chlorpyrifos-methyl.

For PECsoil calculations of TCP, a DT50 of 103.4 days from Ginosa Marina soil (Gut, 2015) was selected. For PECsoil calculations of TMP and DCP, a worst-case DT50 from laboratory degradation studies was proposed by RMS to be used. The respective DT50 were 1000 d for TMP (Oddy, 2015; Clark, 2013b; De Vette, 2001b) and 11.35 d (Ross, 2015).

Field dissipation studies found that the worst-case DT90 value of chlorpyrifos-methyl was < 1 year, indicating that soil accumulation does not need to be addressed. However, for the metabolites TCP and TMP DT90 > 1 year were reported (Abu, 2015a and Abu, 2015b), indicating that soil accumulation studies should be calculated.

The maximum occurrence in soil for TCP, TMP and DCP were 90.27% (Kang, 2014b), 13% (De Vette, 2001b) and 73.6 % (Kang, 2014b), respectively.

For PECgw and PECsw calculations, RMS conducted a a kinetic evaluation according to EFSA Guidance document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products in soil (2014). RMS tested wether or not the field DegT50, matrix values for chlorpyrifos-methyl (geomean = 1.32 d, n=5) were significantly shorter than the laboratory DegT50,matrix (geomean = 2.84 d, n= 11) using the EFSA Endpoint Selector.

As field DegT50, matrix values were significantly shorter than lab, and five field DegT50,matrix values for chlorpyrifos-methyl were available, the geometric mean of 1.32 days was proposed by RMS as adequate DT50 for modelling purposes.

The same approach was followed for TCP. However, since slower degradation in soil was observed in field (geomean = 69.27 d, n= 4) than in laboratory conditions (DegT50, matrix values for TCP geomean = 29.36 d, n=15), significant differences were observed, and therefore, it was decided by RMS that the modelling TCP DegT50 values obtained from field study (Gut, 2015) should not be combined with the laboratory data to calculate an overall geomean DT50 to be used for the assessment of leaching to groundwater and surface water

As it is stated in EFSA Guidance (2014), in general, DegT50 matrix values from field studies are expected to be lower than DegT50 matrix values from laboratory studies, but the opposite may happen occasionally. The scientific opinion (EFSA PPR Panel, 2010) considers it very unlikely that a laboratory study with a certain soil shows a systematically and consistently faster degradation rate than a field study with the same soil at the same temperature and moisture content. It is far more likely that a field DegT50 matrix that is significantly longer than the geomean laboratory DegT50 matrix is caused by systematic errors in the inverse modelling procedure. It can also happen by coincidence because the number of measured laboratory and field DegT50 matrix values in a dossier may be limited to four. In such a case, the magnitude of the effects of conservative assumptions in the inverse modelling procedure should be assessed; if these effects are so large that they may explain the difference with the laboratory DegT50 matrix values, then it is considered justifiable to discard the DegT50 Matrix value of this field study.

In order to address such effects, RMS performed the same statistical analysis, but using all normalized TCP DegT50 values from laboratory and field studies of chlorpyrifos-methyl, chlorpyrifos and trichlopyr which are available in the monography. In this case, the null hypothesis that field studies show equal DegT50 than laboratory studies was accepted. Based on these results, , RMS considers that the field DegT50matrix values determined in Gut (2015) were significatively higher than laboratory due to the limited number of data and they should not be combined with laboratory DegT50matrix values in order to provide an overall geomean**. A TCP geomean DT50 of 29.36 d from laboratory studies is proposed for modelling purposes.**

Nine lab DegT50 values are available for TMP (De Vette, 2001b; Clark 2013b and Oddy, 2015). Since only one degradation data for TMP was derived from field studies (Gut, 2015), a **TMP geometric mean of 146.44 days** from laboratory studies is proposed for modelling purposes.

For metabolites TCP and TMP, arithmetic mean molar formations fractions of 0.915 and 0.543 were determined.

DCP geometric mean DegT50 of 9.06 days from 4 soils (Ross, 2015) was selected as modelling endpoint.

2.8.1.3. Mobility in soil
2.8.1.3.1. Adsorption/Desorption studies
Active substance

Hamaker (1974) investigated the soil adsorption of chlorpyrifos-methyl in 10 representative U.S agricultural soils (organic carbon content 0.3 - 5.8%; clay content 8 - 42%; pH range 4.8 - 7.7). KOC values ranging 1189 to 8100 mL/g (n=10) and no pH dependence is expected. This study was previously evaluated in chlorpyrifos-methyl DAR 1997. However, due to deviation from the current guideline OCDE 106, it was considered as supplementary information by RMS.

A new study submitted for renewal was submitted by DAS (Kang, 2015). This study follows OCDE 106 and it was considered as acceptable for modelling purposes. Data from soil adsorption studies confirms that in general Chlorpyrifos-methyl is a rather immobile substance in soil. KfOC values ranging from 691 to 1892 mL/g (n=5), with a geometric mean of 1376 mL/g. The arithmetic mean of 1/n values was 0.957. No pH dependence is expected.

Table 2.8.1.3.1.1-1: Summary of chlorpyrifos-methyl soil adsorption data (Kang, 2015). No pH dependence was found.

Soil	**pH ($CaCl_2$)**	**% Organic Carbon**	**K_f**	**K_{foc}**	**1/n**
Hareby	7.4	2.03	25.8	1269	0.9782
Empingham	7.2	5.70	39.3	691	0.9823
Brierlow	5.6	3.55	64.5	1820	0.9545
DU	4.8	3.31	62.7	1892	0.9427
MSL	6.3	1.98	32.4	1637	0.9285
Arithmetic mean				1462	**0.9572**
Geometric mean				**1376**	NA
Std dev				494	0.0230
Max				1892	0.9823
Min				691	0.9285

Metabolites

Two adsorption-adsorption studies were conducted for TCP (Racke and Lubinski, 1992; Damon and Starff, 2001). A total of eight different soils were available. KOC values ranged from 51 to 194 mL/g, with a geometric mean of 93 mL/g. The arithmetic mean of Freundlich Isotherm (1/n) was 0.805. No pH dependence was found.

Adsorption and desorption characteristics of TMP were investigated by Heim & Damon (2001). A total of five different soils were available. KOC values ranged from 323 to 640 mL/g, with a geometric mean of 523 mL/g. The arithmetic mean of Freundlich Isotherm (1/n) was 0.839. No pH dependence was found.

The adsorption of DCP was examined in Grant & McLachlan on five different soils. KOC values ranged from 13 to 99 mL/g, with a geometric mean of 33 mL/g. The arithmetic mean of Freundlich Isotherm (1/n) was 0.783. No pH dependence was found

Table 2.8.1.3.1.2-1: Summary of TCP soil adsorption data (Racke and Lubinski, 1992 and Damon and Starff, 2001). No pH dependence was found.

Soil	**Soil Class**	**pH ($CaCl_2$)**	**% OC**	**K_f**	**K_{foc}**	**1/n**
M549	Clay loam	7.4	3.5	1.78	51	0.893
M579	Sand	6.6	1.5	1.29	86	0.833
M584	Loam	6.1	1.0	0.68	68	0.787
M585	Sandy clay loam	7.3	1.6	1.68	105	0.752
M601	Sandy loam	5.5	4.3	6.4	14	0.800
M354	Clay loam	7.8	2.5	1.95	77	0.784
M355	Sandy loam	7.1	0.3	0.60	194	0.811
M404	Silt loam	6.9	2.1	1.69	81	0.781
Arithmetic mean					101	**0.805**
Geometric mean					**93**	0.804
Std dev					47	0.043
Max					194	0.893
Min					51	0.752

Table 2.8.1.3.1.2-2: Summary of TMP soil adsorption data (Heim & Damon, 2001). No pH dependence was found.

Soil	**Soil Class**	**pH ($CaCl_2$)**	**% OC**	**K_f**	**K_{foc}**	**1/n**
M549	Clay loam	7.4	3.1	11.3	323	0.813
M579	Sand	6.6	1.5	9.28	619	0.885
M584	Loam	6.1	1.0	5.62	562	0.877
M585	Sandy clay loam	7.3	1.6	8.69	543	0.725
M601	Sandy loam	5.5	4.3	27.5	640	0.893
Arithmetic mean					537	**0.839**
Geometric mean					**523**	0.836
Std dev					126	0.071
Max					640	0.893
Min					323	0.725

Table 2.8.1.3.1.2-3: Summary of DCP soil adsorption data (Grant & McLachlan, 2015). No pH dependence was found.

Soil	**Soil Class**	**pH (water)**	**% Organic Carbon**	**K_f**	**K_{foc}**	**1/n**
PD-SL-PF	Sandy Loam	6.3	0.81	0.692	85	0.802
E1	Clay Loam	8	3.5	3.453	99	0.773
I2	Sandy Loam	8.4	1.3	0.233	18	0.781
J2	Silt Loam	5.9	5.3	0.689	13	0.812
CA-L	Loam	7.5	0.64	0.119	19	0.747
Arithmetic mean					47	0.783
Geometric mean					33	0.782
Std dev					42	0.025
Max					99	0.812
Min					13	0.747

2.8.2. Summary of fate and behaviour in water and sediment

2.8.2.1. Hydrolysis

One hydrolysis study with chlorpyrifos-methyl (Yon and Muller, 1994a) as well two studies (Reeves 1999 and Jackson and Portwood, 2000) to identify unknown metabolites were submitted. They were already assessed and accepted for the first Annex I inclusion of chlorpyrifos-methyl (June 2005). In these studies chlorpyrifos-methyl was found to hydrolyze with DT50 between 13-27 days at 25ºC and pH 4-9. The rate of hydrolysis was pH dependent, being faster at alkaline than acid conditions. Two hydrolysis products were present in concentrations greater than 10% of applied amount: 3,5,6-trichloro-2-pyridinol (TCP) and O-methyl-O-(3,5,6-trichloro-2-pyridyl) phosphorothioate (desmethyl CHP-Me). Hydrolysis studies for des-methyl-chlorpyrifos-methyl or TCP were not conducted. Therefore, they are considered to be stable in water.

2.8.2.2. Photodegradation

The photochemical transformation of 14C-chlorpyrifos-methyl in sterile buffer solution was studied by Yon, D. and Müller, J. (1994b) in the first Annex I inclusion of chlorpyrifos-methyl. Considering a quantum yield value of 2.06 × 10-3, photolysis half-life values as a function of season were determined to be 1.8-9.1 days (June) and 0.8-3.8 months (December). Due to deviations from the current OECD 306 guideline this report has been considered as supplementary information.

A new study was submitted for the purpose of renewal which complies with the current OECD guidelines: McLaughlin (2015). Aqueous photolysis of chlorpyrifos-methyl was studied in sterile pH 7 buffer using a xenon lamp for 7 days to simulate mid-summer sunlight at 40 °N latitude. The photolytic decomposition of chlorpyrifos-methyl led to the formation of numerous photoproducts, identified as multiple polar organic acids and mineralization to CO2 (42.9% AR at the end of the study). Short-chain polar organic acid compounds accounted for > 45% AR after 7 days of irradiation, but individually were less than 5% AR. Low amounts of TCP (2.5%AR) and Desmethyl reldan (1.4% AR) were also observed. The quantum yield of chlorpyrifos-methyl photolysis was 5.01 × 10-3. The predicted environmental photolytic half-life, derived from the measured half-life in the laboratory under artificial lamp was calculated to be 2.8 days at 40° N latitude in summer sunlight, and the expected DT90 was 9.2 days.

Dark control samples showed a lower degradation of chlorpyrifos-methyl (75% AR remained at the study termination), including two hydrolysis products, TCP (max 9.8% AR) and Desmethyl-reldan (max 12.0 % AR), with no formation of CO2. Therefore, photolysis would be a degrdation route of chlorpyrifos-methyl in water.

2.8.2.3. Biological degradation

One ready biodegradability test was presented (Douglas, M.T. and Pell, I.B, 1985) and indicates that chlorpyrifos-methyl was not readily biodegraded in the standard test.

Two aerobic mineralisation in surface water studies were submitted for the purpose of renewal: Domson, R., 2015 (SAP) and Gassen, M., 2015 (DAS).

In Dobson (2015), [^{14}C]-Chlorpyrifos-Methyl was found to dissipate fairly rapid in natural water systems incubated under aerobic conditions at 20 ± 2°C with water phase DT50 values of 9.3 days at the 10 µg/L dose level and 9.2 days at the 100 µg/L dose level. Data suggests hydrolysis as a dominant process for the degradation of chlorpyrifos-methyl in the test system since degradation of Chlorpyrifos-Methyl in the sterile controls was similar to that found in the sample flasks. Initial degradation of Chlorpyrifos-Methyl was found to proceed via demethylation, resulting desmethyl Chlorpyrifos-Methyl (max. 10.51% AR in low dose treated system), before proceeding to TCP (max. 62.92% AR in low dose treated system) which appears to be the terminal hydrolysis product in the system tested. The mineralization of chlorpyrifos-methyl and its hydrolysis products was minimal (max 2.42% AR). The relatively rapid dissipation of the test item across the headspace of the sample flasks into the PU-foam bungs suggests that volatilisation could be an important dissipation mechanism for the test item from large open water bodies. The levels of volatiles extracted from the PU-bungs for both dose levels of the test item increased steadily up to day 28 reaching levels of 52.6% AR and 44.2% AR at the 10 and 100 µg/L dose levels respectively. Where fitting was corrected for volatile losses to the PU-bungs, degradation DT50 values of 19.9 d and 18.7 d were estimated for 10 and 100 µg/L concentrations, respectively

Gassen (2015) studied the biotransformation of [^{14}C]chlorpyrifos-methyl in aerobic surface water (“pelagic test”) incubated at 23.5 ± 0.194°C in the dark for 64 days in viable test systems and 61 days in sterile test systems. Test concentrations were 12.4 and 12.7 µg/L (low concentration viable test systems, FTL), 104.7 and 106.0 µg/L (high concentration viable test systems, FTH) and 106.1 µg/L (high concentration sterile test systems, FS). The main degradation product was TCP (Max. 93.4% AR at 20 days FTH). Two minor degradation products, Chlorpyrifos-methyl oxon and the Desmethyl reldan sodium salt, were observed during incubation, in all cases representing <5% AR. Mineralization to CO2 was negligible (≤ 3.3% AR). Formation/evolution of other volatile components was insignificant with mean values equating to ≤ 0.5 % AR. However, several samples were excluded from calculations due to radioactive distribution (e.g. high amounts of radioactivity in traps of volatiles) or due to recovery over the individual test system. RMS believes that an incomplete trapping of volatiles could have occurred in Gassen (2015), since volatility was an important route of dissipation of chlorpyrifos-methyl in water as it was observed in other studies (Dobson 2015, Turk 2015). Additionally, no test to check the sterility of the sterile sample flasks was performed. Therefore, RMS considered this study as supplementary information.

DisT50 values of chlorpyrifos-methyl in the water compartment were 5.18 days at the 10 µg/L dose level, 5.19 days at the 100 µg/L dose level and 19.4 d for the sterile test system. No significant difference was observed between the DT50 and DT90 values generated from the SFO kinetics of chlorpyrifos-methyl transforming in the water compartment of the FTL and FTH test systems, it was therefore concluded that the rate of degradation was independent of the two concentrations assessed. When the DT50 and DT90 values of the FTL/FTH and FS test systems were compared a large difference was observed. It was therefore concluded that the rate of degradation was dependent on the presence of a microbial population in the test system. This conclusion contradicts the findings of mineralization study submitted by SAPEC (Dobson, 2015), where degradation of Chlorpyrifos-Methyl in the sterile controls was similar to the one of sample flasks.

Phillips M. and Hall B.E. (1994) was reviwed in the original Annex I inclusion. They investigated the rate and nature of degradation of chlorpyrifos-methyl in sandy loam and clay loam sediments and their natural waters under an aerobic/anaerobic gradient. Samples were treated with [14C]-chlorpyrifos-methyl at a rate approximately equivalent to the maximum field application rate of 560 g/ha. Treated samples were incubated in dark at a temperature of 17-20 ºC for up to 100 d.

The primary degradation product in both the sediment and water layers was TCP. This metabolite reached peak concentrations of 83% and 62% AR in the sandy loam and clay loam systems, respectively, after 30 days. It was found predominantly in the water phase (sandy loam; 59% water: 24% sediment, clay loam; 37% water : 25% sediment) and declined to low levels by 100 days. An unidentified degradation product was also detected at significant levels in sandy Loam water/sediment system (32% after 100 days). Additional works on characterization of unknown metabolites were performed and evaluated in Chlorpyrifos-methyl Addemdum December 2002: Reeves (1999) and Jackson and Portwood (2000). These studies confirmed that the unknown was Desmethyl-chlorpyrifos-methyl. This was already accepted during the first Peer Review of chlorpyrifos-methyl and no further information is deemed necessary.

Non-extractable sediment residues ranged from 12 to 20% AR at 100 days. Little radioactivity was associated to CO_2, organic volatiles. However, the mass balance was low at 100 days in the Sandy loam system (mean recovery 74.01 5%AR) and at 14, 60 and 100 days in the Clay loam system (recoveries ranging from 79.97-88.93 % AR). The same behaviour was observed in the new water/sediment studies with chlorpyrifos-methyl and chlorpyrifos submitted for the renwal (Hawkins and Simmonds (2015), Turk (2015) and Kang (2014b)), where it was demonstrated that the volatization from water of the active substance was the cause of the low recoveries obtained.

RMS recalculated DT50 values according to FOCUS Degradation kinetics. A correction procedure to account for volatilization of chlorpyrifos-methyl was performed. The total system DT50 value for chlorpyrifos-methyl in the sandy loam system was 3.06 days (DT90= 10.14 days). The corresponding value for the clay loam system was not considered robust due to low mass balance and the bad visual fit of data and therefore, it was not included in the DRAR.

Hawkins and Simmonds (2015) investigated the degradation of chlorpyrifos-methyl in two aquatic systems (Calwich Abbey Lake and Swiss Lake). The systems were incubated under aerobic conditions at 20 ± 2 ºC in glass flasks containing sediment and associated water at a ratio of approximately 1:3. Chlorpyrifos-methyl was applied to the water surface at an application rate equivalent to an initial concentration of ca 0.34 mg/L in the water phase and the samples were incubated for up to 100 days.

The applied radioactivity dissipated from the water phase to the sediment. Two significant metabolites, TCP and desmethyl chlorpyrifos-methyl were observed in both test systems. TCP was the most prevalent, reaching maximum amounts up to 70% AR, with the majority being detected in the water. Desmethyl chlorpyrifos-methyl was observed to reach maximum values of 11% AR.

The overall material balances were acceptable for both water-sediment systems ranged from 90.2% AR to 97.1% AR. However, [14C]-Chlorpyrifos-methyl was also found to transfer from the test vessel and irreversibly bind to the test vessel tubing connecting the main vessel to the volatile traps (mean of 17% AR at the end of the study). A volatile test was performed in order to characterize the radioactivity dissipating into the headspace (and then onto the test ring tubing). The radioactivity trapped consisted of CLPM (84.7-88.5%) and desmethyl-CLPM (15.3-11.1%). Low mineralization was observed for both water/sediment systems (<2.7% AR after 100 days of incubation). These results confirmed the findings of the mineralization experiments (Dobson, 2015). Maximum unextractable residues in the sediment amounted from 9.2 to 13.7 %AR after 100 d.

Chlorpyrifos-methyl was found to rapidly degrade in natural water-sediment systems incubated under aerobic conditions at 20 ± 2 ºC, with total system DisT50 values of 2.8 days and 3.6 days for the Calwich Abbey and Swiss Lake systems (DT90 values of 9.4 days and 11.9 days for the two systems), respectively. When data were corrected to account for volatilization a total system DegT50 of 3.42 d and 4.45 d were obtained. The calculated half-lives in the total water/sediment system for Des-methyl chlorpyrifos methyl were 17.34 and 7.95 days and 173.82 and 184.13 d for TCP. Additional calculations for Level P-II were performed by RMS in order to follow the approach presented by DAS. The criteria for an acceptable assessment were not met, therefore, level PII endpoints are not reliable for a higher tier risk assessment.

Turk (2015) assessed the transformation of chlorpyrifos-methyl in two water/sediment systems, Calwich Abbey Lake and Swiss Lake. Chlorpyrifos-methyl was applied to the water surface at a nominal concentration of 0.50 mg/L. Samples were incubated for up to 148 days under aerobic conditions with associated overlying waters at a sediment/water ratio of 1:3 in the dark at 20 ± 2 C. Potassium hydroxide (KOH), ethylene glycol, foam plug, and Harvey Cocktail organic volatiles traps were used in flow-through aerobic test systems to collect 14CO2 and any volatile organic components that evolved during this study.

Residues of the parent compound, chlorpyrifos-methyl, declined rapidly over the first two weeks of the study, reaching 0.8-4.8% in the total system after 14 days. Three metabolites of chlorpyrifos-methyl exceeded 10% AR in the total system: des-methyl chlorpyrifos-methyl (Des-Me; maximum 21.8% on day 3 in the Calwich Abbey Lake system), 3,5,6-trichloro-2-pyridinol (TCP; maximum 80.4% on day 30 in the Swiss Lake system) and 3,4-dichlor-2-pyridinol (DCP; maximum 10.7% on day 139 in the Calwich Abbey system). Several minor transformation products were also formed; in all cases these transformation products represented <5% AR. Trapped 14CO2 accounted for up to 21.1% AR. Mean of non-extractable residues increased from the study up to 32.6% AR at day 148.

Average material balance ranged from 70.2% to 100.9% AR, with acceptable recoveries (>90%) observed up to day 30 of the study. The low recovery (i.e., < 90% AR) for samples incubated beyond Day 30 was evaluated in a bridging study in closed vessels which demonstrated recovery in the range of 92.2 to 98.6% of the applied radioactivity (AR). The bridging study indicated that the low recovery was caused by incomplete trapping of volatiles. In the flow-through system of the definitive test, radioactive residues were detected in the ethylene glycol, foam plug, and Harvey Cocktail organic volatiles traps, as well as in the silicon and Teflon connector tubing. These residues, when combined together, accounted for up to 10% AR. Even though these residues were not characterized during the study, they are likely composed of unchanged chlorpyrifos-methyl. An aerobic aquatic metabolism study with chlorpyrifos was provided (Kang, 2014b) in order to provide further evidences of volatility of chlorpyrifos-methyl from water. In this study, up to 30% of the applied radioactivity was found in the foam plug and rinses of the tubing used in the flow-through system and shown to be 100% unchanged chlorpyrifos. The volatilization of chlorpyrifos-methyl was also observed in Dobson (2015) and Hawking and Simmonds (2015).

The original data from Turk (2015) were used by Carnall (2015) and Yon (2015) to derive persistence and modelling endpoints at Level P-I and Level P-II, respectively.

Due to the low recoveries observed beyond day 30 of the study calculations to derive endpoints at Level M-I neither for Des-methyl chlorpyrifos methyl nor TCP were performed by Carnall (2015). However, RMS considers that the same approach followed for the parent compound chlorpyrifos-methyl can be applied to Des-methyl chlorpyrifos-methyl. Since degradation of TCP metabolite extended beyond this time window, it was not considered in the analysis. Whole system DT50 of chlorpyrifos-methyl were 2.03 d and 2.9 days for Calwich Abbey and Swiss lake system, respectively. Desmethyl-Chloropyrifos-methyl was degraded in the total water/sediment system with DT50 of 8.9 and 10.3 days.

Additionally, DT50 were corrected for volatile losses by RMS following the same approach reported in Hawking & Simmonds (2015), Kang (2014), Abu (2015) and Yon (2015ab). Whole system DT50 for chlorpyrifos-methyl of 2.22 and 3.34 days were obtained.

Yon (2015) performed a higher tier kinetic assessment of chlorpyrifos-methyl and its metabolite Desmethyl-chlorpyrifos-methyl to derive modelling endpoints at level P-II and M-II in order to refine the DT50 of chlorpyrifos-methyl in water. RMS disagrees with the kinetic modelling of the residues of chlorpyrifos-methyl performed in the report. According to the study author the movement of parent compound was only simulated from the water phase to the sediment phase based on the high absorption constant of chlorpyrifos. Additionally, all components are described as degrading to a sink compartment, resulting in formation fractions instead of rate constants for transfer. This approach is not in the line of FOCUS DK guidance. New calculations at Level P-II were performed by RMS. The criteria for an acceptable assessment were not met, therefore, level PII endpoints are not reliable for a higher tier risk assessment.

Tables 2.8.2.3-2 and -3 show the recalculated persistence and modelling endpoints for chlorpyrifos-methyl in accordance with the kinetic approaches recommended in the lastest guidance (FOCUS 2006, 2011, 2014) to support the aquatic risk assessment.

Table 2.8.2.3-1: Summary of laboratory studies on degradation route of chlorpyrifos-methyl in water/sediment systems

Ref	Water/Sediment System	OC%	pH	Temp (ºC)	CO2	Bound	Metabolites Max in w/s % AR
Phillips and Hall 1994	Sandy Loam	2.5	7.8 (water) 7.5 (sed)	20±2	6.9 (100d)	14.37 (100d)	TCP: 88.97% Desmethyl: 37.86% Unknown: 5.77%
	Clay Loam	1.6	8.2 (water) 6.4 (sed)	20±2	0.71 (100d)	20.06 (100d)	TCP: 65.38% TMP: 0.68% Desmethyl: 8.11% Unknown: 3.90%
Hawkins and Simmonds, 2015	Calwich Lake Silt Loam	5.0	8.2 (water) 7.2 (sed)	20±2	2.5 (100d)	10.9 (100d)	TCP: 72.7 % Desmethyl: 9.0% Unknowns: 18.5% Single unknows <5%
	Swiss Lake Loamy Sand	0.7	7.1 (water) 6.6 (sed)	20±2	2.6 (100d)	13.7 (100d)	TCP: 71.4% Desmethyl: 11.7% Total Unknowns: 10.2% Single unknows <5%
Turk, 2015	Calwich Lake Silt Loam	5.8	6.81 (water) 7.5 (sed)	20±2	21.11 (139d)	32.46 (139d)	TCP: 73.8 % Desmethyl: 21.8% Polars: 3.2% DCP:10.6 Unknows <5%
	Swiss Lake Loamy Sand	0.7	6.51 (water) 7.0 (sed)	20±2	16.49 (99d)	34.38 (148d)	TCP: 80.4% Desmethyl: 13.4% Polars: 2% Unknowns >5%

Table 2.8.2.3-2: Summary of persistence endpoints for chlorpyrifos-methyl in water/sediment system

Water / sediment system	pH	pH sed	t. ºC	$DisT_{50}$	$DisT_{90}$	St.	Method of

	water phase	a)		whole sys.	whole sys.	(χ^2)	calculation
DAR study Sandy loam	7.8	7.5	20 ± 3	3.26	10.8	6.4	SFO
Calwich Abbey, Silt loam, (UK)	8.2	7.2	20 ± 2	2.83	9.4	3.7	SFO
Swiss Lake, Loamy sand, (UK)	7.1	6.6	20 ± 2	3.57	11.87	3.8	SFO
Calwich Abbey, Silt loam, (UK)	6.81	7.5	20 ± 2	2.03	6.74	6.7	SFO
Swiss Lake, Loamy sand, (UK)	6.51	7.00	20 ± 2	2.91	9.66	3.1	SFO
Geometric mean at 20°C b)				2.87			SFO

Table 2.8.2.3-3: Summary of DegT50 and Degt90 values of chlorpyrifos-methyl in water/sediment systems

Water / sediment system	pH water phase	pH sed a)	t. °C	DT_{50} whole sys.	DT_{90} whole sys.	St. (χ^2)	Method of calculation
DAR study Sandy loam	7.8	7.5	20 ± 3	3.23	10.73	6.6	SFO
Calwich Abbey, Silt loam, (UK)	8.2	7.2	20 ± 2	3.42	11.38	3.7	SFO
Swiss Lake, Loamy sand, (UK)	7.1	6.6	20 ± 2	4.45	14.78	3.8	SFO
Calwich Abbey, Silt loam, (UK)	6.81	7.5	20 ± 2	2.22	7.39	6.7	SFO
Swiss Lake, Loamy sand, (UK)	6.51	7.00	20 ± 2	3.34	11.09	3.1	SFO
Geometric mean at 20°C b)				3.25			SFO

According to one mineralization study (Dobson, 2015), data suggests hydrolysis as a dominant process for the degradation of chlorpyrifos-methyl in the test system. Hydrolysis of Chlorpyrifos-Methyl initially yielded degradate M1 (desmethyl chlorpyrifos methyl). Further hydrolysis of M1 yielded M4 - (TCP), levels of which increased steadily in the water phase throughout the study duration. This study also indicates that chlorpyrifos-methyl dissipates rapidly from water by volatilization.

This was confirmed by water/sediment studies, where difficulties to maintain the mass balance were reported. Apart from volatilization, chlorpyrifos-methyl rapidly dissipates to the sediment system. However, the results of water/sediment studies indicate that although the primary degradation product, TCP, is detected in both sediment and water layers, it was found predominantly in the water phase. Therefore, RMS proposes to use DT50 whole system of 3.25 d in the water compartment and a default DT50 of 1000 d in the sediment.

The re-calculated half-life values of TCP for the whole system ranged between 174 and 184 d leading a geometric mean value of 179 days (n=2). Maximum amount detected in water was 62.5%AR after 30 d and 38.16 AR% after 100 d in sediment. The maximum in total system was 88.97 % after 30 days. Two kinetic formation fractions were derived, one from Desmethyl-Chlorpyrifos-methyl and other from chlorpyrifos-methyl, with an arithmetic mean of 0.625 and 1.0 respectively.

Table 2.8.2.3-7: Summary of DegT50 and Degt90 values of TCP in water/sediment systems

Reference	Water / sediment system	pH water phase	pH sed a)	t. ^{o}C	DT_{50} whole sys.	DT_{90} whole sys	St. (χ^2)	Method of calculation
Hawkins & Simmonds, 2015	Calwich Abbey, Silt loam, (UK)	8.2	7.2	20 ± 2	174	577	10.3	SFO
	Swiss Lake, Loamy sand, (UK)	7.1	6.6	20 ± 2	184	612	7.1	SFO
	Geometric mean at 20^{o}C$^{b)}$				179			SFO

The re-calculated half-life values of Desmethyl chlorpyrifos-methyl for the whole system ranged between 7.95 and 17.34 d leading a geometric mean value of 10.6 days (n=4). Maximum amount detected in water was 24.81 % after 100 d and 13.05 % after 100 d in sediment. The maximum in total system was 37.86 % after 100 days. The arithmetic mean of kinetic formation fractions was 0.191 from chlorpyrifos-methyl.

Table 2.8.2.3-8: Summary of DegT50 and DegT90 values of Desmethyl chlorpyrifos-methyl in water/sediment systems

Reference	Water / sediment system	pH water phase	pH sed a)	t. ^{o}C	DT_{50} whole sys.	DT_{90} whole sys.	St. (χ^2)	Method of calculation
Hawkins & Simmonds, 2015	Calwich Abbey, Silt loam, (UK)	8.2	7.2	20 ± 2	17.34	57.61	17.8	SFO
	Swiss Lake, Loamy sand, (UK)	7.1	6.6	20 ± 2	7.95	26.42	16.5	SFO
Carnall, 2015	Calwich Abbey, Silt loam, (UK)	6.81	7.5	20 ± 2	8.9	29.6	18.4	SFO
	Swiss Lake, Loamy sand, (UK)	6.51	7.0	20 ± 2	10.3	34.2	17.2	SFO
	Geometric mean at 20^{o}C$^{b)}$				10.6	-		SFO

Degradation rates for DCP could not be derived from data. Accordingly, default values of 1000 days are proposed to be used for modelling purposes.

Three outdoor studies on the fate and behaviour of Chlorpyrifos in aquatic systems were included (Reeves, G.L., Mackie, J.A., 1993, Giddings, J.M., 1993a and Giddings, J.M., 1993b). In the review from Racke (1993) the persistence of chlorpyrifos in aquatic microcosms and the fate of EC formulation in artificial pools were examined. In terms of environmental fate, chlorpyrifos-methyl is less persistent than chlorpyrifos. In aerobic water/sediment systems, chlorpyrifos-methyl exhibited DT50 values of 2.8-3.6 days (depending on sediment type) in whole systems and 1.5-2.4 days in the water phases (Hawkins and Simmonds, 2015)., compared with chlorpyrifos which has DT50 values of 22-51 days for whole systems and 3-6 days for the water phases. Consequently, it is accepted that microcosm data generated on chlorpyrifos may be used to predict a "worst-case" assessment of environmental risk associated with chlorpyrifos-methyl products.

2.8.2.4. Assessment of Persistence (P) in aquatic systems

Hydrolysis of Chlorpyrifos-methyl in sterilized water is pH dependent. Chlorpyrifos-methyl is hydrolytically unstable in sterile aqueous buffers between pH 4 and pH 9. DT50 values at 25ºC are 27, 21 and 13 days at pH 4, 7 and 9, respectively.

The predicted environmental photolytic half-life was calculated to be 2.8 days at 40° N latitude in summer sunlight, and the expected DT90 was 9.2 days. Therefore may have an influence in the degradation of chlopyrifos methyl.

Chlorpyrifos-methyl is considered as not ready biodegradable. Additionally, two studies have been conducted to investigate the aerobic mineralization in surface water. Results indicate that chlorpyrifos-methyl dissipates rapidly in natural water systems (DT50=5-9 days), being volatilization an important route of dissipation of chlorpyrifos-methyl in water. Where fitting was corrected for volatile losses, degradation DegT50 values of 19.9 d -18.7 d were estimated.

The volatilization of chlorpyrifos-methyl from water was confirmed by water/sediment studies. DisT50 for the whole system for Chlorpyrifos-methyl ranged from 2.03 to 3.57 days. However, when volatilization is discarded the re-calculated half-life values (DegT50) ranged from 2.22 to 4.45 d.

Taken all together, chlorpyrifos-methyl does not fulfill with the persistence criterion in aquatic systems set out in points 3.7.1.1 (POP criteria), 3.7.2.1 (PBT criteria), 3.7.3.1 (vPvP criteria) and vPvB substances.

2.8.3. Summary of fate and behaviour in air

Chlorpyrifos-methyl is addressed as volatile considering the result of one study on volatilization from soil and from plant in a wind-tunnel (Day and Rüdel, 1984). The vapour pressure of 3.0 x 10-3 Pa at 25º C (1.945 x 10-3 Pa at 20°C) of chlorpyrifos-methyl is above the trigger for volatilisation of 1 × 10-5 Pa for plants and above the trigger of 1 × 10-4 Pa for soil.

In Day and Rüdel (1984), RELDAN 22 RO (EF-1066), containing 226 g as/l, was fortified with [14C]-chlorpyrifos-methyl and applied to Borstel silty sand soil and dwarf bean plants (Phaseolus vulgaris) at a rate equivalent 2.2 l/ha (0.5 kg as/ha). The evaporisation behaviour from soil and plant leaf surfaces was studied over a 24 hour period, 18% AR volatilised from soil and 79% from plant surfaces.

The photochemical oxidative degradation was calculated to 2.11 hours for chlorpyrifos-methyl using the Atkinson method in the study of Day and Rüdel (1984).

Based on its Henry’s Law Constant (H = 6.45 x 10-1 Pa m3 mol-1) chlorpyrifos-methyl would be considered a semi-volatile substance. Actually, volatilisation of chlorpyrifos-methyl was demonstrated to be moderate under standardised test conditions. However, the rate of indirect photochemical breakdown in air is expected to be very rapid. There are no olefinic and acetylenic moieties in the molecule and therefore reactions with ozone would not be expected.

Measured results from a study conducted in a photoreactor indicated that tropospheric degradation of chlorpyrifos-methyl is mainly controlled by reaction with OH radicals and that the tropospheric lifetime is estimated to be around 3.5 h. Significant aerosol formation was observed following the reaction of chlorpyrifos-methyl with OH radicals, and the main carbon-containing products detected in the gas phase were chlorpyrifos-methyl oxone and 3,5,6-trichloro-2-pyridinol” (Studies on the Atmospheric Degradation of Chlorpyrifos-methyl, Environ. Sci. Technol., 45, 1880-1886, 2011).

The theorethical half-lives in air for the metabolites TCP and TMP, calculated using the Atmospheric Oxidation Program (AOP), were 60.5 d and 12.2 d, respectively (Simon, 2001). **Therefore, according to its DT50, it is expected that they undergo long-range transport.**

CHL and CHLM have similar molecular structures and hence would be expected to show the same reactivity trends. Therefore, it is of interest to compare the results of the submitted studies with those reported on chlorpyrifos.

According to Muñoz et al (2011), atmospheric lifetime in relation to the reaction with OH of approximately 2 h and 11 h for chlorpyrifos and chlorpyrifos-oxon, respectively. Photolysis was found to be unimportant relative to reaction with OH. The main products detected in the gas phase from the reaction of OH with chlorpyrifos were SO2, chlorpyrifos-methyl -oxon, 3,5,6-trichloro-2-pyridinol and diethylphosphate.

On the other hand, Chlorpyrifos-methyl and the analogous compound chlorpyrifos are organophosphorous insecticides and among the most widely employed insecticides for agricultural crop protection (Muñoz et al, 2014).

A number of studies have indicated that emissions of these insecticides into the atmosphere can be significant. Rice et al. (2002) investigated the volatilization of a series of pesticides from soil and found that following application of chlorpyrifos to soil approximately 10% of the compound had evaporated within 20 days.

2.8.4. Summary of monitoring data concerning fate and behaviour of the active substance, metabolites, degradation and reaction products

Dow AgroSciences designed field experiments to bring together elements of catchment-scale water monitoring, edge of field water monitoring and spray drift deposition measurements. In some cases chlorpyrifos was used as a surrogate since both molecules have such similar properties and use patterns.

2.8.4.1. Summary of general European Monitoring Studies

Member States have conducted national water quality surveillance programs which target the determination of a number of active substances, including chlorpyrifos and chlorpyrifos-methyl.

In the revised proposal for a list of priority substances in the context of water framework directive (COMMPS procedure), monitoring data were provided (B.8.4.1/01). The data for chlorpyrifos and chlorpyrifos-methyl came from Belgium, Spain and the UK. They comprised 510 individual measurements from 68 sampling stations for chlorpyrifos and 326 measurements from 42 sampling stations (all from Belgium) for chlorpyrifos-methyl. Maximum concentrations of residues in water for chlorpyrifos were 0.108, 0.004 and 0.248 µg/L in Belgium, Spain and UK, respectively. The overall 90th percentile exposure concentration from the whole dataset was 0.0098 µg/L. Of the 326 samples analysed for chlorpyrifos-methyl, none of the samples contained residues above the detection limit (0.005 µg/L).

A monitoring programme has been carried out by an official agreement between the Agriculture Council of the Valencia region (Consellería de Agricultura) and the University Jaume I, Castellón, Spain (B.8.4.1/02). The Valencia region of Spain is an important citrus-growing area where chlorpyrifos is intensively used. From 1993 to 1999, 579 surface water samples (plus 10 groundwater in 1999) were analysed for a range of pesticides, including chlorpyrifos. Residues of chlorpyrifos were found in seven water samples out of 232 collected during 1993, 1995 and 1998. The maximum concentration was 16.5 µg/L (El Clot, Castellón) measured in 1995. The results were subjected to statistical analysis. The 90th percentile for these three years was 0.186 µg/L. When data are analysed individually the 90th percentile exposure concentrations were 0.056, 1.170 and 0.386 µg/L in 1993, 1995 and 1998, respectively. For 1994, 1996, 1997 and 1999, all samples (347 surface waters, plus 10 groundwater samples) were “nd”, therefore, the 90th percentile exposure concentration will be <0.015 µg/L (1/2 LOD).

A number of official bodies conducted a monitoring program of the waterways of Adige River (and tributaries) in the Trentino province, North of Italy (B.8.4.1/03). This is an important vine-growing area. Samples were analysed for 113 different actives in 1991, and 132 actives in 1993. Both chlorpyrifos and chlorpyrifos-methyl were included in the analyses in both years. Chlorpyrifos was not detected in any of the water samples (76 in total) analysed in both 1991 and 1993. Residues of chlorpyrifos were found in four sediment samples out of the 76 collected over the 2 years. Concentrations of chlorpyrifos in the range 4-52 µg/kg were measured in sediment at three sampling locations (Torrente Noce, Torrente Tresenica and Fossa Dei Gamberi). Three of the four detections were in the autumn and reflect a detection rate of 11%. Trace amounts of chlorpyrifos-methyl (0.01 and 0.05 µg/L) were detected in water during the June sampling at three locations (Torrente Avisio and Fossa di Caldaro-alla Foce and Roviere della Luna). This reflects a detection rate of 8%. Based on the statistical evaluation of the data, the 90th percentile exposure concentrations (realistic worst case) for chlorpyrifos in sediment is 11.7 µg/kg and for chlorpyrifos-methyl in surface water is 0.020 µg/L.

Other surface water monitoring programme was carried out in Italy at national and regional-scale in 2000 (B.8.4.1/04). For chlorpyrifos, 3488 surface water samples were analyzed at National level from 312 different water bodies. It was found in five samples from four water bodies at a maximum concentration of 0.09 µg/L. For chlorpyrifos-methyl, 3047 surface water samples were analyzed from 289 water bodies. It was found in only one sample from one water body at a maximum concentration of 0.09 µg/L. Not enough information was available within the report, particularly with regard to limits of detection/quantitation, to carry out robust statistical analysis.

A total of 5661 water samples, excluding the COMMPS data (and >9 sediment samples) were analysed in Knowles et al. (2003), Ref. K123A (B.8.4.1/29) from chlorpyrifos monitoring programmes that have been conducted in Europe (15 EU Member States, as well as Norway and Switzerland) in 2002. The study focused on data for surface waters and groundwater, although some drinking water data are also included. Not enough information was available within the report, particularly with regard to limits of detection/quantitation, to carry out robust statistical analysis. Results indicated that chlorpyrifos occurrence in groundwater was rare. It was detected only in three samples (maximum ca 1 µg/L), but these may have been isolated pollution incidents. In surface water, chlorpyrifos was not detected at any of the sites in Germany or Greece; it was detected (LOD 0.005 to 0.2 µg/L) once in France (at 0.1 µg/L) and in one of 12 rivers in Switzerland (maximum 0.5 µg/L). It was also detected in Spain, Belgium and the UK, with the highest percentage (4% of samples) and the maximum concentration (0.5 µg/L) being found in Belgium. The total number of detections (>LOD) from the 3453 surface water samples was 74 (2.1%)

In the 2008 survey (B.8.4.1/30), of over 32000 surface water samples from at over 2200 sites in 16 countries, the total number of detections (>LOD) was 567 (1.8%) with about 0.13% at concentrations above 0.1 µg/L. Maximum concentrations were at 104 µg/L in Belgium, 4.9 µg/L, in France, µg/L in Switzerland and 0.019 µg/L in the UK (one sample at 0.149 µg/L was part of a pollution incident). For drinking water, no cases of non-compliance with the drinking water standard of 0.1 µg L-1 were reported in Germany and the UK, nor were any requirements for remedial measures. In groundwater, from more than 20 000 samples analysed, obtained from about 7000 sites, only 97 (0.5%) positive findings were reported, with only 8 samples (0.04%) above 0.1 µg l-1.

Taking into account the proposal of the aquatic risk assessment based on the recommendations of the new EFSA Aquatic Guidance document, the following ETO and ERO RAC values are proposed by RMS:

ETO-RAC = 0.015 µg/L (Assessment Factor = 2)

ERO-RAC = 0.02 µg/L (Assessment Factor = 4)

Therefore, the results of these monitoring must be considered with caution because the proposed RAC are in the same lavel of LOD ore even below the LOD and LOQ values of some of them.

2.8.4.2. Summary of modelling studies

The objective of Pepper & Arnold (2002), Ref. K125 (B.8.4.1/05), was to assess parameters that may affect the extent of spray drift of chlorpyrifos (applied as DURSBAN 4 EC formulation) into edge of field surface water and consequent environmental concentrations.

With this purpose, two series of experiments were conducted.

- The first series of experiments were directed at identifying key factors on chlorpyrifos spray drift and subsequent deposition on surface water in a large scale wind tunnel.
- The second series of experiments were carried out in small scale aquatic systems in the laboratory and to investigate the dissipation of chlorpyrifos from the water surface (Indoor tanks) and its hydrolytic stability in several matrices.

This work showed that residues of chlorpyrifos in the water/sediment test system initially remain on the water surface and with time, a part of this material moves into the water column. According to the study author, this could be the explanation for the lower than expected water concentrations seen in the field scale monitoring.

In order to better understand the fate of chlorpyrifos in small water bodies, a modelling was undertaken in Yon (2003), Ref. K134 (B.8.4.1/06), using the results of the small tank study. The modelling tool MODELMAKER was used to evaluate the data of Pepper (2002). The aim was to construct a simple conceptual model in an attempt to derive rate constants for the dissipation and the degradation of chlorpyrifos in the different model compartments. In this model, where sediment was not included, the majority of chlorpyrifos residues deposited onto the water surface move into the water column (up to 36%) or are lost from the surface by volatilization.

A second model was proposed in Yon (2007b), Ref. K141 (B.8.4.1/07), where samples of surface water, sub-surface water and sediment in the field experiments conducted at Rosemaud (Herefordshire, UK) and Church (Kent, UK) farms were modelled. In total, data from 10 individual tanks were used in a five-compartment model using the kinetic tool MODELMAKER. The results of the laboratory and field experiments on the distribution and dissipation of chlorpyrifos in water and sediment systems showed that volatilization from the surface water layer was an important and rapid process while movement from the sub-surface water to sediment was a much slower process. The amount of chlorpyrifos in the sub-surface water layer was variable between the various tanks but average 50% (range 20-87%). Study author proposed to use this percentage as a correction factor when estimating water column concentrations to which aquatic organism may be exposed. However, the experiments were not designed to address the argument of drift reduction due to a very rapid volatilization. Field studies conducted in UK were designed to study dissipation of chlorpyrifos and its distribution in water bodies after spray application. The volatilization hypothesis is based on theorical calculation but no measures of volatilization were done in any of these studies so the results of the modelling cannot be validated.

While the above higher tier studies only took into account spray drift as possible route of entry of chlorpyrifos and chlorpyrifos-methyl in surface water, Pepper (2014), Ref. XCC4003 (B.8.4.1/08), studied the vegetated buffer strip removal efficiency as a mitigation against the risk of pesticides being transported to surface waters in runoff.

Using R4 climatic data, a storm event was simulated corresponding to an effective 71 mm storm event with 11 mm of associated runoff.

Overall, the study demonstrated that the grass buffer strips tested were capable of very high rates of pesticide removal under the selected conditions. This represents a reduction of close to 100% of the applied chlorpyrifos across 20 m plots, and over 99% on the 10 m plots.

The results of this study were compared with the chlorpyrifos removal efficiencies calculated by VFSMod in order to support that VFSMod tool provides an acceptable estimation of chlorpyrifos runoff reduction efficiencies when similar vegetated filter strips are used to mitigate runoff. For example: 10 m VFSMod: 97.8% versus field values (Pepper, 2014): 99.56-99.96%.

2.8.4.3. Summary of field studies

To investigate the transport of chlorpyrifos-methyl at field-scale (in some cases using chlorpyrifos as a surrogate since both molecules have such similar properties and use patterns), a series of drift experiments and edge-of field monitoring studies have been conducted. They were presented separately as four different crop classes; citrus, pome and stone fruit, vines and arable (vegetables, cereals and pasture).

Citrus: The objective of the study performed by Hernández et al (2002), Ref. K118 (B.8.4.1/09), was to monitor chlorpyrifos concentrations in ecologically-relevant surface water in the Valencia area of Spain (El Clot de la Mare de Deu, Burriana, Castellón), which is an important citrus area (around 200,000 ha). The monitoring was carried out between August 2000 and October 2001 to show actual exposure concentrations under typical use conditions. The study did not include experimental applications of chlorpyrifos since the applications were made locally according to specific insect control needs. However, extensive data were collected on the use of chlorpyrifos in the study area. Following application, pesticides may reach the Clot by different diffuse routes, i.e. via the irrigation channels in the water remaining after irrigation, by run-off after the flood irrigation of the orchards, by run-off after severe rainfall events which are common in the area (e.g. thunderstorms), or transported by spray-drift after application. Monitoring of the surface water was conducted in the study area by collecting samples (ca 60 mL) from seven selected points. Two different frequencies of sampling were established: every two weeks during the months where little or no chlorpyrifos is used, and twice weekly during the periods of typical application (May-June, and August-October). Further samples were taken in response to major run-off events, e.g. thunderstorms. The data show that chlorpyrifos was detected in surface water samples from both the Clot and from the concrete-lined irrigation channels. Chlorpyrifos was detected (>0.019 µg/L) in 155 samples out of the 552 analysed during the study, and it could be quantified (concentrations >0.025 µg/L) in 94 of these. 17 samples out of the 94 quantified showed concentrations >0.1 µg/L (11 were between 0.1-1 µg/L, and 6 were >1 µg/L). In the Clot itself, chlorpyrifos was detected in 49 samples out of 243, and could be quantified (>0.025 µg/L) in 21 of them. Only one sample was above 0.1 µg/L (maximum 0.15 µg/L in September 2001).

Capri, E. & Yon, D. (2002a), Ref. K127A (B.8.4.1/10), assessed surface water and sediment exposure to chlorpyrifos and chlorpyrifos-methy in citrus orchards in Sicily, which is the most important Italian citrus area. The study was organised at three different geographical scales: Regional (Catania Province), catchment (ca 200 km2, with citrus as the main crop) and field (Maugeri farm). At field scale, Chlorpyrifos-methyl (as RELDAN 22) was applied in the field between the rows and along the row using fan-driven application in two plots, one without vegetation and the other with vegetation. Following application, the ditch was monitored for 270 hours, by measuring surface water concentrations. In a second part of the study, Chlorpyrifos-methyl drift was monitored. In water samples collected during the intensive pesticide application period (July to September, 2001), chlorpyrifos and chlorpyrifos-methyl 'were not detected at regional scale in either the sediment (<0.01 mg/kg) or the water (<0.05 ug/L). At catchment-scale, traces of chlorpyrifos (0.01 mg/kg) were detected in the sediment in August and September, 2001. However, chlorpyrifos and chlorpyrifos-methyl were not detected in surface water (<0.05 ug/L). At field scale, sediment samples collected showed no detectable residues of chlorpyrifos-methyl (<0.01 mg/kg). Chlorpyrifos-methyl was detected in three water samples (0.06, 0.08 and 0.08 □g/L). The 90th percentile exposure concentration was 0.067 µg/L. The field study measured down-wind spray drift deposition from applications to citrus crops in Italy and evaluated the influence of some agronomic factor such as spraying equipment. Additionally, an attempt was made to compare these results with the "reference drift values" for FOCUS PECsw calculations (Ganzelmeier data set). According to the study author, these concentrations were lower than predicted based on spray drift tables (Ganzelmeier).

It is noted that theLOQ and LOD values above the proposed ETO and ERO RAC.

Pome and stone fruit: Kennedy, S.H., 2008a, Ref. K158 (B.8.4.1/14), conducted a field-scale experiment where spray drift and edge of the field surface water concentrations were measured after treatment of two orchard sites (Varennes-sur-Loire and Loiré, in Central France) with EF-1551 (an EC formulation containing chlorpyrifos at 480 g/L) at a nominal application rate of 1080 g as/ha (2.25 L formulation/ha) in June 2007. Both orchards were directly adjacent to the water body with a grassed buffer area of between 7 and 10m between the orchard and the bank side. The results of this study were the subject of Yon (2008a), Ref. K159 (B.8.4.1/15). Detailed (hourly averaged) edge of field water monitoring of the Varennes irrigation ditch showed maximum water concentrations of ~0.1 µg/L in three of the samples. All other measurements were in the range "ND" to 0.07 µg/L. Detailed (hourly averaged) edge of field water monitoring of the river at the Loiré site showed a maximum water concentration of 0.75µg/L in one of the samples collected during the first hour after treatment. All other measurements were in the range 0.05 to 0.2 µg/L. Water concentrations measured at one of the sub-plots were significantly higher than those measured at the second (max. concentration = 0.17 µg/L, samples generally <0.1 µg/L). The results for the upstream samples suggested that there may have been a contribution from treated fields upstream of the experimental site. Detailed water monitoring of the irrigation channel at the Varennes site showed no responses at a catchment scale to treatments made to the Varennes experimental site on 12 June or to two further applications made on 19 June, 2007. The results show that for most of the monitoring period concentrations of chlorpyrifos were "ND" or <LOQ. Chlorpyrifos concentrations up to 0.03µg/L were measured during the first three weeks of July and may have been the result of run-off events in response to reasonably heavy rainfall.

In an additional experiment, drift samples were collected up to 9m and 18.5 m from the target crop in two subplots. The spray drift data were used to calculate experimental drift curves which were compared with Ganzelmeier data. Maximum measured hourly concentrations were compared with theoretical PECsw value calculated based on the measured drift deposition data and water depth from the respective field experiments. According to the study author, the average percentage of the difference between theorethical and experimental values (25.6%, individual values were 3, 5, 62 and 32%) can be used as a correction factor (0.256) in order to refine surface water concentrations for chlorpyrifos in water from spray drift measurements.

The limit of quantification I water was 0.01 µg/L

The results of the surface water monitoring carried out as part of the exposure trials conducted in apple orchards in the Loire valley in France (B.8.1.1/16), were combined and analysed using a number of statistical methods (Parkhust, Excel and Dist. Free) in order to derive the reasonable worst case exposure concentrations (defined as the 90th percentile) at edge of field and at catchment (receiving water) scale. The average 90th percentile exposure concentration for the catchment/ receiving water dataset, calculated using the three methods, is 0.006 µg/L.

Vines: Capri and Yon (2002b), Ref. 126A (B.8.4.1/18), monitorized chlorpyrifos and chlorpyrifos-methyl surface waters at field, catchment and regional scale in Trentino (N. Italy, 2001 – 2002). The main crops in this area are vines and apples.

At regional and catchment scale, sediment and water samples were collected during 2000 and 2001 in the Trentino region of Italy (Northern Mediterranean vine and apple agriculture area). The samples were analysed for both chlorpyrifos and chlorpyrifos-methyl. No detections of chlorpyrifos or chlorpyrifos-methyl were observed in either water (i.e. <0.05µg/L) or sediment (i.e. <0.01 mg/kg). It is unclear from the study if the findings can be correlated with the normal and proper use of chlorpyrifos and chlorpyrifos-methyl in the selected region.

At field scale the surface water exposure and the dissipation of chlorpyrifos in a test site located in a vineyard in S. Michele all' Adige (Trento province) was monitored in 2000 and 2001.

On 27 July 2000, chlorpyrifos (DURSBAN 480 EC) was applied to the vineyard (two plots, Campi and Casetti) and drift deposition and chlorpyrifos dissipation in the ditch were monitored. This was repeated on 10 July 2001 to give a second year's data. In Campi field, the application rate was 248 g ai/ha, whilst in Casetti field, 540 g ai/ha was sprayed.

Drift trials using chlorpyrifos showed that drift loadings in the realistic worst-case conditions chosen for this study could reach predicted levels from Ganzelmeier spray-drift tables. However, the measured drift was highly variable. This variability was due to physical factors such as intercepting vegetation and also the agricultural practice of suspending applications when moving between vine rows.

In the edge-of-field experiments conducted in 2000, only seven samples out of a total of 68 collected contained residues >0.05 µg/L and only four of these were >0.1 µg/L during the monitoring programme conducted during 2000. In 2001, only two out of 16 samples contained residues >0.05 µg/L and both were >0.1 µg/L. The maximum measured chlorpyrifos concentrations in the ditch water at field scale were 0.34 µg/L and 0.09 µg/L immediately after the first and second applications, respectively. No sediment samples were collected at field scale. Therefore, concentrations above the RAC were found in this study at field scale (edge of the field surface water concentrations)

It is noted that theLOQ and LOD values above the proposed ETO and ERO RAC.

In Kennedy (2008b), Ref. K160 (B.8.4.1/19), two vineyard sites in the Loire Valley in Central France, were sprayed with applications of EF-1551 (an EC formulation containing chlorpyrifos at 480 g/L) at a nominal application rate of 337.5 g as/ha in July (Earl du domaine des Rondrais) and August 2007 (Earl Laurilleaux). The scope of the experiment involved both field-scale investigations (spray drift, fate in an adjacent water body) following treatment of the vineyards and catchment-scale water monitoring measuring pesticide losses from a wider catchment at the Earl du domaine des Rondrais site, located downstream of the treated area where the stream leaves the farm. The results of this study were the subject of Yon (2008b), Ref. K159 (B.8.4.1/20). Detailed (hourly averaged) edge of field water monitoring of the stream at the Earl Laurilleaux site (pro-rated to a more realistic 30cm water depth) showed maximum water concentrations of 1.1 µg/L. The water level in the stream during the experiment was extremely low (l0 - 15 cm) and the flow rate was very slow (0.02m/s) due to the fact that the stream was drying up at this period in the season. Additionally, due to an error during spraying at the Earl du domaine des Rondrais site, none of the edge of field water samples were analysed.

The measured chlorpyrifos 90th percentile drift for vines (post blossom treatment) was found to be less than the standard data (BBA 2000, FOCUS 2003) at one trial site and greater than the standard at the other site. Overall the findings of the two trials indicate that the standard drift data for vines is generally representative of spray practices for vines in France. According to the study author, the average percentage of the difference between theoretical and experimental values –edge of the field measured concentrations- (15%, individual values were 15.0 and 15.5%) can be used as a correction factor (0.150) in order to refine PECsw for chlorpyrifos from spray drift measurements.

At the Earl du domaine des Rondrais, a total of 153 samples were collected between 7 June 2007 and 14 November 2007. Water monitoring of the stream at the Earl du do maine des Rondrais site for the 2007 season shows a series of responses to chlorpyrifos treatments, resulting in measures concentrattions above 0.1 µg/L. Peak concentrations of 0.12 µ/L, 0.19 µ/L, 0.12 µ/L and 0.1 µ/L were measured on 6 July, 20 July (the day after the Earl du domaine des Rondrais site treatment), 22 July and 24 July respectively. These concentrations could be related with runoff events in response to heavy rainfall.

To allow interpretation ofthe catchment monitoring data, a record of the use of chlorpyrifos at the immediate area was also collected. No other chlorpyrifos based products were used at the Earl du domaine des Rondrais site during the 2007 season. At the Earl Laurilleaux site one other treatment was made on the farm the day before the trial was conducted.

The results of the surface water monitoring carried out as part of the exposure trials conducted in vineyards in the Trentino-Alto Adige region of Northern Italy and the Loire valley in central France were combined and analysed using a number of statistical methods in order to derive the reasonable worst case exposure concentrations (defined as the 90th percentile) at edge of field and at catchment (receiving water) scale (B.8.4.1/21). The average 90th percentile exposure concentration for the catchment/receiving water dataset, calculated using the three methods, is 0.191 µg/L. The average 90th percentile exposure concentration for the catchment/ receiving water dataset, calculated using the three methods, is 0.038 µg/L.

Arable crops: Kennedy, S.H., 2007, Ref K140A (B.8.4.1/24), conducted a detailed field and catchment-scale monitoring study in Herefordshire, UK. Experiments were proposed in cereals and top fruit as representing the major markets for chlorpyrifos use in the UK. The scope of the experiment involved both field-scale investigations (spray drift, fate in contained water bodies and fate in an adjacent stream) following treatment of an arable field and catchment-scale water monitoring. Prestons field (two replicated sub-plots planted with winter oats) at ADAS Rosemaund, UK, was sprayed with applications of EF-1042 (an EC formulation containing chlorpyrifos at 480g/L) at a nominal application rate of 720 g as/ha (1.5L formulation/ha), using standard arable crop spraying equipment on 2 separate occasions (October 2006 and May 2006). The results of this study were the subject of Yon (2007b), Ref. K143 (B.8.4.1/25).

A drift deposition experiment was conducted twice at Prestons field site in two seasons, spring and autumn. The 90th percentile spray deposition values were compared with standard FOCUS drift data for arable crops at distances of 6-12 m. The results for both sub-plots and seasons showed that drift deposition was significantly lower (70 - 90%) than standard FOCUS drift curve.

A second experiment with the aim of compare drift deposition at different height was conducted, concluding that drift deposition in the experiment was higher at the top of the bank than at water level.

An additional experiment was performed in spring with the aim of seeing if chlorpyrifos volatilized from the treated area and redeposited at some distance (potentially in the water body) overnight. The results show that between 0.004 and 0.012% of the applied chlorpyrifos was measured on the drift targets placed 10 cm above the middle of the stream. Similar levels were also measured at 6m from the edge of the treated area and at water level in the middle of stream. Therefore, volatilization and deposition was observed at very low rates. The Notifier proposed to use this experimental field data in order to refine the redeposition contribution of chlorpyrifos. Under RMS' opinion one experimental datum is not robust enough to be used with refinement purposes (see further explanations below).

The fate and behavior of chlorpyrifos in shadow static water bodies was also studied. However, the overall recoveries at the end of the experiment (24 hours) was 190% of the initial applied amount for all tanks. The study author states that it could be due to volatilization and redeposition of volatile residues of chlorpyrifos or due to contamination of tanks with airborn particles of treated soil. Therefore, no conclusions can be derived from this experiment.

Daily water samples were collected from the stream at the Rosemaund farm catchment outlet from November 2004 to November 2006 (2 years) using two automatic samplers. Moreover, records of the use of chlorpyrifos at the immediate area were collected. A total of eight applications of chlorpyrifos were made on the Rosemaund farm during the 2004 season, 10 were made during 2005 and a further 7 applications have been made up to the end of the monitoring period in November 2006.

Detailed (hourly averaged) edge of field water monitoring of the Rosemaund stream during two separate applications (autumn and spring) to a cereal field show that at no time during the sampling did residues of chlorpyrifos in the adjacent were (max.0.04 µg/L for plot 1 and 0.08 µg/L for plot 2.

In Kennedy (2008c), Ref. K162 (B.8.4.1/26), a field experiment was designed to measure spray drift deposition and to provide edge of field and catchment-scale water monitoring. Experiments were proposed in permanent pasture (also a surrogate crop for cereals) as representing a major market for chlorpyrifos use in the EU. Two adjacent fields bordering the River Meden at ADAS Gleadthorpe, UK, were sprayed with applications of EF-1551 (an EC formulation containing chlorpyrifos at 480 g/L) at a nominal application rate of 720 g as/ha (1.5 L formulation/ha), using standard arable crop spraying equipment on a single occasion (nominal spray volume 200 L/ha) in May 2007 .The results of this study were the subject of Yon (2007b), Ref. K143 (B.8.4.1/27).

The drift deposition experiment was conducted in a north east England site at Gleadthorpe research farm (UK), adjacent to River Meden. Data were compared with standard FOCUS drift data for arable crops at distances of 3-18 m (single application). The results for both sub-plots showed that drift deposition was higher and lower than standard FOCUS drift curve. Therefore, the study author concluded that the findings indicate that the drift data obtained for arable crops can be considered approximately the same as standard drift data.

Detailed (hourly averaged) edge of field water monitoring of the Meden stream at the Gleadthorpe farm showed maximum water concentrations of 0.18 µg/L. Daily water samples were collected from the River Meden from 15 May 2007 to 2 October 2007 (one season) using an automatic samplers. Records of the use of chlorpyrifos at the immediate area were not collected. Low chlorpyrifos concentrations in water were detected. The results for the monitoring showed that there were no peaks of chlorpyrifos in response to Gleadhorpe farm treatment. for the whole of the monitoring period concentrations of chlorpyrifos were either "ND" (set = <0.003µg/L) or <LOQ (8 daily events, set = 0.005µg/L).

The results of the surface water monitoring carried out as part of the exposure trials conducted in mixed agricultural catchments at two sites in the UK were combined and analysed using a number of statistical methods in order to derive the reasonable worst case exposure concentrations (defined as the 90th percentile) at edge of field and at catchment (receiving water) scale (B.8.4.1/28). A total of 106 edge of field exposure measurements (excluding data from the pollution incident at Gleadthorpe, samples after 5 hours not used) and 820 catchment/ receiving water scale measurements were analysed. The average 90th percentile exposure concentration for the catchment/ receiving water dataset, calculated using the three methods, is 0.044 µg/L. The average 90th percentile exposure concentration for the catchment/ receiving water dataset, calculated using the three methods, is 0.008 µg/L.

2.8.4.4. . Overall field studies

The results of the surface water monitoring conducted as part of the exposure trials carried out in a variety of agricultural catchments at sites in Spain (citrus), Italy (vines and citrus), France (orchards and vines) and the UK (mixed arable) and summarised above, were combined and analysed using a number of statistical methods (Parkhurst, EXCEL and distribution free method) in order to derive the reasonable worst case exposure concentrations (defined as the 90th percentile) at edge of field and at catchment (receiving water) scale (B.8.4.1/31). A total of 1495 edge of field exposure measurements (excluding data from the pollution incident at Gleadthorpe, UK) and 1389 catchment/ receiving water scale measurements (including a substantial proportion of daily monitoring data) were analysed.

- The overall average 90^{th} percentile exposure concentration for the edge of field water dataset, calculated using the three methods, is 0.026 µg/L.
- The average 90^{th} percentile exposure concentration for the catchment/ receiving water dataset, calculated using the three methods, is 0.014 µg/L.

It is also highlighed the limit of detection is close to the levels producing ecotoxicological effects (LOQ from 0.003 to 0.05 µg/L.

2.8.5. Summary of exposure calculations and product assessment

2.8.5.1. Predicted environmental concentrations in soil (PECsoil)

Predicted Environmental Concentrations in soil (PECsoil) for chlorpyrifos-methyl and its major aerobic soil metabolites TCP and TMP were calculated based on the proposed GAP. The maximum PECsoil value for the anaerobic metabolite DCP was also added for all the intended uses.

Resulting soil concentrations were determined using standard assumptions with respect to soil density (1.5 g/cm3) and depth of incorporation (5 cm). The worst case field soil DT50 value of 2.172 days (persistence endpoint) based on SFO kinetics (K1=0.31914) was used for chlorpyrifos-methyl calculations. Both instantaneous PECsoil values and Time Weighted Average (TWA) PECsoil values were calculated.

As inputs parameters, for TCP metabolite, a DisT50 of 103.4 days (Kslow= 0.006704 from DFOP kinetic) was considered as a worst case value from field dissipation studies. For TMP and DCP, the worst cases of laboratory studies were used to calculate the PECsoil. It was, 11.35 days for DCP and 1000 days for TMP (as no decline of this metabolite was observed in some soils at the end of the study).

The maximum occurrences in soil of the main metabolites were: TCP.- 90.27% (from Kang, 2014; anaerobic study); TMP.-13% (from De Vette, 2001; aerobic degradation of TCP, representing a worst case since this percentage has been obtained from the precursor of TMP and not directly from the active substance) and DCP.- 73.6 % (from Kang, 2014; anaerobic study).

The plateau concentration in soil after consecutive years of application was not calculated for chlorpyrifos-methyl as field dissipation studies indicated that soil accumulation did not need to be addressed (worst case DT90 <1 year) and was considered not applicable for the anaerobic metabolite DCP. However for the metabolites TCP and TMP, the worst case DT90 values were >1 year, indicating that soil accumulation calculations were required.

A summary of the maximum PECsoil and accumulation PECsoil values for each component is presented below:

GF-1684

Table 2.8.5.1-1: Maximum PEC_{soil} values for Chlorpyrifos-methyl

Compound	Crop	$PEC_{soil,max}$ [mg/kg] in 5 cm depth	21-day TWA
Chlorpyrifos-methyl	Citrus	0.343	0.051
Chlorpyrifos-methyl	Maize	0.900	0.134
Chlorpyrifos-methyl	Cotton	0.363	0.054
Chlorpyrifos-methyl	Table grapes	0.324	0.048
Chlorpyrifos-methyl	Grapes	0.180 (single)	0.0269 (single)
		0.1823 (multiple)	0.0272 (multiple)
Chlorpyrifos-methyl	OSR	0.120	0.018
Chlorpyrifos-methyl	Pome fruit	0.480	0.072
Chlorpyrifos-methyl	Potato	0.288	0.043
Chlorpyrifos-methyl	Solanaceous	0.450	0.067
Chlorpyrifos-methyl	Soybean	0.270	0.040
Chlorpyrifos-methyl	Stone fruit	0.544	0.081

Chlorpyrifos-methyl	Strawberry	0.360	0.054

Table 2.8.5.1-2: Maximum PEC_{soil} values for the metabolite TCP

Compound	Crop	$PEC_{soil,max}$ [mg/kg] in 5 cm depth	PEC plateau	21-day TWA
TCP	Citrus	0.192	0.196	0.179
TCP	Maize	0.504	0.516	0.470
TCP	Cotton	0.203	0.208	0.189
TCP	Table grapes	0.181	0.186	0.169
TCP	Grapes	0.101 (single)	0.103 (single)	0.0941 (single)
		0.1927 (multiple)	0.1973 (multiple)	0.1798 (multiple)
TCP	OSR	0.067	0.069	0.063
TCP	Pome fruit	0.269	0.275	0.251
TCP	Potato	0.161	0.165	0.150
TCP	Solanaceous	0.252	0.258	0.235
TCP	Soybean	0.151	0.155	0.141
TCP	Stone fruit	0.304	0.312	0.284
TCP	Strawberry	0.201	0.206	0.188

Table 2.8.5.1-3: Maximum PEC_{soil} values for the metabolite TMP

Compound	Crop	$PEC_{soil,max}$ [mg/kg] in 5 cm depth	PEC plateau	21-day TWA
TMP	Citrus	0.029	0.053	0.029
TMP	Maize	0.077	0.140	0.077
TMP	Cotton	0.031	0.056	0.031
TMP	Table grapes	0.028	0.050	0.028
TMP	Grapes	0.015 (single)	0.0281 (single)	0.0023 (single)
		0.0308 (multiple)	0.0558 (multiple)	0.0306 (multiple)
TMP	OSR	0.010	0.019	0.010
TMP	Pome fruit	0.041	0.075	0.041
TMP	Potato	0.025	0.045	0.025
TMP	Solanaceous	0.039	0.070	0.038
TMP	Soybean	0.023	0.042	0.023
TMP	Stone fruit	0.047	0.085	0.046
TMP	Strawberry	0.031	0.056	0.031

Table 2.8.5.1-4: Maximum PEC_{soil} values for the metabolite DCP

Compound	Crop	$PEC_{soil,max}$ [mg/kg] in 5 cm depth	21-day TWA
DCP	Citrus	0.129	0.072
DCP	Maize	0.338	0.190

DCP	Cotton	0.136	0.077
DCP	Table grapes	0.122	0.069
DCP	Grapes	0.068 (single)	0.0381 (single)
		0.0964 (multiple)	0.0543 (multiple)
DCP	OSR	0.045	0.025
DCP	Pome fruit	0.180	0.102
DCP	Potato	0.108	0.061
DCP	Solanaceous	0.169	0.095
DCP	Soybean	0.101	0.057
DCP	Stone fruit	0.204	0.115
DCP	Strawberry	0.135	0.076

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Table 2.8.5.1-5: Maximum PEC_{soil} values for Chlorpyrifos-methyl

Compound	**Crop**	**$PEC_{soil,max}$ [mg/kg]** in 5 cm depth	**21-day TWA**
Chlorpyrifos-methyl	Grapes	0.113	0.017
Chlorpyrifos-methyl	OSR	0.272	0.041

Table 2.8.5.1-6: Maximum PEC_{soil} values for the metabolite TCP

Compound	**Crop**	**$PEC_{soil,max}$ [mg/kg]** in 5 cm depth	**21-day TWA**
TCP	Grapes	0.063	0.059
Peak residue level after repeated annual uses		0.069	-
TCP	OSR	0.152	0.142
Peak residue level after repeated annual uses		0.167	-

Table 2.8.5.1-7: Maximum PEC_{soil} values for the metabolite TMP

Compound	**Crop**	**$PEC_{soil,max}$ [mg/kg]** in 5 cm depth	**21-day TWA**
TMP	Grapes	0.010	0.010
Peak residue level after repeated annual uses		0.041	-
TMP	OSR	0.023	0.023
Peak residue level after repeated annual uses		0.099	-

Table 2.8.5.1-8: Maximum PEC_{soil} values for the metabolite DCP

Compound	**Crop**	**$PEC_{soil,max}$ [mg/kg]** in 5 cm depth	**21-day TWA**
DCP	Grapes	0.043	0.024
DCP	OSR	0.102	0.058

Additionally, a new data requirement concerning to the definition of residue in soil was identified. The metabolite N-methyl TCP reaches a maximum value of 5.18 %AR at the end of the study (122 d). Therefore, according to (EU) Regulation 283/2013 as stated in the point 7.1.2.1.2c), further information should be necessary regarding to this metabolite.

An approximation based on the correction molar of the maximum PECsoil values for CLP-Methyl was used to calculate the initial concentration in soil of this metabolite. For this, a formation fraction of 1 from parent was assumed as default value.

GF-1684

Table 2.8.5.1-9: Maximum PEC_{soil} values for N-Methyl-TCP

Compound	Chlorpyrifos-methyl Molar mass: 322.6 g/mol	N-Methyl-TCP Molar mass: 210.9 g/mol
Crop	**$PEC_{soil,max}$ [mg/kg]** in 5 cm depth	
Citrus	0.343	0.224
Maize	0.900	0.588
Cotton	0.363	0.237
Table grapes	0.324	0.212
Grapes	0.180 (single)	0.118 (single)
	0.1823 (multiple)	0.119 (multiple)
OSR	0.120	0.078
Pome fruit	0.480	0.313
Potato	0.288	0.188
Solanaceous	0.450	0.294
Soybean	0.270	0.176
Stone fruit	0.544	0.355
Strawberry	0.360	0.235

SAP200CLORI

Table 2.8.6.1-10: Maximum PEC_{soil} values for N-Methyl-TCP

Compound	Chlorpyrifos-methyl 322.6	N-Methyl-TCP 210.9
Crop	**$PEC_{soil,max}$ [mg/kg]** in 5 cm depth	
Grapes	0.113	0.074
OSR	0.272	0.178

2.8.5.2. Predicted environmental concentrations in ground water (PECgw)

Predicted environmental concentrations of chlorpyrifos-methyl and its soil metabolites TCP, TMP and DCP in groundwater (PECGW) were calculated using the leaching models FOCUS-PEARL (v. 4.4.4), FOCUS PELMO (v. 5.5.3) and FOCUS MACRO (v. 5.5.4 Châteaudun scenario) for all the intended uses proposed in the GAP.

In aerobic soil test systems, chlorpyrifos-methyl degrades to its primary metabolite TCP which in turn degrades to the metabolite TMP. In anaerobic conditions chlorpyrifos-methyl degrades to 3,6-DCP.

For modelling purposes the following input values were used:

Chlorpyrifos-methyl: Geometric mean parent DT50 field 1.32 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7); KOC: 1376mL/g, 1/n= 0.957; Water solubility (mg/L): 2.74 at pH 7 and 20°C; Vapour pressure: 1.945 e-03 Pa at 20°C.

TCP: DT50lab= 29.36 d; ff from CHP= 0.915;Koc/Kom= 93/54 mL/g; 1/n= 0.805; Water solubility (mg/L): 3007 at pH 7 and 20°C; Vapour pressure: 1.79 e-03 Pa at 20°C.

TMP: DT50lab= 146.44 d; ff from TCP= 0.593; Koc/Kom= 523/303 mL/g; 1/n= 0.839; Water solubility (mg/L): 7.78 at pH 7 and 20°C; Vapour pressure: 0.90 Pa at 20°C.

3,6-DCP: DT50lab= 9.1 d; applied as parent; Koc/Kom= 33/19 mL/g; 1/n= 0.783; Water solubility mg/L): 3007 at pH 7 and 20°C; Vapour pressure: 1.79 e-03 Pa at 20°C ; Maximum occurrence in soil: 73.6.

Application timing was assumed under consideration of the appropriate expected growth stages and the emergence dates for the different FOCUS scenarios, taking into account early and late seasons.

Chlorpyrifos-methyl, TCP and TMP were simulated in a linked model run based on the formation fractions determined following kinetic assessment. The metabolite DCP only appears under anaerobic conditions from chlorpyrifos-methyl. Simulations have been made with the metabolite applied as parent using a semi-application rate with the maximum occurrence in soil of 73.6%. The application squeme were based on the application dates for the active substances adding the number of days when the maximum occurrence in soil was observed for this metabolite. In this case, the application timing was 70 days after parent application (from the anaerobic study, Kang, S., 2014b).

The following uses were evaluated:

GF-1684

Citrus: Application rate: 1285 g/ha; Crop growth stage: BBCH 11-89; Canopy interception: 80%.

Apples: Application rate: 900 g/ha; Crop growth stage: BBCH 10-87; Canopy interception: 60-65%.

Grapes: Application rate: 676 g/ha; Crop growth stage: BBCH 19-89; Canopy interception: 60-75%.

Maize: Application rate: 900 g/ha; Crop growth stage: BBCH 12-59; Canopy interception: 25-75%.

Tomatoes: Application rate: 675 g/ha; Crop growth stage: BBCH 11-89; Canopy interception: 30-60%.

Cotton: Application rate: 680 g/ha; Crop growth stage: BBCH 30-89; Canopy interception: 60-75%.

OSR summer: Application rate: 450 g/ha; Crop growth stage: BBCH 30-59; Canopy interception: 80%.

Stone fruit: Application rate: 1020 g/ha; Crop growth stage: BBCH 10-87; Canopy interception: 60-65%.

Potatoes: Application rate: 540 g/ha; Crop growth stage: BBCH 31-59; Canopy interception: 60-85%.

Soybean: Application rate: 450 g/ha; Crop growth stage: BBCH 30-59; Canopy interception: 55-85%.

Strawberry: Application rate: 540 g/ha; Crop growth stage: BBCH 35-95; Canopy interception: 50-60%.

SAP200CLORI

Grapes: Application rate: 340 g/ha; Crop growth stage: BBCH 71-85; Canopy interception: 75%.

OSR winter: Application rate: 340 g/ha; Crop growth stage: BBCH 10; Canopy interception: 40%.

OSR spring: Application rate: 340 g/ha, Crop growth stage: BBCH 10; Canopy interception: 40%.

The PECgw represented by the 80th percentile annual average pore water concentration at a soil depth of 1 m, were <0.001 µg/L for chlorpyrifos-methyl and 3,6-DCP for all relevant scenarios and all the intended uses.

The maximum PECgw value of TCP and TMP were 0.002 µg/L and 0.076 µg/L, respectively, for the intended use of stone fruit in Hamburg scenario, late season application (FOCUS PEARL).

In conclusion the calculated PECGW for Chlorpyrifos-methyl and its metabolites TCP, TMP and DCP is below the trigger value of 0.1 µg/L. No unacceptable leaching of Chlorpyrifos-methyl and its metabolites is to be expected from the intended GAP use.

A new data requirement concerning to the definition of residue in soil was identified. The metabolite N-methyl TCP reaches a maximum value of 5.18% AR at the end of the study (122 d). Therefore, according to (EU) Regulation 283/2013 further information should be necessary to assess the potential of groundwater contamination of N-methyl TCP.

2.8.5.3. Predicted environmental concentrations in surface water and sediment (PECsw/PECsed)

The calculation of the predicted environmental concentrations of chlorpyrifos-methyl and its metabolites in surface water and sediment was based on the recommendations provided in FOCUS Generic Guidance for FOCUS Surface Water scenarios (v. 1.4 May 2015).

The substance related input parameter for chlorpyrifos-methyl and its metabolites, TCP, TMP, Desmethyl chlorpyrifos-methyl and DCP, to be used for FOCUS SW simulations are presented in Table 2.8.5.3-1 and -2.

Table 2.8.5.3-1: Substance related input data of chlorpyrifos-methyl used by RMS for the simulations at FOCUS step 3 and 4

	Endpoints used in risk assessment by RMS	**Justification**
Chlorpyrifos-methyl		
Molecular Mass [g/mol]	322.6	
Water solubility [mg/L]	2.74 (20ºC)	
Saturated vapour pressure [Pa]	1.945 x 10^{-03} (20°C)	
K_{FOC} [mL/g]	**1376**	Kang, 2015 Geometric mean (n = 5)
Freundlich sorption exponent (1/n)	**0.957**	Kang, 2015 Arithmetic mean (n = 5)
DT_{50} soil [days]	**1.32**	Gut, 2015 Geometric mean of field studies (n = 5) Normalised to 20°C (Q10 = 2.58) and pF 2.0
DT_{50} w/s system [days]	**3.25***	Phillips & Hall (1994), Hawkins and Simmonds (2015), Turk, 2015. Geometric mean water/sediment system (n=5)
DT_{50} water [days]	**3.25***	Phillips & Hall (1994), Hawkins and Simmonds (2015), Turk, 2015. Geometric mean water/sediment system (n=5)
DT_{50} sediment [days]	**1000***	Worst case default
DT_{50} crop [days]	10 2.7	FOCUS recommendation Refined DT50 from 6 metabolism studies
Plant uptake	0	Worst case default
Max occurrence in soil/water/sediment	100	Worst case default

* According to the current FOCUS SW Guidance Document (2014), for compound with koc between 100 and 2000 mL/g, the FOCUS kinetics advices running simulations with both combinations for ascribing the whole system DT50 and defaults, and selecting the results that give the highest concentrations for the risk assessment. FOCUS Degradation kinetics also states in Appendix 10 that, in practice, the selection of degradation rates as modelling endpoints in each comportment (whole/system vs default value) is unlikely to cause significant differences in the calculated PEC values using FOCUS SW scenarios as long as the overall fits to the water column and sediment are good, due to the system balancing itself and the upscaling and residence time effects of the FOCUS surface water bodies. RMS performed runnings for both combinations (DT50 water = 1000d and DT50 sed = 3.25 d vs. DT50 water = 3.25 d and DT50 sed= 1000d) and no differences in PECsw obtained at step 3 or 4 were observed. To avoid overworking, it was decided to ascribe the whole system DT50 to the water phase since data suggests hydrolysis as a dominant process for the degradation of chlorpyrifos-methyl in the test system and metabolites were found predominantly in the water phase.

Table 2.8.5.3-2: Substance related input data for metabolites TCP, TMP, Desmethyl chlorpyrifos-methyl and DCP selected by RMS for PECsw/sed calculations.

Parameter	**TCP**	**TMP**	**Des-methyl**	**DCP**	**Remarks/reference**
Physico-chemical parameters					
Molecular weight (g/mol)	198.5	212.5	308.6	164.0	Dursban and Reldan Registration Reports (2010)
Solubility in water (mg/L; 20°C)	3007 (pH 7)	7.78	2.74[a]	3007 (pH7)[b]	Dursban and Reldan Registration Reports (2010) and Dow update (2002) for TCP [a]: Assumed same as parent. [b]: Assumed same as TCP.
Degradation in soil					
$DegT_{50}$ soil (days; normalised to 20°C & pF2)	29.36	146.44	1000[a]	9.1	Geometric mean: n=12 (TCP) n=4 (TMP) n=4 (DCP) a – FOCUS default value
Maximum occurrence in soil (%)	90.3	13	0.1[a]	73.6	[a]: Metabolite not observed in soil (low, non-zero value entered)
Degradation in water/sediment systems					
$DegT_{50}$ whole system (days)	1000[b]	1000[b]	1000[b]	1000[b]	b - FOCUS default value
$DegT_{50}$ water (days)	1000[b]	1000[b]	1000[b]	1000[b]	a - Whole system value b - FOCUS default value
$DegT_{50}$ sediment (days)	1000[b]	1000[b]	1000[b]	1000[b]	a - Whole system value b - FOCUS default value
Maximum occurrence in water/sediment (%)	100[a]	0[b]	37.86[c]	73.6[d]	a - Worst-case assumption b - TMP not observed in water/sediment systems c – Phillips & Hall (1994) d – Ross (2015)
Sorption to soil					
K_{foc} (mL/g)	93[b]	523[c]	1376[d]	33[e]	b - Damon & Sarff (2001), Racke & Lubinski (1992) c - Heim & Damon (2001) d - Assumed same as parent value e - Grant & McLachlan (2015) Geometric mean: n=8 (TCP) n=5 (TMP & DCP)

Versions models used by RMS:

Spin (Substances Plug In) v.2.2
SWASH, version 5.1 incorporating:
MACRO, version 5.5.4
PRZM, version 4.3.1
TOXSWA, version 4.4.3
SWAN, version 4.0.1 (not using the VFSmod)

GF-1684

A risk envelope approach was followed by DAS. PECsw calculations were submitted for the claimed uses on orchards (application rate= 1020 g/ha), vines (676 g/ha), maize (900 g/ha), fruiting vegetables (675 g/ha) and citrus (1800 g/ha) to cover the representative uses on cotton (680g/ha), potatoes (540 g/ha), oilseed rape (450 g/ha), strawberries (540 g/ha) and soybean (450 g/ha). RMS agrees with the proposed risk envelope. However, as it is indicated in Table 2.8.5.3-3, D1 scenarios for applications on Oilseed Rape Spring are not covered. Additionally, an indoor use on cereals grain is claimed in the EU GAP but no data to support this indoor use was submitted.

Table 2.8.5.3-3: Risk envelope approach

FOCUS crop	Application timing	Application window	Number of applications	Application rate (g a.s./ha)	FOCUS SW scenarios
Crops used in FOCUS models					
Citrus	Spring	Mar-May	1	1285	D6, R4
	Summer	Jun-Sep			
Pome/stone fruit, early	Early-season	Mar-May	1	1020	D3, D4, D5, R1, R2, R3, R4
Pome/stone fruit, late	Late-season	Jun-Sep			
Vines, early	Early-season	Mar-May	1	676	D6, R1, R2, R3, R4
Vines, late	Late-season	Jun-Sep			
Vines, early	Early-season	Mar-May	2	338	D6, R1, R2, R3, R4
Vines, late	Late-season	Jun-Sep			
Maize	**BBCH 12**	**Mar-May**	**1**	**900**	**D3, D4, D5, D6, R1, R2, R3, R4**
	BBCH 59	**Jun-Sep**			
Fruiting vegetables	Early-season	Mar-May	1	675	D6, R2, R3
	Late-season	Jun-Sep			
Crops covered in the risk assessment by Maize simulations					
Cotton	BBCH 30-89	May-Sep	1	680	D6
Oilseed Rape winter	BBCH 30-59 Spring /Summer	March-May	1	450	D2*, D3, D4, D5, R1, R3
Oilseed Rape spring	BBCH 30-59 Spring /Summer	March-Jun	1	450	D1*, D3, D4, D5, R1
Soybean	BBCH 30-59 Spring /Summer	June-July	1	450	R3, R4
Potatoes	BBCH 31-59 Spring/Summer	Apr-Aug	1	540	D3, D4, D6, R1, R2, R3
Strawberry^	BBCH 35-95 Spring/Summer	Mar-Sep		540	D6, R2, R3
Crops not covered in the risk assessment					
Cereals	Indoor use				

* Scenario not covered
^ Fruiting Vegetables as subrogate crop

Calculations for metabolites TMP, desmethyl chlorpyrifos-methyl, and DCP were performed at FOCUS step 1-2. Predicted environmental concentrations of chlorpyrifos-methyl and TCP in surface water (PECSW) and sediment (PECSED) were calculated in a tiered approach (FOCUS Steps 1 – 4).

The following refinements for higher tier calculations at step 4 were not considered acceptable by the RMS:

- **Refined DT50 water and DT50 sediment from level P-II (Yon, 2015b)**

  The criteria for an acceptable assessment were not met, therefore, RMS considers level PII endpoints as not reliable for a higher tier risk assessment (Please, refer to DRAR Vol.3 CA B8, point B.8.2.2.3/07).

- **F(vol):** a volatilization factor of 0.5 was applied to drift and redeposition contributions

The amount of chlorpyrifos in the sub-surface water layer was variable between the various tanks but averaged 50% (range 20 – 87%) in Yon 2007b. It was proposed to used this percentage as a correction factor when estimating water column concentrations However, the experiments of wind tunnel were not designed to address the argument of drift reduction due to a very rapid volatilization. Field studies were designed to study the deposition of chlorpyrifos and its distribution in water bodies after spray application. The volatilization hypothesis is based on theorical calculation but no measures of volatilization were done in any of these studies, so the results of the modelling cannot be validated and they are considered not acceptable for modelling purposes.

- **F(reded):** a scaling factor of 0.206 was applied to redeposition contribution

  Under RMS' opinion one experimental datum is not robust enough to be used with refinement purposes.

- **Vegetated filter strips according to VFSMod tool**

  Reduction efficiency of the vegetated buffer strips modelled by VFSMOD were applied as a refinement option. The use of VFSMOD was justified by comparison with measured data from two field experiments (Pepper, 2014). The predictions of the model agreed well with the measured data indicating that the model was predicting reliably for this compound and therefore can be used to refine vegetative buffer strips. However, this model is not agreed to be used at EU level at the time being. **MSs will then decide on the acceptability of the proposed refinement at zonal level.**

- **Refined foliar washoff coefficient**

  Since formulation component effects cannot be excluded by RMS, it is proposed to use the recommended default factor values (0.5 cm-1 (PRZM) and 0.05 mm-1 (MACRO)) in the risk assessment.

A refinement of the DT50 foliar of 2.7 was also proposed based on experimental residue data from plant metabolism studies. RMS accepts the use of this value for the risk assessment since it is in accordance with the FOCUS SW Guidance Document (2014) and it is comparable to DT50 foliar used in Birds and Mammals risk assessment (please, refer to DRAR Vol.3 CP B9, GF-1684 under point B.9.3.1.3). RMS has performed some additional calculations (but not included below) to check the impact of the refined DT50crop in PECsw values and no differences were found.

RMS has recalculated FOCUS step 3 and 4 PECsw with the lastest versions of the models. RMS has not performed new PECsw calculations for the metabolites TCP, desmethyl chlorpyrifos-methyl and DCP. Chlorpyrifos-methyl is >10 time more toxic toxic than metabolites. PECsw values from Chlorpyrifos-methyl could be used as conservative worst-case screening. Moreover, the risk assessment of metabolites was covered by the microcosm studies.

At step 4, risk mitigation measures, in line with FOCUS landscape & mitigation guideline (2008) were proposed by RMS: 20 m drift and 20 m runoff. The use of a 95% drift reduction was also modelled in SWAN

The application window used for step 3 and step 4 calculations is presented in **Tables 2.8.5.3-4 to -9**

Table 2.8.5.3-4: Citrus application windows for Step 3 and 4 modelling

	D6	**R4**	**Comment**
Spring			
Start	**91**	**91**	**<first date**
Window (days)	30	30	
End	**121**	**121**	**<last date**
Summer			
Start	**196**	**196**	**<first date**
Window (days)	30	30	
End	**226**	**226**	**<last date**

Table 2.8.5.3-5: Pome/stone fruit application windows for Step 3 and 4 modelling

	D3	D4	D5	R1	R2	R3	R4	Comment
Early-season								
Start	**105**	**110**	**91**	**105**	**74**	**91**	**74**	**<first date**
Window (days)	30	30	30	30	30	30	30	
End	**135**	**140**	**121**	**135**	**104**	**121**	**104**	**<last date**
Late-season								
Start	**252**	**252**	**232**	**252**	**222**	**237**	**237**	**<first date**
Window (days)	30	30	30	30	30	30	30	
End	**282**	**282**	**262**	**282**	**252**	**267**	**267**	**<last date**

Table 2.8.5.3-6: Vine application windows for Step 3 and 4 modelling (single application)

	D6	R1	R2	R3	R4	Comment
Early-season						
Start	**39**	**112**	**81**	**98**	**76**	**<first date**
Window (days)	30	30	30	30	30	
End	**69**	**142**	**111**	**128**	**106**	**<last date**
Late-season						
Start	**270**	**259**	**229**	**261**	**219**	**<first date**
Window (days)	30	30	30	30	30	
End	**300**	**289**	**259**	**291**	**249**	**<last date**

Table 2.8.5.3-7: Vine application windows for Step 3 and 4 modelling (multiple application)

	D6	R1	R2	R3	R4	Comment
Early-season						
Start	**39**	**112**	**81**	**98**	**76**	**<first date**
Window (days)	45	45	45	45	45	
End	**84**	**157**	**126**	**143**	**121**	**<last date**
Late-season						
Start	**270**	**259**	**229**	**261**	**219**	**<first date**
Window (days)	45	45	45	45	45	
End	**315**	**304**	**274**	**306**	**264**	**<last date**

Table 2.8.5.3-8: Maize application windows for Step 3 and 4 modelling

	D3	D4	D5	D6	R1	R2	R3	R4	Comment
BBCH 12									
Start	**125**	**130**	**130**	**110**	**123**	**121**	**121**	**100**	**<first date**
Window (days)	30	30	30	30	30	30	30	30	
End	**155**	**160**	**160**	**140**	**153**	**151**	**151**	**130**	**<last date**
BBCH 59									
Start	**186**	**191**	**191**	**171**	**184**	**182**	**182**	**161**	**<first date**
Window (days)	30	30	30	30	30	30	30	30	
End	**216**	**221**	**221**	**201**	**214**	**212**	**212**	**191**	**<last date**

Table 2.8.5.3-9: Fruiting vegetables application windows for Step 3 and 4 modelling

	D6	R2	R3	R4	Comment
Early-season					
Start	**100**	**74**	**130**	**110**	**<first date**
Window (days)	30	30	30	30	
End	**130**	**104**	**160**	**140**	**<last date**
Late-season					
Start	**187**	**208**	**202**	**161**	**<first date**
Window (days)	30	30	30	30	
End	**217**	**238**	**232**	**191**	**<last date**

Results of FOCUS step 3 and 4 sw/sed modelling (RMS calculations):

Table 2.8.5.3-10: Step 3 & 4- Maximum PECsw values for Chlorpyrifos-methyl in CITRUS considering spring applications

Citrus, Spring appln.	**Single application: 1 x 1285 g a.i./ha**					
	Step 3			**Step 4** **20 m buffer zone** **20 m Vegetated Filter Strip (80/95 % runoff reduction)** **95% spray drift reduction**		
Scenario	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event
D6 ditch	47.38	48.43	Drift	0.2206	0.2473	Drift
R4 stream	36.17	5.029	Drift	0.1947	0.02755	Drift

Table 2.8.5.3-11: Step 3 & 4- Maximum PECsw values for Chlorpyrifos-methyl in CITRUS considering summer applications

Citrus, Summer appln.	**Single application: 1 x 1285 g a.i./ha**					
	Step 3			**Step 4** **20 m buffer zone** **20 m Vegetated Filter Strip (80/95 % runoff reduction)** **95% spray drift reduction**		
Scenario	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event
D6 ditch	47.4	33.56	Drift	0.2207	0.1704	Drift
R4 stream	36.22	5.102	Drift	0.1949	0.02794	Drift

Table 2.8.5.3-12: Step 3 & 4- Maximum PECsw values for Chlorpyrifos-methyl in POME/STONE FRUITS considering early applications

Pome/stone fruits early appln.	**Single application: 1 x 1020 g a.i./ha**					
	Step 3			**Step 4 20 m buffer zone 20 m Vegetated Filter Strip (80/95 % runoff reduction) 95% spray drift reduction**		
Scenario	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event
D3 ditch	79.13	40.43	Drift	0.4364	0.2363	Drift
D4 Pond	4.809	9.417	Drift	0.04803	0.1029	Drift
D4 Stream	74.81	2.731	Drift	0.4513	0.01658	Drift
D5 Pond	4.809	8.145	Drift	0.04803	0.08907	Drift
D5 Stream	78.49	2.363	Drift	0.4734	0.01432	Drift
R1 pond	4.809	7.839	Drift	0.04803	0.0857	Drift
R1 stream	63.98	7.628	Drift	0.386	0.04674	Drift
R2 stream	84.76	5.042	Drift	0.5113	0.0307	Drift
R3 stream	90.52	18.55	Drift	0.546	0.1148	Drift
R4 stream	64	7.675	Drift	0.386	0.04702	Drift

Table 2.8.5.3-13: Step 3 & 4- Maximum PECsw values for Chlorpyrifos-methyl in POME/STONE FRUITS considering late applications

Pome/stone fruits late appln.	**Single application: 1 x 1020 g a.i./ha**					
	Step 3			**Step 4 20 m buffer zone 20 m Vegetated Filter Strip (80/95 % runoff reduction) 95% spray drift reduction**		
Scenario	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event
D3 ditch	37.47	24.51	Drift	0.1742	0.1225	Drift
D4 Pond	1.677	2.446	Drift	0.02422	0.03838	Drift
D4 Stream	36.2	3.088	Drift	0.1948	0.0168	Drift
D5 Pond	1.678	2.029	Drift	0.02423	0.03179	Drift
D5 Stream	40.55	9.517	Drift	0.2182	0.05269	Drift
R1 pond	1.677	2.292	Drift	0.02422	0.03595	Drift
R1 stream	28.75	4.162	Drift	0.1547	0.02278	Drift
R2 stream	38.54	2.958	Drift	0.2074	0.0161	Drift
R3 stream	40.53	9.019	Drift	0.218	0.1313	Drift
R4 stream	28.75	4.088	Drift	0.1547	0.02237	Drift

Table 2.8.5.3-14: Step 3 & 4- Maximum PECsw values for Chlorpyrifos-methyl in MAIZE BBCH 12

Maize BBCH 12	**Single application: 1 x 900 g a.i./ha**					
	Step 3			**Step 4 20 m buffer zone 20 m Vegetated Filter Strip (80/95 % runoff reduction) 95% spray drift reduction**		
Scenario	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event
D3 ditch	4.716	2.395	Drift	0.02136	0.01148	Drift
D4 Pond	0.1904	0.2841	Drift	0.004086	0.006565	Drift
D4 Stream	4.039	0.2654	Drift	0.0235	0.001557	Drift
D5 Pond	0.1904	0.2744	Drift	0.004086	0.006342	Drift
D5 Stream	4.024	0.1303	Drift	0.02342	0.000761	Drift
D6 Ditch	4.716	2.383	Drift	0.02136	0.01139	Drift
R1 pond	0.1903	0.3104	Drift	0.004084	0.008732	Drift
R1 stream	3.206	0.4573	Drift	0.2097	0.06573	Runoff
R2 stream	4.371	0.326	Drift	0.0448	0.0232	Runoff
R3 stream	4.587	0.9199	Drift	0.2438	0.09931	Runoff
R4 stream	3.258	1.211	Drift	0.4038	0.217	Runoff

Table 2.8.5.3-15: Step 3 & 4- Maximum PECsw values for Chlorpyrifos-methyl in MAIZE BBCH 59

Maize BBCH 59	**Single application: 1 x 900 g a.i./ha**					
	Step 3			**Step 4 20 m buffer zone 20 m Vegetated Filter Strip (80/95 % runoff reduction) 95% spray drift reduction**		
Scenario	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event
D3 ditch	4.712	2.183	Drift	0.02134	0.01043	Drift
D4 Pond	0.1905	0.2407	Drift	0.004087	0.005554	Drift
D4 Stream	4.193	0.4937	Drift	0.02439	0.002913	Drift
D5 Pond	0.1905	0.2327	Drift	0.004088	0.005367	Drift
D5 Stream	4.613	1.093	Drift	0.02684	0.00653	Drift
D6 Ditch	4.711	2.097	Drift	0.02134	0.01001	Drift
R1 pond	0.1903	0.2575	Drift	0.005684	0.01157	Runoff
R1 stream	3.229	0.6392	Drift	0.1294	0.06503	Runoff
R2 stream	4.384	0.3375	Drift	0.02551	0.001984	Drift
R3 stream	4.61	1.479	Drift	0.1047	0.1003	Runoff
R4 stream	3.27	0.4703	Drift	0.06618	0.03778	Runoff

Table 2.8.5.3-16: Step 3 & 4- Maximum PECsw values for Chlorpyrifos-methyl in FRUITING VEGETABLES considering early applications

Fruiting vegetable Early applic.	**Single application: 1 x 675 g a.i./ha**					
	Step 3			**Step 4 20 m buffer zone 20 m Vegetated Filter Strip (80/95 % runoff reduction) 95% spray drift reduction**		
Scenario	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event
D6 Ditch	4.277	2.454	Drift	0.01611	0.009851	Drift
R2 stream	3.73	0.4523	Drift	0.03533	0.03177	Runoff
R3 stream	3.967	0.809	Drift	0.1607	0.06583	Runoff
R4 stream	2.819	0.5399	Drift	0.1558	0.08495	Runoff

Table 2.8.5.3-17: Step 3 & 4- Maximum PECsw values for Chlorpyrifos-methyl in FRUITING VEGETABLES considering late applications

Fruiting vegetable Late applic.	**Single application: 1 x 675 g a.i./ha**					
	Step 3			**Step 4 20 m buffer zone 20 m Vegetated Filter Strip (80/95 % runoff reduction) 95% spray drift reduction**		
Scenario	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event
D6 Ditch	4.241	1.259	Drift	0.01597	0.004928	Drift
R2 stream	3.789	0.2924	Drift	0.01897	0.001479	Drift
R3 stream	3.984	1.936	Drift	0.125	0.1336	Runoff
R4 stream	2.826	0.7706	Drift	0.2076	0.1171	Runoff

Table 2.8.5.3-18: Step 3 & 4- Maximum PECsw values for Chlorpyrifos-methyl in VINES considering early applications (Single application: 1 x 676 g a.i./ha)

Vines early applic.	**Single application: 1 x 676 g a.i./ha**					
	Step 3			**Step 4 20 m buffer zone 20 m Vegetated Filter Strip (80/95 % runoff reduction) 95% spray drift reduction**		
Scenario	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event
D6 Ditch	3.773	1.058	Drift	0.01364	0.003966	Drift
R1 Pond	0.1926	0.3344	Drift	0.002989	0.005626	Drift
R1 stream	4.115	0.475	Drift	0.01788	0.002094	Drift
R2 stream	5.454	0.3221	Drift	0.02371	0.0104	Drift
R3 stream	5.821	1.147	Drift	0.1193	0.07628	Runoff

Vines early applic.	**Single application: 1 x 676 g a.i./ha**					
	Step 3			**Step 4** **20 m buffer zone** **20 m Vegetated Filter Strip (80/95 % runoff reduction)** **95% spray drift reduction**		
Scenario	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event
R4 stream	4.113	0.4717	Drift	0.01788	0.002079	Drift

Table 2.8.5.3-19: Step 3 & 4- Maximum PECsw values for Chlorpyrifos-methyl in VINES considering early applications (Multiple application: 2 x 338 g a.i./ha)

Vines early applic.	**Multiple applications: 2 x 338 g a.i./ha (i=14d)**					
	Step 3			**Step 4** **20 m buffer zone** **20 m Vegetated Filter Strip (80/95 % runoff reduction)** **95% spray drift reduction**		
Scenario	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event
D6 Ditch	1.748	1.427	Drift	0.005611	0.005611	Drift
R1 Pond	0.06855	0.1697	Drift	0.000976	0.002629	Runofff
R1 stream	1.26	0.1459	Drift	0.01858	0.00639	Runofff
R2 stream	1.674	0.1301	Drift	0.006742	0.003442	Drift
R3 stream	1.783	0.4819	Drift	0.0388	0.025	Runoff
R4 stream	1.269	0.1945	Drift	0.005113	0.003659	Drift

Table 2.8.5.3-20: Step 3 & 4- Maximum PECsw values for Chlorpyrifos-methyl in VINES considering late applications (Multiple application: 2 x 338 g a.i./ha)

Vines late applic.	**Multiple applications: 2 x 338 g a.i./ha (i=14d)**					
	Step 3			**Step 4** **20 m buffer zone** **20 m Vegetated Filter Strip (80/95 % runoff reduction)** **95% spray drift reduction**		
Scenario	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event
D6 Ditch	5.179	7.044	Drift	0.01946	0.02925	Drift
R1 Pond	0.1968	0.4794	Drift	0.003167	0.008379	
R1 stream	3.749	0.6459	Drift	0.01708	0.00304	Drift
R2 stream	5.025	0.4665	Drift	0.02289	0.002191	Drift
R3 stream	5.284	1.203	Drift	0.02407	0.005631	Drift
R4 stream	3.748	0.6032	Drift	0.01707	0.003542	Drift

Table 2.8.5.3-21: Step 3 & 4- Maximum PECsw values for Chlorpyrifos-methyl in VINES considering late aplications (Multiple application: 2 x 338 g a.i./ha)

Vines late applic.	**Multiple applications: 2 x 338 g a.i./ha (i=14d)**					
	Step 3			**Step 4 20 m buffer zone 20 m Vegetated Filter Strip (80/95 % runoff reduction) 95% spray drift reduction**		
Scenario	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event
D6 Ditch	11.589	10.74	Drift	0.0444	0.0449	Drift
R1 Pond	0.412	0.573	Drift	0.00668	0.01	Drift
R1 stream	8.498	1.233	Drift	0.0393	0.00579	Drift
R2 stream	11.391	0.879	Drift	0.0527	0.00411	Drift
R3 stream*	11.978	2.709	Drift	0.0554	0.0583	Drift
R4 stream*	8.497	1.209	Drift	0.267	0.163	Runoff

*Due to an errorin PRZM calculations PECsw calculation for R3 and R4 scenarios were performed for a DT50 foliar of 10 d

Volatilization/Redeposition contribution to surface waters

Since chlorpyrifos-methyl can be classified as semi-volatile according to its P vapour (1.945 mPa), the potential for volatilization/redeposition of chlorpyrifos-methyl was taken into account as it is stablished in the FOCUS Air guidance (FOCUS, 2008).

Using EVA v. 2.1 spreadsheet tool (UBA, 2011), the maximum contributions of redeposition during the first 24 hours after application were 0.55, 0.37, 0.26, 0.15 and 0.13 µg/L at 20 meters for citrus, pome/stone fruit, vines, maize and fruiting vegetables, respectively. However, these results should be considered with caution according to FOCUS AIR GD:

EVA 2.0 is an empirical model in which the individual processes of emission, transport and deposition are not described separately. As a consequence, a completely empirical version, EVA 2.0, was developed based on the measured deposition data of substances volatilized in an outdoor windtunnel. In EVA 2.0 only the vapour pressure and the deposition after volatilization was correlated. As a confirmation of its conservatism, EVA 2.0 provides a higher prediction for deposed pesticides than measured in two available field volatilization trials. Lindane was used to define a worst-case deposition scenario since significantly higher lindane deposits were observed than expected from the series of vapour pressures of substances involved in the wind tunnel trials.

The deposition data in EVA 2.0 relate to the deposition onto water. The wind tunnel results (Fent 2004) and field experiments (Siebers et. al., 2003b, Gottesbüren et. al., 2003) show that vapour pressure is the most important parameter influencing environmental exposure via air. Using these data, five vapour pressure classes were established in the EVA 2.0 model. These are shown in **Table 2.8.6.3-22.**

Table 2.8.5.3-22: Vapour pressure classes and corresponding deposition rates at 1 m distance as implemented in EVA 2.0 (volatilisation from arable crops)

Vapour pressure range at 20 °C	Deposition (% of application rate)
vp < 10^{-5} Pa (plant) vp < 10^{-4} Pa (soil)	0.00 %
10^{-4} Pa > vp ≥ 10^{-5} Pa	0.09 %
5 . 10^{-3} Pa > vp ≥ 10^{-4} Pa	0.22 %
vp ≥ 5 . 10^{-3} Pa	1.56 %

The following relationship was derived from the wind tunnel data for the decrease of deposition with distance:

DEP(x) = DEP(1) . exp(-0.05446. (x-1)) (r2 = 0.985), (1)

where x is the distance from the field edge in metres, and DEP(1) is the deposition value 1 m from edge of the field for the relevant vapour pressure class.

The following assumptions were made when constructing the EVA 2.0 model from the wind tunnel data:

- A vapour pressure trigger of 10-4 Pa for application to soil and 10-5 Pa for application to plants.
- Vapour pressure classes and deposition at 1m as given in Table 2.8.6.3-22
- Interception values according to the FOCUS groundwater report (FOCUS, 2000) to calculate the fraction of the application on plants and soil.
- deposition after volatilisation from plants is 3-times that from soil
- deposition after volatilisation from orchards, vines and hops is twice that of field crops.
- Single volatilisation events only are considered even in the case of multiple applications.
- First order degradation kinetics is used for the calculation of PECactual and PECtwa values.

Although 15 experiments were carried out and 10 different pesticides were investigated, the number of measurements on which the 90th percentile of deposition class is based is limited. Furthermore, experimental conditions in the wind tunnel did not cover the whole range of conditions that can occur in the field. Therefore, more measurements for different pesticides under different weather conditions are needed to further verify the worst-case nature of the proposed exposure assessment. It should be noted that EVA 2.0 contains only one built-in scenario and it cannot be determined at the moment whether this model is worst-case in all scenarios in all EU Member States.

Since the wind-tunnel tests and consequently EVA 2.0 have uncertainties, the potential risk of volatilization and deposition in surface waters after application of chlorpyrifos-methyl cannot be concluded by the RMS. According to FOCUS AIR GD (2008), the provision of further field data to improve the estimates of environmental exposure via air are desirable.

The Notifier DAS provided a field experiment to investigate the redeposition contribution to surface waters after application of chlorpyrifos adjacent to a treated field of winter cereals at the ADAS Rosemaund experimental farm in Herefordshire, UK (Kennedy, 2007; Yon, 2007b). For the May 2006 spray application only, an additional set of filter papers (6 m, middle of the treamat 9.6m and 10 cm above water level) was deployed 9 hours after application and left in place overnight before collection the following morning. The results for these samples are shown in Table 2.8.6.3-23. Between 0.004 and 0.012% of the applied chlorpyrifos was measured on the drift targets placed at bank top height above the middle of the stream (90th percentile was 0.01%). Similar levels were also measured 6m from the edge of the treated area and at water level in the stream.

Table 2.8.5.3-23: Chlorpyrifos residues on the drift deposition targets from Prestons field Treated May 2006, targets placed on the ground 9 hours after application (data expressed as % of nominal field rate = 720 g AS/Ha).

Drift target	**Loading (% of applied chlorpyrifos)**					
Sub-plot 1	rep A	rep B	rep C	rep D	rep E	90th percentile
P1 - 6m	0.007	0.005	0.007	0.008	0.009	*0.009*
P1 - bank top mid	0.004	0.005	0.007	0.004	0.005	*0.006*
P1 – water level	0.007	0.004	0.005	0.005	0.005	*0.006*
Sub-plot 2						
P2 - 6m	0.007	0.011	0.006	0.007	0.008	*0.010*
P2 - bank top mid	0.008	0.006	0.008	0.008	0.012	*0.010*
P2 – water level	0.008	0.006	0.006	0.008	0.009	*0.009*

Field deposition data indicated that a 0.01% of applied chlorpyrifos deposits at 6-10 m of distance, one order of magnitude below the predicted values by the model (0.17-0.13% of applied at 6-10 m based on the formulae 1 and assuming a deposition of 0.22% of applied at 1 m according to Table 2.8.6.3-22), suggesting that EVA 2.0 model could be overstimating the risk.

However, the study design makes the interpretation of the field results difficult. Re-deposition of chlorpyrifos from the treated area only was measured overnight and between 9 to 24 hours after application instead of 0-24 h. No data for the eight first hours were measured and the volatilization rate was measured mainly at night, therefore, the experimental design could be the reason of the low rates reported. Additionally, only spring applications were tested. In the report (Yon, 2007b) was stated that drift deposition rates were lower in spring than in autumn. The same behaviour could be applied to the deposition due to volatilization.

On the other hand, a total number of 30 measures were obtained (data for one season, one location, one kind of crop –cereals- in two plots, for two distances – 6m and 9.6 m- and a variation of the deposition height – 10 cm above surface water at 9.6 m- with 5 replicates per distance/height). RMS concluded that in general monitoring data are not robust enough to be used in the risk assessment and they can only be considered as additional information.

SAP200CLORI

As representative worst case GAP calculations were performed for the highest rates of application. In this case for Grapes and OSR was chosen as worst case with 340 g a.i./ha rate after a single application.

Table 2.8.5.3-22: Application settings for FOCUS Step 3 – 4 (worst case GAP)

Crop or crop group	**FOCUS sw scenario**	**Application setting**			
		BBCH, timing	**Settings for Step 2**	**Application setting for Step 3+4**	**Application rate [g a.i./ha]**
Grapes	VINES, late appln.	71 - 85	Full canopy (70 %) June-September	June-August*	1 x 340
OSR	OSR Winter	10 - 59	Minimal crop cover (40 %) October-February North Europe South Europe	0 days after emergence	1 x 340
			Average crop cover (70 %) March-May North Europe South Europe	90 days before harvest	1 x 340

Crop or crop group	FOCUS sw scenario	Application setting			
		BBCH, timing	Settings for Step 2	Application setting for Step 3+4	Application rate [g a.i./ha]
OSR	OSR Spring	10 - 59	Minimal crop cover (40 %) Mar.–May North Europe South Europe	0 days after emergence	1 x 340

*Application window recommended by Autorithies for late applications in vines which cover the application period of SAP200CLORI (June to August).

Predicted environmental concentrations of chlorpyrifos-methyl and TCP in surface water (PECSW) and sediment (PECSED) were calculated in a tiered approach (FOCUS Steps 1 – 4). RMS recalculated step 3 and 4 PECsw values taking into account the endpoints determined by RMS for the degradation of chlorpyrifos-methyl in soil and water/sediment systems, and for the adsorption of the active substance to soil.

At step 4, different risk mitigation measures, in line with FOCUS landscape & mitigation guideline (2008) were proposed by RMS: 20 m drift and 20 m runoff. The use of a 95% drift reduction was also modelled in SWAN.

The PEC of the metabolites TCP, TMP and desmethyl chlorpyrifos-methyl, in surface water (PECsw and PECsed) has not been assessed with FOCUS SW by SAP, since the PEC values from Chlorpyrifos-methyl could be used as conservative worst case screening, and the risk assessment for the metabolites also is covered by the microcosm studies.

The application window used for step 3 and step 4 calculations is presented in Table 2.8.6.3-23.

Table 2.8.5.3-23: Application window chosen for FOCUS SWASH Step 3 + 4

Scenario	Application window			
	Beginning		End	
Location	Date	Julian day	Date	Julian day
	Vines, late applications			
D6 ditch	19 July	200	18 August	230
R1 pond	08 July	189	18 August	219
R1 stream	08 July	189	08 July	219
R2 stream	08 June	159	09 August	189
R3 stream	10 July	191	28 June	221
R4 stream	29 May	149	18 August	179
	OSR, Winter (0 days after emergence)			
D2 ditch	15 September	258	15 October	288
D2 stream	15 September	258	15 October	288
D3 ditch	02 September	245	02 October	275
D4 pond	03 September	246	03 October	276
D4 stream	03 September	246	03 October	276
D5 pond	20 September	263	20 October	293
D5 stream	20 September	263	20 October	293
R1 pond	04 September	247	04 October	277
R1 stream	04 September	247	04 October	277
R3 stream	05 October	278	04 November	308
	OSR, Winter (90 days before harvest)			
D2 ditch	16 April	106	16 May	136
D2 stream	16 April	106	16 May	136
D3 ditch	21 April	111	21 May	141
D4 pond	11 May	131	10 June	161

Scenario	Application window			
	Beginning		End	
Location	**Date**	**Julian day**	**Date**	**Julian day**
D4 stream	11 May	131	10 June	161
D5 pond	06 April	96	06 May	126
D5 stream	06 April	96	06 May	126
R1 pond	11 April	101	11 May	131
R1 stream	11 April	101	11 May	131
R3 stream	07 March	66	06 April	96
	OSR, Spring (0 days after emergence)			
D1 ditch	19 May	139	18 June	169
D1 stream	19 May	139	18 June	169
D3 ditch	10 April	100	10 May	130
D4 pond	01 May	121	31 May	151
D4 stream	01 May	121	31 May	151
D5 pond	15 March	74	14 April	104
D5 stream	15 March	74	14 April	104
R1 pond	10 April	100	10 May	130
R1 stream	10 April	100	10 May	130

Results of FOCUS step and 4 sw/sed modelling (RMS calculations):

Table 2.8.5.3-25: Step 3 & 4- Maximum PECsw values for Chlorpyrifos-methyl in GRAPES considering late applications

Vine, Late appln.	**Single application: 1 x 340 g a.i./ha**					
	Step 3			**Step 4 20 m buffer zone 20 m Vegetated Filter Strip (80/95 % runoff reduction) 95% spray drift reduction**		
Scenario	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event
D6 ditch	5.828	4.271	Drift	0.02253	0.01801	Drift
R1 pond	0.2074	0.2576	Drift	0.003287	0.004717	Drift
R1 stream	4.158	0.3305	Drift	0.07966	0.02702	Runoff
R2 stream	5.73	0.4433	Drift	0.02783	0.01963	Runoff
R3 stream	6.026	1.347	Drift	0.02785	0.01449	Drift
R4 stream	4.193	0.3897	Drift	0.01938	0.00182	Drift

Table 2.8.5.3-26: Step 3 & 4- Maximum PECsw values for Chlorpyrifos-methyl in OSR Winter considering emergence dates

OSR Winter, Emergence	**Single application: 1 x 340 g a.i./ha**					
	Step 3			**Step 4 20 m buffer zone 20 m Vegetated Filter Strip (80/95 % runoff reduction) 95% spray drift reduction**		
Scenario	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event
D2 ditch	2.18	2.838	Drift	0.007982	0.007982	Drift
D2 stream	1.939	2.522	Drift	0.009636	0.01378	Runoff
D3 ditch	2.161	1.43	Drift	0.007914	0.005617	Drift
D4 pond	0.07429	0.1155	Drift	0.001495	0.002507	Drift
D4 stream	1.861	0.3569	Drift	0.009248	0.001811	Drift
D5 pond	0.07431	0.09915	Drift	0.001496	0.002149	Drift
D5 stream	2.008	0.4809	Drift	0.009978	0.002453	Drift
R1 pond	0.07425	0.1079	Drift	0.001494	0.002341	Drift
R1 stream	1.423	0.2053	Drift	0.007071	0.001036	Drift
R3 stream	1.99	0.8733	Drift	0.1685	0.1181	Runoff

Table 2.8.5.3-27: Step 3 & 4- Maximum PECsw values for Chlorpyrifos-methyl in OSR Winter considering late application

OSR Winter, Late appln.	**Single application: 1 x 340 g a.i./ha**					
	Step 3			**Step 4 20 m buffer zone 20 m Vegetated Filter Strip (80/95 % runoff reduction) 95% spray drift reduction**		
Scenario	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event
D2 ditch	2.18	2.821	Drift	0.007982	0.01137	Drift
D2 stream	1.939	2.515	Drift	0.009636	0.01368	Drift
D3 ditch	2.153	1.146	Drift	0.007885	0.004447	Drift
D4 pond	0.07428	0.1132	Drift	0.001495	0.002455	Drift
D4 stream	1.813	0.1911	Drift	0.009011	0.000962	Drift
D5 pond	1.744	0.05493	Drift	0.001494	0.002969	Drift
D5 stream	1.744	0.05493	Drift	0.008665	0.000274	Drift
R1 pond	0.07424	0.1314	Drift	0.001494	0.003287	Drift
R1 stream	1.415	0.1775	Drift	0.06823	0.0209	Runoff
R3 stream	1.989	0.36	Drift	0.1233	0.1233	Runoff

Table 2.8.5.3-28: Step 3 & 4- Maximum PECsw values for Chlorpyrifos-methyl in OSR Spring

OSR Spring, emergence	**Single application: 1 x 340 g a.i./ha**					
	Step 3			**Step 4** **20 m buffer zone** **20 m Vegetated Filter Strip (80/95 % runoff reduction)** **95% spray drift reduction**		
Scenario	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Event
D1 ditch	2.178	2.698	Drift	0.007974	0.01089	Drift
D1 stream	1.905	0.8962	Drift	0.009464	0.004656	Drift
D3 ditch	2.151	1.075	Drift	0.007878	0.004159	Drift
D4 pond	0.07427	0.1129	Drift	0.001495	0.002449	Drift
D4 stream	1.763	0.1202	Drift	0.008762	0.000602	Drift
D5 pond	0.07424	0.1363	Drift	0.001494	0.00296	Drift
D5 stream	1.708	0.04716	Drift	0.008489	0.000235	Drift
R1 pond	0.07424	0.1314	Drift	0.001494	0.002854	Drift
R1 stream	1.417	0.1855	Drift	0.007043	0.002762	Drift

Volatilization/Redeposition contribution to surface waters

Since chlorpyrifos-methyl can be classified as semi-volatile according to its P vapour (1.945 mPa), the potential for volatilization/redeposition of chlorpyrifos-methyl was taken into account as it is stablished in the FOCUS Air guidance (FOCUS, 2008).

The maximum contributions of redeposition during the first 24 hours after application was 0.14 µg/L at 20 meters, using EVA v. 2.1 spreadsheet tool (UBA, 2011).

Since the wind-tunnel tests and consequently EVA 2.0 have uncertainties, the potential risk of volatilization and deposition in surface waters after application of chlorpyrifos-methyl cannot be concluded by the RMS (please, refer to RMS comments for PPP GF-1684).

2.8.5.4. Predicted environmental concentrations in air (PECair)

2.8.5.4.1. Short-range transport

The FOCUS Air guidance recommends that substances whose vapour pressure exceeds 10-5 Pa and are applied to plants, or whose vapour pressure exceeds 10-4 Pa and are applied to soil, are of potential concern for short-range transport (FOCUS, 2008). For substances that exceed these triggers and require drift mitigation at Step 4, redeposition following volatilisation must be quantified and added to deposition from spray drift. As the vapour pressure of chlorpyrifos-methyl is 1.945 x 10-3 Pa at 20°C, volatilisation/redeposition has been considered.

The EVA v. 2.1 spreadsheet tool (UBA, 2011) were used to calculate hourly deposition rates for an active substance during the first 24 hours after application. A summary of cumulated deposition rates for all representative uses are presented below:

SAP200CLORI

Table 2.8.5.4-1: Cumulated deposition rate of Chlorpyrifos-methyl over 24 h calculated with the model E.V.A 2.1 for all representative uses (g/ha).

Loading factors	Relevant scenarios	Downwind distance from the treated crop (m)					
		Deposition rates after different times (g/ha)					
		1	3	5	10	15	**20**
340 g as/ha 75%	Vines[1] BBCH 71-85	1.18	1.06	0.95	0.72	0.55	**0.42**
340 g as/ha 40%	OSR winter/spring[2] BBCH 10	0.62	0.56	0.50	0.38	0.29	**0.22**

[1] Effective deposition loadings were calculated using the "vines" spray drift scenario.
[2] Effective deposition loadings were calculated using the "agriculture" spray drift scenario.

Table 2.8.5.4-2: Cumulated deposition rate of Chlorpyrifos-methyl over 24 h calculated with the model E.V.A 2.1 for all representative uses (µg/L).

Loading factors	Relevant scenarios	Downwind distance from the treated crop (m)					
		Deposition rates after different times (µg/L)					
		1	3	5	10	15	**20**
340 g as/ha 75%	Vines[1] BBCH 71-85	0.39	0.35	0.32	0.24	0.18	**0.14**
340 g as/ha 40%	OSR winter/spring[2] BBCH 10	0.21	0.19	0.17	0.13	0.10	**0.07**

[1] Effective deposition loadings were calculated using the "vines" spray drift scenario.
[2] Effective deposition loadings were calculated using the "agriculture" spray drift scenario.

The maximum contributions of redeposition to surface water during the first 24 hours after application was **0.14 µg/L at 20 meters**, using EVA v. 2.1 spreadsheet tool (UBA, 2011).

The interpretation of these results in the risk assessment was discussed in Vol 1, data point 2.8.5.3 Volatilization/Redeposition contribution to surface waters.

GF-1684

Table 2.8.5.4-3: Cumulated deposition rate of Chlorpyrifos-methyl over 24 h calculated with the model E.V.A 2.1 for all representative uses (g/ha).

Loading factors	Relevant scenarios	Downwind distance from the treated crop (m)					
		Deposition rates after different times (g/ha)					
		1	3	5	10	15	**20**
1285 g as/ha 80% interception	Citrus[1] BBCH 11-89	4.67	4.19	3.76	2.86	2.18	**1.66**
1020 g as/ha 65% interception	Pome/stone[2] fruit BBCH 10-87	3.10	2.78	2.49	1.90	1.44	**1.10**
1020 g as/ha 65% interception	Pome/stone[3] fruit BBCH 10-87	3.15	2.83	2.53	1.93	1.47	**1.12**
608 g as/ha 75%	Vines[4] BBCH 19-89	2.23	2.00	1.79	1.36	1.04	**0.79**
900 g as/ha 75%	Maize[5] BBCH 12-59	1.24	1.11	1.0	0.76	0.58	**0.44**
675 g as/ha	Fruiting	1.09	0.98	0.88	0.67	0.51	**0.39**

60%	vegetables[5] BBCH 11-89						

[1] Effective deposition loadings were calculated using the "orcharding late" spray drift scenario.
[2] Effective deposition loadings were calculated using the "orcharding early" spray drift scenario.
[3] Effective deposition loadings were calculated using the "orcharding late" spray drift scenario.
[4] Effective deposition loadings were calculated using the "vines" spray drift scenario.
[5] Effective deposition loadings were calculated using the "agriculture" spray drift scenario.

Table 2.8.5.4-4: Cumulated deposition rate of Chlorpyrifos-methyl over 24 h calculated with the model E.V.A 2.1 for all representative uses (µg/L).

Loading factors	Relevant scenarios	Downwind distance from the treated crop (m)					
		Deposition rates after different times (µg/L)					
		1	3	5	10	15	**20**
1285 g as/ha 80% interception	Citrus[1] BBCH 11-89	1.56	1.40	1.25	0.95	0.73	**0.55**
1020 g as/ha 65% interception	Pome/stone[2] fruit BBCH 10-87	1.03	0.93	0.83	0.63	0.48	**0.37**
1020 g as/ha 65% interception	Pome/stone[3] fruit BBCH 10-87	1.05	0.94	0.84	0.64	0.49	**0.37**
608 g as/ha 75%	Vines[4] BBCH 19-89	0.74	0.67	0.60	0.45	0.35	**0.26**
900 g as/ha 75%	Maize[5] BBCH 12-59	0.41	0.37	0.33	0.25	0.19	**0.15**
675 g as/ha 60%	Fruiting vegetables[5] BBCH 11-89	0.36	0.33	0.29	0.22	0.17	**0.13**

[1] Effective deposition loadings were calculated using the "orcharding late" spray drift scenario.
[2] Effective deposition loadings were calculated using the "orcharding early" spray drift scenario.
[3] Effective deposition loadings were calculated using the "orcharding late" spray drift scenario.
[4] Effective deposition loadings were calculated using the "vines" spray drift scenario.
[5] Effective deposition loadings were calculated using the "agriculture" spray drift scenario.

Using EVA v. 2.1 spreadsheet tool (UBA, 2011), the maximum contributions of redeposition to surface water during the first 24 hours after application were **0.55, 0.37, 0.26, 0.15 and 0.13 µg/L at 20 meters** for citrus, pome/stone fruit, vines, maize and fruiting vegetables, respectively.

The interpretation of these results in the risk assessment was discussed in Vol 1, data point 2.8.5.3 Volatilization/Redeposition contribution to surface waters.

2.8.5.4.2. Long-range transport

The metabolites TCP and TMP are volatile and have estimated half-lives in air of 60.5 days and 12.2 days respectively, which exceed the DT50 trigger in air of 2 days for potential long range transport.

An assessment of the potential risk to surface water and soil, at the global scale, following the long range transport of TCP and TMP was conducted using EUSES 2.1.2. PECs at the global scales (climatic regions: moderate, tropic and arctic) were estimated assuming approximately 2039 tonnes of TCP and 2183 tonnes of TMP are generated in soil annually in the EU.

The results are shown in the table below:

Table 2.8.5.4-5: PECs for TCP and TMP in different environmental compartments at the global scale

Compartment	PEC		Unit
	TCP	TMP	
Global (tropic)			
Surface water	5.08E-04	3.41E-06	µg/L
Air	1.42E-13	2.32E-08	mg/m^3
Soil	1.64E-09	6.50E-09	mg/kg_{dwt}
Sediment	6.20E-06	1.82E-07	mg/kg_{dwt}
Global (moderate)			
Surface water	5.30E-04	1.02E-05	µg/L
Air	5.28E-14	5.82E-08	mg/m^3
Soil	1.60E-09	3.85E-08	mg/kg_{dwt}
Sediment	6.64E-06	5.95E-07	mg/kg_{dwt}
Global (Arctic)			
Surface water	5.29E-04	1.22E-05	µg/L
Air	1.75E-14	2.35E-08	mg/m^3
Soil	2.27E-09	7.98E-08	mg/kg_{dwt}
Sediment	6.70E-06	7.46E-07	mg/kg_{dwt}

2.8.6. Predicted environmental concentrations from other routes of exposure

Information to judge the impact of water treatment processes on water-borne residues of active substances and metabolites has been submitted (please refer Volume 3 – B.4 Further information (AS)).

2.9. Effects on non-target species

2.9.1. Summary of effects on birds and other terrestrial vertebrates

2.9.1.1. Summary of effects on birds

Avian acute oral, short-term dietary and long-term reproduction studies have been carried out with Chlorpyrifos methyl and the formulated products. A summary of the relevant acute, short-term and long-term endpoints is provided in the table below.

Table 2.9.1.1-1 Summary of toxicity endpoints in birds

Data point	Test organism	Test substance[1]	EU Agreed endpoint[2]	Reference
Acute Oral Toxicity to Birds				
CA 8.1.1.1/1	Bobwhite quail (*Colinus virginianus*)	Technical	LD_{50} = 923 mg a.s./kg bw	[redacted] 1991 Monograph Vol. III B-8, p. 117, April 1997, EU-Endpoints 2005

Data point	**Test organism**	**Test substance**[1]	**EU Agreed endpoint**[2]	**Reference**
CA 8.1.1.1/3	Mallard duck (*Anas platyrhynchos*)	Technical	LD_{50} > 1590 mg a.s./kg bw	[redacted] 1983 Monograph Vol. III, B-8, p 117, April 1997
CA 8.1.1.1/2	Bobwhite quail (*Colinus virginianus*)	EF-1066	LD_{50} = 227 mg a.s./kg bw	[redacted] 2001 Monograph Vol. III Addendum B-8, p 3, February, 2003; EU-Endpoints 2005
CP 10.1.1.1	Bobwhite quail	SAP200CHLORI	LD50 = 317.8 mg a.s./kg bw	[redacted] 2015
CA 8.1.1.1/4	Bobwhite quail (*Colinus virginianus*)	TCP	LD_{50} >2000 mg a.s./kg bw	[redacted] 1990, EU Endpoints 2005
Subchronic and Reproductive Toxicity to Birds				
CA 8.1.1.3/1	Mallard duck (*Anas platyrhynchos*)	Technical	NOEC = 15.56 mg a.s./kg bw/day	[redacted] 1998 Monograph Vol. III Addendum B-8, p 3, February, 2003; EU-Endpoints 2005

Acute toxicity endpoint
Three acute studies with the active substance in bobwhite quail were considered during the first approval of the active substance and were included in the monograph (1997) and the endpoints were included in SANCO/3061/99 – rev. 2. Moreover, a new study in bobwhite quail has been submitted with the formulated product SAP200CLORI. The results indicate that the formulated products are of higher toxicity than the active substance. Therefore, the endpoint of the formulated product EF-1066 have been used in the risk assessment i.e. 227 mg a.s/kg bw

Chronic toxicity endpoint
The NOEC of 100 mg/kg diet from the avian reproduction study converts to an equivalent **NOEC of 15.562 mg as/kg bw/day**, based on adult mallard ducks of mean body weight 1041 g/bird consuming food at a rate of 162 g food/bird/day was used in the risk assessment.

2.9.1.2. Summary of effects on terrestrial vertebrates (other than birds)

According to the toxicology section the following endpoints should be considered. Please, refer to Vol. 3 B6 for details.

Table 2.9.1.2-1 Summary of toxicity endpoints in mammals

Data point	**Test organism**	**Test substance**[1]	**EU Agreed endpoint**[2]	**Guidance**	**Reference**
Acute Oral Toxicity to Mammals					
CA 8.1.2.1/1	Rat	Technical	LD_{50} = 2814 mg a.s./kg bw	OECD 401	[redacted] 1985 Monograph Vol. III B-8, p 81, April, 1997; EU-Endpoints 2005
CA 8.1.2.1/2	Rat	GF-1684	LD_{50} = 3129 mg product/kg LD_{50} = (688 mg as/kg bw)	OECD 425	[redacted] 2008.

Data point	**Test organism**	**Test substance**[1]	**EU Agreed endpoint**[2]	**Guidance**	**Reference**
CA, 5.8.1/1	Rat	TCP	LD_{50} =3129 mg a.s./kg bw (female)	OECD 423	[redacted] 2015.
Long-term and Reproductive Toxicity to Mammals					
CA 8.1.2.2/1	Rat	Technical	NOAEL = 3 mg as/kg bw/day	OECD 416	[redacted] 2002 EU-Endpoints 2005

[2] SANCO/3061/99 – rev. 1.6, 3 June 2005
[3]This is not a requirement under Regulation 1107/2009.

Acute toxicity endpoint
For the acute toxicity endpoint, the formulated product of DAS is of higher toxicity than the active substance, therefore, the risk assessment will be performed with the formulated product endpoint i.e **688 mg a.s/kg bw**.

Chronic toxicity endpoint
The reproductive risk assessment will be based on the NOAEL value of 3 mg/kg bw per day from the multigeneration study with rats. According to the toxicology section the conclusion of the study of Carney et al. (2002) are the following: *There was an important adverse effect that was the vacuolisation of the adrenal glands cortex. This effect was evident in females of both parental generations at 3 mg/Kg bw/day and more severe in males and females at the dose of 10 mg/Kg bw/day.*
The histopathologic observations revealed that the adrenal gland weight increased and corresponded with an increase in the incidence and severity of cytoplasmic vacuolisation of the zona fasciculate of the adrenal gland.
Another important critical effect was the inhibition of AChE activity. The dose of 3 mg/Kg bw/day inhibited RBC AChE (65%) in parentals of both generations. The higher dose of 10 mg/Kg bw/day inhibited significantly the brain, heart and more severely the RBC AChE in both generation of parentals, although there were no clinical symptoms throughout the study and the reproduction and developmental parameters were not affected.
As the most important adverse effects occurred at the dose of 3 mg/Kg bw/day, we consider a NOAEL for parental toxicity of 1 mg/Kg bw/day and a NOEL of 10 mg/Kg bw/day for developmental and reproductive toxicity.

However, the toxicology section also indicates that in the two year study in rats *Adrenal vacuolation at 1 mg/kg bw/day and* below were consistent with background findings and that the only dose producing clear effects was the top dose of 50 mg/kg bw/day.

Therefore, based on the above information the NOAEL was set a 3 mg a.s/kg bw/d as included in SANCO/3061/99 – rev. 2.

2.9.2. Summary of effects on aquatic organisms

New studies with the active susbtance were not submitted with renewal proposals. Applicants refers to the studies already evalauted during annex I inclusion.

The toxicity data submitted for environmental relevant metabolites show the risk assessment conducted for the parent compound covers the risk assment for these chemicals.

Table 2.9.2-1: Summary of the end points for aqautic organisms

Group	**Test substance**	**Time-scale (Test type)**	**End point**	**Toxicity**[1]	
Laboratory tests					
Fish					
Onchorhynchus mykiis	Chlopyrifos methyl	Acute 96 hr flow-through	Mortality, LC_{50}	**410 µg a.s./L$_{(mm)}$**	[redacted] 1992a. (B-9 CA Study 9.2.1/01)
Oncorhynchus mykiss	RELDAN 22 (CHP-methyl 224g/L)	Acute 96 hr flow-through)	Mortality, LC_{50}	51 µg a.s./L$_{(mm)}$	[redacted] 1994a (KCA 8.2.1)
Oncorhynchus mykiss	GF1684	Acute 96 hr flow-through)	Mortality, LC_{50}	106 µg a.s./L$_{(mm)}$	[redacted] 2008 (CP 10.2.1/1)
Menidia menidia	Chlorpyrifos	early life-stage 28 d,	Mortality NOEC	0.28 µg a.s./L$_{(mm)}$	[redacted] 1985 (B-9 CA Study 9.2.2.1/04)
Menidia peninsulae			Mortality NOEC	0.38 µg a.s./L$_{(mm)}$	
Leuresthes teniues	Chlorpyrifos	early life-stage, flow-through, 35 d,	Mortality NOEC	0.14 µg a.s./L$_{(mm)}$	[redacted] 1985 (B-9 CA Study 9.2.2.1/05)
Pimephales promelas	Chlorpyrifos Dursban CR	early life-stage, flow-through,32 d,	Weight NOEC	1.6 µg a.s./L$_{(mm)}$ 2.2 µg a.s./L$_{(mm)}$	[redacted] 1988 (B-9 CA Study 9.2.2.1/01
Pimephales promelas	Chlorpyrifos technical	full life cycle, flow-through, 32 d,	Mortality NOEC	0.568 µg a.s./L$_{(mm)}$	[redacted] 1993 (B-9 CA Study 9.2.2.2/01)
Tilapia mossambica	Chlorpyrifos 20 EC (Coroban)		NOEC	5 ug/l	[redacted] 1986 (KCA 8.2.2.2)
Lepomis macrochirus	TCP	Static, 96 h	Mortality, LC_{50}	12500 µg a.s./L$_{(mm)}$	[redacted] 1991b (B-9 CA Study 9.2.1/03)

Group	**Test substance**	**Time-scale (Test type)**	**End point**	**Toxicity**[1]	
Laboratory tests					
Oncorhynchus mykiss	TCP	Static, 96 h	Mortality, LC_{50}	12600 µg a.s./$L_{(nom)}$	[redacted] 1991a (B-9 CA Study 9.2.1/04)
Menidia menidia	TCP	Flow-Through, 96 h	Mortality, LC_{50}	58500 µg TCP/L	[redacted] (B-9 CA Study 9.2.1/05)
Minnow pimephales promelas	3,6-DCP	Static, 96 h	Mortality, LC50	> 15000µg/$L_{(nom)}$)	[redacted] 2015 (B-9 CA Study 9.2.1/06)
Oncorhynchus mykiss	TMP	Static, 96 h	Mortality NOEC	756 µg a.i./L	[redacted] 2010a (B-9 CA Study B.9.2.1/07)
Oncorhynchus mykiss	TCP	early life-stages, flow-through, 31 d,	Weight, Length, days to mean hatch	80.8 µg TCP/$L_{(nom)}$	[redacted] 1999 (B-9 CA Study 9.2.2.1/08)
Aquatic invertebrates					
Daphnia magna	Chlorpytifos-methyl	48 h (static)	Mortality, LC_{50}	0.620 µg a.s./$L_{(mm)}$	Douglas 1992c (B-9 CA Study 9.2.4.1/01)
Daphnia magna	RELDAN 22	48 h (static)	Mortality, LC_{50}	1.1 µg a.s./L (0.24 µg a.s./$L_{((mm)}$)	Bell et al., 1994 (B-9 CA Study 9.2.4.1/02)
Daphnia magna	GF1684	48 h (static)	Mortality, LC_{50}	0.286 µg a.s./$L_{((mm)}$)	Bergfield, A., 2008 (CP 10.2.1/2)
Daphnia magna	SAPCHLORI	48 h (static)	Mortality, LC50	1.57 µg PPP/l	Sabine E. (2014) KCP 10.2.1/01,)
Daphnia magna	Chlorpyrifos-methyl	semi-static, 21 d,	Mortality, NOEC	0.01 µg a.s./L(nom)	Douglas 1992d (B-9 CA Study 9.2.5.1/01)
Gammarus pulex	GF 1684 (21,7% w/w)	96 h (static)	Mortality, LC50	0.36 µg a.s./L($_{mm}$)	Hartgers & Roessink, 2015 (B-9 CA Study 9.2.4.2/01)

Group	**Test substance**	**Time-scale (Test type)**	**End point**	**Toxicity**[1]	
Laboratory tests					
Chironomus riparius	GF 1684 (21,7% w/w)	96 h (static)	EC50	0.29 µg a.s./L(mm)	Hartgers & Roessink, 2015 (B-9 CA Study 9.2.4.2/01)
Procambarus clarkii	Chlopyrifos	96 h (static)	LC50	13.3 µg a.s./L(mm)	Zing 2012 (B-9 CA Study 9.2.4.2/01)
Hyalella azteca	Chlopyrifos	96 h (semi-static)	LC50	0.138 µg a.s./L(mm)	Brown etal 1997 (B-9 CA Study 9.2.4.2/06)
Mysidopsis bahia	Chlopyrifos	35 d (flow-through)	Mortality, NOEC	0.046 µg a.s./L(mm)	Sved, 1993 (B-9 CA Study 9.2.5.3/01)
Daphnia magna	TCP	48 h (static)	Mortality,EC_{50}	10400 µg $TCP/L_{(mm)}$	Gorinsky et al., 1991c (B-9. CA Sutdy 9.2.4.1/03)
Daphnia magna	TCP	semi-static, 21 d,	Mortality, NOEC	NOEC = 0.058 µg TCP/L(mm)	Machado, 2003 (B-9 CA Study 9.2.5.1/01)
Daphnia magna	TMP	48 h (static)	Letthargic NOEC	910 µg $TMP/L_{(nom)}$	Hamitou, 2010b (B-9 CA Study B.9.2.4.1/04)
Daphnia magna	3,6-DCP	48 h (static)	NOEC	24000 µg/L($_{mm)}$	Hoberg, 2015 (B-9 CA Study B.9.2.4.1/05)
Daphnia magna	Desmethyl-Chlorpyrifos-methyl	48 h (static)	NOEC	4300 µg/L(mm)	Kuhl and Härtel, 2015a (B-9 CA Study B.9.2.4.1/06)
Sediment-dwelling organisms					
Chironomus riparius	3,6-DCP	28 d (static)	NOEC	33000 µg/L(nom)	Putt, 2005 (B-9 CA Study B.9.2.4.5.3/01)
°Algae					
Pseudokirchneriella subcapitata	Chlorpyrifos-methyl	96 h	EyC_{50} EyC_{10} ErC_{50}	293 µg/L(mm) 106 µg/L(mm) 633 µg/L(mm)	Rebstock, M., 2012 (B-9 CA Study B.9.2.6.1/02)

Group	**Test substance**	**Time-scale (Test type)**	**End point**	**Toxicity**[1]	
Laboratory tests					
Pseudokirchneriella subcapitata	RELDAN 22 (CHP-methyl 224g/L	Static, 72 h	EC50 NOEC	130 µg/L(mm) 30 µg/L(mm)	Bell et al., 1994 (B-9 CA Study B.9.2.6.1/03
Pseudokirchneriella subcapitata	GF 1684	Static, 72 h	E_yC_{50} E_rC_{50}	256 µg/L(mm) 351 µg/L(mm)	Bergfield, A., 2008 (CP 10.2.1/2)
Pseudokirchneriella subcapitata	TCP	Static, 72	E_bC_{50} E_rC_{50}	610 µg /L (mm) 1110 µg /L(mm)	Kirk et al., 1999 (B-9 CA Study B.9.2.6.1/04)
Pseudokirchneriella subcapitata	TMP	Static, 72 h	E_yC_{50} EyC_{10} E_rC_{50}	1400 µg/L(mm) 760 µg/L(mm) 3300 µg/L(mm)	Biester 2010 B-9 CA Study B.9.2.6.1/05)
Pseudokirchneriella subcapitata	TMP	Static 72-hour	E_yC_{50}	59 µg/L(mm)	Kosak and Härtel 2015 B-9 CA Study B.9.2.6.1/06)
Pseudokirchneriella subcapitata	Desmethyl-Chlorpyrifos-methyl	Static, 72 h	EyC_{10} EyC_{20} E_yC_{50}	19000 µg/L(mm) 61500 µg/L(mm) >96000 µg/L(mm)	Kuhl and Frank, 2015a (B-9 CA Study B.9.2.6.1/07)
Anabaena flos-aquae	TCP	Static 120 h,	E_bC_{50}	1380 µg/L(mm)	Kirck et al., 2000 (B-9 CA Study B.9.2.6.2/02)
Navicula pelliculosa	TCP	Static, 72 h	E_rC_{50}	8900 µg/L(mm)	Sayers, 2003 (B-9 CA Study B.9.2.6.2/01)
Navicula pelliculosa	3,6-DCP	Static, 72 h	EyC50	12000 µg/L(mm)	Hoberg, 2006 (B-9 CA Study B.9.2.6.2/02)
Plant					
Lemna gibba	TCP	14 d, Static	EC_{50}	8750 µg/L(mm)	Kirk et al., 2000 (B-9 CA Study B.9.2.6.7/01)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]	
Laboratory tests					
Microcosm / Mesocosm studies					
Further testing on aquatic organisms *For the current renewal of inclusion of Chlorpyrifos-methyl, the mesocosm data-set previously evaluated during Annex I inclusion together with new mesocosm studies have been (re)-evaluated according to the new EFSA Aquatic Guidance Document (EFSA PPR Panel, 2013; EFSA Journal 2013;11(7):3290).* *A total of six different cosm studies were re-evaluated: Giddings JM. (1993), van den Brink et al. (1996), van Wingaarden (2002), Lopez-Mancisidor et al. (2008a), Lopez-Mancisidor et al. (2008b) and Daam et al. (2008).* *The Minimum Detectable Differences in abundance data (MDDabu) values obtained in each mesocosm study were used to select the most reliable Effect Class and to derive the Regulatory Acceptable Concentration (RAC) on the bases of both the Ecological Threshold Option (ETO-RAC) and the Ecological Recovery Option (ERO-RAC)* *From the six studies evaluated, only four of them :Giddings (1993), Van den Brink et al. (1996), Lopez-Mancisidor et al. (2008b) and Daam et al. (2008a) comply with the criteria (at least 8 taxa of potentially sensitive taxonomic groups with MDDabu values <100%) proposed by Brock et al. (2015). The other two studies were also used by RMS as supporting information* *Adequate numbers of individuals of Cladocera, Copepoda, Ephemoroptera and Amphipoda have been found with enough statistical power to detect statistical significant adverse effects on taxa from these groups. They are the most sensitive taxonomic groups based on the evaluation of tier 1 studies* *The lowest NOECs obtained for the most sensitive species after the evaluation of the micro/mesocosm studies were selected by RMS to derive the Regulatory Acceptable Concentration (RAC)* *The evaluation of the mesocosm data-set provides information on effects of chlorpyrifos products in the most sensitive species (including vulnerable species with long life cycle) which can be considered reliables by assessment of MDDabu values. The micro/mesocosm evaluated were conducted at different climatic conditions (including Mediterranean regions) and under several application patterns (including reapeted applications). Thus, the assignement of Assessment Factor was in accordance to the reliability and representativeness of the information available for understaning the effects of chlorpyrifos on aquatic systems.*					ETO-RAC = 0.03 µg/L (Assessment Factor = 1) ERO-RAC = 0.05 µg/L (Assessment Factor = 2)
Potential endocrine disrupting properties (Annex Part A, point 8.2.3) *[list evidence/indication on the potential for endocrine disrupting properties]*					Non specific effects observed associated to ED MoA

During the Annex I inclusion of chlorpyrifos an Ecologically Acceptable Concentration (EAC) of 0.1 µg/L was derived as critical endpoint to be used in risk assessment in Europe after the evaluation of numerous microcosm/mesocosms studies. Based on the consistency of the effects observed in the mesocosm studies, an assessment factor greater than 1 was considered to be unnecessary for risk assessment purposes. This agreement was also used for chlorpyrifos-methyl (SANCO/3061/99 – rev. 1.6, 3 June 2005)

For the current renewal, the mesocosm data-set previously evaluated during Annex I inclusion together with new mesocosm studies have been (re-)evaluated by DOW (López-Mancisidor, 2015, Study B.9.4.5/03 in CP B-9 GF 1684, data protection claimed) according to the new EFSA Aquatic Guidance Document (EFSA PPR Panel, 2013; EFSA Journal 2013;11(7):3290)

There are a large body of scientific information on the toxicity of CPF to aquatic invertebrates including an abundant number of higher tier studies. In the Review submitted by DOW, a table with published available mesocosm studies performed with chlorpyrifos was summarized including 22 references. From all these studies, only six of them (Giddings JM., 1993; van den Brink et al., 1996; van Wingaarden, 2002; Lopez-Mancisidor et al. 2008a; Lopez-Mancisidor et al. 2008b and Daam et al., 2008) were re-evaluated based on the availability of the raw abundances data and the reliability of the studies.

Table 2.9-1-2: Cosms studies re-evalauted in the DRARaccording to EFSA aquatic GD

Author	DAS Study ID	treatments	exposure regime	zooplankton	macro-invertebrates	emerged insects
Giddings JM. (1993)	92-6-4288 101879	0.03, 0.1, 0.3, 1, 3 µg/L	- single spray or - 3× slurry (2-wk intervals)	X	X	X
Van den Brink et al. (1996)	n.a	0.1, 0.9, 6, 44 µg/L	single spray	X	X	
Van Wingaarden (2002)	101423	0, 0.01, 0.1 and 1 µg/L	single spray	X		
Lopez-Mancisidor et al. (2008a)	n.a	0.1 and 1 µg/L	single spray	X		
Lopez-Mancisidor et al. (2008b)	n.a	0.033, 0.1, 0.33 and 1 µg/L	4× slurry (1-wk intervals)	X		
Daam et al. (2008)	n.a	0.1, 1, 10, 100 µg/L	single spray	X	X	

Note: n.a: no applicable.

According to the new Aquatic EFSA GD (EFSA, 2013), MDDs can be used to assess the reliability of the microcosm/mesocosm studies and for the assignement of Effect Classes which can be used to derive Regulatory Acceptable Concentration (RAC).

The raw abundance data are essential to identify the robusteness of the obtained endpoints and to determine the statistical power provided by the calculation of MMD (Minimum Detectebla Difference). In consequence, RMS has focused its evaluation on the mesocosm studies for which MDD values and raw abundance data are available for deriving a final RAC.

The Minimum Detectable Differences (MDD) were calculated following the method proposed by Brock et al. (2015) for results from parametric tests (i.e. variants of the t-test as Williams test) using the Community Analysis software version 4.3.14 (Udo Hommen, Aachen, Germany).

As the MDD calculations are used for assess the statistical power of univariate analysis for measured endpoints (e.g. abundance values), the MDD values cannot be calculated for secondarily derived results, e.g. multivariate analysis of whole community responses. As such the results at community level (when available and relevant) are only presented for informative purposes.

RMS has assessed the re-evaluation submitted for each one of these mesocoms in CP-9 GF 1684 , including the Categories for the taxa as well as the Effect Classes assigned to the different treatment levels (based on the Brock et al. 2015 proposal) for the taxa of each mesocoms study.

From the six studies evaluated, only four of them (Giddings (1993), Van den Brink et al. (1996), Lopez-Mancisidor et al. (2008b) and Daam et al. (2008a)) comply with the criteria (at least 8 taxa of potentially sensitive taxonomic groups with MDDabu values <100%) proposed by Brock et al. (2015). The other two studies performed by Van Wijngaarden (2002) and Lopez-Mancisidor et al. (2008a) do not fulfill these criteria as there were less than 8 potentially sensitive taxonomic groups belonging to Category 1 taxa.

In these four mesocosm studies used by RMS to derive a RAC, adequate numbers of individuals of Cladocera, Copepoda, Ephemoroptera and Amphipoda have been found with enough statistical power to detect statistical significant adverse effects on taxa from this groups. They are the most sensitive taxonomic group based on the evaluation of tier 1 studies (see points B.9.2.4 and B.9.2.5, particularly the studies of Giddings *et al.*, 2012- B.9.2.4.2/12 and Rubach et al., 2011- B.9.2.4.2/11). Consequently, it can be concluded that potentially sensitive taxonomic group are well represented in studied mesocosms

In order to derive a RAC, a summary of the most sensitive species to chlorpyrifos detected in each mesocosm of the 4 selected studies is detailed below.

Table 2.9.2-1-3: Summary of results of most affected Category 1 taxa identified in the re-evaluation of the data of the cosm experiments. NOECs were grouped by its capacity to derive the ETO or ERO-RAC.

Specie	**Toxonomic group**	**NOEC (µg/L)**			**Exposure profile**	**References**
		Effect Class 1. ETO-RAC	**Effect Class 3A. ERO-RAC**	**NOEC (Effect Class)* No RAC**		
Chydorus sphaericus	Cladocera (Z)	0.03	0.1		Single applicantion	Giddings et al., 1996
Chydorus sphaericus	Cladocera (Z)	0.03		0.1 (4B)	Repeated application	Giddings et al., 1996
Daphnia longispina	Cladocera (Z)	0.1	0.9		Single application	Van den Brink et al., 1996
Gammarux pulex	Amphipoda (MI)			<0.1 (1)	Single application	Van den Brink et al., 1996
Caenis horaria **Cloeon dipterum**	Ephemeroptera (MI)	0.1	0.9		Single application	Van den Brink et al., 1996
Daphnia gr galeata	Cladocera (Z)	0.03	0.1		Repeated application	López-Mancisidor 2008b
Moina micrura	Cladocera (Z)	0.1		< 0.1 (1)	Single application	Daam et al., 2008

*These NOECs were included in the table as supporting information although RAC cannot be derived based on them.

According to the Aquatic GD (EFSA, 2013), the endpoints based on effect categorized as Class 1 and 2 can be used as estimates of the ecological threshold concentrations of PPPs and to derive a ETO-RAC. The most sensitive endpoint (NOEC = 0.03 µg/L) corresponds to *Chydorus sphaericus* from the study of Giddings et al., (1996) and *Daphnia* gr *galeata* from López-Mancisidor et al., (2008).

Both species showed low abundance during the experimental period which could indicate that the endpoints should be considered with caution. However, in the case of *C. sphaericus*, a clear treatment-related effect was observed and values of %MDDabu during the post-application period indicates this effects would be considered realiable to be used in the risk assessment (please refers to study B.9.2.8/01-Giddings *et al.*, 1996 and study B.9.2.8/03 -López-Mancisidor *et al*., 2008 for details).

The study of López-Mancisidor and collaborators (2008b) was conducted under Mediterranean conditions and repeated application which could explain also the low endpoint obtained. The possibility of higher sensitivy in Mediterranean systems was already discussed during the previously EU Review of chlorpyrifos. In order to test this issue, the study of Van Wingaarden (2002) was submited and after its evaluation the endpoint settled initially on 0.1 µg/L was considered representative of all European regions. Unfortunately, this study does not comply with the criteria described in the Aquatic EFSA GD (PPR Panel, 2013) to be considered realiable for deriving a RAC. Consequently, RMS considers the concerns regarding to the higher sensitivity of edge-of-field surface water under Mediterranean conditions would be covered by including the lowest endpoint obtained for *D. galeata*.

Regarding to the RAC derivation taking into account the ecological recovery of populations (ERO-RAC), NOECs of 0.1 µg/L and 0.9 µg/L for the most sentive species were obtained (please see Table 9.2.8-02).
These results are partially in line with the Ecologically Acceptable Concentration (EAC) of 0.1 µg/L concluded during the Annex I inclusion of a.s.

It is reasonable to find differences in the conclusions reached in the previous and current evaluation of the microcosm. The current evaluation of micro/mesocosms studies was conducted considering the new requirement described in the EFSA Aquatic GD (PPR Panel, 2013) which imply a new interpretation of the effects by the assessment of its reliability (based on MDD values) and the new assignment of Effect Class compared to Jong et al., (2008).

RMS considers all information detailed in Table 9.2.8-02 should be taken into account to derive a RAC. It is important to note that the number of micro/mesocosm conducted using chlorpyrifos is enormous (probably there are more microcosm studies on chlorpyrifos than any other active substance approved in the EU). This has largely resulted from the molecule becoming a 'benchmark' test item for microcosm experiments conducted by researchers at Wageningen Research (WR). The information summarized in Table 9.2.8-02 corresponds to effects observed in the most sensitive species (including vulnerable species with long life cycle sucha as *Cloen dipterum*) from the studies with high statistical power. In addition, the studies were conducted at different climatic conditions including Mediterranean regions and under several application patterns. The study design of repeated applications could be considered representative not only for multiples application of PPP directly on crops but also of repeated entry of pesticides to water bodies due to different process such as runoff and/or drainage events.
At Tier 2 level, two different HC_5 derived from SSD curves published in open scientific literature (please refers to Study B.9.2.4.2/11 – Rubach et al., 2011- and B.9.2.4.2/12- Giddings et al., 2014-for details) were included in the dossier. The SSD curves were constructed with a limited dataset containing only the most sensitive species reaching values of HC_5 of 0.038 µg/L and 0.03 µg/L respectively. These values are in agreement with the lowest NOECs obtained in several microcosm at Tier 3 level.

Consequently, the assignement of Assessment Factor should be in accordance to the reliability and representativeness of the information available for understaning the effects of chlorpyrifos-methyl on aquatic systems.

RMS considers an AF= 1 would be applied to derive a RAC for the threshold option (ETO-RAC). In the case of recovery option, RMS proposes an AF = 2 by considering the effects observed on *Chydorus sphaericus* (please refers to study of Giddings 1993; B.9.4.5/01) on which recovery could not be guaranteed completely due to high %MDDabu values in recovery period.

In conclusion, RMS proposes to select the lowest NOECs to derive the RACs by appliying an AF = 1 for the threshold option and AF = 2 for the recovery option resulting on the following endpoints:

a) ETO-RAC =0.03 µg/L (based on NOEC = 0.03 µg/L with AF = 1)
b) ERO-RAC = 0.05 µg/L (based on NOEC = 0.1 µg/L with AF = 2)

On the other hand, new acute toxicity tests with GF 1684 were performed on aquatic invertebrate *Gammarus pulex*, *Chironomus riparius Asellus aquaticus* and *Cloeon dipterum* (see Study B.9.2.4.2/01 in B-9 CA). The experimental results, reveals a clear dose-response for *Chironomus riparius* (EC50, 96h: 0.29 µg/L, LC50, 96h: 0.33 µg/L), *and Gammarus pulex* (EC50, 96h: 0.36 µg/L, LC50, 96h: 0.36 µg/L). The crustacean *Asellus aquaticus* showed no clear treatment effects and consequently no E(L)C50 could be calculated, indicating that for this test E(L)C 50, 96h will be > 27µg/L. For the case of *Cloeon dipterum*, the calculation of endpoint could entail serious uncertainties as the highest tested concentration showed very high mortality (around 70%) while the just below tested concentration did not cause mortality.

The results of this study were introduced in a TK/TD modelling to reduce uncertainty in the ETO-RAC considering the time-varying concentration patterns represented in FOCUS surface water modelling scenarios where mitigation schemes were incorporated to limit the PECsw;max. (see Focks, A. and Van den Brink, P.J., 2015 in B-9 CP GF 1684).

Based on this modelling excercise, the applicants proposes to mantain the AF of 1 for the renwal. This proposal was not agreed by the RMS because :

1.- The modelling is based on the experimental toxicity data on *Chironomus riparius* , *Gammarus pulex and Cloeon dipterum* . The results of the mesocoms studies clearly show Cladocera is one of the most sensitive groups and they were not considered in the modelling exercise

2.- . the dedicated objective of TK/TD models from the GUTS framework is to extrapolate mortalities across exposure time series. It is currently, however, not possible to extrapolate mortality predictions between species. That means, the modelling results presented in this report are representative only for the parameterised species.

3.- This in line with the proposal of EFSA Guidance document which considres this kind of models to decide to base the risk assessment onPECmax or TWA and not to change theAF proposed in the GD.

With respect to the CS formulation SAP200 CHLORI, the applicant only submited an study on *Daphnia* with the PPP. Based on the results of this study, the applicant states that considering the high level of mortality registered in the 1st 24h, it is possible to conclude that the chlorpyrifos-methyl is released from the capsules immediately after dilution of capsule in the daphnia medium

However, no enough information is found in the dossier in order to establsih if SAPCHLORI is slow or rapid realese. As a general principle, the nature of the pesticide and the type, structure and properties of the capsule shell will drive the rate of release of the pesticide.

This information is considered essesntial because it will affect to the chronic risk assessment of SAP200CHLORI

During annex I inclusion peer review, a BCF_{fish}= 1800 CT50=2.6 d for Rainbow trout (*Oncorhynchus mykiss*) was agreed. During renewal, no new study has been submitted. BCFs were estimated at different times throughout the exposure period of the study and were based on whole fish and steady-state concentration ratio. RMS considers the steady-state approach could entails uncertainties because no clear plateau was reach before 13 days of exposure.

The study was not performed following the latest state-of-art of science neither following the updated OECD guidance document 305 adopted on October, 2012.

Data of fish lipid content is not provided and thus it is not possible to perform a normalization to lipid content. Dilution by growth was not considered. The kinetic BCF (BCF_K) was estimated by RMS as the ratio of the rate constant of uptake (k_1) and depuration (k_2) for each exposure level.

The narrow difference among kintetic parameters, k_1 and k_2, regadless of the exposure concentration in water, indicates the fiability of obtained values of BCF. Thus, a geomean of both BCF was calculated obtaining a BCF_K = 1581.

EI-Amrani S, et al (2012) studied the Bioconcentration of chlorpyrifos in zebrafish (*Danio rerio*) eleutheroembryos as an alternative protocol to the one proposed by test 305. The authors highligts the possibility of overestimation of the calculated BCF values or, alternatively, underestimation due to a (possible) metabolism process cannot be ruled out. They point out :

Overestimation of BCF values by using larvae for bioaccumulation experiments have been previously observed by other authors. Different factors have been suggested as responsible for this type of observation. On the one hand, the relatively higher lipid content of larvae and/or their slow metabolism as compared to those of adult and juvenile fishes have been pointed out as possible explanations for this result. The lipid content of the zebrafish eleutheroembryo at the end of the yolk sac stage has been reported to be ca. 20% (dry weight, dw), whereas that of juvenile zebrafish is around 11.0% (dw).

On the other hand, other explanation considers the possibility of metabolic biotransformations of the investigated compounds […] the microsomal aryl hydrocarbon hydroxylase (AHH) activity, an indicator of the presence of hepatic P-450 systems, remains uniformly low at the different embryonic stages of killifish assayed before hatching- […] However, after 24 h of hatching, AHH-specific activity increases about nine-folds. Other study compared the induction of P-450 in both larvae and juveniles of cod exposed to crude oils. Results showed that the induction process was dose-dependent and that it was restricted until hatching, when the P-450 activity gradually increased

There are not details of the BCF values were normalized to lipid content. Taking into account the data requirements stated in Regulation 283/2013 The RMS considers this study cannot replace the proposed BCF, and the use of zebrafish (*Danio rerio*) eleutheroembryos as an alternative protocol to TG305 should be discussed in corresponding fora.

With respect to the Potential for endocrine disruption, DOW submitted a study with chlorpyrifos on fathead minnow (*Pimephales promelas)* following the USEPA and OECD guidelines "Fish Short Term Reproduction Assay , This study did not meet the validity criteria detailed in the OECD 229 and OCSPP Guideline 890.1350 as the mortality in control exceeds the 10% required and the measured concentration was not within 20% of mean measured values per treatment level. The results only show statistical differences among treated vessels with controls with respect to the fecundity and the concentrations of cholinesterase in brain of fishes (male and female) For the control groups, fecundity ranged from 30.0 to 37.3 eggs/female/reproductive day, while fertility ranged from 98.1 to 99.2%. A decrease of fecundity with increasing of concentration of chlorpyrifos can be established unequivocally. The variability of results is scarce and the trend of decrease can be observed clearly showing statistics difference to the control from the lowest tested concentration (0.251 µg/L). The median male and female cholinesterase data exhibited a dose response with increasing concentrations of chlorpyrifos. Thus, this effect exhibits a clear-dose response relationship.

With the available data it is not possible to know wether or not the adverse effect on fecundity (nºeggs/ surviving female/day) could be due to a endocrine disruption mode of action but clearly will affect the reproduction and viability of population (CA B-9 study B.9.2.3/01) . In order to adress the effects observed in the fecundity a second study was submitted (Coady 2015, CA B-9 study B.9.2.3/02) where the potential effects of chlorpyrifos on reproduction of the fathed minnow (*Pimephales promelas*) to a single nominal cocnetration for 0, 24, 48, 96 and 192 h . The reduction of exposure time decreasesthe time of life cycle which the fish are exposed and the study does not give additional information on this point.

Additionally, an amphibian metamorphosis assay on *Xenopus laevis* follwing TG OECD 231 was submitted for renewal purposes (Study 9.2.3/03 CA B-9). Adverse effects were observed on development stage, hind limb length, sonoul-vent lenght and body weigh. It is known that an advanced developmented stages or an incrementation of hind-limb legnth between tested cocnetration and controls are indicative of some short thyroid aactivity. However, the effect on delayed developemt stage and reduction in growth could be occurred by indirec toxicity. It was noted that morpholical characteristics on which the stage of the tadpoles were not provided.

2.9.3. Summary of effects on arthropods

2.9.3.1. Bees

A summary of the available data on bees that are considered as acceptable and relevant for the risk assessment is given in the table below.

Table 2.9.3.1-1. Summary of available studies on toxicity to honeybees exposed to chlorpyrifos-methyl and representative formulations that were accepted and considered as relevant.

Type of test	Test substance	Species/ Life stage	Doses / Rate	Results	Reference / Owner
Acute oral and contact toxicity	Reldan 22 (EF1066) (224 g chlorpyrifos-	*Apis mellifera* adult sterile female bees	Both oral and contact tests: 0.25, 0.50, 1.0, 2.0 and 4.0	**LD_{50} oral = 0.177 µg a.s./bee**; **LD_{50} contact =**	Bell, G. (1994)[a] No data

Type of test	Test substance	Species/ Life stage	Doses / Rate	Results	Reference / Owner
	methyl/L)		µg/bee	**0.148 µg a.s./bee**	protection
Acute oral and contact toxicity	TCP (metabolite)	*Apis mellifera* adult female worker bees	Oral test: 105.8, 55.2, 27.5, 13.7 and 6.8 µg a.i. of TCP/bee Contact test: 100.0, 50.0, 25.0, 12.5 and 6.3 µg a.i. of TCP/bee	Oral TCP LD_{50} (48 h) = 80.7 µg a.i./bee; Contact TCP LD_{50} (48 h) = 37.9 µg a.i./bee.	Sekine, T. (2014)[c] SAPEC AGRO
Acute oral and contact toxicity	Reldan 22EC (GF-1684) (225 g chlorpyrifos-methyl/L)	*Apis mellifera* adult female worker bees	Oral test (measured): 5.1, 2.8, 1.4, 0.7 and 0.3 µg of GF-1684/bee; Contact test: 5.0, 2.5, 1.3, 0.6 and 0.3 µg of GF-1684/bee	Oral LD_{50} = 0.50 µg a.s./bee; Contact LD_{50} = 0.25 µg a.s./bee	Schmitzer, S. (2008)[d] DAS
Acute oral and contact toxicity	SAP200CHLORI (200 g chlorpyrifos-methyl/L, CS)	*Apis mellifera* adult worker bees	Oral test: 0.40, 0.80, 1.60, 3.20 and 6.40 µg a.s./bee; Contact test: 0.0045, 0.0081, 0.0146, 0.0262 and 0.0472 µl of SAP200CHLORI /bee	Oral LD_{50} = 0.86 µg a.i./bee; Contact LD_{50} = 5.42 µg a.i./bee	Ansaloni, T. (2015a)[c] SAPEC AGRO
Chronic oral toxicity	Chlorpyrifos-methyl Technical (≥ 98% w/w chlorpyrifos-methyl)	*Apis mellifera* adult worker bees	0.016, 0.047, 0.140, 0.419 and 1.257 mg a.s/L sucrose solution	**Chronic oral 10 d LD_{50} = 0.007 µg a.s./bee/day**; **NOEC hpg = 0.0233 µg a.s./mL/bee**	Nöel, E. (2015a)[c] SAPEC AGRO
Acute larval oral toxicity	Chlorpyrifos (97.6 %)	*Apis mellifera* larvae	0.0063, 0.0125, 0.0250, 0.0500 and 0.1000 µg a.i./bee larva	Laboratory *Apis mellifera* larvae chlorpyrifos LD_{50} oral = 0.021 µg a.i./bee	Odemer, R. (2015)[b] DAS
Acute larval oral toxicity	Chlorpyrifos-methyl Technical (98.5% w/w)	*Apis mellifera* larvae	0.03, 0.08, 0.24, 0.7 and 2.1 µg a.s./larva on day 4 of the rearing period	**Laboratory *Apis mellifera* larvae NOED = 0.08 µg a.i./bee**	Deslandes, L. (2014)[c] SAPEC AGRO
Semi-field cage study (fresh and aged residues -1, 3, 7 and 14 days-) on *Phacelia*	Reldan 22EC (EF-1066) (225 g as chlorpyrifos-methyl/L, EC)	Small *Apis mellifera* colonies	1000 g a.s./ha, single application	Chlorpyrifos-methyl applied to *Phacelia* at 2700 g a.s./ha during bee flight and aged residues up to 3	Bakker, F.M. (2002)[b] No data protection

Type of test	Test substance	Species/ Life stage	Doses / Rate	Results	Reference / Owner
				days old caused significant levels of mortality compared to the control 1 day after treatment (1 DAT) and strongly reduced foraging throughout the whole post-exposure period (3 DAT). A significant reduction in foraging effect occurs 1 DAT with residues 7 days old. No significant effects on mortality were observed with residues 7 and 14 days old. No significant effects in the bee foraging behaviour were detected with residues 14 days old. No significant effects compared with the control were observed on queen or brood development for all treatments of Reldan 22.	
Semi-field cage study on oilseed rape	Reldan 22EC (EF-1066) (225 g as chlorpyrifos-methyl/L, EC)	Small *Apis mellifera* colonies	- 450 g a.s./ha chlorpyrifos-methyl 3 days before flowering. The set-up of the colonies was three days thereafter - 338 g a.s./ha chlorpyrifos-methyl applied 3 days after set-up of the colonies and after daily flight of the bees - 450 g a.s./ha chlorpyrifos-	Chlorpyrifos-methyl applied during flowering but after daily bee-flight at rates of 1.5 L product/ha (338 g a.s./ha) and 2.0 L product/ha (450 g a.s./ha) significantly increased the bee mean mortality rate on the day of application. No effects in the from day 0 after application to 7 days after	Hecht-Rost, S. (2007)[c] DAS

Type of test	Test substance	Species/ Life stage	Doses / Rate	Results	Reference / Owner
			methyl applied 3 days after set-up of the colonies and after daily flight of the bees	application mean mortality and flight intensity values have been detected in any of the chlorpyrifos-methyl treatments. When applied 3 days before flowering at 450 gr as/ha chlorpyrifos-methyl caused no unacceptable adverse effects on honeybees in terms of mortality, foraging and brood.	
Semi-field cage study on buckwheat (*Fagopyrum esculentum*)	GF-1684 (225 g chlorpyrifos-methyl/L)	Small *Apis mellifera* colonies	353 g a.i./ha	No statistically significant biologically relevant endpoints were determined for the bees (brood development, adult bee mortality, colony strength and residues levels) when treated with chlorpyrifos-methyl during bee flight at an application rate of 353 g a.i./ha compared to the control.	Howerton, J. (2015)[c] DAS
Field study (apple orchards) in UK	EF-1551 (480 g chlorpyrifos/L)	Community of unmanaged pollinators in apple orchards	480 g a.s./ha	Monitoring of pollinator's activity in different scenarios (crops, weeds, field margins…). Comparisons between the treated and the control plots were made outside the apple blossom time. There were great differences in the abundance of flower-visiting insect species between the different orchards.	Zumkier, U. (2015)[c] DAS

Type of test	Test substance	Species/ Life stage	Doses / Rate	Results	Reference / Owner
				Thus, no clear conclusions can be stated on the adverse effects of chlorpyrifos on pollinator populations.	

[a] submitted in September 1997 for the Active Approval
[b] In DAR 1999
[c] Submitted for renewal purposes
[d] submitted for the national registration of GF-1684 in Spain, and evaluated by the Spanish regulatory authority in the registration report (February 2010)

No accepted acute oral and/or contact toxicity study was available for the active substance (the study submitted did not meet the validity criteria; for details please refer to CA-B9). Additionally, the applicants submitted three different studies conducted with GF1684, SAP200CLORI and Reldan 22EC, the last one already evaluated for the original annex I inclusion. The respective acute oral and contact LD_{50} endpoints for bees derived from these studies were 0.5 and 0.25 µg a.i./bee for GF1684, 0.84 and 5.42 µg a.i./bee for SAP200CLORI and 0.177 and 0.148 µg a.i./bee for Reldan 22EC (Please see Table 2.9.3.1-1).

These laboratory data also show that as a rule chlorpyrifos-methyl appears to be more toxic to honey bees by contact than through the oral route (with the exception of the formulation SAP200CLORI, for which the reported laboratory contact toxicity is about an order of magnitude lower)

In view of the above, the risk assessment proposed by the RMS is based on the most sensitive acute oral and contact endpoints observed, that is the endpoints for Reldan 22EC (EF1066, 224 g chlorpyrifos-methyl/L).

The chronic LD_{50} and The NOEC for larvae and HPG values used by the RMS in the first tier risk assessment of chlorpyrifos-methyl are all obtained from studies with the technical substance of SAPEC AGRO and they are all subject to data protection (Please see Table 2.9.3.1-1).

Under laboratory conditions, TCP, shows a lower acute toxicity to bees than chlorpyrifos-methyl. The submitted study for TCP has been included in this risk assessment for chlorpyrifos-methyl for completeness, but no sufficient data are available (chronic LD_{50}, NOEC for larvae and HPG) to further conduct an appropriate risk assessment for bees according to the EFSA GD. From the RMS's point of view, the possible risk from metabolites would be covered by the assessment of the parent active ingredient(s).

The tier 1 risk assessment of chlorpyrifos-methyl has been made according to the EFSA Bee Guidance Document (EFSA, 2013), which has not yet been noted by the Standing Committee, using the most conservative acute oral and contact, chronic oral, HPG NOEC and acute larval laboratory values from those given by the accepted studies regardeless the formulation tested. Based on this scheme, further refinement is needed for **all** proposed uses´**.** As no applications are proposed during flowering, the risk is identified for the following scenarios of the EFSA:exposure of the bees to the weeds in the treated field, to the plants in the field margins or to adjacent crops where the product can be drifted (For more details, please see the chlorpyrifos-methyl list of endpoints for bees).

The exposure through the guttation water is considered negeglible due to the mode of action of the active susbtance.

When tested under more realistic semi-field conditions (cage and tunnel tests), applications of 2700 g a.s./ha of chlorpyrifos-methyl to *Phacelia* during the bee flight (Bakker, F.M. 2002; No data protection) and aged residues up to 3 days old caused significant levels of mortality compared to the control 1 day after treatment (1 DAT) and strongly reduced foraging throughout the whole post-exposure period (3 DAT). A significant reduction in foraging effect occurs 1 DAT with residues 7 days old. No significant effects on mortality were observed with residues 7 and 14 days old. No significant effects in the bee foraging behaviour were detected with residues 14 days old. No significant effects compared with the control were observed on queen or brood development for all treatments of Reldan 22.

The rest of the semi-field and field studies presented for the risk assessment are all of the property of Dow Agrosciences and subject to data protection:

In a large tunnel test (Hecht-Rost, S. 2007) in oilseed rape, chlorpyrifos-methyl applied during flowering but after daily bee-flight at rates of 338 g a.s./ha and 450 g a.s./ha significantly increased the bee mean mortality rate on the day of application, but no effects were seen when treated at 450 g a.s./ha 3 days before flowering and the set-up of the bee colonies. No effects in the from day 0 after application to 7 days after application mean mortality and flight intensity values have been detected in any of the chlorpyrifos-methyl treatments.

A more recent cage test on buckwheat (Howerton, J. 2015) showed no statistically significant biologically relevant endpoints for bee brood (brood development, adult bee mortality, colony strength and residues levels) compared to the control when treated with chlorpyrifos-methyl during bee flight at an application rate of 353 g a.i./ha. This experimental rate does not cover the majority of the intended uses for chlorpyrifos-methyl. Only for oilseed rape and grapes treated at 340 g a.s./ha, a safe use for the honeybee brood can be stated.

From an recent field test (Zumkier, U. 2015) that monitored pollinator's activity in different scenarios (crops, weeds, field margins…) in apple orchards, the great differences in the abundance of flower-visiting insect species between the different orchards make that no clear conclusions can be stated on the adverse effects of chlorpyrifos on pollinator populations. Comparisons between the treated and the control plots were made outside the apple blossom time.

Taking into account the results from the available cage or tunnel tests, several concerns need to be pointed out:

- The applications of chlorpyrifos-methyl, independently of the formulation and the intended use, have to be made in the absence of honeybees.

- From all the intended uses, safety for the honeybee brood can only be confirmed for oilseed rape and grapes treated at 340g a.s./ha.

- Dry residues for applications up to 2700 g a.s./ha are not toxic from 14 days on (no mortality nor foraging effects). Additional mitigation measures may be necessary to ensure that applications are made at times when bees are not actively foraging in the crop, that in-field and field margins' flowering weeds are absent/removed before application (e.g. by mowing in orchards and vines, good weed control in arable crops) and that hives adjacent to the treated area are removed/relocated prior to application.

- Careful management practices application of chlorpyrifos-methyl should be followed to protect bees. Member states need to consider mitigation measures at the local level.

In conclusion, based on the available data, for a safety use of chlorpyrifos-methyl for honeybees, applications should be restricted to periods of low bee activity. The treatments should be performed out of the crop flowering period and when the field margins are not flowering. The honeybee hives and colonies have to be removed (or covered) from the areas to be treated **for at least up to 14 days after applications** and flowering weeds should be removed (e.g. by mowing) prior to application.

However, nothing can be stated for the wild bees (bumble bees and solitary bees) as no study has been presented to assess the risk of chlorpyrifos-methyl on these groups. The only work developed in UK in apple orchards could not shed light on the risk of chlorpyrifos-methyl for these species because of the variable results depending on the orchard. It has also to be taken into account that the applications of chlorpyrifos were made outside the apple blossom time.

2.9.3.2. Non target arthropods other than bees

There are no new available laboratory data of chlorpyrifos-methyl on non-target arthropods to conduct the Tier I risk assessment.
Since glass plate laboratory studies with chlorpyrifos were anticipated to show effects, this level of testing was not carried out with chlorpyrifos-methyl, and the risk assessment was 'elevated' to the Tier II level using the more realistic extended laboratory studies.
Under laboratory conditions, chlorpyrifos-methyl (and chlorpyrifos) metabolite, TCP, shows lower acute toxicity than chlorpyrifos-methyl. The submitted study for TCP has been accepted as supplementary data in this risk assessment, but from the RMS's point of view, the possible risk from metabolites would be covered by the assessment of the parent active ingredient(s).

A summary of the available extended laboratory and aged residues data on non-target arthropods that are considered as acceptable and relevant for the risk assessment is given in the table below.

Table 2.9.3.2-1. Summary of available extended laboratory and aged residues studies on toxicity to non-target arthropods exposed to chlorpyrifos-methyl and representative formulations that were accepted and considered as relevant.

Test substance	Species/ Life stage	Time scale	Rates (g a.s./ha)	Type of test/ Substrate	Results[1]	Reference / Owner
Reldan 22 EC	*Typhlodromus pyri* (Acari: Phytoseiidae) proto-nymphs	0 DAT	49.95 and 286.2	Tier 2; Extended laboratory test Initial residues on bean leaf discs	No effects	Taruza, S. (2001)[b] No data protection
GF 1684	*Typhlodromus pyri* (Acari: Phytoseiidae) proto-nymphs	0 DAT	25, 50, 100, 200, 400 and 800	Tier 2 dose-response Initial residues on bean leaf disc	**ER_{50}: 158.2 g a.s./ha**	Hutcheson, K. (2007a)[c] DAS
SAP 200 CHLORI	*Typhlodromus pyri* (Acari: Phytoseiidae) proto-nymphs	1, 14 and 21 DAT	136.34, 550.56 and 700	Tier 2; Aged residues study Aged residues on bean plants	1 DAT 136.34 g a.s./ha M: 18% R: 7.30% of reduction 550.56 g a.s./ha M: 20% R: 10.12% of reduction 700 g a.s./ha M: 31% R: 5.08% of reduction 14 DAT 136.34 g a.s./ha M: 17% R: 17.84% of reduction 550.56 g a.s./ha M: 19% R: 11.27% of reduction 700 g a.s./ha M: 15% R: -0.88% of reduction 21 DAT 136.34 g a.s./ha M: 19% R: -11.32% of reduction 550.56 g a.s./ha M: 18% R: 2.80% of reduction 700 g a.s./ha M: 17% R: 3.52% of	Luna, F. (2015a)[c] SAPEC AGRO

Test substance	Species/ Life stage	Time scale	Rates (g a.s./ha)	Type of test/ Substrate	Results[1]	Reference / Owner
					reduction	
Reldan 22 EC	*Aphidius rhopalosiphi* (Hym.: Braconidae) adults	0, 7 DAT	49.95 and 286.2	Tier 2; Extended laboratory study Initial & aged residues on barley seedlings	0 DAT M: 100% (both doses) 7 DAT M: < 3% (worst case) R: No effects	Vinall, S. (2001)[b] No data protection
GF 1684	*Aphidius rhopalosiphi* (Hym.: Braconidae) adults	0 DAT	0.1, 0.2, 0.4, 0.8, 1.6 and 3.2	Tier 2 dose-response Initial residues on barley seedlings	**ER_{50}: 0.56 g a.s./ha**	Hutcheson, K. (2007b)[c] DAS
SAP 200 CHLORI	*Aphidius rhopalosiphi* (Hym.: Braconidae) adults	1, 14 and 21 DAT	47.1, 136.34, 340, 550.56 and 700	Tier 2; Aged residues study Aged residues on bean plants	1 DAT M: 100% (all doses) 14 DAT 47.1 g a.s./ha M: 0% R: 14.87% of reduction 136.34 g a.s./ha M: 17.5% R: 28.02% of reduction 340 g a.s./ha M: 25% R: 26.37% of reduction 550.56 g a.s./ha M: 52.5% 700 g a.s./ha M: 62.5% 21 DAT 47.1 g a.s./ha M: 7.5% R: -1.52% of reduction 136.34 g a.s./ha M: 0% R: 26.79% of reduction 340 g a.s./ha M: 0% R: 30.40% of reduction 550.56 g a.s./ha M: 10% R: 31.44% of reduction 700 g a.s./ha M: 7.5% R: 22.08% of reduction	Luna, F. (2015b)[c] SAPEC AGRO
Reldan 50 EC	*Aphidius colemani*	0, 1, 3, 5, 8,	120 and 480	Tier 2; Extended	120 g a.s./ha: 0 DAT	Mead-Briggs, M. (1997a)[b]

Test substance	Species/ Life stage	Time scale	Rates (g a.s./ha)	Type of test/ Substrate	Results[1]	Reference / Owner
	(Hym.: Braconidae) adults	11 and 14 DAT		laboratory study Initial & aged residues on wheat leaf	M 100% 1 DAT M 100% 3 DAT M 100% 5 DAT M 68% 8 DAT M 6% 11 DAT M 2% AE 39% 480 g a.s./ha: 0 DAT M 100% 1 DAT M 100% 3 DAT M 100% 5 DAT M 100% 8 DAT M 48% 11 DAT M 10% 14 DAT M 4% AE 37%	No data protection
GF 1684	*Chrysoperla carnea* (Neur.: Chrysopidae) larvae	0 DAT	5, 10, 20, 40 and 80	Tier 2 dose-response Initial residues on bean leaf	**ER_{50}: 36.89 g a.s./ha**	Hutcheson, K. (2007c)[c] DAS
SAP 200 CHLORI	*Chrysoperla carnea* (Neuroptera: Chrysopidae) larvae	1, 14 and 21 DAT	27.26, 110.12 and 700	Tier 2; Aged residues study Aged residues on bean plants	1 DAT 27.26 g a.s./ha M: 40% R: -33.02% of reduction 110.12 g a.s./ha M: 53.33% R: -18.52% of reduction 700 g a.s./ha M: 80% 14 DAT 27.26 g a.s./ha M: 23.33% R: -15.04% of reduction 110.12 g a.s./ha M: 27.59% R: -4.88% of reduction 700 g a.s./ha M: 23.33% R: -8.94% of reduction 21 DAT	Luna, F. (2015c)[c] SAPEC AGRO

Test substance	Species/ Life stage	Time scale	Rates (g a.s./ha)	Type of test/ Substrate	Results[1]	Reference / Owner
					27.26 g a.s./ha M: 10% R: 9.54% of reduction 110.12 g a.s./ha M: 20% R: 5.13% of reduction 700 g a.s./ha M: 17.24% R: 2.20% of reduction	
GF 1684	*Aleochara bilineata* (Col.: Staphylinidae) adults	0, 7 DAT	0 DAT: 5, 10, 20, 40, 80 and 160 7 DAT: 100, 200, 300, 400, 500 and 600	Tier 2 dose-response Initial & aged residues sprayed on soil	0 DAT **LR_{50}:** **139.8 g a.s./ha** 7 DAT LR_{50}: 244.75 g a.s./ha	Hutcheson, K. (2007d)[c] DAS
Reldan 22 EC	*Coccinella septempunctata* (Col.: Coccinellidae) adults	0, 1, 2, 5, 9 and 13 DAT	120 and 480	Tier 2; Extended laboratory study Initial & aged residues on wheat plants	120 g a.s./ha: 0 DAT M 9% 1 DAT M 3% 480 g a.s./ha: 0 DAT M 5% 1 DAT M 15% 2 DAT M 26% 5 DAT M 0%	Mead-Briggs, M. (1997b)[b] No data protection
SAP 200 CHLORI	*Coccinella septempunctata* (Col.: Coccinellidae) larvae	1, 14 and 21 DAT	110.12, 550.56 and 700	Tier 2; Aged residues study Aged residues on bean plants	1 DAT 110.12 g a.s./ha M: 62.5% 550.56 g a.s./ha M: 85% 700 g a.s./ha M: 85% 14 DAT 110.12 g a.s./ha M: 37.5% R: 22.02% of reduction 550.56 g a.s./ha M: 53.85% R: -82.57% of reduction 700 g a.s./ha M: 50% R: -5.50% of reduction 21 DAT 110.12 g a.s./ha M: 12.82%	Luna, F. (2015d)[c] SAPEC AGRO

Test substance	Species/ Life stage	Time scale	Rates (g a.s./ha)	Type of test/ Substrate	Results[1]	Reference / Owner
					R: -72.60% of reduction 550.56 g a.s./ha M: 10% R: -8.22% of reduction 700 g a.s./ha M: 12.5% R: -105.48% of reduction	
Reldan 50 EC	*Pardosa* spp. (Araneae: Lycosidae)	0, 2 DAT	120 and 480	Tier 2; Extended laboratory study Initial & aged residues sprayed on soil	120 g a.s./ha: 0 DAT M 0% 2 DAT M 0% 480 g a.s./ha: 0 DAT M 35% 2 DAT M 0%	Mead-Briggs, M. (1997d)[b] No data protection
Reldan 50 EC	*Bembidion lampros* (Col.: Carabidae) adults	0, 2, 5 and 9 DAT	120 and 480	Tier 2; Extended laboratory study Initial & aged residues sprayed on soil	120 g a.s./ha: 0 DAT M 95% 2 DAT M 0% 5 DAT M 15% 480 g a.s./ha: 0 DAT M 100% 2 DAT M 70% 5 DAT M 65% 9 DAT M 90%	Mead-Briggs, M. (1997c)[b] No data protection

[1] M = Mortality; R = Reproduction; AE = Adult Emergence

[a] In DAR 1999
[b] In the dossier submitted in February 2003 for the Active Approval
[c] Submitted for renewal purposes

The extended laboratory studies conducted with the standard sensitive species *Typhlodromus pyri*, *Aphidius rhopalosiphi*, *Chrysoperla carnea* and *Aleochara bilineata* examined the lethal effects of chlorpyrifos-methyl. No study was available for the active substance. Thus, the risk assessment proposed by the RMS is based on the most sensitive endpoints observed in any of the available formulation studies. The resulting ER_{50} values from these studies ranged from 0.56 g a.s./ha for *Aphidius rhopalosiphi* to 158.25 g a.s./ha for *Typhlodromus pyri*.
Other extended laboratory or aged residues studies conducted also evaluated sub-lethal effects but did not include a dose-response estimation or were not performed with the sensitive standard species according to ESCORT 2 guidelines. Therefore, only the studies with the sensitive species were used for the higher tier risk assessment.

Possibility for recovery can be assessed by aged residue studies that give information on the time after which individuals entering a treated area would survive and reproduce normally. However, it should be kept in mind that according to ESCORT 3 document “the concept of the possibility for recovery can be applied for the in-crop risk assessment but does not guarantee that actual recovery will occur. Therefore, the potential for recovery times in the aged residue studies indicate the theoretical time period after application when sensitive NTAs could start to recover/re-colonize the treated area, but ecological recovery may be longer due to many factors which are not treatment related e.g. the initial knock-down toxic effect, the moment of the year, phenology and biology of the affected arthropods or the availability of prey for predatory species. Therefore, the "potential for recovery" or "actual recovery" as assessed in this current risk assessment is not a robust predictive indicator for the probable effect of landscape-scale usage of chlorpyrifos-methyl. These limitations could be partly overcome by monitoring exposure over time in field experiments.

A summary of the available semi field and field studies on non-target arthropods considered as acceptable and relevant for the risk assessment is given in the table below. The majority of them were conducted with PPP cointaing chlorpyrifos. During the original annex I inclusion peer review this was considered a surrogate of the active Chlorpyrifos methyl. This assumption is considered still valid for the renwal process.

Table 2.9.3.2-2. Summary of available semi field and field studies on toxicity to non-target arthropods exposed to chlorpyrifos-methyl and representative formulations that were accepted and considered as relevant.

Test substance	Species	Rates (g a.s./ha)	Type of test	Results	Reference / Owner
Dursban Delta (GF-1668) (197 g chlorpyrifos/L, CS)	NTAs full arthropod fauna	Full rates: 1x 960 2x 960 Drift rate: 2x 162	Apple, NW France In-crop and off-crop field study	Both chlorpyrifos full rate treatments either of 1 x 960 g as/ha or 2x 960 g as/ha induced adverse community effects, that for the 2x 960g a.s./ha rate lasted until the end of the first sampling season. Arthropod populations were no longer different from the control at the onset of the next growing season, with the exception of the predatory beetles of the family Staphylinidae whose populations showed no clear recovery within one year. The arthropod community was significantly affected by the chlorpyrifos drift rate of 2x 162 g a.s/ha. The populations of Psocoptera, some parasitic wasps (Ceraphonoidea) and the beetle family Coccinellidae showed statistically significant adverse effects.	Bakker, F.; Aldershof, S.; Bruin, J. (2007)[c] DAS
EF-1315 (750 g chlorpyrifos/Kg) GF-1684 (225 g chlorpyrifos-	NTAs full arthropod fauna	EF-1315 Full rates: 1x 2400 2x 2400 GF-1684	Citrus, Spain In-crop field study	For the chlorpyrifos 1x 2400 rate, recovery within one year could not be probed for the coleopteran family Latridiidae and populations of the	Aldershof, S.; Roig, J.; Bakker, F. (2008)[c] DAS

Test substance	Species	Rates (g a.s./ha)	Type of test	Results	Reference / Owner
methyl/L)		Full rate: 2x 2400		hunting spider families Zodariidae, Gnaphosidae and Clubionidae were still smaller than those from the control at the end of the sampling period. For the chlorpyrifos 2x 2400 rate, no clear leaf community recovery was observed one year after the application and at the end of the first sampling season no clear canopy dwelling community recovery was demonstrated. At the end of the sampling period, the arthropod populations of Dermaptera and the hunting spiders Zodariidae, Gnaphosidae and Clubionidae had not recovered to biologically acceptable levels. At that time, the groups of spiders Heteropodidae (= Sparassidae), Xysticus sp. (Thomisidae) and Salticidae were still statistically significantly reduced compared to the control; hence it was not possible to confirm full recovery for these spiders one year after application. For the chlorpyrifos-methyl 2x 2400 rate, fewer and shorter adverse effects on arthropod populations than the lowest chlorpyrifos treatment were observed. Only Signiphoridae (Hymenoptera), adult Coccinellidae (Coleoptera), Clubionidae (Araneae) and Dermaptera showed	

Test substance	Species	Rates (g a.s./ha)	Type of test	Results	Reference / Owner
				reduced populations over a period longer than two months. Otherwise the array of taxa affected was similar to the 1x EF-1315 treatment. The leaf dwelling mite community recovered within 2 months after application and the canopy dwelling arthropod community within 6 months.	
Dursban Delta (GF-1668) (197 g chlorpyrifos/L, CS)	NTAs full arthropod fauna	Drift rates: 1x 1 1x 5 1x 10 1x 25 1x 100	Pasture, NW France Off-crop field study	At 1, 5 and 10 g a.s./ha, chlorpyrifos did not influence the arthropod community in a true off-crop habitat. Less than 5% of the individual arthropod populations prevailing in grasslands showed statistically significantly adverse effects. For Staphylinidae, Scelionidae and Formicidae these effects were consistent over time, though not significantly, at 5 g a.s./ha. At 25 g a.s./ha chlorpyrifos caused statistically significant but non persistent reductions to 4% of the arthropod taxa examined. This rate led to an adverse community response which was statistically detectable on one sampling moment. A rate of 100 g a.s./ha induced a statistically significant community response. For several taxa, no recovery occurred within the selected sampling period of one month.	Noordam, A.; Bakker, F. M.; Bruin, J.; Aldershof, S. (2007)[c] DAS
Dursban Delta	NTAs full	Drift	Pasture, SW	At 1, 5 and 10 g a.s./ha	Bakker, F.

Test substance	Species	Rates (g a.s./ha)	Type of test	Results	Reference / Owner
(GF-1668) (197 g chlorpyrifos/L, CS)	arthropod fauna	rates: 1x 1 1x 5 1x 10 1x 25 1x 100	France Off-crop field study	chlorpyrifos had no detectable effect on the arthropod community. Slight effects were recorded at 10 g a.s./ha for individual arthropod populations (being statistically different for Scelionidae parasitoids). At the 25 g a.s./ha rate statistically response on the arthropod community was detected on one sampling moment. At the population level, a statistically significant reduction was detected for several arthropod taxa, which showed a tendency towards recovery within one month after application. At 100 g a.s./ha chlorpyrifos induced a statistically significant, dose-related, population and community response.	(2008)[c] DAS

[a] In DAR 1999
[b] In the dossier submitted in February 2003 for the Active Approval
[c] Submitted for renewal purposes

From all the higher tier field studies submitted, there are four new acceptable studies addressing the in-crop and off-crop effects to non-target arthropods in several crops but **no acceptable field studies are available to assess the in-field risk to NTA from the representative uses in corn/maize, cotton, grapevine, oilseed rape, potato, vegetables and strawberry**.

In this point, during the CoRMS and the applicants' consultation period, the applicant DAS pointed out that each specific crop does not have its own individual range of non-target arthropod species and hence, extrapolation is possible between broadly similar (from an arthropod habitat perspective) crops. For example, the applicant defended the use of cereals as a representative crop and considered to adequately demonstrate effects in other broad acre crops (vegetables). However, the RMS respectfully disagrees with the applicant's argument: the arthropod communities are different from one specific crop to another and though some generalist species are common to many environments, factors like the crop physiology, the management calendar or the pesticides application regimes, among others, are continuously selecting the species inhabiting a particular crop. The RMS is of the opinion that to discard any field effect in a specific crop, no extrapolated results from a different one can be used. However, this point could be discussed during the peer-review.

As a general acceptability criterion for the in-field effects, the potential for re-colonisation after a toxic effect should usually be demonstrated within one year. Where significant off-field effects are detected, the duration of effect and the range of taxa affected should also be taken into consideration, but no effect or only transient effects are considered acceptable (de Jong et al. 2010), and therefore measuring recovery is not applicable.

There was one new study in **apple** in southern Europe (NW France) performed at different rates: 1x 960; 2x 960 (full rates) and 2x 162 g a.s./ha (drift rate). In NW France, both chlorpyrifos full rate treatments either of 1 x 960 g a.s./ha or 2x 960 g a.s./ha induced adverse community effects that for the 2x 960g a.s./ha rate lasted until the end of the first sampling season. The populations of the predatory beetles of the family Staphylinidae showed no clear recovery within one year. In addition, the arthropod community was significantly affected by the chlorpyrifos drift rate of 2x 162 g a.s/ha.

There was one study in **citrus** in Spain performed with chlorpyrifos at 1x and 2x 2400 g a.s./ha rates and with chlorpyrifos-methyl at 2x 2400 rate showing no populations nor community recovery within one year after the chlorpyrifos treatment. However, the chlorpyrifos-methyl treatment induced fewer and shorter adverse effects on arthropod populations than the lowest chlorpyrifos treatment. Only *Signiphoridae* (*Hymenoptera*), adult *Coccinellidae (Coleoptera)*, *Clubionidae (Araneae)* and *Dermaptera* showed reduced populations over a period longer than two months. Otherwise the array of taxa affected was similar to the 1x 2400 chlorpyrifos treatment. The leaf dwelling mite community recovered within 2 months after application and the canopy dwelling arthropod community within 6 months.

Two new studies conducted in **pasture** fields in SW and NW France at the same drift rates of 1, 5, 10, 25 and 100 g a.s./ha were considered as relevant to assess the off-crop effects for any of the intended uses. Both studies showed populations effects for rates under 25 g a.s./ha and clear community and populations effects at 25 and 100 g a.s./ha.

In conclusion, from the field data only potential for recovery/recolonization has been demonstrated within one year after the application of chlorpyrifos-methyl for the citrus in-field habitat one year after the treatment. However, no off-field effects have been investigated for this specific intended use and the other acceptable higher tier field studies showed clear effects at rates lower than 100 g a.s./ha.

Overall the field studies demonstrate a tendency to a continuous decline in different arthropod populations if the non-selective insecticide chlorpyrifos-methyl is used year after year at the tested rates.

During the CoRMS and the applicants' consultation period, the applicant DAS strongly objected the use for the renewal process (Annex I inclusion) guidance that either is not adopted yet in the EU regulatory process or reflect national approaches/requirements or scientific opinions. The applicant stated that up to now the only relevant document for NTA evaluation for the renewal process for all molecules is the Terrestrial Guidance Document (SANCO, 2002) and not the ESCORT 3 and a Dutch scientific manuscript (de Jong et al. 2010) cited by the RMS which both of them are not implemented yet in EU for the renewal process (for the off-crop protection goal) and proposed the RMS to evaluate the tiered NTA risk assessment and interpret findings from the higher tier field studies based on the protection goals proposed in the Terrestrial Guidance document (SANCO, 2002) for both the in-crop and off-crop risk assessment as for any other molecule evaluated up to now in the renewal process. The RMS disagrees with this opinion and considers that this point could be discussed during the peer-review.

2.9.4. Summary of effects on non-target soil meso- and macrofauna

2.9.4.1. Effects on earthworms

Some acute studies have been presented with the a.s and GF1684. However, according to EU regulation 283/2013 acute tests are not relevant any more. Therefore acute studies with the a.s or the formulated product are useful as supplementary information but they cannot be used in the risk assessment and therefore, they have not been included in the table above.

No reproductive studies have been presented by DOW with the active substance, chlorpyrifos methyl, neither with a formulated product GF 1684. Only one reproduction study have been presented with a formulated product containing chlorpyrifos (480 g/L). As CPF-M has a logPow > 2 and according to the recomendations of PRAPeR 133 (2015), a correction factor of 2 should be applied to all the endpoints, even if a lower organic matter content was used in the test i.e 5 % resulting in a NOEC of 6.35 mg/kg soil. SAPEC submitted a reproduction study on earthworms with chlorpyrifos methyl technical. The NOEC derived from this suty is equivalent to the one proposed by DOW

According to the E-fate section, the following metabolites should be considered in the soil risk assessment: TCP, TMP, DCP and N-methyl-TCP (NMTCP).

Acute and chronic studies are available for TCP. The NOEC is 2.20 mg TCP/kg soil. As the logPow of TCP is 1.85 (pH7, 40ºC), the correction factor of 2 is not applied.

A chronic study is available for TMP (submitted by SAPEC). The NOEC is 42.86 mg TMP/kg soil. The correction factor has to be applied to the NOEC of TMP since its log Pow is >2 (log Pow 3.7 at pH7). Therefore, NOEC = 21.43 mg TMP/kg soil.

A Chronic study is available for the metabolite DCP (submitted by DOW). The derived NOEC = 1.25 mg DCP/kg soil.

~~**With respect to the metabolite NMTCP, further toxicity information is needed to address the risk assessment**~~
During the CoRMS and the applicants' consultation period, the applicant SAPEC has provided a new study of the effects of the metabolite NMTCP on earthworms. The derived NOEC = 25 mg NMTCP/kg soil. As no data about the logPow of NMTCP are available, the worst case scenario is considered and a correction factor of 2 is applied. Thus, NOECcorrected = 12.5 mg NMTCP/kg soil

The following toxicity data is available for earthworms:

Table 2.9.4.1-1 Summary of effects on non-target soil meso- and macro-fauna

Data point	**Species**	**Test substance**	**Endpoint**	**Reference**
Earthworms – Acute toxicity and Sub-lethal Effects				
CA 8.4.1/01 Reproduction SAPEC	*Eisenia fetida*	Chlorpyrifos-methyl technical	28-d NOEC mortality = 50 mg a.s/kg soil 56-d NOEC reproduction = 12.5 mg a.s/kg soil 56-d EC10 reproduction = 18.4 mg a.s/kg bw (13.5-20.4) 56-d EC20 mortality = 20.2 mg a.s/kg bw (16.3 - 21.7) *Corrected: NOEC mortality = 25 mg a.s/kg soil NOEC reproduction = **6.3 mg a.s/kg soil** EC_{20} = 10.1 mg a.s/kg soil EC_{10} = 9.2 mg a.s/kg soil	Witte, 2014a Submitted for the purpose of renewal.
CP 10.4.1.1/3 reproduction DAS	*Eisenia foetida*	480 g chlorpyrifos/L (Dursban 480 EC)	28-d NOEC mortality = 26.7 mg a.s/kg soil 56-d NOEC reproduction = 12.7 mg a.s/kg soil *Corrected: 28-d NOEC mortality = 13.35 mg a.s/kg soil 56-d NOEC reproduction = 6.35 mg a.s/kg soil	Hayward, 2002 SANCO/3059/99

Data point	**Species**	**Test substance**	**Endpoint**	**Reference**
CP 10.4.1.1 (SAPEC)	*Eisenia foetida*	200 g chlorpyrifos/L (SAP200CHLORI)	28-d NOEC mortality = 19.25 mg a.s/kg soil 56-d NOEC reproduction = 19.25 mg a.s/Kg soil EC10 reproduction > 19.25 mg a.s/kg soil *Corrected: 28-d NOEC mortality = 9.62 mg a.s/kg soil 56-d NOEC reproduction = 9.62 mg a.s/Kg soil EC10 reproduction > 9.62 mg a.s/kg soil	Ansaloni, T., 2015 Submitted for the purpose of renewal
CA 8.4.1/4 reproduction DAS and SAPEC	*Eisenia foetida*	TCP	28-d NOEC mortality = 10 mg TCP/kg soil **56-d NOEC reproduction = 2.20 mg TCP/kg soil**	Mallett, M.J., 2003 SANCO/3059/99
CA 8.4.1/02 (SAPEC*)*	*Eisenia fetida*	TMP	56-d NOEC reproduction = 42.86 mg TMP/kg bw. EC10, EC20, EC50 > 42.86 mg TMP/kg bw. Tests substance was mixed through soil. 10 % OM *Corrected: **56-d NOEC reproduction = 21.43 mg TMP/kg soil.**	~~(KCA 8.4.1/02~~ Ansaloni, T., 2015 Submitted for the purpose of renewal.
CA 8.4.1/03 (SAPEC*)*	*Eisenia fetida*	NMTCP	56-d NOEC reproduction = 25 mg NMTCP/kg soil. EC10 = 45.7 mg NMTCP/kg soil. EC20 = 89.6 mg NMTCP/kg soil. Tests substance was mixed through soil. 10 % OM *Corrected: **56-d NOEC reproduction = 12.5 mg NMTCP/kg soil.**	Lührs, U., 2015 Submitted for the purpose of renewal
CA 8.4.1/6 reproduction DAS	*Eisenia foetida*	3.6-DCP	28-d NOEC mortality = 5 mg DCP/kg soil **56-d NOEC reproduction = 1.25 mg DCP/kg soil** 56-d EC10 reproduction = 1.75 mg DCP/kg soil (0.85-2.35)	Ganßmann, 2015 Submitted for the purpose of renewal

2.9.4.2. Non-target soil meso- and macrofauna other than Earthworms

Two new studies exploring the chronic effect of the product GF1684 (chlorpyrifos-methyl) on *Folsomia candida* and *Hypoaspis aculeifer* have been provided by DAS during the comenting period. The endpoints for *F. candida* is NOECreproduction = 0.05 mg a.s./kg soil and for *H. aculeifer* is NOECreproduction = 3.20 mg a.s./kg soil. As CPF-M has a logPow > 2 and according to the recomendations of PRaPER 133 (2015), a correction factor of 2 should be applied to all the endpoints, even if a lower organic matter content was used in the test i.e 5 %. Thus, ***F. candida*** **$NOEC_{corr}$ = 0,025 mg a.s./kg soil** and ***H. aculeifer*** **NOEC = 1.60 mg a.s./kg soil**. On the other hand, SAPEC submitted two reproduction studies on *Folsomia candida* and *Hypoaspis aculeifer* with the formulated product SAP224I with similar corrected endpoints: ***F. candida*** **NOEC = 0,039 mg a.s./kg soil** and ***H. aculeifer*** **$NOEC_{corr}$ = 1.25 mg a.s./kg soil.**

Both DAS and SAPEC provided toxicity for the metabolite TCP:

<u>DAS</u>

TCP *Folsomia candida* NOEC = 50 mg a.s/kg soil
TCP *Hypoaspis aculeifer* NOEC = 50 mg a.s/kg soil

<u>SAPEC</u>

TCP *Folsomia candida* NOEC = 16 mg a.s/kg soil
TCP *Hypoaspis aculeifer* NOEC = 64 mg a.s/kg soil

However, no toxicity data are available for the metabolites TMP, DCP and NMTCP. Therefore, the risk assessment for *F. candida* and *H. aculeifer* have been performed by considering that TMP and DCP are 10x of higher toxicity than the parent compound. As TMP has a logPow > 2 and according to the recomendations of PRaPER 133 (2015), a correction factor of 2 should be applied.

<u>DAS (GF1684)</u>

TMP *Folsomia candida* $NOEC_{corr}$ = 0.0025 mg a.s/kg soil
TMP *Hypoaspis aculeifer* $NOEC_{corr}$ = 0.16 mg a.s/kg soil

DCP *Folsomia candida* NOEC = 0.005 mg a.s/kg soil
DCP *Hypoaspis aculeifer* NOEC = 0.32 mg a.s/kg soil

<u>SAPEC (SAP224I)</u>

TMP *Folsomia candida* $NOEC_{corr}$ = 0.0039 mg a.s/kg soil
TMP *Hypoaspis aculeifer* $NOEC_{corr}$ = 0.125 mg a.s/kg soil

DCP *Folsomia candida* NOEC = 0.0078 mg a.s/kg soil
DCP *Hypoaspis aculeifer* NOEC = 0.25 mg a.s/kg soil

With respect to the metabolite NMTCP, further toxicity information is needed to address the risk assessment

A summary of the toxicity data presented is included in the following table:

Data point	Species	Test substance	Endpoint	Reference
Effects on Non-Target Soil Meso- and Macrofauna				
CA 8.4.2/1 reproduction (DAS / SAPEC during the consulting period)	*Hypoaspis aculeifer*	chlorpyrifos	LOEC = 10 mg/kg soil NOEC = 3.2 mg/kg soil *Corrected $NOEC_{corr}$ = 1.6 mg/kg soil Test substance mixed with the soil. OM = 5%	Publication. Owojori et al., 2014. Environmental Toxicology and Chemistry, Vol 33, No. 1, pp 230-237 Submitted for the purpose of renewal
CP 10.4.2.1/1 reproduction (DAS during the consulting period)	*Folsomia candida*	GF1684 (226 g/L chlorpyrifos-methyl)	**28-d NOEC = 0.05 mg/kg soil** *Corrected **$NOEC_{corr}$ = 0.025 mg a.s./kg soil** Test substance was mixed with the soil. 5% OM	Straube, 2016a Submitted for the purpose of renewal

Data point	Species	Test substance	Endpoint	Reference
CP 10.4.2.1/2 reproduction (DAS during the consulting period)	*Hypoaspis aculeifer*	GF1684 (226 g/L chlorpyrifos-methyl)	**14-d NOEC = 3.20 mg/kg soil** *Corrected **$NOEC_{corr}$ = 1.60 mg a.s./kg soil** Test substance was mixed with the soil. 5% OM	Straube, 2016b Submitted for the purpose of renewal
KCA 8.4.2.1/01 (SAPEC)	*Folsomia candida*	SAP224I	**NOEC reproduction = 0.0784 mg a.s/kg soil** EC10 reproduction = 0.11 (0.09-0.13) EC20 reproduction = 0.13 (0.10-0.13) Corrected: **NOEC reproduction = 0.0392 mg a.s/kg soil** Test item mixed through soil. 5 % OM	Witte, 2014b Submitted for the purpose of renewal.
KCA 8.4.2.1/03 (SAPEC)	*Hypoaspis aculeifer*	SAP224I	**14-d NOEC reproduction = 2.5 mg a.s/kg soil** EC10 reproduction = 2.39 mg a.s/kg soil (0.50 – 3.65). EC20 reproduction = 3.13 mg a.s/kg soil (0.58 – 4.41) EC50 reprodcution = 5.21 mg a.s/kg soil (3.20 – 8.51) Corrected: **$NOEC_{corr}$ = 1.25 mg a.s/kg soil** Test item was mixed through soil. 5% OM	Witte, 2014d Submitted for the purpose of renewal.
CA 8.4.2/2 reproduction (DAS)	*Hypoaspis aculeifer*	TCP	**14-d NOEC = 50 mg TCP/kg soil** [highest concentration] EC10, EC20 and EC 50 > 50 mg/kg soil.	Vinall, 2011 Submitted for the purpose of renewal
CA 8.4.2/3 reproduction (DAS)	*Folsomia candida*	TCP	**28-d NOEC =50 mg TCP/kg soil** [highest test concentration] Test substance was mixed with the soil. 5% OM	Vinall, 2011 Submitted for the purpose of renewal.
CA 8.4.2.1/02 (SAPEC)	*Folsomia candida*	TCP	**NOEC (reproduction) = 16 mg TCP/kg soil** Test substance was mixed with the soil. 5% OM	Witte, 2014c Submitted for the purpose of renewal.
CA 8.4.2.1/04 (SAPEC)	*Hypoaspis aculeifer*	TCP	**NOEC reproduction = 64 mg TCP/kg soil.** Test item was mixed through soil. 5 % OM.	Witte, 2014e

2.9.5. Summary of effects on soil nitrogen transformation

A summary of the effects on soil nitrogen transformation is presented in the following table:

Table 2.9.5-1 Summary of effects on nitrogen transformation

Data point	Test substance	Test	Soil concentration (mg/kg dry soil)	Findings	Reference
CA 8.5/1 DAS and SAPEC	Reldan 22 (EF-1066)	Nitrogen mineralisation	0.5 and 5.0 kg a.s./ha (equivalent to 0.67 and 6.7 mg a.s./kg soil, respectively)	< 25 % effect after 62 days at 0.67 mg a.s/kg soil (0.5 kg a.s/ha).	Hale, K. and Forster, J., 1994
CA 8.5/2 DAS	Chlorpyrifos-methyl	Nitrogen mineralisation	1.41 and 7.07 mg a.s./kg soil dry weight	<25% effects at 7.07 mg a.s./kg soil dry weight.	Schobinger, U., 2012
CA 8.5/01 (SAPEC)	Chlorpyrifos methyl	Nitrogen mineralisation	1.34 and 6.72 mg a.s/kg soil	<25 % effect after 28 days at 6.72 mg a.s/kg soil.	Hammesfahr U., 2014. Submitted for the purpose of renewal
CA 8.5/3 DAS and SAPEC	3,5,6-TCP	Nitrogen mineralisation	No data	<25% effect after 100 days at 3.53 mg 3,5,6-TCP/kg soil.	Mallett & Hayward, 1999
CA 8.5/04 DAS	TMP	Nitrogen mineralisation	No data	<25% effect after 28 days at 0.415 mg/kg soil.	Baumgartner, 2009
CA 8.5/02 (SAPEC)	TMP	Nitrogen mineralisation	0.407 and 2.03 mg a.s/kg soil	<25 % effect after 28 days at 2.03 mg a.s/kg soil.	Hammesfahr U., 2015. Submitted for the purpose of renewal

2.9.6. Summary of effects on terrestrial non-target higher plants

Table 2.9.6-1 : Summary of effects on terrestrial vascular plants

Data point	Test substance	Test	Agreed results[1]	New results	Reference
Testing on Non-Target Plants					
CA 8.6.2	GF-1684 (225 g a.s./L EC formulation)	Vegetative vigour	No data	**ER_{50} >2250 g a.s./ha**	CA 8.6.2/1 Paterson & Toft, 2007 M104
CA 8.6.2	GF-1684 (225 g a.s./L EC formulation)	Seedling emergence and seedling growth	No data	**ER_{50} >2250 g a.s./ha**	CA 8.6.2/2 Paterson & Toft, 2007 M105
	SAP224I	Vegetative vigour		**ER50>1008gas/ha**	
	SAP224I	Seedling emergence and seedling growth		**ER50> 1008 gas/ha**	

No data on the potential effects of SAP200CLORI on seedling emergence and vegetative vigour of terrestrial plants is submitted as this product does not exhibit herbicidal or plant growth regulator activity, and its toxicity can be established from data on the active substance (point 8.6.1 of Part A of the Annex to Regulation (EU) No 283/2013). Nevertheless, In addition the potential effects of SAP224I (equivalent to CHLORPYRIFOS METHYL 224 EC) on seedling emergence and vegetative vigour of ten non-target terrestrial plants has been tested. The estimated EC50-value for mortality in the vegetative vigour test and for emergence in the seedling emergence can be established >4.5 L test product/ha equivalent to 1008 g as/ha. Thus the risk assessment will be based in the active substance data obtained from the formulation CHLORPYRIFOS METHYL 224 EC.

2.9.7. Summary of effects on other terrestrial organisms (flora and fauna)

No further information submitted.

2.9.8. Summary of effects on biological methods for sewage treatment

A study to evaluate the effects of chlorpyrifos methyl on biological methods for sewage treatment was submitted (CA B.9.8/01). The following uncertainties were detected in the study:

- It was not performed under GLP.
- The study was not performed according to the current guidelines (OECD 209) and no details about the validity criteria fulfilment are provided.
- No calculations of the Oxygen uptake rates, oxygen uptake rate due to nitrification or percentage of inhibition are provided.
- No ECx values or NOEC estimation are presented.

Therefore, the study was considered as supplementary information. No other data was submitted

2.9.9. Summary of product exposure and risk assessment

2.9.9.1. Summary of product exposure and risk assessment on birds

Risk assessment has been performed according to the EFSA GD on birds and mammals (2009). As a first step the default assumptions on residue levels of the guidance document have been considered (Tier 1). However, if further refinement is needed the default assumptions on residue levels (EFSA, 2009) were replaced by actual measured values derived from field trials conducted with chlorpyrifos. The following tables give an overview of the higher tier data (tier 2) used for the refinement of residue data.

2.9.9.1.1. Refinement of exposure data (insectivores)

Summary of arthropod residue data: In order to obtain an estimate of overall Residue per Unit Dose (RUD) specifically for chlorpyrifos residues in arthropods, the following RUDs have been calculated on a daily basis for a series of field trials and for each of the relevant categories (foliage-dwellers and ground-dwellers). For the acute risk assessment only the initial (e.g. maximum) RUDs were used.

Eight studies of residues on arthropods have been evaluated in the dossier. In these studies the residues on **foliage dwelling** (sampling by inventory spraying and sweep net) and **soil dwelling** (sampling by pitfall trapping) arthropods were measured. Residue levels in dead foliage insects were significantly higher than in insects caught alive (on average by a factor of 3-6 times). Only the studies with dead insects were considered appropriate to derive mean and 90th percentile RUD values for **foliage dwelling** insects by EFSA (EFSA Journal 2011;9(1):1961). RMS considered also appropriate to use those studies in which due to the sampling method, dead arthropods were potentially analysed (CP 10.1.1.2/8; CP 10.1.1.2/7; CP 10.1.1.2/9 and CP 10.1.1.2/6) for acute risk assessment and long term risk assessment.
With respect to soil dwelling arthropods a correction factor of 3.4 was considered to account the potential residues on dead and moribound individues for acute and long term risk assessment.

Therefore, the following chlorpyrifos RUD are proposed by RMS and used in the refined RA:

Table 2.9.9.1-1 Summary of mean RUD values for chlorpyrifos on invertebrates

Parameter	RUD		
	Foliage dwelling arthropods	Ground dwelling arthropods	
	Potentially dead arthropods analysed	All studies available	Estimated residues (x 3.4) to account for dead arthropods
Nº studies	4*	8	
Mean RUD	**16.34**	1.48	**5.05**
90^{th} RUD	**22.88**	2.00	**6.81**

Values in bold will be used in the RA.

*Considering the 4 studies were dead arthropods were potentially analysed and the worst-case RUD of each study.
**Considering the worst-case RUD of the 8 studies presented.

RMS considers that the database of experimental studies is large enough to be used for refinement purposes of the risk assessment. However, with repect to DT50 values, the applicant proposes to use the mean DT50 value of a database of only 4 studies. However, RMS is of the opinion to use the worst case DT50 value of 4.05 d and 3.09 for ground and foliar dweller organisms respectively, as considered during the peer review of the confirmatory data.

2.9.9.1.2. Refinement of exposure data (herbivores)

Summary of residue data on grass : Specific residue data are available from a number of trials conducted on grassland, with mostly two applications, each at a rate of 0.72 kg a.s./ha. The mean, median and 90th centile RUD values for the initial (i.e. maximum) residues in grass were calculated using standard Excel spreadsheet procedures. The DT_{50} values were calculated using Excel Solver assuming 1st order kinetics.

In addition, six GLP supervised residue trials were conducted in Central Europe during 2007 to determine the residue of chlorpyrifos in grassland after single application of CS formulation GF-1668. Application was made at a nominal application rate of 0.720 kg a.s./ha. The results were consistent with the results observed in the trials conducted with different formulations as presented in table 10.1.1-15. A summary of these residue data is presented in table below.

For the Southern zone no residue data on grass are available. However, the residue levels and decline rates of different formulations in the Central zone are very similar. Thus, the data from the three formulated products have been combined to give more robust endpoints which can be employed in the refined risk assessments for herbivorous birds and mammals feeding on leafy crops.

The chlorpyrifos-specific parameters to be used in the higher tier risk assessment for birds feeding on grass are summarised in the table below. This data has been calculated considering all chlorpyrifos residues available in grass.

Table 2.9.9.1-2 Summary of residue parameters for chlorpyrifos in grass of pasture. Values highlighted in bold are used for the refined risk assessment

Parameter	**Residue per Unit Dose (RUD)**		
Formulation	**GF-1668 (n=6)**	**EF-1551/EF-1315 (n=16)**	**All studies (n=22)**
Mean T_0	50.44	40.61	**43.83**
Median	48.05	41.29	44.44
90th centile T_0	73.25	69.76	**72.82**
Mean DT_{50}	2.70 days	2.39 days	**2.55 days**

Summary of residue data leafy crops : Similar residual trials as for the analysis in grass have been conducted in order to obtain residue data on leafy crops. Sugar beet (tops) was regarded as a representative crop. Seven decline trials were available for the Central zone and four decline trials for the Southern zone.

Table 2.9.9.1-3 Summary of residue parameters for chlorpyrifos in leafy crops. Values highlighted in bold are used for the refined risk assessment

Parameter	**Residue per Unit Dose (RUD)**		
Zone	**Central zone (n=7)**	**Southern zone (n=4)**	**Central and Southern zone combined (n=11)**
Mean T_0	22.39	31.50	**25.71**
Median T_0	14.18	32.37	25.85
90th centile T_0	41.47	44.85	**46.51**
Mean DT_{50} [days]	**2.09**	**1.58**	**1.91**

2.9.9.1.3. Refinement of exposure data (granivores)

Summary of residue data on seeds Specific residue data on seeds are available from two of trials. The trials were conducted in citrus, where seed heads of black-beared wheat were analysed (McQuillen et al. 1998a) and in alfalfa (McQuillen et al., 1998b) with applications of 2.3 kg a.s./ha and 1.1 kg as /ha, respectively.

No mean, median and 90th centile RUD values in seed heads were calculated to consider the different interception of chlorpyrifos in the field trials. Thus, the RUDs are directly used for the refined risk assessment. The citrus RUDs are used for refinement of TER values for orchards and vineyards, and the alfalfa RUDs for refinement of TER values for all other crops. Since for the residues in alfalfa no reliable DT_{50} value could be calculated (R^2=0.14) the 11-Day TWA RUD is used for the long-term risk assessment. Therefore, it presents a worst-case scenario.

Table 2.9.9.1-4 : Summary of RUD values for chlorpyrifos in seed heads after application of DURSBAN 4 (0.72 kg a.s./ha). Values highlighted in bold are used for the refined risk assessment

Country, year, (Reference)	Crop	Daily RUD values				11-day TWA RUD [1]
		0 d	1 d	5 d	10 d	
USA, 1998 (McQuillen et al., 1998a, CP 10.1.1.2/7)	Citrus (seeds of black-bearded wheat)	0.07	**0.07**	0.03	0.02	**0.04**
USA, 1998 (McQuillen et al., 1998b, CP 10.1.1.2/7)	Alfalfa	0.16	**0.27**	0.23	0.24	**0.24**

[1] The 11-day TWA RUD was calculated by interpolation of the daily RUD values presented in the study reports.

2.9.9.1.4. Refinement of exposure data (frugivore)

Several studies on residues in orchard fruits (apples, pears, peaches, apricots, cherries and wine grapes) and orchard grass have been conducted (Hansford, 2008b-f). These data are used in order to refine the risk to frugivorous birds in vineyards and are summarised in the following table.

The results of residue trials show that the RUDs in several fruits are very similar after application of the different formulations (EF-1551, EF-1315 and GF-1668). It is therefore appropriate to combine these values for the use in the risk assessment in order to have a more robust data base. However, residues are lower in the Southern zone than in the Central zone. Thus, the overall mean, median and 90th centile RUDs are calculated separately for each zone.

Table 2.9.9.1-5 Summary of residue parameters for chlorpyrifos in <u>fruits</u>.

Parameter	Residue per Unit Dose (RUD)					
Zone	**Central zone**		**Southern zone**		**Central zone**	**Southern zone**
Formulation	**EF-1551/ EF-1315 (n=11)**	**GF-1668 (n=11)**	**EF-1551/ EF-1315 (n=5)**	**GF-1668 (n=5)**	**Fomulations combined (n=22)**	**Fomulations combined (n=10)**
Mean T_0	1.67	1.68	0.76	0.79	1.68	0.78
Median T_0	0.94	0.65	0.75	1.03	0.93	0.82
90th centile T_0	2.63	2.64	1.06	1.10	2.64	1.11
Mean DT_{50} [days]	5.22	4.99	4.53	6.15	6.29	5.34

In order to address and refine the risk of frugivorous birds and mammals feeding on citrus fruits the residues measured in fruits with similar size (apple, pear, peach) from trials conducted in the Southern zone (Hansford, 2008b, 2008d) were used. The resulting mean, median and 90th centile RUDs are presented in the following table.

Table 2.9.9.1-6 Summary of residue parameters for chlorpyrifos in apples, pears and peaches in the Southern zone. Values highlighted in bold are used for the refined risk assessment

Parameter	**Residue per Unit Dose (RUD)**
Zone / Formulation	**Southern zone / Formulations combined (n=8)**
Mean T_0	0.72
Median T_0	0.66
90th centile T_0	1.11
Mean DT_{50} [days]	6.12

In order to address and refine the risk of frugivorous birds and mammals feeding on grapes, strawberries, bush and cane fruits as well as on fruiting vegetables (tomatoes, eggplants and pepper, see GAP), the residues available for small fruits (grapes) are used (Hansford, 2008f). It was assumed that due to the larger surface compared to the volume of small fruits the residues in small fruits present a worst-case. This assumption is supported by the higher mean RUDs of apples, pears and peaches compared to grapes. No residue data on small fruits like grape are available for the Southern zone. However, the residue decline trials on grapes have been conducted in France and Hungary, whose climatic conditions are more similar to those of the Southern zone than to the climatic conditions of several central countries. Additionally, the overall residues in the Central zone were higher than in the Southern zone. Thus, the use of RUDs from grapes in the Central zone represents a worst-case.

Table 2.9.9.1-7 Summary of residue parameters for chlorpyrifos in grapes. Values highlighted in bold are used for the refined risk assessment

Parameter	**Residue per Unit Dose (RUD)**
Zone / Formulation	**Central zone / Formulations combined (n=4)**
Mean T_0	**0.98**
Median T_0	1.05
90th centile T_0	**1.23**
Mean DT_{50} [days]	**8.16**

Refinement of exposure data (calculation of 3-week TWA RUDs)

From the mean T_0 values and DT_{50} values of different food items as presented above the 3-week-TWA RUD values have been calculated. These values were used to refine the chronic risk assessment.

Table 2.9.9.1-8 Calculation of 3-week TWA RUD values for the use in the refined chronic risk assessment for birds

Matrix	Used for food item	Mean T_0 RUD	DT_{50} [days]	TWA	3-week TWA RUD
Foliage-dwelling arthropods	Foliar insects	16,34	3,09	0,21	3,43
Ground-dwelling arthropods	Ground arthropods	5,05	4,05	0,27	1,36
Leafy crops	Leaves/crop leaves	25,71	1,91	0,13	3,34
Pasture grass (surrogate for cereal shoots)	Cereal shoots	43,83	2,55	0,17	7,45
Seeds in citrus	Seeds / weed seeds in orchards and vineyards	0,07	-		-
Seeds in alfalfa	Seeds / weed seeds in crops other than orchards and vineyards	0,27	-		-
Grapes	Grapes / fruits	0,98	8,16	0,47	0,46

	(fruiting vegetables, strawberries, bush and cane fruits)				

Refinement of PD and PT values (insectivorous species)

The mean PT values determined for focal species in the generic monitoring studies are used to further refine the TER_{LT} values based on measured residue data.

Table 2.9.9.1-9 PD and PT values for insectivorous focal species (RMS proposal)

Focal species	Crop	PD value (insectivorous diet)	PT value (mean)	PT value (90th centile)	Reference
Great Tit (*Parus major*)	Citrus	1	**0.67**	0.89	Wilkens and Selbach, 2008, CP 10.1.1.2/26
Sardinian Warbler (*Sylvia melanocephala*)	Citrus	0.52	0.53	1.00	
Great Tit (*Parus major*)	Citrus	1	0.25[1]	-	Dittrich et al., 2015a, CP 10.1.1.2/31
Blackbird (*Turdus merula*)	Citrus	-	**0.73[1]**	-	
Sardinian Warbler (*Sylvia melanocephala*)	Citrus	-	0.38[1]	-	
Great Tit (*Parus major*)	Pome	0.999	**0.83**	1.0	Wilkens et al., 2008b, CP 10.1.1.2/41
Black cap (*Sylvia atricapilla*)	Pome	0.804	0.84	0.98	
Blackbird (*Turdus merula*)	Pome	0.48	0.82	1.0	
Yellow Wagtail (*Motacilla flava*)	Brassicas	1	0.15	0.31	Nack et al., 2008, CP 10.1.1.2/54
Skylark (*Alauda arvensis*)	Brassicas	0.586	0.30	0.71	
Meadow Pipit	Brassicas	-	**0.38**	0.53	
Black Redstart (*Phoenicurus ochruros*)	Vine	n.a.	**0.29**	0.7	Brown et al., 2007a, CP 10.1.1.2/50
Cirl Bunting (*Emberiza cirlus*)	Vine	0.499	0.43	0.77	Selbach, A., 2007; CP 10.1.1.2/52
Great Tit (*Parus major*)	Vine	0.955	0.05	0.08	
Linnet (*Carduelis cannabina*)	Vine	0.027	0.78	0.97	
Wood Lark (*Lullula arborea*)	Vine	0.921	0.86	1	

[1]After application
Values in **bold** are used for RA refinement.

In leafy vegetables Yellow Wagtail and Meadow Pipit were the most abundant insectivorous bird species according to Moosmayer and Wilkens (2008). PT values are available for both species (please refer to the table above). Therefore, RMS considers that the worst-case value for Meadow pipit should be used in the RA i.e. 0.38.

During confirmatory data on birds and mammals (EFSA conclusion, 2011), black restard was considered the focal specie in vines. Therefore, the mean PT value of 0.29 will be used in the refined RA for vines.

Field studies on bird communities, including breeding-success

Several field studies have been presented to refine the risk assessment of GF1684on birds . A summary of all the studies presented is included in the following table. For details, please refer to Vol 3 CP GF-1684 (Appendix I)

Table 2.9.9.1-10 Higher tier data submitted in birds: field studies

Data point	Test organism	Test substance	Findings*
Higher Tier Data on Birds (field study assessing effects of chlorpyrifos-methyl applications)			
CP 10.1.1.2/28	Field study on the status of bird communities and reproductive performance in citrus in 2014	EF-1066 (2.5 kg a.s./ha) sprayed to 3 citrus plots near Valencia, ES	No effects on population size and nest survival during the year.
Higher Tier Data on Birds (field studies: generic, determination of focal species, and assessing effects of chlorpyrifos applications)			
CP 10.1.1.2/29 chlorpyrifos study	Field study on effects to birds and mammals	LORSBAN 4E (1.7 to 6.7 kg a.s./ha) to 8 plots in California, USA	No treatment related casualties; no abnormal behaviour observed; residues found on 2 birds in total.
CP 10.1.1.2/30	Field study for determination of focal bird species in citrus	None, 21 citrus orchards near Valencia, ES	List of focal species; Goldfinch , Serin and Blackbird were the most abundant species
CP 10.1.1.2/31	Generic field monitoring study to refine dietary estimates of Sardinian Warblers and Great Tits in citrus	None, 4 plots near Xàtiva, ES	Mean PT: 0.53 (Sardinain Warbler) and 0.67 (Great Tit) Sardinian Warblers fed mainly on fruits (47.4%) and arthropods Orthoptera (13.8%) and Hemiptera (11.3%). Great Tits fed entirely on arthropods (Hymenoptera (38.6%) and Arachnida (27.9%)).
CP 10.1.1.2/32	Interpretive report	Not applicable	Not applicable
CP 10.1.1.2/33 chlorpyrifos study	Field study on exposure and effects on wild birds in citrus	Dursban 75 WG (2.4 kg a.s./ha) sprayed to 3 plots near Xàtiva; ES	No adverse effects on radio-tracked birds and nest; 1 possible sub-lethal effect during survey; no treatment related carcasses.
CP 10.1.1.2/34 chlorpyrifos study	Field study on status of bird communities and reproductive performance in citrus in 2010	Applications of 1.20 – 4.80 kg a.s./ha made to 10 citrus plots near Valencia, ES	No observed effects on nests and reproductive behaviour within chlorpyrifos treated orchards during the year.
CP 10.1.1.2/35 chlorpyrifos study	Field study on the status of bird communities and reproductive performance in citrus in 2011	EF-1551 (2.4 kg a.s./ha) sprayed to 10 citrus plots near Valencia, ES	No treatment related effects on nests and reproductive behaviour; 41 carcasses found mostly on one site. In post-mortem, they showed malnutrition and disease.
CP 10.1.1.2/36 chlorpyrifos study	Field study on the status of bird communities and reproductive performance in citrus in 2012	EF-1551 (2.4 kg a.s./ha) sprayed to 10 citrus plots near Valencia, ES	No effects on nests and reproduction during this year; except slight effect on Blackbird nest survival (1 to 3.2%). Carcasses at one site, in which misuse observed.

Data point	**Test organism**	**Test substance**	**Findings***
CP 10.1.1.2/37 chlorpyrifos study	Follow-up study on stewardship actions for breeding avian species in citrus in 2013	EF-1551 (2.4 kg a.s./ha) sprayed to 10 citrus plots near Valencia, ES	No treatment related effects on nests and reproductive behaviour in this year. Some dead birds found with signs of disease and/or parasitosis also showed histological signs of OP exposure. When the reproductive success is considered along the years, a possible influence of CP or CP-M in the reproductive success of birds cannot be disregarded, especially for blackbird.
CP 10.1.1.2/38 chlorpyrifos study	Wildlife survey in pome fruit orchards	Dursban 48E (1x0.42 kg a.s./ha & 3x0.84 kg a.s./ha) sprayed to 2 pome fruit orchards int he UK	The study was designed to evaluate only short-term effects. Successful hatching during this year; 3 dead vertebrates found.
CP 10.1.1.2/39	Field study for the determination of focal species in pome fruit orchards	None; 15 pome fruit orchards in the Midi-Pyrénées, FR	Greenfinch, Magpie and Blackbird were the most characteristic bird species
CP 10.1.1.2/40	Field study for the determination of focal species in pome fruit orchards	None; 13 pome fruit orchards in the Cataluña region, ES	Magpie, House Sparrow and Serin were the most characteristic bird species
CP 10.1.1.2/41	Field study for the determination of focal species in stone fruit orchards	None; 15 stone fruit orchards in the Languedoc-Roussillon, FR	Serin, Blackbird, Goldfinch , Mistle Thrush, Magpie and Chaffinch were the most characteristic bird species
CP 10.1.1.2/42	Field study for the determination of focal species in stone fruit orchards	None; 15 stone fruit orchards in the Cataluña region, ES	Magpie, Serin and House Sparrow were the most characteristic bird species
CP 10.1.1.2/43	Field study for the determination of focal species in stone fruit orchards	None; 20 stone fruit orchards in the Valencia region, ES	Serin, Blackbird and Goldfinch were the most characteristic bird species
CP 10.1.1.2/44	Field study for the determination of focal species in pome fruit orchards	None; 28 stone fruit orchards in Centre and Pays de la Loire, FR	Blackbird were the most characteristic bird species
CP 10.1.1.2/45 chlorpyrifos study	Pilot field study on exposure and effects on wildlife in pome fruit	Pyrinex 25 CS 0.5 kg a.s./ha sprayed to 10 orchards, S. FR	No pesticide-related mortalities; no abnormal behaviour or sub-lethal effects
CP 10.1.1.2/46	Generic field monitoring study to refine dietary estimates for Blackcaps, Great Tits and Blackbirds in pome fruit orchards	None; 7 locations near Verona, IT	Mean PT: 0.84 (Blackcap), 0.83 (Great Tit), 0.82 (Blackbird). Blackcaps fed mainly on Lepidoptera (58.2%) and fruits (19.5%); Great Tits on Lepidoptera (75.8) and Blackbirds on fruits (Rosaceae, 25.5%) and Lepidoptera (19.5%)
CP 10.1.1.2/47	Interpretive report	Not applicable	Not applicable
CP 10.1.1.2/48 chlorpyrifos study	Field study on exposure and effects on wild birds in pome fruit	Dursban 75 WG (2-3x0.96 kg a.s./ha) sprayed to 7 locations near Verona, IT	Radio-tracking of birds during and after applications. No treatment related mortalities; no impact on survival or behaviour or nest survival

Data point	**Test organism**	**Test substance**	**Findings***
CP 10.1.1.2/49 chlorpyrifos study	Field study on status of bird and mammal communities and reproductive performance in pome fruit in 2012	EF-1551 (0.48 and 0.96 kg a.s./ha) to 10 cider apple orchards in Hereford, UK	Off-crop was much more attractive for small mammals than in-crop; diverse bird community; no negative effects on survival or reproductive success
CP 10.1.1.2/50 chlorpyrifos study	Field study on status of bird communities and reproductive performance in pome fruit orchards in 2013	EF-1551 (0.48 and 0.96 kg a.s./ha) to 10 cider apple orchards in Hereford, UK	No treatment related effect on reproduction success; slight effect on nest fate; home range & time foraging of Great Tits & Blue Tits in orchards decreased after CP application
CP 10.1.1.2/51 chlorpyrifos study	Field study on status of bird communities and reproductive performance in pome fruit orchards in 2014	EF-1551 (0.48 and 0.96 kg a.s./ha) to 10 cider apple orchards in Hereford, UK	No treatment related effect on reproduction success; slight effect on nest fate; home range & time foraging of Great Tits & Blue Tits in orchards decreased after CP application. Blood ChE activity revealed exposure to an OP. No clinical signs observed in any bird.
CP 10.1.1.2/52	Field study for the determination of focal species in vineyards	None; 22 vineyards in the Centre and Pays de la Loire, FR	Skylark, Wood Lark and Linnet were the most characteristic bird species
CP 10.1.1.2/53	Field study for the determination of focal species in vineyards	None; 15 vineyards in the Languedoc-Roussillon, FR	Skylark, Wood Lark and Linnet were the most characteristic bird species
CP 10.1.1.2/54	Field study for the determination of focal species in vineyards	None; 20 vineyards in the Cataluña region, ES	Linnet and Crested Lark were the most characteristic bird species
CP 10.1.1.2/55	Field study to refine dietary estimates for insectivorous birds in vineyards	None; 8 vine fields in Vaucluse, S. FR	Mean PT value of Black Redstart was 0.285
CP 10.1.1.2/56 chlorpyrifos study	Field study on exposure and effects on wild birds in vineyards	Dursban 480 EC (0.36 kg a.s./ha) sprayed to 8 fields in Vaucluse, S. FR	No treatment related mortalities; no discernible short-term impact on the survival or behaviour. Useful as additional information but is not sufficient to give a clear indication of low risk to birds.
CP 10.1.1.2/57	Generic field study to refine dietary estimates for Cirl Bunting, Great Tits, Linnet and Wood Lark in vineyards	None; Burgundy, FR	Mean PT values: 0.43 (Cirl Bunting), 0.05 (Great Tit), 0.78 (Linnet) and 0.86 (Wood Lark)
CP 10.1.1.2/58	Field study for the determination of focal species in oilseed rape	None; 22 oilseed rape fields in Centre region of FR	Yellow Wagtail and Corn Bunting were the most characteristic bird species
CP 10.1.1.2/59	Generic field study to refine dietary estimates Skylarks, Yellow Wagtails and Meadow Pipits in brassica fields	None; near Sochaczew, PL	Mean PT values: 0.30 (Skylark), 0.15 (Yellow Wagtail) and 0.38 (Meadow Pipit)

Data point	Test organism	Test substance	Findings*
CP 10.1.1.2/60 chlorpyrifos study	Field study on exposure and effects on wild birds in brassica crop	EF-1551(0.96 kg a.s./ha) to 3 brassica fields in Sochaczew, PL	Radiotracking of birds during and after application. No treatment related mortalities; no impact on nestlings or behaviour.
CP 10.1.1.2/61 chlorpyrifos study	Field study on exposure and effects on wild birds and mammals on golf courses	DURSBAN* & DURSBAN 2.5G (2x4.48 kg a.s./ha) applied to 4 reps, Florida, USA	No significant increase in the number of vertebrate casualties after application.
CP 10.1.1.2/62 chlorpyrifos study	Study to assess short-term effects on Wigeon on grassland	Dursban WG (2x0.75 kg a.s./ha)	No effect on the health or behaviour of Wigeon
CP 10.1.1.2/63 chlorpyrifos study	Field study on short term effects on wild goose behaviour	EF-1551 (0.72 kg a.s./ha) to 3 pastures in UK	No statistically significant effect on numbers of geese visiting the sites or on their behaviour or well-being
CP 10.1.1.2/64 chlorpyrifos study	Field study on exposure and effects on wild birds and mammals in cereal fields	LORSBAN 4E (4x1.68 - 3.36 kg a.s./ha) and LORSBAN 15G (4x1.09 - 2.92 kg a.s./ha), Iowa, USA	The study was conducted in Iowa. No indication that treatment had adversely affected avian abundance.
CP 10.1.1.2/65 chlorpyrifos study	Literature and internet survey on wildlife incidents in citrus, vine, fruit orchard and arable crops	-	No incidences of effects on free-ranging terrestrial wildlife animals that could be clearly ascribed to chlorpyrifos applications on orchards and arable crops. Wildlife incident reporting is not conducted outside the UK and Germany, and therefore the lack of reporting incidents cannot be regarded as conclusive evidence in itself.

a) FORMULATED PRODUCT: GF-1684

Based on the above refinements a summary of the conclusions for the different representative uses of each product is given in the table below:

Table 2.9.9.1.5-2.9.9.1-11 Summary of the risk assessment conclusions for the representative uses of GF-1685.

Proposed use/Crop	**Dose**	**Number of application (interval)**	**Grothw stage (BBCH)**	**Conclusions of the Risk Assessment**	
				Birds	
				Acute	**Long-term**
Cotton	0,68	1	30-89	Tier 1 > 10	Tier 2 > 5
Solanaceus vegetables	0,675	1	11-89	Tier 2 > 10	Tier 2 > 5
Maize	0,9	1	12-59	Risk identified. Further refinement is needed.	Tier 2 > 5
Oilseed rape	0,45	1	30-59	Tier 1 > 10	Tier 1 > 5
Orchards (excl. Citrus)	1,02	1	10-87	Tier 1 > 10	Tier 2 > 5
Citrus	1,285	1	11-89	Risk identified. Further refinement is needed.	Tier 2 > 5
Potato	0,54	1	31-59	Tier 1 > 10	Tier 2 > 5
Soybean	0,45	1	30-59	Tier 1 > 10	Tier 1 > 5

Proposed use/Crop	**Dose**	**Number of application (interval)**	**Grothw stage (BBCH)**	**Conclusions of the Risk Assessment**	
Strawberry	0,54	1	35-95	Tier 1 > 10	Tier 2 > 5
Grapes	0,608	1	19-89	Tier 1 > 10	Tier 2 > 5
Cereal grain	5 mg/kg	1	Pre-storage	No RA submitted	No RA submitted

Tier 1 > 10 or Tier 1 > 5: Low acute or chronic risk based on EFSA (2009) Tier I.
Tier 2 >10 or Tier 2 > 5: Low acute or chronic risk identified based on actual measured values derived from field trials.

Refinement of actual residue levels (and their dissipation) together with refinement of PT (proportion of time in the treated area) were sufficient to conclude no unaceptable chronic risk due to CPF-M application according to the GAP. However, considering the RMS proposal acute endpoint (LD50 = 227 mg a.s/kg bw), acute risk is identified for Medium herbivorous/granivorous bird "pigeon" in maize and Small insectivorous bird "tit" in citrus. Therefore, further refinement is required for citrus and maize.

Citrus
Several field studies in citrus are available in the CPF dossier that combine telemetry and traditional methods to find evidence of intoxication in treated fields. RMS recognizes the complexity of all these studies given the lack of agreed protocols and multiple factors which can influence on the results (weather conditions, landscape factors, distances to refugee areas, agricultural practices, ecology of species, interaction among species, sampling methodologies).

The study submitted intended to enable bridging of a 10-site 3-year program on CP to the use of CPM. The previous multi-year program of studies (2010-2012) assessed the long-term impact of CP application on wild birds in commercially used citrus orchards of Spain. A diverse bird community was found. In general, the three most abundant bird species were the granivorous Serin, insectivorous Sardinian warbler and the omnivorous Blackbird. The omnivorous House Sparrow, granivorous Greenfinch and Goldfinch and insectivorous Great Tit were also present in a relative high number.
For the evaluation of the reproductive performance the fate of the nest is crucial information, since only successful breeders will contribute to the survival of the population. There are available 3 studies performed in citrus in the same area of Spain during 2010, 2011, 2012, 2013 and 2014 (CP 10.1.1.2/28, CP 10.1.1.2/35 and CP 10.1.1.2/36). Results of the reproductive performance of each study has been included in the studies summary in Vol 3 CP GF-1684, Appendix I. However, in order to obtain a global vision, the results of number of nests and apparent survival rate (ASR) along the years have been pooled in one table by RMS.

Table 2.9.9.1-12 Summary table of the reproductive performance (pool of all species tested) during the years 2010, 2011, 2012, 2013 and 2014.

	Study code	CP 10.1.1.2/31						CP 10.1.1.2/28	CP 10.1.1.2/32
	Year	2010	2011	2012	2010	2011	2012	2014	2013
		CPF all sites	CPF all sites	CPF all sites	CPF sites 2,7,9	CPF sites 2,7,9	CPF sites 2,7,9	CPF-M sites 2,7,9	CPF sites 4 and 4A
	Number of nests	329	313	375	128	76	90	153	97
ASR	Fate of nests (%successful)	-	43,2	35,2	-	40,7	34,2	27,6	41,1
	Fate of nests (%failed)	-	56,8	64,8	-	59,3	65,8	72,4	58,9
	Nº fleedings/nest	-	1,1	1	-	1,3	1,2	1,3	0,7

CPF: chlorpyrifos; CPF-M: Chlopryrifos methyl. '-' no data available

From the table, it is noted that the % of successful nests is decreasing along the years (From 40.7 % in 2011 to 34.2 % and 27.6 % in 2012 and 2014 respectively, in the same study sites). However, the number of fleedings/nest seems to be stable along these years when all species are tested.

However, when the blackbird is considered, the following results are observed:

Table 2.9.9.1-13 Summary table of the reproductive performance of blackbird during the years 2010, 2011, 2012, 2013 and 2014.

	BLACKBIRD								
	Study code	CP 10.1.1.2/31						CP 10.1.1.2/28	CP 10.1.1.2/32
	Year	2010	2011	2012	2010	2011	2012	2014	2013
		CPF all sites	CPF all sites	CPF all sites	CPF sites 2,7,9	CPF sites 2,7,9	CPF sites 2,7,9	CPF-M sites 2,7,9	CPF sites 4 and 4A
	Number of nests	-	143	153	-	34	37	44	41
ASR	Fate of nests (%successful)	-	46,4	28,6		30,4	25	2,6	48,8
	Fate of nests (%failed)	-	53,6	71,4		69,6	75	97,5	51,2
	Nº fleedings/nest	-	1,3	0,7		1,1	0,8	0,3	0,7

It is noted that the percentage of successful nests decrease from 30.4 % in 2011 to 2.6 % in 2014. Moreover, the number of fleedings/nest also decreases from 1.1 in 2011 to 0.3 in 2014.

The study authors indicate that the estimate of ASR is susceptible to be biased by the scheme of nest monitoring and the timing of nest search. Therefore, the daily survival rate (DSR), was performed as a better method for comparing survival than ASR. The following results of DSR were obtained for each study:

Study CP 10.1.1.2/31 (CP): In order to test for factors affecting the nest survival a logistic-exposure model for daily survival rate (DSR) of nests was used. The best model for DSR estimated a coefficient significantly different from 0 for following factors: Species, Time (quadratic), Study Site, Exposure to CP, and Year. The results obtained are shown in the following table:

Table 18: Estimates of logistic-exposure model for each species. The parameter estimates, standard errors, and p value levels for each parameter are presented.

	Blackbird	Great Tit	Greenfinch	Serin	Sardinian Warbler
(Intercept)	2.35***	7.99***	2.20**	2.81***	4.12**
	-0.33	-1.39	-0.73	-0.48	-1.56
Date^2	0	0.00***	0.00*	0.00**	0
	0	0	0	0	0
Year, 2012	-0.44*	-1.47	0.56	-0.12	-1.81*
	-0.19	-0.78	-0.37	-0.33	-0.87
Exposure, Non-exposed	0.87***	0.55	0.14	0.14	-0.76
	-0.23	-0.84	-0.61	-0.44	-1.12
Site Category[1]:					
Site 4	0.73***		0.90*	0.70*	1.08
	-0.2		-0.42	-0.34	-0.87
Site A4	0.92**		1.19**	1.19**	3.03*
	-0.28		-0.46	-0.44	-1.23
AIC	766.42	60.13	265.6	272	47.42
BIC	795.29	72.77	288.5	293.68	60.08
Log Likelihood	-377.21	-26.07	-126.8	-130	-17.71
Deviance	754.42	52.13	253.6	260	35.42
No. observations	908	174	336	274	61

$^{***}p < 0.001$, $^{**}p < 0.01$, $^{*}p < 0.05$, [1]Site category is categorical variable, intercept values are related to a the group of all sites except 4 & A4

A statistically significant effect of exposure to CP was found for Blackbirds as the model of DSR identified a reduction in survival-probability for nests active at the time of application and/or in the subsequent four days (all being classified as ‘exposed’ nests). The modelled proportion of Blackbird nests which were not successful due to application of CP was slight, being 1 to 3.2%.

Study CP 10.1.1.2/32 (CP): The daily survival rate (DSR) was calculated for the nests of all species and separately for the most common species Blackbird and Greenfinch in relation to the application of CP. Comparisons were made for nests of study site 4, study site A4 and both sites together. The following results were obtained:

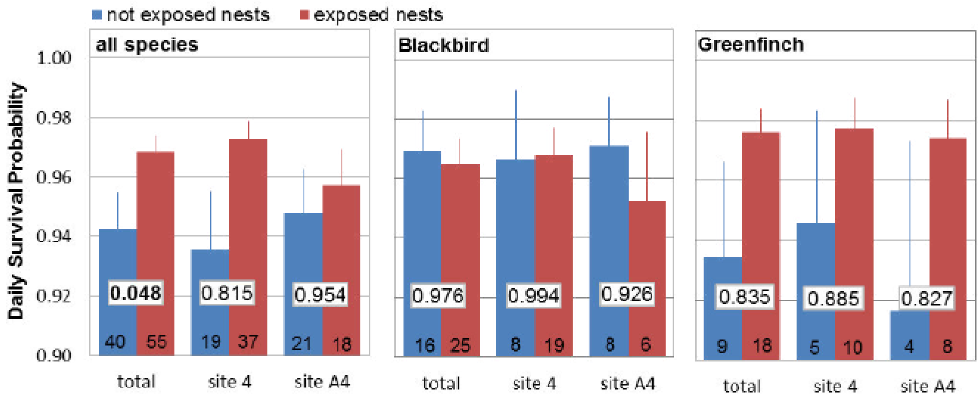


Figure 3: Daily Survival Rate of nests including all species (left), only Blackbird nests (middle) and Greenfinch nests (right) in relation to the application of CP.

There is no influence of the CP application in the DSR when al species are considered. However, a slight influence is indicated by the figure for blackbird, although RMS recognizes that these difference is not statistically significant.

Study CP 10.1.1.2/28 (CPF-M): The daily survival rate (DSR) was calculated for the nests of the most common species in relation to the application of CPM. The following results are obtained per species:

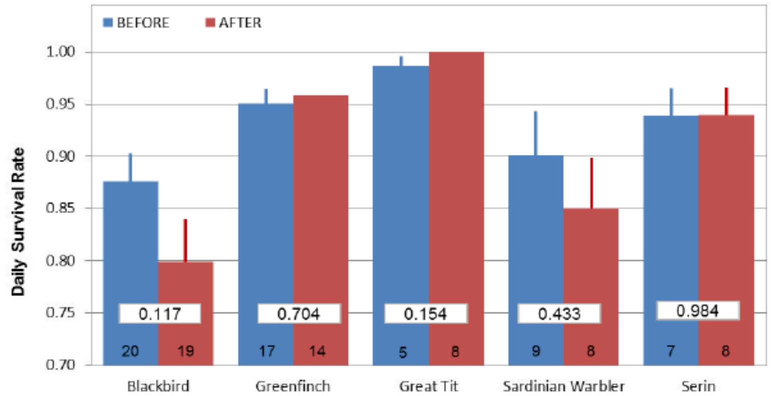


Figure 7: Daily Survival Rate of nests including of the most common species in relation to the application of CPM. Numbers at the bottom of the bars indicate the number of nests included in the analysis. Numbers in the boxes indicate the p-values of the pairwise comparison of the daily survival probability.

For none of these species, a statistically significant effect was found. However, in this case, the effect observed in the blackbird population is more marked than in the study CP 10.1.1.2/32. Moreover, a slight effect was also observed in the Sardinian warbler daily survival rate.

Based on the above information, a possible influence of CP or CP-M in the reproductive success of birds cannot be disregarded, especially on blackbird. A downward trend along the years is observed in the % of successful nests. Moreover, in blackbird, the decrease in the % of successful nests is even higher, and confirmed with the results obtained in the calculations of the DSR. **Therefore, acceptable risk cannot be concluded for the use of CPF-M in citrus. A statement/justification that explains the decrease in the nest success could be submitted.**

During the commenting period, a statement was submitted by the applicant (DAS) to address the concerns identified by RMS (please refer to Vol 3 CP B.9 for details).

After reviewing of the statement submitted, RMS considers that the final reason for the reduction in DSR could not be determined. However, several information is submitted to address the significance of the effect for the population. It seems that predation and agricultural activities have a clear impact in the nest success. An evident effect of the CPF application cannot be concluded, nor disregarded. Therefore, **RMS considers that the aproval of the a.s. should be conditionated to a monitoring of birds populations in areas of continuous use of CPF/CPF-M with the submission of the results by 2 years, in order to detect possible effects on population due to application of the active substance.**

Maize

Only one field study was submitted for maize. The study covers the GAP for maize but it is performed in Iowa (USA), therefore, the representativeness for EU agroclimatic conditions should be questioned. Moreover, two years of monitoring in fields of winter wheat in UK were conducted and submitted. These studies on cereals show the viability of the bird community within chlorpyrifos-treated winter cereal fields in the North of Europe. However, it is noted that the AR of the studies on cereals do not cover the application rate in maize (1 x 0.9 kg a.s/ha) and therefore, the results obtained in these studies cannot be directly extrapolated to the current GAP. **Therefore, no acceptable risk can be concluded for the use of CPF in maize. More information is required to support this use.**

The following statement was submitted furing the commenting period by DAS: For maize the herbivorous scenario fail at early stage. As it has been already reported, over for cereals, small omnivorous birds common to several regions were:

- Skylark (ground feeder tracked in vegetables, seen in vines and cereals)
- Crested Lark (ground feeder seen in vines, pome/stone and cereals),
- Wood Lark (ground feeder seen in vines and cereals).

For this reason the "lark" scenario can be used as a refinement option based on previous evidence.

Alternative in the dRAR, the TERa is 6.68 for woodpigeons consuming maize foliage. This is based on a pigeon's diet consisting entirely of treated maize foliage for one day, and an RUD of 46.5 mg/kg. The latter is based on the 90th percentile measured initial residue in sugar beet foliage. At comparable growth stages, sugar beet leaves are wider than the leaves of maize. The beet leaves also grow in a more horizontal orientation than those of maize. Hence, it could be predicted that the RUD for maize foliage would be lower than for sugar beet. Measured initial residues of CPM in maize foliage (whole plants) are available. These data are in Table 7.3.1.13-1 of Vol. 3 AS B7 (p229-234). The day 0 results, and RUD values are provided below:

Report number	Country/year	Growth stage	Rate (kg a.s./ha)	Day 0 residue mg/kg	RUD (i.e. normalised to 1 kg a.s./ha)
GHE-P-10991	Spain/2004	34	0.5601	14.73	26.29
	France/2004	34	0.5644	14.56	25.80
GHE-P-11217	Spain/2005	16	0.59459	12.426	20.90
	Spain/2005	89	0.61636	0.526	0.8534
	France/2005	71	0.60185	1.674	2.781
	France/2005	83	0.6435	6.663	10.35
GHE-P-11806	France/2007	59	0.940	28.570	30.39
	Spain/2007	83	0.906	11.211	12.37
	Spain/2007	83	0.886	8.069	9.107
	Italy/2007	59	0.844	8.566	10.15

In total, there are 10 values for initial residues of CPM, with the studies covering a range of growth stages from 16 to 89. As one might predict based on surface area to volume ratio, the latest growth stages (71-89) tend to have the lowest RUD values. In any case, these growth stages are unlikely to be grazed by pigeons. Out of the range of earlier growth stages (16-59), there are 5 RUD values. These range from 10.15 to 30.39. As a worst case, the RUD of 30.39 can be used in the risk assessment. The refined TER can be calculated as 46.5/30.39 * 6.68 = 10.22. This is greater that the trigger of 10, indicating an acceptable acute risk to wood pigeons for the proposed use in maize.

Based on this statement, acceptable acute and chronic risk could be concluded for the useof CPF-M in maize.

Moreover, no risk assessment is presented for the intended use in Cereals (pre-storage; 1 x 5 mg/kg grain). Therefore, a conclusion cannot be derived for this use.

The following information was submitted during the commenting period by DAS: The pre-storage treatment of grain is administered by a spray onto the grain whilst it is on a moving conveyer-belt which transfers the grain into the store. There is no potential for exposure of birds and wild mammals when the treated grain is on the conveyor, nor when the treated grain is inside the store (the latter being designed to minimise ingress of pests of stored grain, including rodents). Hence, there is a low risk to birds and mammals from the proposed pre-storage use on grain.

Based on the information provided, no risk assessment is required for cereal grains. No exposure to birds is expected.

b) FORMULATED PRODUCT: SAP200CHLORI

Table 2.9.9.1-14 Summary of the risk assessment conclusions for the representative uses of SAP200CHORI

Proposed use	**Dose (kg/ha)**	**Number of application (interval)**	**Grothw stage (BBCH)**	**remarks**	**Conclusions on the Risk Assessment**	
					Acute	**LT**
Grapes	0,34	1	71-85		Tier 1 > 10	Tier 1 > 5
OSR	0,34	1	oct-59		Tier 1 > 10	Tier 2 > 5

Tier 1 > 10 or Tier 1 > 5: Low acute or chronic risk based on EFSA (2009) Tier I.
Tier 2 >10 or Tier 2 > 5: Low acute or chronic risk identified based on actual measured values derived from field trials.

No unacceptable risk can be concluded for the use of SAP200CHLORI according to the GAP.

2.9.9.2. Summary of product exposure and risk assessment on terrestrial vertebrates (other than birds)

Risk assessment has been performed according to the EFSA GD on birds and mammals (2009). As a first step the default assumptions on residue levels of the guidance document have been considered (Tier 1). However, if further refinement is needed the default assumptions on residue levels (EFSA, 2009) were replaced by actual measured values derived from field trials conducted with chlorpyrifos (please, refer to point 2.9.9.1.2 for details on the data use for residues refinement).

Field studies on mammals communities: Several field studies have been presented to refine the risk assessment of mammals. A summary of all the studies presented is included in the following table. For details, please refer to Vol 3 CP GF-1684 (Appendix I) and Vol 3 CP SAP200CHLORI (higher Tier studies).

Table 2.9.9.2.6-2.9.9.2-1 Higher tier data on mammals: field studies

Data point	**Test organism**	**Test substance**	**Findings***
Higher Tier Data on Mammals (field studies: generic, determination of focal species, and assessing effects of chlorpyrifos applications)			
CP 10.1.2.2/7	Field study for the determination of focal species in citrus orchards	None; 7 study orchards in the Valencia region, ES	The Algerian mouse (*Mus spretus*) was the most abundant mammal species
CP 10.1.2.2/8 chlorpyrifos study	Field study on exposure and effects on wild mammals in citrus	Dursban 75 WG (2.4 kg a.s./ha) to 3 orchards in Valencia region, ES	No incidents related to chlorpyrifos applications; no negative effect on survival of Algerian mice

Data point	Test organism	Test substance	Findings*
CP 10.1.2.2/9 chlorpyrifos study	Field study on exposure and long-term effects on wild mammals in citrus in 2009	Dursban 75 WG (2.4 kg a.s./ha) to 3 orchards in the Valencia region, ES	No long-term effects on the abundance and reproduction of the Algerian mice
CP 10.1.2.2/10 chlorpyrifos study	Field study on exposure and long-term effects on wild mammals in citrus in 2011	EF-1551 (2x2.4 kg a.s./ha) to 6 sites in the Valencia region, ES	No long-term effects on abundance and diversity of small mammal species.
CP 10.1.2.2/11 chlorpyrifos study	Field study on exposure and effects on wild mammals in pome fruit orchards	EF-1551 (1x0.96 kg a.s./ha) to 3 plots in Czech Rep.	No impact on small mammal individuals or populations
CP 10.1.2.2/12 chlorpyrifos study	Field study on exposure and long-term effects on wild mammals in pome fruit orchards	EF-1551 (1x0.96 kg a.s./ha) to 3 plots in S. Moravia, Czech Rep.	No long-term effect on the abundance of common voles and wood mice and on the reproduction of common vole populations
CP 10.1.2.2/13	Generic field study to refine the diet composition of wood mice in vineyards	None; 4 vineyards in the Burgundy region, FR	Mean PT value: 0.15; main food were seeds (80.1%) and fruits (14.0%)
CP 10.1.2.2/14	Generic field study on focal species in brassica fields	None; 6 fields in Central PL	The European brown hare is the relevant herbivorous mammal species
CP 10.1.2.2/15 chlorpyrifos study	Field study on exposure and effects on wild mammals in brassica fields	EF-1551 (1x or 2x0.96 kg a.s./ha) to 5 plots in PL	Brown hare is the only herbivorous mammal (no woodmice); no incidents related to applications
CP 10.1.2.2/16	Generic field study on the common vole in grassland	None; 6 grassland plot in south-west DE	Mean population size was 217± SD 65 voles/ha; mean daily turnover rate was 9.2 ± SD 2.0%; mean home range size was 399 m²
CP 10.1.2.2/17 chlorpyrifos study	Field study on exposure and effects on common vole in grassland	Dursban 75 WG (0.5 kg a.s./ha) to 3 meadows near Bruchsal, DE	No significant differences in overall survival
CP 10.1.2.1 (SAPEC)	Small Mammal focal species in vineyards in southern Europe	Not applicable	An argumentation for the selection of an appropriate mammal focal species for vineyards in southern Europe, with a focus on France, Spain, Portugal and Italy.

Conclusions on the risk assessment on mammals

Based on the above refinements a summary of the conclusions for the different representative uses of each formulated product is given below:

a) FORMULATED PRODUCT: GF 1684

Table 2.9.9.2.6-2.9.9.2-2 Summary of the risk assessment conclusions for mammals for the representative use of the formulated product GF-1684.

Proposed use/Crop	**Dose**	**Number of application (interval)**	**Grothw stage (BBCH)**	**Conclusions on the risk assessment**	
				Acute	**LT**
Cotton	0,68	1	30-89	Tier 2 > 10	Risk identified. More information is required to cover the risk to lagomorphs.
Solanaceus vegetables	0,675	1	11-89	Tier 2 > 10	Risk identified. More information is required to cover the risk to lagomorphs.
Maize	0,9	1	12-59	Field monitoring.	Risk identified. More information is required to cover the risk to lagomorphs and shrew.
Oilseed rape	0,45	1	30-59	Tier 1 > 10	Risk identified. More information is required to cover the risk to lagomorphs.
Orchards (excl. Citrus)	1,02	1	10-87	Field monitoring.	Risk identified. More information is required to cover the risk to lagomorphs.
Citrus	1,285	1	11-89	Field monitoring.	Risk identified. More information is required to cover the risk to lagomorphs.
Potato	0,54	1	31-59	Tier 1 > 10	Risk identified. More information is required to cover the risk to lagomorphs.
Soybean	0,45	1	30-59	Tier 1 > 10	Risk identified. More information is required to cover the risk to lagomorphs.
Strawberry	0,54	1	35-95	Tier 1 > 10	Risk identified. More information is required to cover the risk to lagomorphs.
Grapes	0,608	1	19-89	Tier 1 > 10	Risk identified. More information is required to cover the risk to lagomorphs.
Cereal grain	5 mg/kg	1	Pre-storage	No RA submitted	No RA submitted

Tier 1 > 10 or Tier 1 > 5: Low acute or chronic risk based on EFSA (2009) Tier I.
Tier 2 >10 or Tier 2 > 5: Low acute or chronic risk identified based on actual measured values derived from field trials.

Refinement of actual residue levels (and their dissipation) were not sufficient to conclude acceptable acute and chronic risk due to CPF-M application. Acute risk was identified for Small herviborous mammal 'vole' in Maize, citrus and orchards (other than citrus). Moreover, chronic risk was identified for Small herviborous mammal 'vole' and large herbivorous mammal 'lagomorph' in all intended uses in the GAP. Furthermore, chronic risk was also identified for small insectivorus mammal 'shrew' in maize. Therefore, further refinement is required for these intended uses.

Some field studies have been submitted to refine the risk assessment. With respect to small herbivorous mammal, field studies in citrus and pommes indicates that Algerian mouse and the common vole were the most relevant focal species in these crops, respectively. No relevant effects on these species were identified in any of the field studies presented.

Taking into account that there will be little cover vegetation in intensively cultivated crops to support significant populations of these species and in view of the high reproductive potential and ecological redundancy of small mammalian species, together with the opportunity for populations to be replenished rapidly through immigration, the reproductive long-term risk to any resident mammal populations in the vicinity of the treated crops is considered to be low. A potential for recovery should be expected.

Therefore, no unaceptable risk for small herviborous mammal could be concluded for the use of CPF-M according to the GAP.

However, no information is provided to conclude for the risk identified to large herbivorous mammals 'lagomorph'. Applicant is called to submit more information on the representativeness of this species for the intended uses proposed in the GAP which indicates that the available field studies cover the risk identifed for lagomorph in all the intended uses.

Moreover, more information is requiered to cover the risk identified for insectivorous mammal shrew in maize.

Furthermore, RMS is of the opinion that, although acceptable risk could be concluded for small herbivorous mammal, the aproval of the a.s. should be conditionated to a monitoring of mammals populations in areas of continuous use of CPF/CPF-M with the submission of the results by 2 years, in order to detect possible effects on population due to application of the active substance (CPF-M).

Moreover, no risk assessment is presented for the intended use in Cereals (pre-storage; 1 x 5 mg/kg grain). Therefore, a conclusion cannot be derived for this use.

The following information was submitted during the commenting period by DAS: The pre-storage treatment of grain is administered by a spray onto the grain whilst it is on a moving conveyer-belt which transfers the grain into the store. There is no potential for exposure of birds and wild mammals when the treated grain is on the conveyor, nor when the treated grain is inside the store (the latter being designed to minimise ingress of pests of stored grain, including rodents). Hence, there is a low risk to birds and mammals from the proposed pre-storage use on grain.

Based on the information provided, no risk assessment is required for cereal grains. No exposure to mammals is expected.

b) FORMULATED PRODUCT: SAP200CHLORI

Table 2.9.9.2.6-2.9.9.2-3 Summary of the risk assessment conclusions for mammals for the representative use of the formulated product SAP200CHLORI.

Proposed use	Dose (kg/ha)	Number of application (interval)	Grothw stage (BBCH)	Conclusions on the risk assessment	
				Acute	**LT**
Grapes	0,34	1	71-85	Screening > 10	Tier 2 > 5**
OSR	0,34	1	oct-59	Screening > 10	Riks identified. Further refinement needed

Screening > 10: Low acute or chronic risk identified based on EFSA (2009) screening step.
Tier 1 > 10 or Tier 1 > 5: Low acute or chronic risk based on EFSA (2009) Tier I.
Tier 2 >10 or Tier 2 > 5: Low acute or chronic risk identified based on actual measured values derived from field trials.
**The long term risk assessment of small herbivorus mammals could be covered by the risk assessment on onmivorous mammals. MS should consider the suitability of small omnivorous mammals as focal species on vineyards to cover the risk assessment for small herbivorous mammals 'vole'.

Refinement of actual residue levels (and their dissipation) were not sufficient to conclude acceptable acute and chronic risk due to CPF-M application. TER values below the trigger were identified for Small herviborous mammal 'vole (BBCH >40) in both intended uses.

<u>Vineyards</u>

The aplicant has submitted an statement (please refer to Vol 3 CP SAP200CHLORI for details) about the representativeness of "vole" for the intended uses in vineyards and the suitability of using *Apodemus sylvaticus* "wood mouse" as more representative focal species for the risk assessment.
It should be taken into account that, in view of the high reproductive potential and ecological redundancy of small mammalian species, together with the opportunity for populations to be replenished rapidly through immigration, the reproductive long-term risk to any resident mammal populations in the vicinity of the treated crops could be considered to be low. Therefore, a potential for recovery should be expected. RMS considers that the long term risk assessment of small herbivorus mammals is covered by the risk assessment onmivorous mammals. **MS should consider the suitability of small omnivorous mammals as focal species on vineyards to cover the risk assessment for small herbivorous mammals 'vole'.**

<u>OSR</u>
No information has been submitted about the representativeness of 'vole' in OSR. More information about the representativeness of vole in oilseed rape should be submitted to conclude the risk assessment.

2.9.9.3. Drinking water risk assessment for terrestrial vertebrates

No drinking water assessment is required for chlorpyrifos-methyl as the ratio of effective application rate to toxicological endpoint does not exceed the trigger of 3000. Therefore, a risk to birds by the uptake of chlorpyrifos-methyl via drinking water is not indicated.

2.9.9.4. Secondary poisoning for terrestrial vertebrates

a) FORMULATED PRODUCT: GF-1685

Risk assessment for secondary poisoning to earthworm-eating birds

Dry soil approach

Table 2.9.9.4-1 TERlt calculations for secondary poisoning to earthworm eating-bird (dry soil approach)

Crop	$PEC_{Soil, twa}$ [mg a,s,/kg]	BCF_{worm}	PEC_{worm} [mg a,s,/kg]	DDD [mg a,s,/kg bw]	TER_{LT}	Trigger
Dry soil approach						
Citrus	0,051	10,98	0,560	0,588	26	5
Corn/Maize	0,134	10,98	1,472	1,545	10	5
Cotton	0,054	10,98	0,593	0,623	25	5
Grapes, Table	0,048	10,98	0,527	0,554	28	5
Grapes, Wine	0,027	10,98	0,297	0,311	50	5
Oilseed rape	0,018	10,98	0,198	0,208	75	5
Pome fruit	0,072	10,98	0,791	0,830	19	5
Potato	0,043	10,98	0,472	0,496	31	5
Solanaceous	0,067	10,98	0,736	0,773	20	5
Soybean	0,04	10,98	0,439	0,461	34	5
Stone fruit	0,081	10,98	0,890	0,934	17	5
Strawberry	0,054	10,98	0,593	0,623	25	5

Pore water approach

Table 2.9.9.4-2 TERlt calculations for secondary poisoning to earthworm eating-bird (pore water approach)

Pore water approach										
Crop	**$PEC_{Soil, twa}$ [mg a.s./kg]**	**BCF_{worm}**	**Kairwater**	**Ksoil-water**	**Cpore water**	**CONVsoil**	**Cearthworm**	**DDD [mg a.s./kg bw]**	**TER_{LT}**	**Trigger**
Citrus	0,051	302,3	9,92E-05	41,48	0,002	1,133	0,003	0,003	4518	5
Corn/Maize	0,134	302,3	9,92E-05	41,48	0,005	1,133	0,023	0,024	654	5
Cotton	0,054	302,3	9,92E-05	41,48	0,002	1,133	0,004	0,004	4030	5
Grapes, Table	0,048	302,3	9,92E-05	41,48	0,002	1,133	0,003	0,003	5101	5
Grapes, Wine	0,027	302,3	9,92E-05	41,48	0,001	1,133	0,001	0,001	16120	5
Oilseed rape	0,018	302,3	9,92E-05	41,48	0,001	1,133	0,000	0,000	36271	5
Pome fruit	0,072	302,3	9,92E-05	41,48	0,003	1,133	0,007	0,007	2267	5
Potato	0,043	302,3	9,92E-05	41,48	0,002	1,133	0,002	0,002	6356	5
Solanaceous	0,067	302,3	9,92E-05	41,48	0,003	1,133	0,006	0,006	2618	5
Soybean	0,04	302,3	9,92E-05	41,48	0,002	1,133	0,002	0,002	7345	5
Stone fruit	0,081	302,3	9,92E-05	41,48	0,003	1,133	0,008	0,009	1791	5
Strawberry	0,054	302,3	9,92E-05	41,48	0,002	1,133	0,004	0,004	4030	5

According to the TERlt calculations above, no unacceptable risk to earthworm eating birds is expected for the use of GF-1685 according to the GAP.

Risk assessment for secondary poisoning to fish-eating birds

A RACsp is estimated according to the new EFSA Aquatic Guidance documen

$$RAC_{sp} = \frac{NOAEL_{bird}}{5 \cdot 0.159 \, BCF_{fish} \cdot BMF}$$

RACsp= 15.562/(5*0.159*1581*1)= 12 µg/L

This RACsp has been compared with the FOCUS SW PECmax. According to the PECsw proposed by the RMS in B-8 CP with the STEP 3, PECsw refinement would be neccesary for the intended uses in Citrus, Pomes, Vines. Considering the STEP 4 calculations proposed in B8 CP no further refinement is necessary.

Risk assessment for secondary poisoning to earthworm-eating mammals

Dry soil approach

Table 2.9.9.4-3 TERlt calculations for secondary poisoning to earthworm eating-mammals (dry soil approach)

Crop	$PEC_{Soil, twa}$ [mg a,s,/kg]	BCF_{worm}	PEC_{worm} [mg a,s,/kg]	DDD [mg a,s,/kg bw]	TER_{LT}	Trigger
Dry soil approach						
Citrus	0,051	10,98	0,560	0,717	4,18	5
Corn/Maize	0,134	10,98	1,472	1,884	1,59	5
Cotton	0,054	10,98	0,593	0,759	3,95	5
Grapes, Table	0,048	10,98	0,527	0,675	4,45	5
Grapes, Wine	0,027	10,98	0,297	0,380	7,90	5
Oilseed rape	0,018	10,98	0,198	0,253	11,86	5
Pome fruit	0,072	10,98	0,791	1,012	2,96	5
Potato	0,043	10,98	0,472	0,605	4,96	5
Solanaceous	0,067	10,98	0,736	0,942	3,19	5
Soybean	0,04	10,98	0,439	0,562	5,33	5
Stone fruit	0,081	10,98	0,890	1,139	2,63	5
Strawberry	0,054	10,98	0,593	0,759	3,95	5

Risk is identified for earthworm eating-mammals in all intendes uses except grapes (wine), oilseed rape and Soy been. Further refinement is required.

Pore water approach

Table 2.9.9.4-4 TERlt calculations for secondary poisoning to earthworm eating-mammals (pore water approach)

Pore water approach										
Crop	**$PEC_{Soil, twa}$ [mg a,s,/kg]**	**BCF_{worm}**	**Kairwater**	**Ksoil-water**	**Cpore water**	**CONVsoil**	**Cearthworm**	**DDD [mg a.s./kg bw]**	**TER_{LT}**	**Trigger**
Citrus	0,051	302,3	9,92E-05	41,48	0,002	1,133	0,003	0,004	715	5
Corn/Maize	0,134	302,3	9,92E-05	41,48	0,005	1,133	0,023	0,029	104	5
Cotton	0,054	302,3	9,92E-05	41,48	0,002	1,133	0,004	0,005	637	5
Grapes, Table	0,048	302,3	9,92E-05	41,48	0,002	1,133	0,003	0,004	807	5
Grapes, Wine	0,027	302,3	9,92E-05	41,48	0,001	1,133	0,001	0,001	2550	5
Oilseed rape	0,018	302,3	9,92E-05	41,48	0,001	1,133	0,000	0,001	5737	5
Pome fruit	0,072	302,3	9,92E-05	41,48	0,003	1,133	0,007	0,008	359	5
Potato	0,043	302,3	9,92E-05	41,48	0,002	1,133	0,002	0,003	1005	5
Solanaceous	0,067	302,3	9,92E-05	41,48	0,003	1,133	0,006	0,007	414	5
Soybean	0,04	302,3	9,92E-05	41,48	0,002	1,133	0,002	0,003	1162	5

Stone fruit	0,081	302,3	9,92E-05	41,48	0,003	1,133	0,008	0,011	283	5
Strawberry	0,054	302,3	9,92E-05	41,48	0,002	1,133	0,004	0,005	637	5

No unacceptable risk is identified for earthworm eating mammal when the pore water approach is considered.

Risk assessment for secondary poisoning to fish-eating mammals

A RACsp is estimated according to the new EFSA Aquatic Guidance document:

$$\frac{NOAEL_{mammal}}{5 \cdot 0.138 \cdot BCF_{fish} \cdot BMF}$$

0.138 is a multiplying factor to convert the PECfish (PECwater*BCF) to daily dose . The proposed multiplacator factor is based on the TGD recomendations (3000 g mammal eating 415 go fresh fish). However the RMS considers more appropriate to use the factor of 0.142 given in the B&M GD (base on 3000 g mammals eating 425 g of fresh fish/d)

RACsp= 3/(5*0.142*1581*1)= 2.67 µg/L

This RACsp has been compared with the FOCUS SW PECmax . According to the PECsw proposed by the RMS in B-8 CP with the STEP 3 PECsw refinement is necessary for the intended uses. Considering the STEP 4 calculations proposed in B8 CP no further refinement is necessary.

b) FORMULATED PRODUCT: SAP200CHLORI

Risk assessment for secondary poisoning to earthworm-eating birds

Dry soil approach

Table 2.9.9.4-5 TERlt calculations for secondary poisoning to earthworm eating birds (dry soil approach)

Crop	$PEC_{Soil, twa}$ [mg a,s,/kg]	BCF_{worm}	PEC_{worm} [mg a,s,/kg]	DDD [mg a,s,/kg bw]	TER_{LT}	Trigger
Dry soil approach						
Grapes	0,017	4,39	0,075	0,078	199	5
OSR	0,041	4,39	0,180	0,189	82	5

Pore water approach

Table 2.9.9.4-6 TERlt calculations for secondary poisoning to earthworm eating birds (pore water approach)

Crop	$PEC_{Soil, twa}$ [mg a.s./kg]	BCF_{worm}	Kairwater	Ksoil-water	Cpore water	CONVsoil	Cearthworm	DDD [mg a.s./kg bw]	TER_{LT}	Trigger
Grapes	0,017	120,8	9,92E-05	41,48	0,001	1,133	0,00015	0,00015	101711	5
OSR	0,041	120,8	9,92E-05	41,48	0,002	1,133	0,00085	0,0008	17486	5

								9		

No long-term risk for earthworms eating birds is expected for the use of SAP200CHLORI according to the GAP.

Risk assessment for secondary poisoning to fish-eating birds
A RACsp is estimated according to the new EFSA Aquatic Guidance documen

$$RAC_{SP} = \frac{NOAEL_{bird}}{5 \cdot 0.159\, BCF_{fish} \cdot BMF}$$

RACsp= 15.562/(5*0.159*1581*1)= 12 µg/L

This RACsp has been compared with the FOCUS SW PECmax . According to the PECsw proposed by the RMS in B-8 CP the worst case STEP 3 PECsw is 6.026 µg/L in FOCUS scenario R3 for the intended use on grapes.

Based on these calculations, no further action required.

Risk assessment for secondary poisoning to earthworm-eating mammals

Dry soil approach

Table 2.9.9.4-7 TERlt calculations for secondary poisoning to earthworm eating mammal (dry soil approach)

Crop	**$PEC_{Soil, twa}$ [mg a,s,/kg]**	**BCF_{worm}**	**PEC_{worm} [mg a,s,/kg]**	**DDD [mg a,s,/kg bw]**	**TER_{LT}**	**Trigger**
Dry soil approach						
Grapes	0,017	4,39	0,075	0,096	163	5
OSR	0,041	4,39	0,180	0,230	68	5

Pore water approach

Table 2.9.9.4-8 TERlt calculations for secondary poisoning to earthworm eating mammal (pore water approach)

Crop	**$PEC_{Soil, twa}$ [mg a,s,/kg]**	**BCF_{worm}**	**Kairwater**	**Ksoil-water**	**Cpore water**	**CONVsoil**	**Cearthworm**	**DDD [mg a.s./kg bw]**	**TER_{LT}**	**Trigger**
Grapes	0,017	120,8	9,92E-05	41,48	0,001	1,133	0,000	0,000	83435	5
OSR	0,041	120,8	9,92E-05	41,48	0,002	1,133	0,001	0,001	14344	5

No risk to earthworm eating mammals is expected for the use of SAP200CHLORI according to the GAP.

Risk assessment for secondary poisoning to fish-eating mammals

A RACsp is estimated according to the new EFSA Aquatic Guidance document

$$\frac{NOAEL_{mammal}}{5 \cdot 0.138\, BCF_{fish} \cdot BMF}$$

0.138 is a multiplying factor to convert the PECfish (PECwater*BCF) to daily dose . The proposed multiplacator factor is based on the TGD recomendations (3000 g mammal eating 415 go fresh fish) : However the RMS considers more approriate to use the factor of 0.142 given in the B& M GD (base on 3000 g mammals eating 425 g of fresh fish/d)

RACsp= 3/(5*0.142*1581*1)= 2.67 µg/L

This RACsp have been compared with the FOCUS SW PECmax . According to the PECsw proposed by the RMS in B-8 CP the worst case STEP 3 PECsw is 6.026 µg/L in FOCUS scenario R3 for the intended use on grapes. Based on these calculations, no further action required.

2.9.9.5. Aquatic organisms

The risk assessment on aquatic organisms was based on STEP4 FOCUS calculations conducted by RMS considering FOCUS L&M recomendations of 20m VBS ,. Additionally 95% DRN were used in the calculations. The risk managers should decide wether or not these risk mitigation measures are considered reliable under agrioenvironmental conditions of use . The output of the risk assessment based on an ETO-RAC and ERO RAC of 0.015 and 0.02µg/l, respectively for the intended use of each one of the PPP is shown in the table below. For details of the aquatic risk assessment please refer to CP B-9 of GF 1684 and CP B-9 of SAP200CHLORI.

Table 2.9.2-1-4. Summary of risk assessment conclusions for all intended uses of PPPs containing chlorpyrifos-methyl for its renewal.

Crop scenario (Application at)	**Product name**	**Nº of treatments**	**Application rate per treatment (g a.s./ha)**	**Conclusion**
Grapes (BBCH 71-85)	SAP200CLORI	1	340	Safe use was identified in all FOCUS scenarios excepting in R1 where risk was found.
Oilseed rape winter (BBCH 10)	SAP200CLORI	1	340	Safe use was identified in all FOCUS scenarios excepting in R3 where risk was found.
Oilseed rape winter (BBCH 89)	SAP200CLORI	1	340	Safe use was identified in all FOCUS scenarios excepting in R1 and R3 where risk was found.
Oilseed rape spring (BBCH 10)	SAP200CLORI	1	340	Safe use was identified in all FOCUS scenarios excepting in R1 where risk was found.
Citrus	GF1684	1	1285	Safe use cannot be guarantee for this intended use. Risk was identified in all FOCUS scenarios for Citrus.
Maize (BBCH 12)	GF1684	1	900	Safe use was identified in D3, D4, D5 and D6 FOCUS scenarios. In the rest of scenarios, safe use cannot be guarantee.
Maize (BBCH 59)	GF1684	1	680	Safe use was identified in D3, D4, D5, D6 and R2 FOCUS scenarios In the rest of scenarios, safe use cannot be guarantee.
Grapes (early)	GF1684	1		Safe use was identified in all FOCUS scenarios excepting in R3 where risk was found.

Crop scenario (Application at)	**Product name**	**Nº of treatments**	**Application rate per treatment (g a.s./ha)**	**Conclusion**
Grapes (early)	GF1684	2		Safe use was identified in all FOCUS scenarios excepting when the risk assessment was based on the recovery of aquatic population (ERO-RAC).
Grapes (late)	GF1684	1		Safe use was identified in D6 and R1 FOCUS scenarios In the rest of scenarios (R2, R3 and R4), safe use cannot be guarantee.
Grapes late	GF1684	2		Safe use was identified for this intended use in all FOCUS scenarios
Pome fruits (early and late)	GF1684	1	900	Safe use was identified in D4 and FOCUS scenarios. In the rest of scenarios (D5, R1, R2, R3 and R4), safe use cannot be guarantee.
Fruiting vegetable (early)	GF1684	1	675	Safe use was identified in D6 and R2 FOCUS scenarios when the risk assessment was based on the recovery of aquatic population (ERO-RAC). In the rest of scenarios (R3 and R4), safe use cannot be guarantee.
Fruiting vegetable (late)	GF1684	1	675	Safe use was identified in D6 and R2 FOCUS scenarios. Risk was identified in R3 and R4 scenarios.

A risk envelope approach was followed by DAS. PECsw calculations were submitted for the claimed uses on orchards (application rate= 1020 g/ha), vines (676 g/ha), maize (900 g/ha), fruiting vegetables (675 g/ha) and citrus (1800 g/ha) to cover the representative uses on cotton (680g/ha), potatoes (540 g/ha), oilseed rape (450 g/ha), strawberries (540 g/ha) and soybean (450 g/ha). RMS agrees with the proposed risk envelope.

Finally, it is mentioned that the applicants proposes to use VFSMOD model to reduce the VBS. The use of this tool is not adopted yet at EU level and not considered in the risk assessment. In any case it could be included in the CP at request.

2.9.9.6. Bees and other non target arthropds

Please refer to sections 2.9.3.1 and 2.9.3.2 for a summary of the risk assessment for bees and other non target arthropods, for details. In the table below and overall

Table 2.9.9.3 -1. Bees risk assessment : summary of conclusions for the representative uses for the renewal of chlorpyrifos-methyl.

Crop scenario	Region	Product name	Nº of treatments (BBCH)	Application rate per treatment (g a.s./ha)	Conclusion
Citrus	EU-S	GF1684	1	1285	No effects observed on bee brood at the tested application rate of 1x 353 gas/ha Application rate above the tested one for bee brood. **Further informtation needed for the supported use**

Crop scenario	Region	Product name	Nº of treatments (BBCH)	Application rate per treatment (g a.s./ha)	Conclusion
					Risk managagers to consider the long-lasting and overlapping flowering period inoder to establish possible risk mitigation measures.
Maize	EU-S	GF1684	1	900	No effects observed on bee brood at the tested application rate of 1x353 gas/ha Application rate above the tested one for bee brood. **Further informtation needed for the supported use**
Cotton	EU-S	GF1684	1	680	No effects observed on bee brood at the tested application rate of 1x353 gas/ha Application rate above the tested one for bee brood. **Further informtation needed for the supported use**
Grapes	EU-C and EU-S	GF1684	2	338	No effects observed on bee brood at the tested application rate of 1x353 gas/ha Application rate above the tested one for bee brood. **Further informtation needed for the supported use**
Grapes	EU-C and EU-S	SAP200CHLORI	1	340	Acceptable use following the mitigation measures.
Oilseed rape	EU-C and EU-S	GF1684	1	450	No effects observed on bee brood at the tested application rate of 1x353 gas/ha **Application rate above the tested one for bee brood. Further informtation needed for the supported use.**
Oilseed rape	EU-C and EU-S	SAP200CHLORI	1	340	Acceptable use following the mitigation measures.
Pome fruits	EU-C and EU-S	GF1684	1	900	No effects observed on bee brood at the tested application rate of 1x353 gas/ha Application rate above the tested one for bee brood. Further informtation needed for the supported use
Stone fruits	EU-C and EU-S	GF1684	1	1020	No effects observed on bee brood at the tested application rate of 1x353 gas/ha Application rate above the

Crop scenario	Region	Product name	Nº of treatments (BBCH)	Application rate per treatment (g a.s./ha)	Conclusion
					tested one for bee brood. Further informtation needed for the supported use
Potato	EU-C and EU-S	GF1684	1	540	No effects observed on bee brood at the tested application rate of 1x353 gas/ha Application rate above the tested one for bee brood. Further informtation needed for the supported use
Solanaceous vegetables	EU-C and EU-S	GF1684	1	675	No effects observed on bee brood at the tested application rate of 1x353 gas/ha Application rate above the tested one for bee brood. Further informtation needed for the supported use
Soybean	EU-C and EU-S	GF1684	1	450	No effects observed on bee brood at the tested application rate of 1x353 gas/ha Application rate above the tested one for bee brood. Further informtation needed for the supported use
Strawberry	EU-C	GF1684	1	540	No effects observed on bee brood at the tested application rate of 1x353 gas/ha Application rate above the tested one for bee brood. Further informtation needed for the supported use
Cereal grain	EU-C and EU-S	GF1684	1	5 mg/kg grain	No exposure is expected.

Table 2.9.9.3-2. NTAs risk asssessment : summary of conclusions for the representative uses for the renewal of chlorpyrifos.

Crop scenario	Region	Product name	Nº of treatments	Application rate per treatment (g a.s./ha)	Conclusion
Citrus	EU-S	GF1684	1	1285	In-field populations and community recovery within one year after treatment. Statistically significant population adverse off-crop effects. Considering the ESCORT II drift values for fruit crops, a buffer zone of between 200 and 225 m for an early application and of more than 250 m for a late application of chlorpyrifos-methyl is needed to reduce the exposure of the most sensitive species to acceptable levels.
Maize	EU-S	GF1684	1	900	There are no data to conduct the in-field risk assessment for the intended use.
Cotton	EU-S	GF1684	1	680	There are no data to conduct the in-field risk assessment for the intended use.
Grapes	EU-C and EU-S	GF1684	2	338	There are no data to conduct the in-field risk assessment for the intended use.
Grapes	EU-C and EU-S	SAP200CHLORI	1	340	There are no data to conduct the in-field risk assessment for the intended use. The possibility for recovery showed in aged residue studies does not guarantee that actual recovery will occur.
Oilseed rape	EU-C and EU-S	GF1684	1	450	There are no data to conduct the in-field risk assessment for the intended use.
Oilseed rape	EU-C and EU-S	SAP200CHLORI	1	340	There are no data to conduct the in-field risk assessment for the intended use. The possibility for recovery showed in aged residue studies does not guarantee that actual recovery will occur.
Pome fruits	EU-C and EU-S	GF1684	1	900	No in-field full recovery at the end of the sampling period for several arthropod taxa and statistically significant

Crop scenario	Region	Product name	Nº of treatments	Application rate per treatment (g a.s./ha)	Conclusion
					population adverse off-crop effects.
Stone fruits	EU-C and EU-S	GF1684	1	1020	No in-field full recovery at the end of the sampling period for several arthropod taxa and statistically significant population adverse off-crop effects.
Potato	EU-C and EU-S	GF1684	1	540	There are no data to conduct the in-field risk assessment for the intended use.
Solanaceous vegetables	EU-C and EU-S	GF1684	1	675	There are no data to conduct the in-field risk assessment for the intended use.
Soybean	EU-C and EU-S	GF1684	1	450	There are no data to conduct the in-field risk assessment for the intended use.
Strawberry	EU-C	GF1684	1	540	There are no data to conduct the in-field risk assessment for the intended use.
Cereal grain	EU-C and EU-S	GF1684	1	5 mg/kg grain	No exposure is expected.

2.9.9.7. Non-target soil meso- and macrofauna

The risk assessment of chlorpyrifos methyl and its metabolites have been conducted according to the SANCO Terrestrial Ecotoxicology Guidance document (SANCO/10329/2002 rev 2 final) and the agreed PECsoil derived in the E-fate section see point 2.8.6 for details.

The TER values for the supported uses of GF 1684 and SAP200CHLORI are summarised in the sections below.

2.9.9.7.1. FORMULATED PRODUCT: GF-1684

A risk envelope approach was followed considering the worst case PECsoil= 0.9 mg ai /kg soil.

Table 2.9.9.5-1 TERLT calculation for earthworms

Compound	Endpoint	[mg/kg soil]	PEC_{soil} [mg/kg soil]	TER_{LT}
Chlorpyrifos-methyl	$NOEC_{corr}$	6.35	0.9	7.06
TCP	NOEC	2.2	0.516	4.26
TMP	$NOEC_{corr}$	0.635	0.140	4.54
DCP	NOEC	1.25	0.338	3.70

Aceptable risk can be identified for the active substance. However, TERLT values below the trigger of 5 are identifed for the metabolites using the worst case PECs. Therefore, the metabolites risk assessment has been performed using the PECsoil calculated for each intended use.

Table 2.9.9.5-2TER$_{LT}$ calculation for earthworms for the metabolite TCP

Compound	Crop	PEC plateau	TER	Trigger
TCP	Citrus	0.196	11.22	5
TCP	Maize	0.516	4.26	5
TCP	Cotton	0.208	10.58	5
TCP	Table grapes	0.186	11.83	5
TCP	Grapes	0.103 (single)	21.36	5
		0.1973 (multiple)	11.15	5
TCP	OSR	0.069	31.88	5
TCP	Pome fruit	0.275	8.00	5
TCP	Potato	0.165	13.33	5
TCP	Solanaceous	0.258	8.53	5
TCP	Soybean	0.155	14.19	5
TCP	Stone fruit	0.312	7.05	5
TCP	Strawberry	0.206	10.68	5

Table 2.9.9.5-3 TER$_{LT}$ calculation for earthworms for the metabolite TMP

Compound	Crop	Pec plateau	TER	Trigger
TMP	Citrus	0.053	11.98	5
TMP	Maize	0.14	4.54[1]	5
TMP	Cotton	0.056	11.34	5
TMP	Table grapes	0.05	12.70	5
TMP	Grapes	0.0281 (single)	22.60	5
		0.0558 (multiple)	11.38	5
TMP	OSR	0.019	33.42	5
TMP	Pome fruit	0.075	8.47	5
TMP	Potato	0.045	14.11	5
TMP	Solanaceous	0.07	9.07	5
TMP	Soybean	0.042	15.12	5
TMP	Stone fruit	0.085	7.47	5
TMP	Strawberry	0.056	11.34	5

[1] It is noted the risk assessment for TMP have been performed by considering that TMP 10x of higher toxicity than the parent compound. **However, taking into account the experimental end point of 21.43 mg/kg soil, TER values for this metabolite are above the trigger value of 5. (21.43/0.14=153)**

Table 2.9.9.5-4 TER$_{LT}$ calculation for earthworms for the metabolite DCP

Compound	Crop	PEC$_{soil,max}$ [mg/kg]	TER	Trigger
DCP	Citrus*	0.129	9.69	5
DCP	Maize	**0.338**	3.70	5
DCP	Cotton	0.136	9.19	5
DCP	Table grapes	0.122	10.25	5
DCP	Grapes	0.068 (single)	18.38	5
		0.0964 (multiple)	12.97	5
DCP	OSR	0.045	27.78	5
DCP	Pome fruit	0.18	6.94	5
DCP	Potato	0.108	11.57	5
DCP	Solanaceous	0.169	7.40	5
DCP	Soybean	0.101	12.38	5
DCP	Stone fruit	0.204	6.13	5
DCP	Strawberry	0.135	9.26	5

Risk is identified for the metabolites TCP and DCP for the intended use in maize. Further refinement is required. Moreover, according to the E-fate section NMTCP is a relevant metabolite for the risk assessment and **further toxicity information is needed to address the risk of NMTCP** on earthworms.

With respect to other soil meso- and macrofauna TER calculations for the parent compound and its metabolites are as follows:

Table 2.9.9.5-5: TER calculations for non-target soil meso- and macrofauna (other than earthworms).

Compound	Test organism	Endpoint	[mg p.m./kg soil]	PEC_{soil} [mg/kg soil]	TER_{LT}
Chlorpyrifos-methyl	*Folsomia candida*	$NOEC_{corr}$	0.025	0.9	**0.028**
TCP	*Folsomia candida*	NOEC	50	0.516	96.9
TMP	*Folsomia candida*	$NOEC_{corr}$	0.0025*	0.140	**0.018**
DCP	*Folsomia candida*	NOEC	0.005*	0.338	**0.015**
Chlorpyrifos-methyl	*Hyposaspis aculeifer*	$NOEC_{corr}$	1.6	0.9	**1.78**
TCP	*Hyposaspis aculeifer*	NOEC	50	0.516	96.9
TMP	*Hyposaspis aculeifer*	$NOEC_{corr}$	0.16*	0.140	**1.14**
DCP	*Hyposaspis aculeifer*	NOEC	0.32*	0.338	**0.95**

*Endpoint derived from the parent compound (10x more toxic)

As a conservative assumption is assumed that TMP and DCP have a NOEC 10x lower than the active substance. No PECs values are available for NMTCP and hence no TER calculations could be performed.

TERlt values below the trigger of 5 is identified for the parent compound and the metabolites TMP and DCP in both *Folsomia candida* and *Hypoaspis aculeifer*.

No unaceptable risk can be concluded for the metabolited TCP.

Further refinement is required.

Three field studies have been presented to address the risk identified. In the studies 10.4.2.2/1 and 2 chlorpyrifos was used as toxic reference in order to evaluate the effects of other active substance in soil organisms.

The results of the **study CP 10.4.2.2/01** indicates that recovery in two consecutive sampling days was not observed for all collembolan groups (Brachystomellidae). Moreover, similar results were observed in the **study CP 10.4.2.2/2 ;** recovery was not found in two consecutive sampling times in any of the soil core, litter bag or pitfall traps samples (except for coleoptera in pitfall traps and collembolan and Entomobryoidea in litter bag samples). Furthermore, the following uncertainties are identified in both studies :

- CPF was used as a toxic reference and not the main substance investigated in the field experiment.
- No residues of CPF were measured in the treated soils. According to EU regulation 283/2013 higher tier studies shall be supported by chemical analysis to verify exposure has ocurred at an appropriate level.

The conclusions of the third study (**CP 10.4.2.2-3; CPF specific field study in cider apple orchards**) are the following:

Soil-surface active arthropods (monitored by pitfall trapping):

For the pitfall trapping data, the PRC analysis revealed that 6 soil arthropod taxa were not favoured by the conventional farming system: Katiannidae, Orchesellinae, Tomoceridae, Sminthuridae, Dicyrtomyidae, and Uropodina. Only the collembolan family Hypogastruridae was favoured by the conventional farming system. For the other 13 taxa no clear response was detected (i.e. the conventional and organic orchards were similar). **The data provide an indication that the chlorpyrifos application had a detrimental effect on the soil arthropods (eg. collembolan family Katiannidae).**

Euedaphic arthropods (monitored by soil cores which were heat-extracted)

For the soil core data, the PRC analysis revealed that 7 soil arthropod taxa were not favoured by the conventional farming system: Katiannidae, Uropodina, Entomobryidae, Isotomidae, Neelidae, Mesostigmata and Sminthurididae. For the other 11 taxa no clear response was detected (i.e. the conventional and organic orchards were similar).

Moreover, the following uncertainty is identified:

- CPF is aplied to apple cider orchards. Some uncertainties are identified in extrapolating the results to other crops at lower BBCH with no interception (eg. Solanaceus vegetables at BBCH 11 or maize at BBCH 12).

Based on the above information (no recovery in two consecutive samplings in many taxa), and the uncertainties identified, safe use for soil meso and macrofauna (other than earthworms) cannot be concluded for the use of CPF-M according to the GAP.

2.9.9.7.2. FORMULATED PRODUCT: SAP200CHLORI

The potential long-term risk of SAP200CLORI to earthworms was assessed by calculating long-term TER (TERLT) values by comparing the NOEC values and the maximum instantaneous PECs.

Table 2.9.9.4.2-1. Toxicity/exposure ratios for earthworms and other soil non-target macro-organisms (Values below the trigger are marked in bold)

Compound	Endpoint [mg/kg soil]		PEC_{soil} [mg/kg soil]	TER_{LT}
Chlorpyrifos-methyl	$NOEC_{corr}$	6.3	0.272	23.16
TCP	NOEC	2.2	0.156	14.10
TMP	$NOEC_{corr}$	21.43	0.042	510.24
DCP	NOEC	1.25	0.102	12.25
NMTCP	$NOEC_{corr}$	12.5	0.178	70.22

No unacceptable risk to earthworm can be concluded for the use of CPF-M according to the GAP. Moreover, no unacceptable risk can be concluded for the metabolites TCP, TMP, DCP and NMTCP.
~~According to the E-fate section NMTCP is a relevante metabolite for risk assessment. With respect to the metabolite NMTCP, further toxicity information is needed to address the risk assessment~~

With respect- other soil meso- and macro-fauna TER calculations were as follows:

Table 2.9.9.4.2-2. Toxicity/exposure ratios for soil non-target meso- and macrofauna other than earthworms

Compound	Test organism	Endpoint	[mg,/kg soil]	PEC_{soil} [mg/kg soil]	TER_{LT}
SAP224 I	*Folsomia candida*	$NOEC_{corr}$ as mg a.s/kg	0.0392	0.272	0.144
TCP	*Folsomia candida*	NOEC	16	0.156	102.564
TMP	*Folsomia candida*	NOEC	0.00392	0.042	0.093
DCP	*Folsomia candida*	NOEC	0.00784	0.102	0.077
SAP224 I	*Hyposaspis aculeifer*	$NOEC_{corr}$	1.25	0.272	4.596
TCP	*Hyposaspis aculeifer*	NOEC	64	0.156	410.256
TMP	*Hyposaspis aculeifer*	NOEC	0.125	0.042	2.976

Compound	Test organism	Endpoint	[mg,/kg soil]	PEC_{soil}	TER_{LT}
DCP	*Hyposaspis aculeifer*	NOEC	0.25	0.102	2.451
Chlorpyrifos 99%	*Hyposaspis aculeifer*	NOEC	1.6	0.272	5.882

According to the Tier I risk assessment, risk is identified for CPF-M in *Folsomia candida* and *Hypoaspis aculeifer*. Moreover, risk was also identified for the metabolites TMP and DCP in both species.

In order to adress the risk identified, an aged residues study with the formulated product SAP 224I (224 g/L) on *Folsomia candida* (CP 10.4.2.1/03) was submitted. The following results could be concluded:

- Twenty four weeks after application (Bioassay 5), the rate of SAP224I used at 0.36L/ha had not significant remaining effect on *F.candida* mortality and reproduction compared with the control. The corrected mortality (9.43%) and the reduction of reproduction (21.83%) were below 50% compared with the control treatment group. Thirty two weeks after application (Bioassay 6), 0.9L/ha and 1.35L/ha of SAP224I always had a significant remaining effect (superior to 50% compared with the control treatment group) on *F.candida* mortality and reproduction compared with the control.

However, the following uncertainties should be taken into account:

- The experiment was performed with the formulated product SAP224I. It is not the representative formulation submitted in the dossier. Data on the equivalence of both formulated product (SAP224I and SAP200CHLORI) should be submitted in order to use the studies performed with SAP224I for the risk assessment of SAP200CHLORI.
- The validity criteria in bioassays 2 and 3 are not met.
- It is noted that once the corrected mortality or the corrected reproduction was below 50 % at one dose level, no more measurements were made in the subsequent days. RMS is of the opinion that measurements along all the experimental period are useful to conclude full recovery.
- According to the applicant *SAP200CLORI should be applied at 1.7 kg pf/ha, taking into account the crop interceptions (75% in grapes and 40% in OSR), the dose reaching soil surface is estimated to be 0.425 L/ha and 1.02L/ha, respectively. These doses are equivalent to the tested rates 0.36 L/ha in grapes and 0.9 L/ha in OSR, in the aged residues study with SAP224I*. Doses in the study are slighly below the expected doses of SAP200CHLORI. The study do not represent a worst-case situation and do not cover the worst case GAP.

No aged residues data are provided for *Hypoaspis aculeifer*. As solicited by the applicant SAPEC during the consultation period on the working document and since no studies with chlorpyrifos-methyl are available, the publication submitted by DAS, performed with the active substance chlorpyrifos, Owojori et al. 2014. Environmental Toxicology and Chemistry, Vol 33, No. 1, pp 230-237 (Vol. 3 AS, Point 9.4.2/01), with the endpoint for *Hypoaspis aculeifer* **$NOEC_{corr}$ = 1.6 mg chlorpyrifos/kg soil,** was accepted for the refined risk assessment of this species as chlorpyrifos can be used as surrogate due to similar toxicological properties of both molecules and degradation to the same metabolites. It has to be noted that his study is an open publication but was not provided by SAPEC for the assessment of the risk of chlorpyrifos-methyl in *Hypoaspis aculeifer* in the first instance.

However, even though that study was accepted for the risk assessment and no unacceptable risk to *H. aculeifer* can be concluded after the consideration of this endpoint with chlorpyrifos 99% (See table 2.9.9.4.2-2), the test was not specifically designed to evaluate the effects of chlorpyrifos-methyl in the predatory mite and was not performed under GLP. Thus, according to the previous evaluation of this study, the RMS considers necessary a more detailed description of the results including the presentation of the EC10 or EC20 values to verify the validity of the NOEC.

On the other hand, a higher tier study with the formulated product Chlorpyrifos-ethyl 5G was performed to determine the effect of a field application on populations of collembolans, soil mites and earthworms (KCP 10.4.2.2). Chlorpyrifos 5 G is a granulated formulation containing chlorpyrifos. Residues in soil were measured at 7, 28, 56, 112 and 280 DAA. Initial measured residues (0 DAA) and more intermediate sampling points (e.g. 2, 4, 10, 14, 21 DAA) would have been helpful to establish residues decline. Furthermore, effects were measured at day 7 and 28. Higher effect were observed in *Folsomia candida* at day 28with respect the effects observed at 7 DAT. Intermediate measures (day 14 and 21) would have clarify the effects observed.

2.9.9.7.3. OVERALL CONCLUSION FOR SOIL MESO AND MACRO FAUNA

CP-1684: Acceptable risk could be concluded for **earthworms** for all intended uses except for maize, where a risk is identified for the metabolites TCP and DCP. **Further refinement is required for this supported use.** Moreover according to the E-fate section NMTCP is a relevante metabolite. **Therefore, risk assessment should be performed for this metabolite.**

With the information provided for **non-target meso and macrofauna (other than earthworms)** safe use cannot be concluded for the use of CPF-M according to the GAP.

SAP200CHLORI: No unacceptable risk to **earthworm** can be concluded for the use of SAP200CHLORI according to the GAP. Moreover, no unacceptable risk can be concluded for the metabolites TCP, TMP, DCP and NMTCP.

Safe use can only be concluded for the metabolite TCP to **soil meso- and macrofauna (other than earthworms)**. However, no safe use can be concluded for any of the other metabolites nor for the parent compound.

2.9.9.8. Summary of product exposure and risk assessment on soil nitrogen transformation

The risk assessment of chlorpyrifos methyl and it s metabolites have been conducted according to the SANCO Terrestrial Ecotoxicology Guidance document (SANCO/10329/2002 rev 2 final) and the agreed PECsoil derived in the E-fate section see point 2.8.6 for details.

The risk assessment for the supported uses of GF 1684 and SAP200CHLORI are summarised in the sections below.

2.9.9.8.1. FORMULATED PRODUCT: GF-1684

A laboratory study showed that soil treated with Reldan 22 at 0.5 and 5 kg a.s/ha and assuming distribution within a 5 cm soil profile will reduce microbial respiration and nitrogen transformation, however recovery is observed after 62 days at 0.5 kg as/ha (equivalent to 0.67 mg a.s/kg soil). In a second study, soil was treated with 1.05 and 5.25 kg as/ha (equivalent to 1.40 and 7.07 mg as/kg soil, respectively). The study showed that soil respiration and nitrogen transformation rate did not deviate significantly from untreated soil (less than 25% deviation from control) within 28 days at both doses. It seems that the formulated product is of higher toxicity than the active substance.
Therefore, the endpoint of the formulated product (in terms of acrtive substance) have been used in the risk assessment.

Table 2.9.9.5.1-1 Risk assessment for soil micro-organisms following the proposed uses of GF-1684

Test	Substance	Endpoint (mg/kg dry soil)	PEC_{soil} (mg/kg dry soil)	Acceptable (< 25% effect after 100 days)?
Nitrogen mineralisation	Chlorpyrifos-methyl	0,67	0.900	No
	TCP	1.6	0,516	Yes
	TMP	2,03	0,14	Yes
	3,6-DCP*	0,067	0,338	No

*Endpoint derived from the parent compound (10 x more toxic)

Rik sis identified for CPF-methyl and the metabolite DCP (10x more toxic than the parent) by using the worst-case PECs. Therefore, risk assessment has been performed by considering all intended uses:

Table 2.9.9.5.1-2: Risk assessment of CPF-M for soil micro-organisms following the proposed uses of GF-1684

Test	Substance	Endpoint	PECsoil	Acceptable (< 25% effect

		(mg/kg dry soil)	(mg/kg dry soil)	after 100 days)?
Citrus	Chlorpyrifos-methyl	0,67	0.343	Yes
Maize	Chlorpyrifos-methyl	0,67	0.900	No
Cotton	Chlorpyrifos-methyl	0,67	0.363	Yes
Table grapes	Chlorpyrifos-methyl	0,67	0.324	Yes
Grapes	Chlorpyrifos-methyl	0,67	0.180 (single)	Yes
	Chlorpyrifos-methyl	0,67	0.1823 (multiple)	Yes
OSR	Chlorpyrifos-methyl	0,67	0.120	Yes
Pome fruit	Chlorpyrifos-methyl	0,67	0.480	Yes
Potato	Chlorpyrifos-methyl	0,67	0.288	Yes
Solanaceous	Chlorpyrifos-methyl	0,67	0.450	Yes
Soybean	Chlorpyrifos-methyl	0,67	0.270	Yes
Stone fruit	Chlorpyrifos-methyl	0,67	0.544	Yes
Strawberry	Chlorpyrifos-methyl	0,67	0.360	Yes

No unaceptable risk is identified for the use of GF-1684 in citrus, cotton, grapes, OSR, Pomme fruit, Potato, Solanaceous, Soybean, Stone fruit and Strawberry accroding to the GAP. **However, Further refinement is requiered for the intended use in maize.**

A study with the metabolites TCP and TMP have been presented. TCP shows higher toxicity for soil microorganisms than the parent compound. However, < 25 % effect was observed at 3.53 kg as/ha (equivalent to 4.15 mg as/kg soil after 100 days, which covers the worst-case GAP. For TMP, <25% effect after 28 days at 2.075 mg/kg soil were observed. For both metabolites no unacceptable risk could be concluded.

No studies have been presented for the metabolites DCP and NMTCP, and both are considered as relevant in soil.

In case of the metabolite if DCP is considered to be 10x more toxic than the parent safe use is identified for the only for the intended use in grapes and OSR. For the rest of the intended urther refinement is required.

Table 2.9.9.5.1-2: Risk assessment of the metabolite DCP for soil micro-organisms following the proposed uses of GF-1684

Test	Substance	Endpoint*	PECsoil	Acceptable (< 25% effect after 100 days)?
		(mg/kg dry soil)	(mg/kg dry soil)	
Citrus	DCP	0,067	0.129	No
Maize	DCP	0,067	0.338	No
Cotton	DCP	0,067	0.136	No
Table grapes	DCP	0,067	0.122	No
Grapes	DCP	0,067	0.068 (single)	Yes
	DCP	0,067	0.0964 (multiple)	No
OSR	DCP	0,067	0.045	Yes
Pome fruit	DCP	0,067	0.180	No
Potato	DCP	0,067	0.108	No
Solanaceous	DCP	0,067	0.169	No

Soybean	DCP	0,067	0.101	No
Stone fruit	DCP	0,067	0.204	No
Strawberry	DCP	0,067	0.135	No

*Endpoint derived from the parent compound (10 x more toxic)

2.9.9.8.2. FORMULATED PRODUCT: SAP200CHLORI

Table 2.9.9.8-1 Risk assessment for soil micro-organisms following the proposed uses of GF-1684

Test	Substance	Endpoint	PEC_{soil}	Acceptable (< 25% effect after 100 days)?
		(mg/kg dry soil)	(mg/kg dry soil)	
Nitrogen mineralisation	Chlorpyrifos-methyl	0.67	0.272	Yes
	TCP	1.66	0.156	Yes
	TMP	2.03	0.042	Yes

A laboratory study showed that soil treated with CPF-M at 1.34 and 6.75 mg a.s/kg soil showed effects < 25 % after 28 days. Moreover, a study with the formulated product Reldan 22, which is not the representative formulation of the dossier, showed < 25 % of effect after 62 days at 0.67 mg as/kg soil. Therefore, it could be concluded that CPF-m have no unaceptable effect in soil micro-organisms.
A study with the metabolites TCP and TMP have been presented. TCP shows < 25 % effect at 3.53 kg as/ha (equivalent to 4.15 mg as/kg soil after 100 days, which covers the worst-case GAP). For TMP, <25% effect after 28 days at 2.03 mg/kg soil were observed. The risk assessment in table above is based on the critical end point For both metabolites no unacceptable risk for soil microorganisms is concluded. No studies have been presented for the metabolites DCP and NMTCP . Nevertheless, the risk of DCP can be considered neglegible considering it 10x more toxic than parent compound

2.9.9.8.3. OVERALL CONCLUSION ON THE RISK ASSESSMENT OF SOIL MICRO-ORGANISMS.

Formulated product: GF-1684: No unaceptable risk is identified for the use of GF-1684 in citrus, cotton, grapes, OSR, Pomme fruit, Potato, Solanaceous, Soybean, Stone fruit and Strawberry accroding to the GAP.

However, further refinement is requiered for the intended use in maize. Moreover, risk was also identified for the metabolite DCP in Citrus, Maize, Cotton, Pome fruit, Potato, Solanaceous, Soybean, Stone fruit and Strawberry.

Formulated product: SAP200CHLORI: No unacceptable risk can be concluded for the use of SAP200CHLORI according to the GAP. **More information is needed for metabolite NMTCP.**

2.9.9.9. Summary of product exposure and risk assessment on non-target terrestrial plants

2.9.9.9.1. FORMULATED PRODUCT: GF-1684

The predicted exposure rates (PERs) for the proposed uses of GF-1684 have been calculated according to the current terrestrial guidance document (SANCO/10329/2002) and are summarised in Table 2.9.9.6.1-1.

Table 2.9.9.6.1-1 : Predicted exposure rates (PERs) for non-target terrestrial plants following the proposed uses of GF-1684

Group	Crop	Maximum application rate (g a.s./ha)	Distance from field margin (m)	Drift (%) for single application[1]		Predicted exposure rate (PER; g a.s./ha)[2]	
				Early growth stage	Late growth stage	Early growth stage	Late growth stage
Field crop	Corn/Maize	900	1	2.77	n.a.	*25*	n.a.
	Cotton	680	1	2.77	n.a.	*19*	n.a.
	Oilseed rape	450	1	2.77	n.a.	*12*	n.a.
	Potato	540	1	2.77	n.a.	*15*	n.a.
	Strawberry (SZ)	506	1	2.77	n.a.	*14*	n.a.
	Strawberry (CZ)	540	1	4.44[3]	n.a.	*24*	n.a.
	Soybean	450	1	2.77	n.a.	*12*	n.a.
Fruit crop	Pome fruit	900	3	29.2	15.73	*263*	142
	Stone fruit	1020	3	29.2	15.73	*298*	160
	Citrus	1800[#]	3	29.2	15.73	*526*	283
Grape vine	Grapes (wine)	676	3	2.7	8.02	18	*54*
	Grapes (table)	608	3	2.7	8.02	16	*49*
Vegetables, ornamentals, small fruits	Tomato, pepper, eggplant	675	1	2.77	n.a.	*19*	n.a.
		675	3	n.a.	8.02	n.a.	*54*

[1]: Taken from Section 7.2 of SANCO/10329/2002
[2]: PER = (drift %/100) * maximum application rate
[3]: Drift rate of 4.44% applies to field crop water application rate >900 L/ha (Section 7.2 of SANCO/10329/2002)
[#]The maximum application rate proposed for citrus was reduced at a late stage during dossier production. As such, the application rate for citrus used in the risk assessment (1800 g a.s./ha) is higher than that proposed for the representative use of GF-1684 (1283 g a.s./ha). For information, the PEC values for the lower application rate of 1283 g a.s./ha would be a factor of 0.71 lower (1283/1800=0.71) than those used in the current risk assessment. The risk assessment presented here for citrus is therefore conservative.
NB. Predicted exposure rates (PERs) in **bold** are used in the risk assessment

The risk assessment based on these PER values is shows below

Table 2.9.9.6.1-2 : Risk assessment for potential exposure of non-target terrestrial plants via spray drift following the proposed uses of GF-1684

Group	Crop	Worst-case PER (g a.s./ha)	ER_{50} (g a.s./ha)	TER	Trigger
Field crop	Corn/Maize	25	>2250	>90	5
	Cotton	19	>2250	>118	
	Oilseed rape	12	>2250	>187	
	Potato	15	>2250	>150	
	Strawberry (SZ)	14	>2250	>160	
	Strawberry (CZ)	24	>2250	>93	
	Soybean	12	>2250	>187	
Fruit crop	Pome fruit	263	>2250	>8.5	
	Stone fruit	298	>2250	>7.5	
	Citrus	526	>2250	>4.2	
Grape vine	Grapes (wine)	54	>2250	>41	
	Grapes (table)	49	>2250	>45	
Vegetables, ornamentals, small fruits	Tomato, pepper, eggplant	54	>2250	>41	

The TER values for non-target terrestrial plants potentially exposed to GF-1684 *via* spray drift are all above the trigger of 5 with the exception of the proposed use on early-stage citrus. It is noted that the TER for use on late-stage citrus would be above the trigger of 5, with a TER of >7.9, and therefore it is only early-stage citrus that requires further discussion.

The toxicity endpoints for effects on vegetative vigour and seedling emergence of non-target terrestrial plants are both >2250 g a.s./ha. In both cases, the ER_{50} was above the highest application rate tested of 2250 g a.s./ha, with the true ER_{50} value likely to be much higher given that GF-1684 is an insecticidal formulation and therefore unlikely to have significant effects on plants. As such, the TER of >4.2 calculated for use on early-stage citrus is considered to be an artefact of the application rates tested in the toxicity studies and the true TER is likely to be much higher, and thus above the trigger of 5. Therefore acceptable risks from all proposed uses of GF-1684 are concluded for non-target terrestrial plants and no further assessment is required.

2.9.9.9.1. FORMULATED PRODUCT: SAP200CHLORI

Considering the lowest toxicity figure (EC50 > 1008 g as/ha) and the predicted exposure rate, the TER value is as follows:

Table 2.9.9.6.1 TER values for non target plants

Crop	Appl. Rate (g as/ha)	Distance	Drift (%)	PER (g as/ha)	Toxicity (g as/ha)	TER
Grapes	340	3 m	8.02	30	1008	34
OSR	340	1 m	2.77	10	1008	101

bold letters: below Annex VI trigger of 5 (TER_{LT})

Based on the lowest toxicity values that cause injuries to agronomically important, the TER obtained for the maximum rate of chlorpyrifos-methyl for a distance of 3 m in grapes and 1 m for oil seed rape, is above the trigger value of 5. It is concluded that there is acceptable risk to terrestrial non-target plants on adjacent areas from the use of SAP200CLORI.

In the light of all the above mentioned, the risk to non-target plants is considered low. Therefore, no test or risk assessment is considered necessary.

2.10. Classification and Labelling

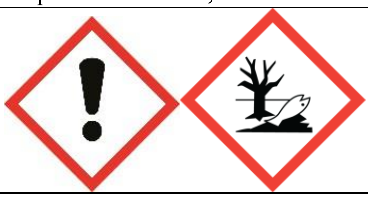
Proposed classification according to Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification [1)]	Reason for no classification [2)]
2.1.	Explosives				
2.2.	Flammable gases				
2.3.	Flammable aerosols				
2.4.	Oxidising gases				
2.5.	Gases under pressure				
2.6.	Flammable liquids				
2.7.	Flammable solids				
2.8.	Self-reactive substances and mixtures				
2.9.	Pyrophoric liquids				
2.10.	Pyrophoric solids				
2.11.	Self-heating substances and mixtures				
2.12.	Substances and mixtures which in contact with water emit flammable gases				
2.13.	Oxidising liquids				
2.14.	Oxidising solids				
2.15.	Organic peroxides				
2.16.	Substance and mixtures corrosive to metals				
3.1.	Acute toxicity - oral				Conclusive but not sufficient for classification
	Acute toxicity - dermal				Conclusive but not sufficient for classification
	Acute toxicity - inhalation				Conclusive but not sufficient for classification
3.2.	Skin corrosion / irritation				Conclusive but not sufficient for classification
3.3.	Serious eye damage / eye irritation				Conclusive but not sufficient for classification
3.4.	Respiratory sensitisation				Data lacking
3.4.	Skin sensitisation	H 317		R43	
3.5.	Germ cell mutagenicity	-	-	-	Conclusive but not sufficient for classification
3.6.	Carcinogenicity		-	-	Conclusive but not

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification [1)]	Reason for no classification [2)]
					sufficient for classification
3.7.	Reproductive toxicity	-	-		Conclusive but not sufficient for classification
3.8.	Specific target organ toxicity –single exposure	-	-		Conclusive but not sufficient for classification
3.9.	Specific target organ toxicity – repeated exposure	-	-	-	Conclusive but not sufficient for classification
3.10.	Aspiration hazard				
4.1.	Hazardous to the aquatic environment	Aquatic Acute 1, Aquatic Chronic 1	Macute = 1000; Mchronic= 10000	Aquatic Acute 1 Aquatic Chronic 1	0,0001 < EC50 <= 0,001mg/l 0,000001 < NOEC <= 0,00001mg/l and not ready biodegradable
5.1.	Hazardous to the ozone layer	None			

[1)] Including specific concentration limits (SCLs) and M-factors
[2)] Data lacking, inconclusive, or conclusive but not sufficient for classification

Proposed labelling according to Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures

Hazard Category	Skin sens. 1 Aquatic Acute 1, Aquatic Chronic 1,
GHS Pictogram:	
Signal Word:	Warning
Hazard Statement:	H317: May cause an allergic skin reaction H410: Very toxic to aquatic life with long lasting effects
Supplemental Hazard Information:	EUH401: To avoid risks to human health and the environment, comply with the instructions for use
Precautionary Statement: Prevention	P280: Wear protective gloves/protective clothing/eye protection/face protection P261: Avoid breathing fumes/vapours P270: Do not eat, drink or smoke when using this product. P272: contaminated work clothing should not be allowed out of the workplace P273: Avoid release to the environment.

Precautionary Statement Response	P302+352: IF ON SKIN wash with plenty of soap and water P333+P313: If skin irritation or rush occured Get medical advice/attet P321: Specific treatment (see … on the label). P363: Wash contamined clothing before reuse P391: Collect spillage.
Precautionary Statement Storage	P405: Store locked up.
Precautionary Statement Disposal	P501: Dispose of contents/container in accordance with local/national/international regulations.

2.11. Relevance of metabolites in groundwater

No metabolites of the active substance exceeding 0.1 μg/L are identified in groundwater. Thus, a toxicological hazard and risk assessment of metabolites in groundwater is not relevant.

2.12. Consideration of isomeric composition in the risk assessment

None

2.13. Residue definitions

2.13.1. Definition of residues for exposure/risk assessment

Food of plant origin: Chlorpyrifos-methyl plus TCP and its conjugates, expressed as chlorpyrifos-methyl.

Food of animal origin: Chlorpyrifos-methyl plus TCP and its conjugates, expressed as chlorpyrifos-methyl.

Soil: Chlorpyrifos-methyl, TCP, TMP, DCP, N-methyl TCP

Surface water: Chlorpyrifos-methyl, Desmethyl chlorpyrifos-methyl, TCP, TMP, DCP, N-methyl TCP

Sediment: Chlorpyrifos-methyl, Desmethyl chlorpyrifos-methyl, TCP, TMP, DCP, N-methyl TCP

Ground water: Chlorpyrifos-methyl, TCP, TMP, DCP, N-methyl TCP

Air: Chlorpyrifos-methyl, TCP, Chlopyrifos-methyl oxon

2.13.1. Definition of residues for monitoring

Food of plant origin: Chlorpyrifos-methyl

Food of animal origin: Chlorpyrifos-methyl

Soil: Chlorpyrifos-methyl.

Surface water: Chlorpyrifos-methyl,

Sediment: Chlorpyrifos-methyl,

Ground water: Chlorpyrifos-methyl,

Drinking water: Chlorpyrifos-methyl,

Air: Chlorpyrifos-methyl

Field tests

Only one field study was presented to assess the risk of chlorpyrifos-methyl on bees. This study was conducted in different apple orchards in UK treated with chlorpyrifos (EF 1551 -480 g chlorpyrifos/L-) monitoring pollinators activity in different scenarios (crops, weeds, field margins…). Comparisons between the treated and the control plots were made outside the apple blossom time. There were great differences in the abundance of flower-visiting insect species between the different orchards. Thus, no clear conclusions can be stated on the adverse effects of chlorpyrifos on pollinator populations.

Risk assessment for:

FORMULATED PRODUCT: GF-1684

Citrus (EU South) at 1x 1285 g a.s./ha

Test substance	Risk quotient	scenario	BBCH	Honeybee (Apis mellifera)	
				ETR	trigger
GF-1684	HQcontact	treated crop	10 - 19	0.0	85
		treated crop	20 - 39	0.0	85
		treated crop	≥ 40	0.0	85
		weeds	10 - 19	6945.9	42
		weeds	20 - 39	5209.5	42
		weeds	≥ 40	2604.7	42
		field margin	10 - 19	1363.1	42
		field margin	20 - 39	1363.1	42
		field margin	≥ 40	1363.1	42
	ETRacute adult oral	treated crop	10 - 19	76.95	0.2
		treated crop	20 - 39	76.95	0.2
		treated crop	40 - 69	76.95	0.2
		treated crop	≥ 70	0.00	0.2
		weeds	10 - 19	21.49	0.2
		weeds	20 - 39	16.12	0.2
		weeds	40 - 69	8.06	0.2
		weeds	≥ 70	8.06	0.2
		field margin	10 - 19	1.40	0.2
		field margin	20 - 39	1.40	0.2
		field margin	40 - 69	1.40	0.2
		field margin	≥ 70	1.40	0.2
		adjacent crop	10 - 19	1.71	0.2
		adjacent crop	20 - 39	1.71	0.2
		adjacent crop	40 - 69	1.71	0.2
		adjacent crop	≥ 70	1.71	0.2
		next crop	10 - 19	5.08	0.2
		next crop	20 - 39	5.08	0.2
		next crop	40 - 69	5.08	0.2
		next crop	≥ 70	5.08	0.2
	ETRchronic adult oral	treated crop	10 - 19	1083.81	0.03
		treated crop	20 - 39	1083.81	0.03
		treated crop	40 - 69	1083.81	0.03
		treated crop	≥ 70	0.00	0.03
		weeds	10 - 19	306.64	0.03
		weeds	20 - 39	229.98	0.03
		weeds	40 - 69	114.99	0.03
		weeds	≥ 70	114.99	0.03
		field margin	10 - 19	19.93	0.03
		field margin	20 - 39	19.93	0.03
		field margin	40 - 69	19.93	0.03
		field margin	≥ 70	19.93	0.03
		adjacent crop	10 - 19	23.76	0.03
		adjacent crop	20 - 39	23.76	0.03
		adjacent crop	40 - 69	23.76	0.03
		adjacent crop	≥ 70	23.76	0.03
		next crop	10 - 19	71.37	0.03
		next crop	20 - 39	71.37	0.03
		next crop	40 - 69	71.37	0.03
		next crop	≥ 70	71.37	0.03
	ETRlarvae	treated crop	10 - 19	83.28	0.2

Test substance	Risk quotient	scenario	BBCH	Honeybee (Apis mellifera)	
				ETR	**trigger**
		treated crop	20 - 39	83.28	0.2
		treated crop	40 - 69	83.28	0.2
		treated crop	≥ 70	0.00	0.2
		weeds	10 - 19	24.03	0.2
		weeds	20 - 39	18.02	0.2
		weeds	40 - 69	9.01	0.2
		weeds	≥ 70	9.01	0.2
		field margin	10 - 19	1.56	0.2
		field margin	20 - 39	1.56	0.2
		field margin	40 - 69	1.56	0.2
		field margin	≥ 70	1.56	0.2
		adjacent crop	10 - 19	1.86	0.2
		adjacent crop	20 - 39	1.86	0.2
		adjacent crop	40 - 69	1.86	0.2
		adjacent crop	≥ 70	1.86	0.2
		next crop	10 - 19	5.46	0.2
		next crop	20 - 39	5.46	0.2
		next crop	40 - 69	5.46	0.2
		next crop	≥ 70	5.46	0.2
	ETRhpg	treated crop	10 - 19	170.75	1
		treated crop	20 - 39	170.75	1
		treated crop	40 - 69	170.75	1
		treated crop	≥ 70	0.00	1
		weeds	10 - 19	66.71	1
		weeds	20 - 39	50.03	1
		weeds	40 - 69	25.02	1
		weeds	≥ 70	25.02	1
		field margin	10 - 19	4.34	1
		field margin	20 - 39	4.34	1
		field margin	40 - 69	4.34	1
		field margin	≥ 70	4.34	1
		adjacent crop	10 - 19	4.68	1
		adjacent crop	20 - 39	4.68	1
		adjacent crop	40 - 69	4.68	1
		adjacent crop	≥ 70	4.68	1
		next crop	10 - 19	11.52	1
		next crop	20 - 39	11.52	1
		next crop	40 - 69	11.52	1
		next crop	≥ 70	11.52	1

Corn/Maize (EU South) at 1x 900 g a.s./ha

Test substance	Risk quotient	scenario	BBCH	Honeybee (Apis mellifera)	
				ETR	**trigger**
GF-1684	HQcontact	treated crop	< 30	0.0	42
		treated crop	30 - 39	0.0	42
		treated crop	≥ 40	0.0	42
		weeds	< 30	6081.1	42
		weeds	30 - 39	3040.5	42
		weeds	≥ 40	1520.3	42
		field margin	< 30	170.3	42
		field margin	30 - 39	170.3	42
		field margin	≥ 40	170.3	42
	ETRacute adult oral	treated crop	10 - 29	4.68	0.2
		treated crop	30 - 39	4.68	0.2

Test substance	**Risk quotient**	**scenario**	**BBCH**	**Honeybee (Apis mellifera)**	
				ETR	**trigger**
		treated crop	40 - 69	4.68	0.2
		weeds	10 - 29	18.81	0.2
		weeds	30 - 39	9.41	0.2
		weeds	40 - 69	4.70	0.2
		field margin	10 - 29	0.17	0.2
		field margin	30 - 39	0.17	0.2
		field margin	40 - 69	0.17	0.2
		adjacent crop	10 - 29	0.13	0.2
		adjacent crop	30 - 39	0.13	0.2
		adjacent crop	40 - 69	0.13	0.2
		next crop	10 - 29	3.56	0.2
		next crop	30 - 39	3.56	0.2
		next crop	40 - 69	3.56	0.2
	ETRchronic adult oral	treated crop	10 - 29	85.17	0.03
		treated crop	30 - 39	85.17	0.03
		treated crop	40 - 69	85.17	0.03
		weeds	10 - 29	268.46	0.03
		weeds	30 - 39	134.23	0.03
		weeds	40 - 69	67.11	0.03
		field margin	10 - 29	2.47	0.03
		field margin	30 - 39	2.47	0.03
		field margin	40 - 69	2.47	0.03
		adjacent crop	10 - 29	1.77	0.03
		adjacent crop	30 - 39	1.77	0.03
		adjacent crop	40 - 69	1.77	0.03
		next crop	10 - 29	49.99	0.03
		next crop	30 - 39	49.99	0.03
		next crop	40 - 69	49.99	0.03
	ETRlarvae	treated crop	10 - 29	1.43	0.2
		treated crop	30 - 39	1.43	0.2
		treated crop	40 - 69	1.43	0.2
		weeds	10 - 29	21.04	0.2
		weeds	30 - 39	10.52	0.2
		weeds	40 - 69	5.26	0.2
		field margin	10 - 29	0.19	0.2
		field margin	30 - 39	0.19	0.2
		field margin	40 - 69	0.19	0.2
		adjacent crop	10 - 29	0.14	0.2
		adjacent crop	30 - 39	0.14	0.2
		adjacent crop	40 - 69	0.14	0.2
		next crop	10 - 29	3.83	0.2
		next crop	30 - 39	3.83	0.2
		next crop	40 - 69	3.83	0.2
	ETRhpg	treated crop	10 - 29	25.59	1
		treated crop	30 - 39	25.59	1
		treated crop	40 - 69	25.59	1
		weeds	10 - 29	58.40	1
		weeds	30 - 39	29.20	1
		weeds	40 - 69	14.60	1
		field margin	10 - 29	0.54	1
		field margin	30 - 39	0.54	1
		field margin	40 - 69	0.54	1
		adjacent crop	10 - 29	0.35	1
		adjacent crop	30 - 39	0.35	1
		adjacent crop	40 - 69	0.35	1
		next crop	10 - 29	8.07	1

Test substance	Risk quotient	scenario	BBCH	Honeybee (Apis mellifera)	
				ETR	trigger
		next crop	30 - 39	8.07	1
		next crop	40 - 69	8.07	1

Cotton (EU South) at 1x 680 g a.s./ha

Test substance	Risk quotient	scenario	BBCH	Honeybee (Apis mellifera)	
				ETR	trigger
GF-1684	HQcontact	treated crop	< 50	0.0	42
		treated crop	≥ 50	0.0	42
		weeds	< 50	4594.6	42
		weeds	≥ 50	1148.6	42
		field margin	< 50	128.6	42
		field margin	≥ 50	128.6	42
	ETRacute adult oral	treated crop	≥ 70	0.00	0.2
		treated crop	10 - 49	29.20	0.2
		treated crop	50 - 69	29.20	0.2
		weeds	≥ 70	3.55	0.2
		weeds	10 - 49	14.21	0.2
		weeds	50 - 69	3.55	0.2
		field margin	≥ 70	0.13	0.2
		field margin	10 - 49	0.13	0.2
		field margin	50 - 69	0.13	0.2
		adjacent crop	≥ 70	0.10	0.2
		adjacent crop	10 - 49	0.10	0.2
		adjacent crop	50 - 69	0.10	0.2
		next crop	≥ 70	2.69	0.2
		next crop	10 - 49	2.69	0.2
		next crop	50 - 69	2.69	0.2
	ETRchronic adult oral	treated crop	≥ 70	0.00	0.03
		treated crop	10 - 49	405.67	0.03
		treated crop	50 - 69	405.67	0.03
		weeds	≥ 70	50.71	0.03
		weeds	10 - 49	202.83	0.03
		weeds	50 - 69	50.71	0.03
		field margin	≥ 70	1.87	0.03
		field margin	10 - 49	1.87	0.03
		field margin	50 - 69	1.87	0.03
		adjacent crop	≥ 70	1.34	0.03
		adjacent crop	10 - 49	1.34	0.03
		adjacent crop	50 - 69	1.34	0.03
		next crop	≥ 70	37.77	0.03
		next crop	10 - 49	37.77	0.03
		next crop	50 - 69	37.77	0.03
	ETRlarvae	treated crop	≥ 70	0.00	0.2
		treated crop	10 - 49	31.79	0.2
		treated crop	50 - 69	31.79	0.2
		weeds	≥ 70	3.97	0.2
		weeds	10 - 49	15.90	0.2
		weeds	50 - 69	3.97	0.2
		field margin	≥ 70	0.15	0.2
		field margin	10 - 49	0.15	0.2
		field margin	50 - 69	0.15	0.2
		adjacent crop	≥ 70	0.10	0.2
		adjacent crop	10 - 49	0.10	0.2
		adjacent crop	50 - 69	0.10	0.2

Test substance	Risk quotient	scenario	BBCH	Honeybee (Apis mellifera)	
				ETR	trigger
		next crop	≥ 70	2.89	0.2
		next crop	10 - 49	2.89	0.2
		next crop	50 - 69	2.89	0.2
	ETRhpg	treated crop	≥ 70	0.00	1
		treated crop	10 - 49	79.85	1
		treated crop	50 - 69	79.85	1
		weeds	≥ 70	11.03	1
		weeds	10 - 49	44.13	1
		weeds	50 - 69	11.03	1
		field margin	≥ 70	0.41	1
		field margin	10 - 49	0.41	1
		field margin	50 - 69	0.41	1
		adjacent crop	≥ 70	0.26	1
		adjacent crop	10 - 49	0.26	1
		adjacent crop	50 - 69	0.26	1
		next crop	≥ 70	6.09	1
		next crop	10 - 49	6.09	1
		next crop	50 - 69	6.09	1

Grapes (EU South and Central) at 2x 338 g a.s./ha

Test substance	Risk quotient	scenario	BBCH	Honeybee (Apis mellifera)	
				ETR	trigger
GF-1684	HQcontact	treated crop	10 - 19	0.0	85
		treated crop	20 - 39	0.0	85
		treated crop	≥ 40	0.0	85
		weeds	10 - 19	2740.5	42
		weeds	20 - 39	2283.8	42
		weeds	≥ 40	1370.3	42
		field margin	10 - 19	123.3	42
		field margin	20 - 39	365.4	42
		field margin	≥ 40	365.4	42
	ETRacute adult oral	treated crop	10 - 19	40.48	0.2
		treated crop	20 - 39	40.48	0.2
		treated crop	40 - 69	40.48	0.2
		treated crop	≥ 70	0.00	0.2
		weeds	10 - 19	8.48	0.2
		weeds	20 - 39	7.07	0.2
		weeds	40 - 69	4.24	0.2
		weeds	≥ 70	4.24	0.2
		field margin	10 - 19	0.13	0.2
		field margin	20 - 39	0.38	0.2
		field margin	40 - 69	0.38	0.2
		field margin	≥ 70	0.38	0.2
		adjacent crop	10 - 19	0.14	0.2
		adjacent crop	20 - 39	0.42	0.2
		adjacent crop	40 - 69	0.42	0.2
		adjacent crop	≥ 70	0.42	0.2
		next crop	10 - 19	2.67	0.2
		next crop	20 - 39	2.67	0.2
		next crop	40 - 69	2.67	0.2
		next crop	≥ 70	2.67	0.2
	ETRchronic adult oral	treated crop	10 - 19	570.16	0.03
		treated crop	20 - 39	570.16	0.03
		treated crop	40 - 69	570.16	0.03

Test substance	Risk quotient	scenario	BBCH	Honeybee (Apis mellifera)	
				ETR	trigger
		treated crop	≥ 70	0.00	0.03
		weeds	10 - 19	120.98	0.03
		weeds	20 - 39	100.82	0.03
		weeds	40 - 69	60.49	0.03
		weeds	≥ 70	60.49	0.03
		field margin	10 - 19	1.81	0.03
		field margin	20 - 39	5.44	0.03
		field margin	40 - 69	5.44	0.03
		field margin	≥ 70	5.44	0.03
		adjacent crop	10 - 19	1.90	0.03
		adjacent crop	20 - 39	5.77	0.03
		adjacent crop	40 - 69	5.77	0.03
		adjacent crop	≥ 70	5.77	0.03
		next crop	10 - 19	37.55	0.03
		next crop	20 - 39	37.55	0.03
		next crop	40 - 69	37.55	0.03
		next crop	≥ 70	37.55	0.03
	ETRlarvae	treated crop	10 - 19	43.81	0.2
		treated crop	20 - 39	43.81	0.2
		treated crop	40 - 69	43.81	0.2
		treated crop	≥ 70	0.00	0.2
		weeds	10 - 19	9.48	0.2
		weeds	20 - 39	7.90	0.2
		weeds	40 - 69	4.74	0.2
		weeds	≥ 70	4.74	0.2
		field margin	10 - 19	0.14	0.2
		field margin	20 - 39	0.43	0.2
		field margin	40 - 69	0.43	0.2
		field margin	≥ 70	0.43	0.2
		adjacent crop	10 - 19	0.15	0.2
		adjacent crop	20 - 39	0.15	0.2
		adjacent crop	40 - 69	0.45	0.2
		adjacent crop	≥ 70	0.45	0.2
		next crop	10 - 19	2.87	0.2
		next crop	20 - 39	2.87	0.2
		next crop	40 - 69	2.87	0.2
		next crop	≥ 70	2.87	0.2
	ETRhpg	treated crop	10 - 19	89.82	1
		treated crop	20 - 39	89.82	1
		treated crop	40 - 69	89.82	1
		treated crop	≥ 70	0.00	1
		weeds	10 - 19	26.32	1
		weeds	20 - 39	21.93	1
		weeds	40 - 69	13.16	1
		weeds	≥ 70	13.16	1
		field margin	10 - 19	0.39	1
		field margin	20 - 39	1.18	1
		field margin	40 - 69	1.18	1
		field margin	≥ 70	1.18	1
		adjacent crop	10 - 19	0.37	1
		adjacent crop	20 - 39	1.14	1
		adjacent crop	40 - 69	1.14	1
		adjacent crop	≥ 70	1.14	1
		next crop	10 - 19	6.06	1
		next crop	20 - 39	6.06	1
		next crop	40 - 69	6.06	1

Test substance	Risk quotient	scenario	BBCH	Honeybee (Apis mellifera)	
				ETR	**trigger**
		next crop	≥ 70	6.06	1

Oilseed rape (EU South and Central) at 1x 450 g a.s./ha

Test substance	Risk quotient	scenario	BBCH	Honeybee (Apis mellifera)	
				ETR	**trigger**
GF-1684	HQcontact	treated crop	30 - 39	0.0	42
		treated crop	≥ 40	0.0	42
		weeds	30 - 39	912.2	42
		weeds	≥ 40	760.1	42
		field margin	30 - 39	85.1	42
		field margin	≥ 40	85.1	42
	ETRacute adult oral	treated crop	30 - 39	19.32	0.2
		treated crop	40 - 69	19.32	0.2
		weeds	30 - 39	2.82	0.2
		weeds	40 - 69	2.35	0.2
		field margin	30 - 39	0.09	0.2
		field margin	40 - 69	0.09	0.2
		adjacent crop	30 - 39	0.06	0.2
		adjacent crop	40 - 69	0.06	0.2
		next crop	30 - 39	1.78	0.2
		next crop	40 - 69	1.78	0.2
	ETRchronic adult oral	treated crop	30 - 39	268.46	0.03
		treated crop	40 - 69	268.46	0.03
		weeds	30 - 39	40.27	0.03
		weeds	40 - 69	33.56	0.03
		field margin	30 - 39	1.23	0.03
		field margin	40 - 69	1.23	0.03
		adjacent crop	30 - 39	0.89	0.03
		adjacent crop	40 - 69	0.89	0.03
		next crop	30 - 39	24.99	0.03
		next crop	40 - 69	24.99	0.03
	ETRlarvae	treated crop	30 - 39	21.04	0.2
		treated crop	40 - 69	21.04	0.2
		weeds	30 - 39	3.16	0.2
		weeds	40 - 69	2.63	0.2
		field margin	30 - 39	0.10	0.2
		field margin	40 - 69	0.10	0.2
		adjacent crop	30 - 39	0.07	0.2
		adjacent crop	40 - 69	0.07	0.2
		next crop	30 - 39	1.91	0.2
		next crop	40 - 69	1.91	0.2
	ETRhpg	treated crop	30 - 39	52.84	1
		treated crop	40 - 69	52.84	1
		weeds	30 - 39	8.76	1
		weeds	40 - 69	7.30	1
		field margin	30 - 39	0.27	1
		field margin	40 - 69	0.27	1
		adjacent crop	30 - 39	0.17	1
		adjacent crop	40 - 69	0.17	1
		next crop	30 - 39	4.03	1
		next crop	40 - 69	4.03	1

Pome fruit (EU South and Central) at 1x 900 g a.s./ha

Test substance	Risk quotient	scenario	BBCH	Honeybee (Apis mellifera)	
				ETR	trigger
GF-1684	HQcontact	treated crop	10 - 19	0.0	85
		treated crop	20 - 39	0.0	85
		treated crop	≥ 40	0.0	85
		weeds	10 - 19	4864.9	42
		weeds	20 - 39	3648.6	42
		weeds	≥ 40	1824.3	42
		field margin	10 - 19	954.7	42
		field margin	20 - 39	954.7	42
		field margin	≥ 40	954.7	42
	ETRacute adult oral	treated crop	10 - 19	53.90	0.2
		treated crop	20 - 39	53.90	0.2
		treated crop	40 - 69	53.90	0.2
		treated crop	≥ 70	0.00	0.2
		weeds	10 - 19	15.05	0.2
		weeds	20 - 39	11.29	0.2
		weeds	40 - 69	5.64	0.2
		weeds	≥ 70	5.64	0.2
		field margin	10 - 19	0.98	0.2
		field margin	20 - 39	0.98	0.2
		field margin	40 - 69	0.98	0.2
		field margin	≥ 70	0.98	0.2
		adjacent crop	10 - 19	1.20	0.2
		adjacent crop	20 - 39	1.20	0.2
		adjacent crop	40 - 69	1.20	0.2
		adjacent crop	≥ 70	1.20	0.2
		next crop	10 - 19	3.56	0.2
		next crop	20 - 39	3.56	0.2
		next crop	40 - 69	3.56	0.2
		next crop	≥ 70	3.56	0.2
	ETRchronic adult oral	treated crop	10 - 19	759.09	0.03
		treated crop	20 - 39	759.09	0.03
		treated crop	40 - 69	759.09	0.03
		treated crop	≥ 70	0.00	0.03
		weeds	10 - 19	214.77	0.03
		weeds	20 - 39	161.07	0.03
		weeds	40 - 69	80.54	0.03
		weeds	≥ 70	80.54	0.03
		field margin	10 - 19	13.96	0.03
		field margin	20 - 39	13.96	0.03
		field margin	40 - 69	13.96	0.03
		field margin	≥ 70	13.96	0.03
		adjacent crop	10 - 19	16.64	0.03
		adjacent crop	20 - 39	16.64	0.03
		adjacent crop	40 - 69	16.64	0.03
		adjacent crop	≥ 70	16.64	0.03
		next crop	10 - 19	49.99	0.03
		next crop	20 - 39	49.99	0.03
		next crop	40 - 69	49.99	0.03
		next crop	≥ 70	49.99	0.03
	ETRlarvae	treated crop	10 - 19	58.33	0.2
		treated crop	20 - 39	58.33	0.2
		treated crop	40 - 69	58.33	0.2
		treated crop	≥ 70	0.00	0.2
		weeds	10 - 19	16.83	0.2

Test substance	**Risk quotient**	**scenario**	**BBCH**	**Honeybee (Apis mellifera)**	
				ETR	**trigger**
		weeds	20 - 39	12.62	0.2
		weeds	40 - 69	6.31	0.2
		weeds	≥ 70	6.31	0.2
		field margin	10 - 19	1.09	0.2
		field margin	20 - 39	1.09	0.2
		field margin	40 - 69	1.09	0.2
		field margin	≥ 70	1.09	0.2
		adjacent crop	10 - 19	1.30	0.2
		adjacent crop	20 - 39	1.30	0.2
		adjacent crop	40 - 69	1.30	0.2
		adjacent crop	≥ 70	1.30	0.2
		next crop	10 - 19	3.83	0.2
		next crop	20 - 39	3.83	0.2
		next crop	40 - 69	3.83	0.2
		next crop	≥ 70	3.83	0.2
	ETRhpg	treated crop	10 - 19	119.59	1
		treated crop	20 - 39	119.59	1
		treated crop	40 - 69	119.59	1
		treated crop	≥ 70	0.00	1
		weeds	10 - 19	46.72	1
		weeds	20 - 39	35.04	1
		weeds	40 - 69	17.52	1
		weeds	≥ 70	17.52	1
		field margin	10 - 19	3.04	1
		field margin	20 - 39	3.04	1
		field margin	40 - 69	3.04	1
		field margin	≥ 70	3.04	1
		adjacent crop	10 - 19	3.28	1
		adjacent crop	20 - 39	3.28	1
		adjacent crop	40 - 69	3.28	1
		adjacent crop	≥ 70	3.28	1
		next crop	10 - 19	8.07	1
		next crop	20 - 39	8.07	1
		next crop	40 - 69	8.07	1
		next crop	≥ 70	8.07	1

Stone fruits (EU South and Central) at 1x 1020 g a.s./ha

Test substance	**Risk quotient**	**scenario**	**BBCH**	**Honeybee (Apis mellifera)**	
				ETR	**trigger**
GF-1684	HQcontact	treated crop	10 - 19	0.0	85
		treated crop	20 - 39	0.0	85
		treated crop	≥ 40	0.0	85
		weeds	10 - 19	5513.5	42
		weeds	20 - 39	4135.1	42
		weeds	≥ 40	2067.6	42
		field margin	10 - 19	1082.0	42
		field margin	20 - 39	1082.0	42
		field margin	≥ 40	1082.0	42
	ETRacute adult oral	treated crop	10 - 19	61.08	0.2
		treated crop	20 - 39	61.08	0.2
		treated crop	40 - 69	61.08	0.2
		treated crop	≥ 70	0.00	0.2
		weeds	10 - 19	17.06	0.2
		weeds	20 - 39	12.79	0.2

Test substance	Risk quotient	scenario	BBCH	Honeybee (Apis mellifera)	
				ETR	trigger
		weeds	40 - 69	6.40	0.2
		weeds	≥ 70	6.40	0.2
		field margin	10 - 19	1.11	0.2
		field margin	20 - 39	1.11	0.2
		field margin	40 - 69	1.11	0.2
		field margin	≥ 70	1.11	0.2
		adjacent crop	10 - 19	1.36	0.2
		adjacent crop	20 - 39	1.36	0.2
		adjacent crop	40 - 69	1.36	0.2
		adjacent crop	≥ 70	1.36	0.2
		next crop	10 - 19	4.03	0.2
		next crop	20 - 39	4.03	0.2
		next crop	40 - 69	4.03	0.2
		next crop	≥ 70	4.03	0.2
	ETRchronic adult oral	treated crop	10 - 19	860.30	0.03
		treated crop	20 - 39	860.30	0.03
		treated crop	40 - 69	860.30	0.03
		treated crop	≥ 70	0.00	0.03
		weeds	10 - 19	243.40	0.03
		weeds	20 - 39	182.55	0.03
		weeds	40 - 69	91.28	0.03
		weeds	≥ 70	91.28	0.03
		field margin	10 - 19	15.82	0.03
		field margin	20 - 39	15.82	0.03
		field margin	40 - 69	15.82	0.03
		field margin	≥ 70	15.82	0.03
		adjacent crop	10 - 19	18.86	0.03
		adjacent crop	20 - 39	18.86	0.03
		adjacent crop	40 - 69	18.86	0.03
		adjacent crop	≥ 70	18.86	0.03
		next crop	10 - 19	56.65	0.03
		next crop	20 - 39	56.65	0.03
		next crop	40 - 69	56.65	0.03
		next crop	≥ 70	56.65	0.03
	ETRlarvae	treated crop	10 - 19	66.11	0.2
		treated crop	20 - 39	66.11	0.2
		treated crop	40 - 69	66.11	0.2
		treated crop	≥ 70	0.00	0.2
		weeds	10 - 19	19.07	0.2
		weeds	20 - 39	14.31	0.2
		weeds	40 - 69	7.15	0.2
		weeds	≥ 70	7.15	0.2
		field margin	10 - 19	1.24	0.2
		field margin	20 - 39	1.24	0.2
		field margin	40 - 69	1.24	0.2
		field margin	≥ 70	1.24	0.2
		adjacent crop	10 - 19	1.48	0.2
		adjacent crop	20 - 39	1.48	0.2
		adjacent crop	40 - 69	1.48	0.2
		adjacent crop	≥ 70	1.48	0.2
		next crop	10 - 19	4.34	0.2
		next crop	20 - 39	4.34	0.2
		next crop	40 - 69	4.34	0.2
		next crop	≥ 70	4.34	0.2
	ETRhpg	treated crop	10 - 19	135.53	1
		treated crop	20 - 39	135.53	1

Test substance	Risk quotient	scenario	BBCH	Honeybee (Apis mellifera)	
				ETR	trigger
		treated crop	40 - 69	135.53	1
		treated crop	≥ 70	0.00	1
		weeds	10 - 19	52.95	1
		weeds	20 - 39	39.71	1
		weeds	40 - 69	19.86	1
		weeds	≥ 70	19.86	1
		field margin	10 - 19	3.44	1
		field margin	20 - 39	3.44	1
		field margin	40 - 69	3.44	1
		field margin	≥ 70	3.44	1
		adjacent crop	10 - 19	3.71	1
		adjacent crop	20 - 39	3.71	1
		adjacent crop	40 - 69	3.71	1
		adjacent crop	≥ 70	3.71	1
		next crop	10 - 19	9.14	1
		next crop	20 - 39	9.14	1
		next crop	40 - 69	9.14	1
		next crop	≥ 70	9.14	1

Potato (EU South and Central) at 1x 540 g a.s./ha

Test substance	Risk quotient	scenario	BBCH	Honeybee (Apis mellifera)	
				ETR	trigger
GF-1684	HQcontact	treated crop	< 40	0.0	42
		treated crop	≥ 40	0.0	42
		weeds	< 40	3648.6	42
		weeds	≥ 40	1094.6	42
		field margin	< 40	102.2	42
		field margin	≥ 40	102.2	42
	ETRacute adult oral	treated crop	10 - 39	2.81	0.2
		treated crop	40 - 69	2.81	0.2
		weeds	10 - 39	11.29	0.2
		weeds	40 - 69	3.39	0.2
		field margin	10 - 39	0.10	0.2
		field margin	40 - 69	0.10	0.2
		adjacent crop	10 - 39	0.08	0.2
		adjacent crop	40 - 69	0.08	0.2
		next crop	10 - 39	2.14	0.2
		next crop	40 - 69	2.14	0.2
	ETRchronic adult oral	treated crop	10 - 39	51.10	0.03
		treated crop	40 - 69	51.10	0.03
		weeds	10 - 39	161.07	0.03
		weeds	40 - 69	48.32	0.03
		field margin	10 - 39	1.48	0.03
		field margin	40 - 69	1.48	0.03
		adjacent crop	10 - 39	1.06	0.03
		adjacent crop	40 - 69	1.06	0.03
		next crop	10 - 39	29.99	0.03
		next crop	40 - 69	29.99	0.03
	ETRlarvae	treated crop	10 - 39	0.86	0.2
		treated crop	40 - 69	0.86	0.2
		weeds	10 - 39	12.62	0.2
		weeds	40 - 69	3.79	0.2
		field margin	10 - 39	0.12	0.2
		field margin	40 - 69	0.12	0.2

Test substance	Risk quotient	scenario	BBCH	Honeybee (Apis mellifera)	
				ETR	trigger
		adjacent crop	10 - 39	0.08	0.2
		adjacent crop	40 - 69	0.08	0.2
		next crop	10 - 39	2.30	0.2
		next crop	40 - 69	2.30	0.2
	ETRhpg	treated crop	10 - 39	15.35	1
		treated crop	40 - 69	15.35	1
		weeds	10 - 39	35.04	1
		weeds	40 - 69	10.51	1
		field margin	10 - 39	0.32	1
		field margin	40 - 69	0.32	1
		adjacent crop	10 - 39	0.21	1
		adjacent crop	40 - 69	0.21	1
		next crop	10 - 39	4.84	1
		next crop	40 - 69	4.84	1

Solanaceous vegetables (EU South and Central) at 1x 675 g a.s./ha

Test substance	Risk quotient	scenario	BBCH	Honeybee (Apis mellifera)	
				ETR	trigger
GF-1684	HQcontact	treated crop	< 50	0.0	42
		treated crop	≥ 50	0.0	42
		weeds	< 50	4560.8	42
		weeds	≥ 50	1368.2	42
		field margin	< 50	127.7	42
		field margin	≥ 50	127.7	42
	ETRacute adult oral	treated crop	10 - 49	3.51	0.2
		treated crop	50 - 69	3.51	0.2
		treated crop	≥ 70	0.00	0.2
		weeds	10 - 49	14.11	0.2
		weeds	50 - 69	4.23	0.2
		weeds	≥ 70	4.23	0.2
		field margin	10 - 49	0.13	0.2
		field margin	50 - 69	0.13	0.2
		field margin	≥ 70	0.13	0.2
		adjacent crop	10 - 49	0.10	0.2
		adjacent crop	50 - 69	0.10	0.2
		adjacent crop	≥ 70	0.10	0.2
		next crop	10 - 49	2.67	0.2
		next crop	50 - 69	2.67	0.2
		next crop	≥ 70	2.67	0.2
	ETRchronic adult oral	treated crop	10 - 49	63.87	0.03
		treated crop	50 - 69	63.87	0.03
		treated crop	≥ 70	0.00	0.03
		weeds	10 - 49	201.34	0.03
		weeds	50 - 69	60.40	0.03
		weeds	≥ 70	60.40	0.03
		field margin	10 - 49	1.85	0.03
		field margin	50 - 69	1.85	0.03
		field margin	≥ 70	1.85	0.03
		adjacent crop	10 - 49	1.33	0.03
		adjacent crop	50 - 69	1.33	0.03
		adjacent crop	≥ 70	1.33	0.03
		next crop	10 - 49	37.49	0.03
		next crop	50 - 69	37.49	0.03
		next crop	≥ 70	37.49	0.03

Test substance	Risk quotient	scenario	BBCH	Honeybee (Apis mellifera)	
				ETR	**trigger**
	ETRlarvae	treated crop	10 - 49	1.08	0.2
		treated crop	50 - 69	1.08	0.2
		treated crop	≥ 70	0.00	0.2
		weeds	10 - 49	15.78	0.2
		weeds	50 - 69	4.73	0.2
		weeds	≥ 70	4.73	0.2
		field margin	10 - 49	0.15	0.2
		field margin	50 - 69	0.15	0.2
		field margin	≥ 70	0.15	0.2
		adjacent crop	10 - 49	0.10	0.2
		adjacent crop	50 - 69	0.10	0.2
		adjacent crop	≥ 70	0.10	0.2
		next crop	10 - 49	2.87	0.2
		next crop	50 - 69	2.87	0.2
		next crop	≥ 70	2.87	0.2
	ETRhpg	treated crop	10 - 49	19.19	1
		treated crop	50 - 69	19.19	1
		treated crop	≥ 70	0.00	1
		weeds	10 - 49	43.80	1
		weeds	50 - 69	13.14	1
		weeds	≥ 70	13.14	1
		field margin	10 - 49	0.40	1
		field margin	50 - 69	0.40	1
		field margin	≥ 70	0.40	1
		adjacent crop	10 - 49	0.26	1
		adjacent crop	50 - 69	0.26	1
		adjacent crop	≥ 70	0.26	1
		next crop	10 - 49	6.05	1
		next crop	50 - 69	6.05	1
		next crop	≥ 70	6.05	1

Soybean (EU South and Central) at 1x 450 g a.s./ha

Test substance	Risk quotient	scenario	BBCH	Honeybee (Apis mellifera)	
				ETR	**trigger**
GF-1684	HQcontact	treated crop	< 50	0.0	42
		treated crop	≥ 50	0.0	42
		weeds	< 50	3040.5	42
		weeds	≥ 50	912.2	42
		field margin	< 50	85.1	42
		field margin	≥ 50	85.1	42
	ETRacute adult oral	treated crop	10 - 49	19.32	0.2
		treated crop	50 - 69	19.32	0.2
		weeds	10 - 49	9.41	0.2
		weeds	50 - 69	2.82	0.2
		field margin	10 - 49	0.09	0.2
		field margin	50 - 69	0.09	0.2
		adjacent crop	10 - 49	0.06	0.2
		adjacent crop	50 - 69	0.06	0.2
		next crop	10 - 49	1.78	0.2
		next crop	50 - 69	1.78	0.2
	ETRchronic adult oral	treated crop	10 - 49	268.46	0.03
		treated crop	50 - 69	268.46	0.03
		weeds	10 - 49	134.23	0.03
		weeds	50 - 69	40.27	0.03

Test substance	Risk quotient	scenario	BBCH	Honeybee (Apis mellifera)	
				ETR	trigger
		field margin	10 - 49	1.23	0.03
		field margin	50 - 69	1.23	0.03
		adjacent crop	10 - 49	0.89	0.03
		adjacent crop	50 - 69	0.89	0.03
		next crop	10 - 49	24.99	0.03
		next crop	50 - 69	24.99	0.03
	ETRlarvae	treated crop	10 - 49	21.04	0.2
		treated crop	50 - 69	21.04	0.2
		weeds	10 - 49	10.52	0.2
		weeds	50 - 69	3.16	0.2
		field margin	10 - 49	0.10	0.2
		field margin	50 - 69	0.10	0.2
		adjacent crop	10 - 49	0.07	0.2
		adjacent crop	50 - 69	0.07	0.2
		next crop	10 - 49	1.91	0.2
		next crop	50 - 69	1.91	0.2
	ETRhpg	treated crop	10 - 49	52.84	1
		treated crop	50 - 69	52.84	1
		weeds	10 - 49	29.20	1
		weeds	50 - 69	8.76	1
		field margin	10 - 49	0.27	1
		field margin	50 - 69	0.27	1
		adjacent crop	10 - 49	0.17	1
		adjacent crop	50 - 69	0.17	1
		next crop	10 - 49	4.03	1
		next crop	50 - 69	4.03	1

Strawberry (EU Central) at 1x 540 g a.s./ha

Test substance	Risk quotient	scenario	BBCH	Honeybee (Apis mellifera)	
				ETR	trigger
GF-1684	HQcontact	treated crop	< 40	0.0	42
		treated crop	≥ 40	0.0	42
		weeds	< 40	3648.6	42
		weeds	≥ 40	1459.5	42
		field margin	< 40	102.2	42
		field margin	≥ 40	102.2	42
	ETRacute adult oral	treated crop	≥ 70	0.00	0.2
		treated crop	10 - 39	23.19	0.2
		treated crop	40 - 69	23.19	0.2
		weeds	≥ 70	4.52	0.2
		weeds	10 - 39	11.29	0.2
		weeds	40 - 69	4.52	0.2
		field margin	≥ 70	0.10	0.2
		field margin	10 - 39	0.10	0.2
		field margin	40 - 69	0.10	0.2
		adjacent crop	≥ 70	0.08	0.2
		adjacent crop	10 - 39	0.08	0.2
		adjacent crop	40 - 69	0.08	0.2
		next crop	≥ 70	2.14	0.2
		next crop	10 - 39	2.14	0.2
		next crop	40 - 69	2.14	0.2
	ETRchronic adult oral	treated crop	≥ 70	0.00	0.03
		treated crop	10 - 39	322.15	0.03
		treated crop	40 - 69	322.15	0.03

Test substance	**Risk quotient**	**scenario**	**BBCH**	**Honeybee (Apis mellifera)**	
				ETR	**trigger**
		weeds	≥ 70	64.43	0.03
		weeds	10 - 39	161.07	0.03
		weeds	40 - 69	64.43	0.03
		field margin	≥ 70	1.48	0.03
		field margin	10 - 39	1.48	0.03
		field margin	40 - 69	1.48	0.03
		adjacent crop	≥ 70	1.06	0.03
		adjacent crop	10 - 39	1.06	0.03
		adjacent crop	40 - 69	1.06	0.03
		next crop	≥ 70	29.99	0.03
		next crop	10 - 39	29.99	0.03
		next crop	40 - 69	29.99	0.03
	ETRlarvae	treated crop	≥ 70	0.00	0.2
		treated crop	10 - 39	25.25	0.2
		treated crop	40 - 69	25.25	0.2
		weeds	≥ 70	5.05	0.2
		weeds	10 - 39	12.62	0.2
		weeds	40 - 69	5.05	0.2
		field margin	≥ 70	0.12	0.2
		field margin	10 - 39	0.12	0.2
		field margin	40 - 69	0.12	0.2
		adjacent crop	≥ 70	0.08	0.2
		adjacent crop	10 - 39	0.08	0.2
		adjacent crop	40 - 69	0.08	0.2
		next crop	≥ 70	2.30	0.2
		next crop	10 - 39	2.30	0.2
		next crop	40 - 69	2.30	0.2
	ETRhpg	treated crop	≥ 70	0.00	1
		treated crop	10 - 39	63.41	1
		treated crop	40 - 69	63.41	1
		weeds	≥ 70	14.02	1
		weeds	10 - 39	35.04	1
		weeds	40 - 69	14.02	1
		field margin	≥ 70	0.32	1
		field margin	10 - 39	0.32	1
		field margin	40 - 69	0.32	1
		adjacent crop	≥ 70	0.21	1
		adjacent crop	10 - 39	0.21	1
		adjacent crop	40 - 69	0.21	1
		next crop	≥ 70	4.84	1
		next crop	10 - 39	4.84	1
		next crop	40 - 69	4.84	1

Ceral grain (EU South and Central) at 1x 5 mg/Kg grain

No data to conduct the risk assessment.

FORMULATED PRODUCT: SAP200CLORI

Grapes (EU South and Central) at 1x 340 g a.s./ha

Test substance	Risk quotient	scenario	BBCH	Honeybee (Apis mellifera)	
				ETR	trigger
SAP200CLORI	HQcontact	treated crop	≥ 40	0.0	85
		weeds	≥ 40	689.2	42
		field margin	≥ 40	183.8	42
	ETRacute adult oral	treated crop	≥ 70	0.00	0.2
		weeds	≥ 70	2.13	0.2
		field margin	≥ 70	0.19	0.2
		adjacent crop	≥ 70	0.21	0.2
		next crop	≥ 70	1.34	0.2
	ETRchronic adult oral	treated crop	≥ 70	0.00	0.03
		weeds	≥ 70	30.43	0.03
		field margin	≥ 70	2.74	0.03
		adjacent crop	≥ 70	2.90	0.03
		next crop	≥ 70	18.88	0.03
	ETRlarvae	treated crop	≥ 70	0.00	0.2
		weeds	≥ 70	2.38	0.2
		field margin	≥ 70	0.21	0.2
		adjacent crop	≥ 70	0.23	0.2
		next crop	≥ 70	1.45	0.2
	ETRhpg	treated crop	≥ 70	0.00	1
		weeds	≥ 70	6.62	1
		field margin	≥ 70	0.60	1
		adjacent crop	≥ 70	0.57	1
		next crop	≥ 70	3.05	1

Oilseed rape (EU South and Central) at 1x 340 g a.s./ha

Test substance	Risk quotient	scenario	BBCH	Honeybee (Apis mellifera)	
				ETR	trigger
SAP200CLORI	HQcontact	treated crop	< 30	0.0	42
		treated crop	30 - 39	0.0	42
		treated crop	≥ 40	0.0	42
		weeds	< 30	2297.3	42
		weeds	30 - 39	689.2	42
		weeds	≥ 40	574.3	42
		field margin	< 30	64.3	42
		field margin	30 - 39	64.3	42
		field margin	≥ 40	64.3	42
	ETRacute adult oral	treated crop	10 - 29	14.60	0.2
		treated crop	30 - 39	14.60	0.2
		treated crop	40 - 69	14.60	0.2
		weeds	10 - 29	7.11	0.2
		weeds	30 - 39	2.13	0.2
		weeds	40 - 69	1.78	0.2
		field margin	10 - 29	0.07	0.2
		field margin	30 - 39	0.07	0.2
		field margin	40 - 69	0.07	0.2
		adjacent crop	10 - 29	0.05	0.2
		adjacent crop	30 - 39	0.05	0.2

Test substance	Risk quotient	scenario	BBCH	Honeybee (Apis mellifera)	
				ETR	trigger
		adjacent crop	40 - 69	0.05	0.2
		next crop	10 - 29	1.34	0.2
		next crop	30 - 39	1.34	0.2
		next crop	40 - 69	1.34	0.2
	ETRchronic adult oral	treated crop	10 - 29	202.83	0.03
		treated crop	30 - 39	202.83	0.03
		treated crop	40 - 69	202.83	0.03
		weeds	10 - 29	101.42	0.03
		weeds	30 - 39	30.43	0.03
		weeds	40 - 69	25.35	0.03
		field margin	10 - 29	0.93	0.03
		field margin	30 - 39	0.93	0.03
		field margin	40 - 69	0.93	0.03
		adjacent crop	10 - 29	0.67	0.03
		adjacent crop	30 - 39	0.67	0.03
		adjacent crop	40 - 69	0.67	0.03
		next crop	10 - 29	18.88	0.03
		next crop	30 - 39	18.88	0.03
		next crop	40 - 69	18.88	0.03
	ETRlarvae	treated crop	10 - 29	15.90	0.2
		treated crop	30 - 39	15.90	0.2
		treated crop	40 - 69	15.90	0.2
		weeds	10 - 29	7.95	0.2
		weeds	30 - 39	2.38	0.2
		weeds	40 - 69	1.99	0.2
		field margin	10 - 29	0.07	0.2
		field margin	30 - 39	0.07	0.2
		field margin	40 - 69	0.07	0.2
		adjacent crop	10 - 29	0.05	0.2
		adjacent crop	30 - 39	0.05	0.2
		adjacent crop	40 - 69	0.05	0.2
		next crop	10 - 29	1.45	0.2
		next crop	30 - 39	1.45	0.2
		next crop	40 - 69	1.45	0.2
	ETRhpg	treated crop	10 - 29	39.92	1
		treated crop	30 - 39	39.92	1
		treated crop	40 - 69	39.92	1
		weeds	10 - 29	22.06	1
		weeds	30 - 39	6.62	1
		weeds	40 - 69	5.52	1
		field margin	10 - 29	0.20	1
		field margin	30 - 39	0.20	1
		field margin	40 - 69	0.20	1
		adjacent crop	10 - 29	0.13	1
		adjacent crop	30 - 39	0.13	1
		adjacent crop	40 - 69	0.13	1
		next crop	10 - 29	3.05	1
		next crop	30 - 39	3.05	1
		next crop	40 - 69	3.05	1

First tier for guttation (independent of the crop and application rate)

1st tier for guttation

	water cons. (µL)	ETR	Trigger	Risk indicator
acute	11.4	0.18	0.2	OK
chronic	11.4	2.410	0.03	!
larvae	111	2.74	0.2	!
HPG	11.4	0.7	1	OK

Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Toxicity
Typhlodromus pyri (Acari: Phytoseiidae)			
Aphidius colemani (Hymenoptera: Braconidae)			
Additional species			

First tier risk assessment for:

No data available to conduct the Tier I risk assessment.

Extended laboratory tests, aged residue tests

Species	**Life stage**	**Test substance, substrate**	**Time scale**	**Dose (g a.s./ha)1,2**	**End point**	**% effect3**
Extended laboratory tests						
Typhlodromus pyri (Acari: Phytoseiidae)	proto-nymphs	Reldan 22 EC, Initial residues on bean leaf disc	0 DAT	49.95 and 286.2	Mortality (7 DAT), Reproduction (7-14 DAT)	No effects
Typhlodromus pyri (Acari: Phytoseiidae)	proto-nymphs	GF 1684, Initial residues on bean leaf disc	0 DAT	25, 50, 100, 200, 400 and 800	Mortality (7 DAT)	LR50: 158.25 g a.s./ha
Aphidius rhopalosiphi (Hym.: Braconidae)	adults	Reldan 22 EC, Initial & aged	0, 7 DAT	49.95 and 286.2	Mortality (48 h), Reproduction (24 h)	0 DAT M: 100% (both doses) 7 DAT

Species	**Life stage**	**Test substance, substrate**	**Time scale**	**Dose (g a.s./ha)1,2**	**End point**	**% effect3**
Extended laboratory tests						
		residues on barley seedlings				M: < 3% (worst case) R: No effects
Aphidius rhopalosiphi (Hym.: Braconidae)	adults	GF 1684, Initial residues on barley seedlings	0 DAT	0.1, 0.2, 0.4, 0.8, 1.6 and 3.2	Mortality (48 h)	LR50: 0.56 g a.s./ha
Chrysoperla carnea (Neur.: Chrysopidae)	larvae	GF 1684, Initial residues on bean leaf	0 DAT	5, 10, 20, 40 and 80	Mortality (5 DAT)	LR50: 36.89 g a.s./ha
Aleochara bilineata (Col.: Staphylinidae)	adults	GF 1684, Initial & aged residues sprayed on soil	0, 7 DAT	0 DAT: 5, 10, 20, 40, 80 and 160 7 DAT: 100, 200, 300, 400, 500 and 600	Mortality (6 DAT)	0 DAT LR50: 139.84 g a.s./ha 7 DAT LR50: 244.75 g a.s./ha
Coccinella septempunctata (Col.: Coccinellidae)	adults	Reldan 50 EC, Initial & aged residues on wheat plants	0, 1, 2, 5, 9 and 13 DAT	120 and 480	Mortality (48 h)	120 g a.s./ha: 0 DAT M 9% 1 DAT M 3% 480 g a.s./ha: 0 DAT M 5% 1 DAT M 15% 2 DAT M 26% 5 DAT M 0%
Pardosa spp. (Araneae: Lycosidae)	n.e.	Reldan 50 EC, Initial & aged residues sprayed on soil	0, 2 DAT	120 and 480	Mortality (48 h)	120 g a.s./ha: 0 DAT M 0% 2 DAT M 0% 480 g a.s./ha: 0 DAT M 35% 2 DAT M 0%
Aphidius colemani (Hym.: Braconidae)	adults	Reldan 50 EC, Initial & aged residues on wheat leaf	0, 1, 3, 5, 8, 11 and 14 DAT	120 and 480	Mortality (24 h), Adult Emergence (8 DAT)	120 g a.s./ha: 0 DAT M 100% 1 DAT M 100% 3 DAT M 100% 5 DAT

Species	**Life stage**	**Test substance, substrate**	**Time scale**	**Dose (g a.s./ha)1,2**	**End point**	**% effect3**
Extended laboratory tests						
						M 68% 8 DAT M 6% 11 DAT M 2% AE 39% 480 g a.s./ha: 0 DAT M 100% 1 DAT M 100% 3 DAT M 100% 5 DAT M 100% 8 DAT M 48% 11 DAT M 10% 14 DAT M 4% AE 37%
Bembidion lampros (Col.: Carabidae)	adults	Reldan 50 EC, Initial & aged residues sprayed on soil	0, 2, 5 and 9 DAT	120 and 480	Mortality (48 h)	120 g a.s./ha: 0 DAT M 95% 2 DAT M 0% 5 DAT M 15% 480 g a.s./ha: 0 DAT M 100% 2 DAT M 70% 5 DAT M 65% 9 DAT M 90%
Typhlodromus pyri (Acari: Phytoseiidae)	proto-nymphs	SAP 200 CLORI, Aged residues on bean plants	1, 14 and 21 DAT	136.34, 550.56 and 700	Mortality (7 DAE) Reproduction (7-14 DAE)	1 DAT 136.34 g a.s./ha M: 18% R: 7.30% of reduction 550.56 g a.s./ha M: 20% R: 10.12% of reduction 700 g a.s./ha M: 31% R: 5.08% of reduction

Species	**Life stage**	**Test substance, substrate**	**Time scale**	**Dose (g a.s./ha)1,2**	**End point**	**% effect3**
Extended laboratory tests						
						14 DAT 136.34 g a.s./ha M: 17% R: 17.84% of reduction 550.56 g a.s./ha M: 19% R: 11.27% of reduction 700 g a.s./ha M: 15% R: -0.88% of reduction 21 DAT 136.34 g a.s./ha M: 19% R: -11.32% of reduction 550.56 g a.s./ha M: 18% R: 2.80% of reduction 700 g a.s./ha M: 17% R: 3.52% of reduction
Aphidius rhopalosiphi (Hym.: Braconidae)	adults	SAP 200 CLORI, Aged residues on bean plants	1, 14 and 21 DAT	47.1, 136.34, 340, 550.56 and 700	Mortality (48 h), Reproduction (24 h)	1 DAT M: 100% (all doses) 14 DAT 47.1 g a.s./ha M: 0% R: 14.87% of reduction 136.34 g a.s./ha M: 17.5% R: 28.02% of reduction 340 g a.s./ha M: 25% R: 26.37% of reduction 550.56 g a.s./ha M: 52.5% 700 g a.s./ha M: 62.5% 21 DAT 47.1 g a.s./ha M: 7.5% R: -1.52% of reduction 136.34 g a.s./ha M: 0%

Species	**Life stage**	**Test substance, substrate**	**Time scale**	**Dose (g a.s./ha)1,2**	**End point**	**% effect3**
Extended laboratory tests						
						R: 26.79% of reduction 340 g a.s./ha M: 0% R: 30.40% of reduction 550.56 g a.s./ha M: 10% R: 31.44% of reduction 700 g a.s./ha M: 7.5% R: 22.08% of reduction
Chrysoperla carnea (Neuroptera: Chrysopidae)	larvae	SAP 200 CLORI, Aged residues on bean plants	1, 14 and 21 DAT	27.26, 110.12 and 700	Mortality (22-23 DAE) Reproduction (24h)	1 DAT 27.26 g a.s./ha M: 40% R: -33.02% of reduction 110.12 g a.s./ha M: 53.33% R: -18.52% of reduction 700 g a.s./ha M: 80% 14 DAT 27.26 g a.s./ha M: 23.33% R: -15.04% of reduction 110.12 g a.s./ha M: 27.59% R: -4.88% of reduction 700 g a.s./ha M: 23.33% R: -8.94% of reduction 21 DAT 27.26 g a.s./ha M: 10% R: 9.54% of reduction 110.12 g a.s./ha M: 20% R: 5.13% of reduction 700 g a.s./ha M: 17.24% R: 2.20% of reduction
Coccinella septempunctata (Col.: Coccinellidae)	larvae	SAP 200 CLORI, Aged	1, 14 and 21 DAT	110.12, 550.56 and 700	Mortality (17-18 DAE) Reproduction	1 DAT 110.12 g a.s./ha M: 62.5%

Species	**Life stage**	**Test substance, substrate**	**Time scale**	**Dose (g a.s./ha)1,2**	**End point**	**% effect3**
Extended laboratory tests						
		residues on bean plants			(24h)	550.56 g a.s./ha M: 85% 700 g a.s./ha M: 85% 14 DAT 110.12 g a.s./ha M: 37.5% R: 22.02% of reduction 550.56 g a.s./ha M: 53.85% R: -82.57% of reduction 700 g a.s./ha M: 50% R: -5.50% of reduction 21 DAT 110.12 g a.s./ha M: 12.82% R: -72.60% of reduction 550.56 g a.s./ha M: 10% R: -8.22% of reduction 700 g a.s./ha M: 12.5% R: -105.48% of reduction

1 indicate whether initial or aged residues
2 for preparations indicate whether dose is expressed in units of a.s. or preparation
3 indicate if positive percentages relate to adverse effects or not

Risk assessment based on extended laboratory tests (with a correction factor CF = 5) for:

Citrus (EU South) at 1x 1285 g a.s./ha (3D)

Species	ER50 (g/ha)	In-field rate (g/ha)	Off-field rate1 (g/ha)
Typhlodromus pyri	158.25	1285	187.61
Aphidius rhopalosiphi	0.56	1285	1876.1
Chrysoperla carnea	36.89	1285	187.61
Aleochara bilineata	139.84	1285	1876.1

1 In accordance with ESCORT II, the distance assumed to calculate the off-field rate is 3 m (orchards). VDF = 10 for T. pyri and C. carnea; VDF = 1 for A. rhopalosiphi and A. bilineata.

Corn/Maize (EU South) at 1x 900 g a.s./ha (2D)

Species	ER50 (g/ha)	In-field rate (g/ha)	Off-field rate1 (g/ha)
Typhlodromus pyri	158.25	900	12.465
Aphidius rhopalosiphi	0.56	900	124.65
Chrysoperla carnea	36.89	900	12.465
Aleochara bilineata	139.84	900	124.65

1 In accordance with ESCORT II, the distance assumed to calculate the off-field rate is 1 m (arable crops). VDF = 10 for T. pyri and C. carnea; VDF = 1 for A. rhopalosiphi and A. bilineata.

Cotton (EU South) at 1x 680 g a.s./ha (2D)

Species	ER50 (g/ha)	In-field rate (g/ha)	Off-field rate1 (g/ha)
Typhlodromus pyri	158.25	680	9.42
Aphidius rhopalosiphi	0.56	680	94.18
Chrysoperla carnea	36.89	680	9.42
Aleochara bilineata	139.84	680	94.18

1 In accordance with ESCORT II, the distance assumed to calculate the off-field rate is 1 m (arable crops). VDF = 10 for T. pyri and C. carnea; VDF = 1 for A. rhopalosiphi and A. bilineata.

Grapevines (EU South and Central) at 2x 338 g a.s./ha (3D)

Species	ER50 (g/ha)	In-field rate2 (g/ha)	Off-field rate1 (g/ha)
Typhlodromus pyri	158.25	574.6	20.77
Aphidius rhopalosiphi	0.56	574.6	207.72
Chrysoperla carnea	36.89	574.6	20.77
Aleochara bilineata	139.84	574.6	207.72

1 In accordance with ESCORT II, the distance assumed to calculate the off-field rate is 3 m (vineyards). VDF = 10 for T. pyri and C. carnea; VDF = 1 for A. rhopalosiphi and A. bilineata.
2 MAF after 2 applications = 1.7

Grapevines (EU South and Central) at 1x 340 g a.s./ha (3D)

Species	ER50 (g/ha)	In-field rate (g/ha)	Off-field rate1 (g/ha)
Typhlodromus pyri	158.25	340	13.63
Aphidius rhopalosiphi	0.56	340	136.34
Chrysoperla carnea	36.89	340	13.63
Aleochara bilineata	139.84	340	136.34

1 In accordance with ESCORT II, the distance assumed to calculate the off-field rate is 3 m (vineyards). VDF = 10 for T. pyri and C. carnea; VDF = 1 for A. rhopalosiphi and A. bilineata.

Oilseed rape (EU South and Central) at 1x 450 g a.s./ha (2D)

Species	ER50 (g/ha)	In-field rate (g/ha)	Off-field rate1 (g/ha)
Typhlodromus pyri	158.25	450	6.23
Aphidius rhopalosiphi	0.56	450	62.32
Chrysoperla carnea	36.89	450	6.23
Aleochara bilineata	139.84	450	62.32

1 In accordance with ESCORT II, the distance assumed to calculate the off-field rate is 1 m (arable crops). VDF = 10 for T. pyri and C. carnea; VDF = 1 for A. rhopalosiphi and A. bilineata.

Oilseed rape (EU South and Central) at 1x 340 g a.s./ha (2D)

Species	ER50 (g/ha)	In-field rate (g/ha)	Off-field rate1 (g/ha)
Typhlodromus pyri	158.25	340	4.71
Aphidius rhopalosiphi	0.56	340	47.09
Chrysoperla carnea	36.89	340	4.71
Aleochara bilineata	139.84	340	47.09

1 In accordance with ESCORT II, the distance assumed to calculate the off-field rate is 1 m (arable crops). VDF = 10 for T. pyri and C. carnea; VDF = 1 for A. rhopalosiphi and A. bilineata.

Pome fruit (EU South and Central) at 1x 900 g a.s./ha (3D)

Species	ER50 (g/ha)	In-field rate (g/ha)	Off-field rate1 (g/ha)
Typhlodromus pyri	158.25	900	131.4
Aphidius rhopalosiphi	0.56	900	1314

Species	ER50 (g/ha)	In-field rate (g/ha)	Off-field rate1 (g/ha)
Chrysoperla carnea	36.89	900	131.4
Aleochara bilineata	139.84	900	1314

1 In accordance with ESCORT II, the distance assumed to calculate the off-field rate is 3 m (orchards). VDF = 10 for T. pyri and C. carnea; VDF = 1 for A. rhopalosiphi and A. bilineata.

Stone fruits (EU South and Central) at 1x 1020 g a.s./ha (3D)

Species	ER50 (g/ha)	In-field rate (g/ha)	Off-field rate1 (g/ha)
Typhlodromus pyri	158.25	1020	148.92
Aphidius rhopalosiphi	0.56	1020	1489.2
Chrysoperla carnea	36.89	1020	148.92
Aleochara bilineata	139.84	1020	1489.2

1 In accordance with ESCORT II, the distance assumed to calculate the off-field rate is 3 m (orchards). VDF = 10 for T. pyri and C. carnea; VDF = 1 for A. rhopalosiphi and A. bilineata.

Potato (EU South and Central) at 1x 540 g a.s./ha (2D)

Species	ER50 (g/ha)	In-field rate (g/ha)	Off-field rate1 (g/ha)
Typhlodromus pyri	158.25	540	7.48
Aphidius rhopalosiphi	0.56	540	74.79
Chrysoperla carnea	36.89	540	7.48
Aleochara bilineata	139.84	540	74.79

1 In accordance with ESCORT II, the distance assumed to calculate the off-field rate is 1 m (arable crops). VDF = 10 for T. pyri and C. carnea; VDF = 1 for A. rhopalosiphi and A. bilineata.

Solanaceous vegetables (EU South and Central) at 1x 675 g a.s./ha (2D)

Species	ER50 (g/ha)	In-field rate (g/ha)	Off-field rate1 (g/ha)
Typhlodromus pyri	158.25	675	9.35
Aphidius rhopalosiphi	0.56	675	93.49
Chrysoperla carnea	36.89	675	9.35
Aleochara bilineata	139.84	675	93.49

1 In accordance with ESCORT II, the distance assumed to calculate the off-field rate is 1 m (arable crops). VDF = 10 for T. pyri and C. carnea; VDF = 1 for A. rhopalosiphi and A. bilineata.

Soybean (EU South and Central) at 1x 450 g a.s./ha (2D)

Species	ER50 (g/ha)	In-field rate (g/ha)	Off-field rate1 (g/ha)
Typhlodromus pyri	158.25	450	6.23
Aphidius rhopalosiphi	0.56	450	62.32
Chrysoperla carnea	36.89	450	6.23
Aleochara bilineata	139.84	450	62.32

1 In accordance with ESCORT II, the distance assumed to calculate the off-field rate is 1 m (arable crops). VDF = 10 for T. pyri and C. carnea; VDF = 1 for A. rhopalosiphi and A. bilineata.

Strawberry (EU Central) at 1x 540 g a.s./ha (2D)

Species	ER50 (g/ha)	In-field rate (g/ha)	Off-field rate1 (g/ha)
Typhlodromus pyri	158.25	540	7.48
Aphidius rhopalosiphi	0.56	540	74.79
Chrysoperla carnea	36.89	540	7.48
Aleochara bilineata	139.84	540	74.79

1 In accordance with ESCORT II, the distance assumed to calculate the off-field rate is 1 m (arable crops). VDF = 10 for T. pyri and C. carnea; VDF = 1 for A. rhopalosiphi and A. bilineata.

Ceral grain (EU South and Central) at 1x 5 mg/Kg grain

No data to conduct the risk assessment.

Semi-field tests
Field studies

GF1684

Four NTAs field studies were accepted to assess the in-field and off-field arthropod populations and community recovery after different scenarios of chlorpyrifos-methyl or chlorpyrifos applications in several crops, among which there are no data to conduct the in-field risk assessment for the intended uses in corn/maize, cotton, grapevine, oilseed rape, potato, vegetables and strawberry.
For these remaining studies, as a general acceptability criterion for in-field effects, the potential for re-colonisation after a toxic effect should usually be demonstrated within one year. Where significant off-field effects are detected, the duration of effect and the range of taxa affected should also be taken into consideration. For off-crop risk assessment, no effect or only transient effects are considered acceptable (de Jong et al. 2010), and therefore measuring recovery is not applicable.

Pome (intended use at 1x 900 g a.s./ha) and Stone fruits (intended use at 1x 1020 g a.s./ha)

NW France: NTAs full arthropod fauna in-field and off-field study in apple (B.9.3.2.4/05).
Full rates (in-field): 1x and 2x 960 g a.s./ha chlorpyrifos.
Both chlorpyrifos full rate treatments either of 1 x 960 g as/ha or 2x 960 g as/ha induced adverse community effects that for the 2x 960g a.s./ha rate lasted until the end of the first sampling season. Samples collected in the following spring indicated that recovery processes seemed to have continued, and populations were no longer different from the control at the onset of the next growing season, with the exception of the predatory beetles of the family Staphylinidae whose populations showed no clear recovery within one year.
Drift rate (off-crop): 2x 162 g a.s./ha chlorpyrifos.
The arthropod community was significantly affected by the chlorpyrifos drift rate of 2x 162 g a.s/ha. The populations of Psocoptera, some parasitic wasps (Ceraphonoidea) and the beetle family Coccinellidae showed statistically significant adverse effects.

Citrus (intended at 1x 12850 g a.s./ha)

Spain: NTAs full arthropod fauna in-field study in citrus (B.9.3.2.4/10).
Full rates (in-field): 1x and 2x 2400 g a.s./ha chlorpyrifos.
For the 1x 2400 rate, the leaf dwelling mite community was observed to have recovered 2 months after application and the canopy dwelling arthropod community within 6 months. Populations of most hunting spiders were however affected for a longer period. Recovery within one year could not be probed for the coleopteran family Latridiidae and populations of the hunting spider families Zodariidae, Gnaphosidae and Clubionidae were still smaller than those from the control at the end of the sampling period.
For the 2x 2400 rate, no clear leaf community recovery was observed one year after the application and at the end of the first sampling season no clear canopy dwelling community recovery was demonstrated. At the end of the sampling period, the arthropod populations of Dermaptera and the hunting spiders Zodariidae, Gnaphosidae and Clubionidae had not recovered to biologically acceptable levels. At that time, the groups of spiders Heteropodidae (= Sparassidae), Xysticus sp. (Thomisidae) and Salticidae were still statistically significantly reduced compared to the control; hence it was not possible to confirm full recovery for these spiders one year after application.
Full rate (in-field): 2x 2400 g a.s./ha chlorpyrifos-methyl.
Chlorpyrifos-methyl applied twice with a 14-day interval at 2400 g a.s./ha induced fewer and shorter adverse effects on arthropod populations than the lowest chlorpyrifos treatment. Only Signiphoridae (Hymenoptera), adult Coccinellidae (Coleoptera), Clubionidae (Araneae) and Dermaptera showed reduced populations over a period longer than two months. Otherwise the array of taxa affected was similar to the 1x 2400 chlorpyrifos treatment. The leaf dwelling mite community recovered within 2 months after application and the canopy dwelling arthropod community within 6 months.

Applicable for any of the intended uses (off-crop effects)

NW France: NTAs full arthropod fauna off-field study in pasture (B.9.3.2.4/09).
Drift rate (off-crop): 1, 5, 10, 25 and 100 g a.s./ha chlorpyrifos.
At 1, 5 and 10 g a.s./ha chlorpyrifos did not influence the arthropod community in a true off-crop habitat. Less

than 5% of the individual arthropod populations prevailing in grasslands showed statistically significantly adverse effects. For Staphylinidae, Scelionidae and Formicidae these effects were consistent over time, though not significantly, at 5 g a.s./ha. At 25 g a.s./ha chlorpyrifos caused statistically significant but non persistent reductions to 4% of the arthropod taxa examined. This rate led to an adverse community response which was statistically detectable on one sampling moment. A rate of 100 g a.s./ha induced a statistically significant community response. For several taxa, no recovery occurred within the selected sampling period of one month. SW France: NTAs full arthropod fauna off-field study in pasture (B.9.3.2.4/11). Drift rate (off-crop): 1, 5, 10, 25 and 100 g a.s./ha chlorpyrifos. At 1, 5 and 10 g a.s./ha chlorpyrifos had no detectable effect on the arthropod community. Slight effects were recorded at 10 g a.s./ha for individual arthropod populations (being statistically different for Scelionidae parasitoids). At the 25 g a.s./ha rate statistically response on the arthropod community was detected on one sampling moment. At the population level, a statistically significant reduction was detected for several arthropod taxa, which showed a tendency towards recovery within one month after application. At 100 g a.s./ha chlorpyrifos induced a statistically significant, dose-related, population and community response.
Additional specific test

Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

Test organism	**Test substance**	**Application method of test a.s./ OM1**	**Time scale**	**End point**	**Toxicity (mg a.s/kg soil)**
Earthworms					
Eisenia fetida	CPF-M technical	Mixed to soil/10 % OM	Chronic	Reproduction EC10 EC20 NOEC	 18.4 (13.5-20.4) 20.2 (16.3-21.7) 12.5
Eisenia fetida	200 g CPF-M/L (SAP200CHLORI)	Mixed to soil/5 % OM	Chronic	Reproduction EC10 EC20 NOEC	 >19.25 >19.25 19.25
Eisenia fetida	480 g CPF/L (Dursban 480 EC)	Mixed to soil/10 % OM	Chronic	Reproduction EC10 EC20 NOEC	 - - 12.7
Eisenia fetida	TCP	Mixed to soil/10 % OM	Chronic	Reproduction EC10 EC20 NOEC	 - - 2.20
Eisenia fetida	3,6-DCP	Mixed to soil/10 % OM	Chronic	Reproduction EC10 EC20 NOEC	 1.75 (0.85-2.35) 3 (2.16-3.73) 1.25
Eisenia fetida	NMTCP	Mixed to soil/10 % OM	Chronic	Reproduction EC10 EC20 NOEC	 45.7 89.6 25
Eisenia fetida	TMP	Mixed to soil/10 % OM	Chronic	Reproduction EC10 EC20 NOEC	 >42.86 >42.86 42.86

Test organism	**Test substance**	**Application method of test a.s./ OM1**	**Time scale**	**End point**	**Toxicity (mg a.s/kg soil)**
Other soil macroorganisms					
Folsomia candida	SAP224I	Mixed to soil/5 % OM	Chronic	Reproduction EC10 EC20 NOEC	 0.11 (0.09-0.13) 0.13 (0.10-0.13) 0.0784
Folsomia candida	GF-1684	Mixed to soil/5 % OM	Chronic	Reproduction EC10 EC20 NOEC	 0.05 0.06 0.05
Folsomia candida	TCP	Mixed to soil/5 % OM	Chronic	Reproduction EC10 EC20 NOEC	 >50 >50 50
Folsomia candida	TCP	Mixed to soil/5 % OM	Chronic	Reproduction EC10 EC20 NOEC	 - - 16
Hypoaspis aculeifer	Chlorpyrifos	Mixed to soil/5 % OM	Chronic	Reproduction EC10 EC20 NOEC	- - - 3.2
Hypoaspis aculeifer	GF-1684	Mixed to soil/5 % OM	Chronic	Reproduction EC10 EC20 NOEC	 3.31 3.97 3.20
Hypoaspis aculeifer	SAP224I	Mixed to soil/5 % OM	Chronic	Reproduction EC10 EC20 NOEC	 2.39 (0.50-3.65) 3.13 (0.58-4.41) 1.25
Hypoaspis aculeifer	TCP	Mixed to soil/5 % OM	Chronic	Reproduction EC10 EC20 NOEC	 >50 >50 50
Hypoaspis aculeifer	TCP	Mixed to soil/5 % OM	Chronic	Reproduction EC10 EC20 NOEC	 - - 64

1To indicate whether the test substance was oversprayed/to indicate the organic content of the test soil (e.g. 5 % or 10 %).

Higher tier testing (e.g. modelling or field studies)

Higher tier tests submitted by DAS: Three field studies have been presented to address the risk identified. It is noted that 2 of the 3 field studies (CP 10.4.2.2/2 and CP 10.4.2.2/3) submitted do not cover the maximum rate applied for chlorpyrifos methyl for orchards and citrus and the field study CP 10.4.2.2/1 do not cover the maximum application rate for citrus.

Study CP 10.4.2.2/1: Community composition and abundance of selected soil living invertebrates were monitored over the period of one year. The study was conducted on a permanent grassland field site near Pforzheim, Southern Germany. In this study soil living invertebrate populations were exposed to the toxic reference test item Dursban 2 (4 L product/ha; 1152 g a.s./ha). Soil micro-arthropod communities were assessed for their species composition and abundance prior to application and at approximately 1, 6 and 12 months after application. The extraction of the arthropods was based on ISO 23611-2. The data were analysed with pair-wise and multivariante statistics. CPF achived a reduction for the family Entomobrydae (Arthropleona), for the order Symphypleona and for the family Sminthuridae (Symphypleona) in the second sampling (37 DAA2). In addition the multivariante analysis showed a statistically significant change in community composition compared to the control 37 days after application 2. Recovery in two consecutive sampling cannot be concluded for total collembola (Arthropleona and Brachystomellidae).

Study CP 10.4.2.2/2: The trial took place in permanent grassland in southern England from summer 2007 through to summer 2008. Dursban 480 EC (480 g a.s./L) was applied at 1.5 L/ha (as a toxic reference treatment). One plot was remained untreated as control. Invertebrates active on the soil surface (epigeal species) were sampled from the plots using pitfall traps and those in the soil (eudaphic species) were sampled using soil cores and 'litter-bags'. PRC analysis of chlorpyrifos at 720 g a.s/ha indicated statistically significant reductions in the soil arthropod fauna meso-community at two consecutive time points following application. Less than 50 % effect was observed 10 months after application by soil core sampling and 7 months after application by litterbag sampling althoug in many case the recovery was not observed in two consecutive samplings. It is noted that for total soil mites a 41,3% decrase respect to the control is observed at 195 DAA and a 16.9 % decrase respect to the control is still observed after 309 DAA. No full recovery can be concluded for soil mites.

Furthermore, the following uncertainties are identified in both studies: CPF was used as a toxic reference and it was not the main substance investigated in the field experiment; the application rate used do not cover the worst case application rate proposed in the GAP and no residues of CPF were measured in the treated soils and according to EU regulation 283/2013 higher tier studies shall be supported by chemical analysis to verify exposure has ocurred at an appropriate level.

Study CP 10.4.2.2/2: A 2-year field monitoring study has been conducted on the soil fauna of three treated commercial cider apple orchards in UK. The aim of this study was to assess the diversity and abundance of the soil community in a perennial cropping system which is treated with chlorpyrifos every year. Also, three untreated traditional non-commercial orchards were sampled as reference sites. Community composition and abundance of soil living invertebrates were monitored over the period of two years (April 2013 – March 2015). The conclusions of the third study (CP 10.4.2.2-3 ; CPF specific field study in cider apple orchards) are the following:

Soil-surface active arthropods (monitored by pitfall trapping):

For the pitfall trapping data, the PRC analysis revealed that 6 soil arthropod taxa were not favoured by the conventional farming system: Katiannidae, Orchesellinae, Tomoceridae, Sminthuridae, Dicyrtomyidae, and Uropodina. Only the collembolan family Hypogastruridae was favoured by the conventional farming system. For the other 13 taxa no clear response was detected (i.e. the conventional and organic orchards were similar). The data provide an indication that the chlorpyrifos application had a detrimental effect on the soil arthropods (eg. collembolan family Katiannidae).

Euedaphic arthropods (monitored by soil cores which were heat-extracted)
For the soil core data, the PRC analysis revealed that 7 soil arthropod taxa were not favoured by the conventional farming system: Katiannidae, Uropodina, Entomobryidae, Isotomidae, Neelidae, Mesostigmata and Sminthurididae. For the other 11 taxa no clear response was detected (i.e. the conventional and organic orchards were similar).

Moreover, the following uncertainties were identified: The application rate proposed in the study do not cover the worst-case application rate proposed in the GAP; CPF is aplied to apple cider orchards. Some uncertainties are identified in extrapolating the results to other crops at lower BBCH with no interception (eg. Solanaceus vegetables at BBCH 11 or maize at BBCH 12).

Higher tier tests submitted by SAPEC: an aged residues study with the formulated product SAP224I and a field study with the formulated product Chlorpyrifos-ethyl 5G were submitted to adress the risk identified in soil meso and macrofauna (other than earthworms).

The aged residues study was designed to evaluate the effects of aged residues of SAP224I, applied to a Lufa 2.2 soil as substrate, on survival and reproduction of the Collembola Folsomia candida. The following application rates were used: 0.096, 0.36, 0.9 and 1.35 L/ha. The first bioassay was carried out with freshly dried residues on the day of application. Next bioassays on aged residues were started on 4 weeks, 8 weeks, 16 weeks, 24 weeks and until 32 weeks after application. The following results were obtained: Twenty four weeks after application, the rate of SAP224I used at 0.36L/ha had not significant remaining effect on F.candida mortality and reproduction compared with the control. The corrected mortality (9.43%) and the reduction of reproduction (21.83%) were below 50% compared with the control treatment group. Thirty two weeks after application, 0.9L/ha and 1.35L/ha of SAP224I always had a significant remaining effect (superior to 50% compared with the control treatment group) on F.candida mortality and reproduction compared with the control. However, the following uncertainties should be taken into account: The experiment was performed with the formulated product SAP224I. It is not the representative formulation submitted in the dossier. Data on the equivalence of both formulated product (SAP224I and SAP200CHLORI) should be submitted in order to use the studies performed with SAP224I for the risk assessment of SAP200CHLORI; The validity criteria in bioassays 2 and 3 are not met; It is noted that once the corrected mortality or the corrected reproduction was below 50 % at one dose level, no more measurements were made in the subsequent days; According to the applicant SAP200CLORI should be applied at 1.7 kg pf/ha, taking into account the crop interceptions (75% in grapes and 40% in OSR), the dose reaching soil surface is estimated to be 0.425 L/ha and 1.02L/ha, respectively. These doses are equivalents to the tested rates 0.36 L/ha in grapes and 0.9 L/ha in OSR, in the aged residues study with SAP224I. Doses in the study are slighly below the expected doses of SAP200CHLORI. The study do not represent a worst-case situation and do not cover the worst case GAP. Moreover, no aged residues data are provided for Hypoaspis aculeifer, therefore, a conclusion cannot be derived on this specie.

On the other hand, a higher tier study with the formulated product Chlorpyrifos-ethyl 5G was performed to determine the effect of a field application on populations of collembolans, soil mites and earthworms (KCP 10.4.2.2). This study was designed to determine the effect of a single commercial field application of 15 kg product/ha of Chlorpyrifos 5G on populations of collembolans, soil mites and earthworms in comparison to a blank granule control. The results 7 DAA indicate that there was no effect on the survival of Folsomia or Hypoaspis in either the mid-point or in-furrow locations of the Chlorpyrifos 5G treated plots. However, chlorpyrifos 5 G is a granulated formulation containing chlorpyrifos. Therefore, some uncertainties are identified from the extrapolation of the results obtained in a field study with a granulated formulation to a spray application (SAP200CHLORI). Both formulated products are not comparable in application rate, type of application or method of application. Moreover, residues in soil were measured at 7, 28, 56, 112 and 280 DAA. Initial measured residues (0 DAA) and more intermediate sampling points (e.g. 2, 4, 10, 14, 21 DAA) would have been helpful to establish residues decline. Furthermore, effects were measured at day 7 and 28. Higher effect were observed in Folsomia candida at day 28 that those observed at day 7. Intermediate measures (day 14 and 21) would have clarify the observed effects.

Nitrogen transformation	Reldan 22 (EF-1066)	< 25 % effect after 62 days at 0.67 mg a.s/kg soil (0.5 kg a.s/ha).
Nitrogen transformation	Chlorpyrifos-methyl	<25% effects at 7.07 mg a.s./kg soil dry weight.
Nitrogen transformation	Chlorpyrifos methyl	<25 % effect after 28 days at 6.72 mg a.s/kg soil.
Nitrogen transformation	3,5,6-TCP	<25% effect after 100 days at 3.53 mg 3,5,6-TCP/kg soil.
Nitrogen transformation	TMP	<25% effect after 28 days at 0.415 mg/kg soil.
Nitrogen transformation	TMP	<25 % effect after 28 days at 2.03 mg a.s/kg soil.

Toxicity/exposure ratios for soil organisms
Formulated product: GF-1684

Maize at 900 g a.s./ha x 1 (worst-case)

Test organism	**Test substance**	**Time scale**	**Soil PEC1**	**TER**	**Trigger**
Earthworms					
Eisenia foetida	Chlorpyrifos-methyl	Chronic	0,9	7,06	5
Eisenia foetida	TCP	Chronic	0,516	4,26	5
Eisenia foetida	TMP	Chronic	0,140	4,54	5
Eisenia foetida	DCP	Chronic	0,338	3,70	5

Risk is identified for the metabolites TCP, TMP and DCP by using the worst-case (maize) PEC soil. Therefore, detailed assessment for metabolites for each intended use is provided below:

Compound	**Crop (nºapplication x application rate (kg a.s/ha))**	**PEC plateau**	**TER**	**Trigger**
TCP	Citrus (1 x 1.285)	0,196	11,22	5
TCP	Maize (1 x 0.9)	0,516	4,26	5
TCP	Cotton (1 x 0.68)	0,208	10,58	5
TCP	Table grapes (1 x 0.608)	0,186	11,83	5
TCP	Grapes (2 x 0.338)	0,103 (single)	21,36	5
		0,1973 (multiple)	11,15	5
TCP	OSR (1 x 0.45)	0,069	31,88	5
TCP	Pome fruit (1 x 1.02)	0,275	8,00	5
TCP	Potato (1 x 0.54)	0,165	13,33	5
TCP	Solanaceous (1 x 0.675)	0,258	8,53	5
TCP	Soybean (1 x 0.45)	0,155	14,19	5
TCP	Stone fruit (1 x 1.02)	0,312	7,05	5
TCP	Strawberry (1 x 0.506)	0,206	10,68	5
Compound	**Crop (nºapplication x application rate (kg a.s/ha))**	**PEC plateau**	**TER**	**Trigger**
TMP	Citrus (1 x 1.285)	0,053	11,98	5
TMP	Maize (1 x 0.9)	0,14	4,54	5
TMP	Cotton (1 x 0.68)	0,056	11,34	5
TMP	Table grapes (1 x 0.608)	0,05	12,70	5
TMP	Grapes (2 x 0.338)	0,0281 (single)	22,60	5
		0,0558 (multiple)	11,38	5
TMP	OSR (1 x 0.45)	0,019	33,42	5
TMP	Pome fruit (1 x 1.02)	0,075	8,47	5
TMP	Potato (1 x 0.54)	0,045	14,11	5
TMP	Solanaceous (1 x 0.675)	0,07	9,07	5
TMP	Soybean (1 x 0.45)	0,042	15,12	5
TMP	Stone fruit (1 x 1.02)	0,085	7,47	5
TMP	Strawberry (1 x 0.506)	0,056	11,34	5
Compound	**Crop (nºapplication x application rate (kg a.s/ha))**	**PEC Plateau**	**TER**	**Trigger**
DCP	Citrus (1 x 1.285)	0,129	9,69	5
DCP	Maize (1 x 0.9)	0,338	3,70	5
DCP	Cotton (1 x 0.68)	0,136	9,19	5
DCP	Table grapes (1 x 0.608)	0,122	10,25	5
DCP	Grapes (2 x 0.338)	0,068 (single)	18,38	5
		0,0964 (multiple)	12,97	5
DCP	OSR (1 x 0.45)	0,045	27,78	5

DCP	Pome fruit (1 x 1.02)	0,18	6,94	5
DCP	Potato (1 x 0.54)	0,108	11,57	5
DCP	Solanaceous (1 x 0.675)	0,169	7,40	5
DCP	Soybean (1 x 0.45)	0,101	12,38	5
DCP	Stone fruit (1 x 1.02)	0,204	6,13	5
DCP	Strawberry (1 x 0.506)	0,135	9,26	5

It is noted the risk assessment for TMP have been performed by considering that TMP 10x of higher toxicity than the parent compound. **However, taking into account the experimental end point of 21.43 mg/kg soil, TER values for this metabolite are above the trigger value of 5. (21.43/0.14=153)**

Other soil macroorganisms

Test organism	Test substance	Time scale	Soil PEC1	TER	Trigger
Hyposaspis aculeifer	Chlorpyrifos-methyl	Chronic	0,9	1,78	5
Hyposaspis aculeifer	TCP	Chronic	0,516*	96,90	5
Hyposaspis aculeifer	DCP	Chronic	0,338*	0.95	5
Hyposaspis aculeifer	TMP	Chronic	0,14*	1,14	5
Folsomia candida	Chlorpyrifos-methyl	Chronic	0.9	0.028	5
Folsomia candida	TCP	Chronic	0.516	96.9	5
Folsomia candida	DCP	Chronic	0.338	0.015	5
Folsomia candida	TMP	Chronic	0.140	0.018	5

1indicate which PEC soil was used (e.g. plateau PEC)
*plateau PEC

<u>Formulated product: SAP200CHLORI</u>

All uses at 340 g a.s./ha x 1

Test organism	Test substance	Time scale	Soil PEC1	TER	Trigger
Earthworms					
Eisenia foetida	Chlorpyrifos-methyl (SAP224I)	Chronic	0,272	23,16	5
Eisenia foetida	TCP	Chronic	0,156	14,10	5
Eisenia foetida	TMP	Chronic	0,042	510,24	5
Eisenia foetida	DCP	Chronic	0,102	12,25	5
Eisenia foetida	NMTCP	Chronic	0,178	70.22	5
Other soil macroorganisms					
Folsomia candida	Chlorpyrifos-methyl	Chronic	0,272	0,144	5
Folsomia candida	TCP	Chronic	0,156	102	5
Folsomia candida	TMP	Chronic	0,042	0,093	5
Folsomia candida	DCP	Chronic	0,102	0,077	5
Hyposaspis aculeifer	Chlorpyrifos-methyl (SAP224I)	Chronic	0,272	4,596	5
Hyposaspis aculeifer	Chlorpyrifos	Chronic	0,272	5.882	5
Hyposaspis aculeifer	TCP	Chronic	0,156	410	5

Test organism	Test substance	Time scale	Soil PEC1	TER	Trigger
Hyposaspis aculeifer	TMP	Chronic	0,042	2,976	5
Hyposaspis aculeifer	DCP	Chronic	0,102	2,451	5

1indicate which PEC soil was used (e.g. plateau PEC)

Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

Screening data

Less that 50 % of phytotoxic effect at the maximum application rate proposed in the GAP.

Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

Test type/organism	end point
Activated sludge	The study submitted is considered as supplementary data. No other data is available.
Pseudomonas sp	No data submitted.

Monitoring data (Regulation (EU) N° 283/2013, Annex Part A, point 8.9 and Regulation (EU) N° 284/2013, Annex Part A, point 10.8)

Available monitoring data concerning adverse effect of the a.s: A monitoring study was conducted at Mar Menor (SE Spain) which is a hypersaline coastal lagoon located in the Mediterranean Sea with a superficial area of 135 km2. The lagoon was split into 3 main sites. The northern, central and southern areas, these areas were designated as clean, contaminated and contaminated, respectively. The sites were monitored for contaminant effects by placing clams, Ruditapes decussatus, within each site and noting physiological and biometric parameters. Significant effects were seen in the more contaminated sites (S2-4) in most of the biometric endpoints at 22 days. The significant differences were seen in dry weights of total soft tissue, gill and digestive gland as well as rest. Further significant differences were found in the condition index (CI), gill index (GI), hepatosomatic index (HI) and rest index (RI). Clams were taken to the laboratory and tested for clearance, clearance efficiency respiration rate and scope for growth. Of the sites S3 had the most chlorpyrifos contamination likely due to its close proximity to the river mouth, the river having well documented levels of agrochemicals due to agricultural land use further upstream. Furthermore in this site AChE disturbances were seen indicative of chlorpyrifos exposure. Of the two chlorpyrifos moieties chlorpyrifos-ethyl showed the highest level of contamination. Available monitoring data concerning effect of the PPP: no data submitted.

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds1

Compartment	
soil	Chlorpyrifos-methyl.
water	Chlorpyrifos-methyl,
sediment	Chlorpyrifos-methyl,
groundwater	Chlorpyrifos-methyl,

1 metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent

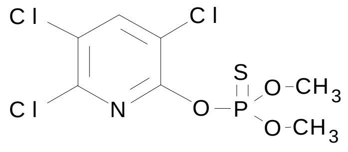
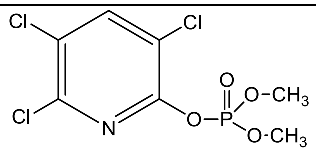
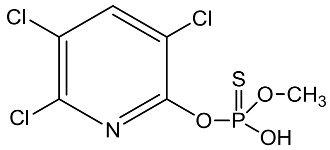
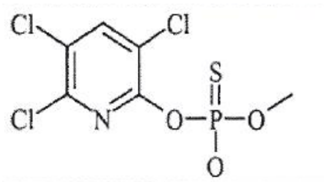
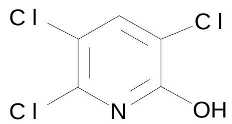
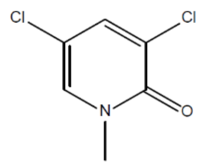
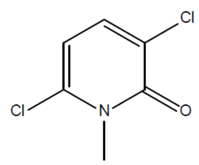
Classification and labelling with regard to ecotoxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

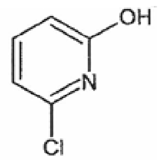
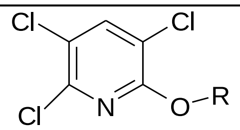
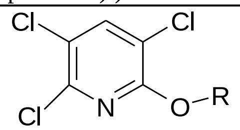
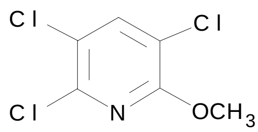
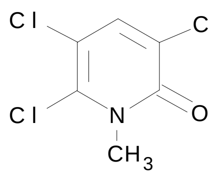
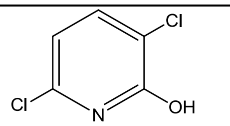
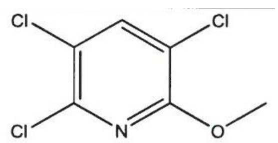
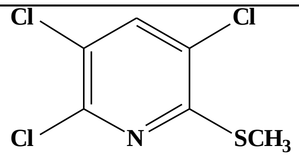
Substance	Chlorpyrifos methyl
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]3:	Aquatic Acute 1 Aquatic Chronic 1
Peer review proposal4 for harmonised classification according to Regulation (EC) No 1272/2008:	Aquatic Acute 1, Aquatic Chronic 1 Macute = 1000; Mchronic= 10000

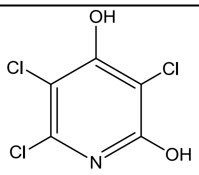
3 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

4 It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

Used compounds code(s)

Code Number (Synonyms)	**Description**	**Structure**
Chlorpyrifos-methyl (E-ISO, BSI, ANSI, ESA), Chlorpyriphos-methyl, (F-ISO, JMAF) CLP-Me CLPM DOWCO 214, ENT 27 520, OMS 1155 EC 227-011-5, CAS 5598-13-0, CIPAC 486 (221.A), CODEX 090	O,O-Dimethyl-O-(3,5,6-trichloro-2-pyridyl)phosphorothioate [IUPAC] O,O-Dimethyl-O-(3,5,6-trichloro-2-pyridinyl)phosphorothioate [CAS]	 C7H7Cl3NO3PS
Chlorpyrifos-methyl oxon, X143491 CAS 5598-52-7	O,O-Dimethyl-O-(3,5,6-trichloro-2-pyridinyl)phosphate	 C7H7Cl3NO4P
Des-methyl chlorpyrifos-methyl, Des-methyl Reldan (DEM)	O-methyl-O-(3,5,6-trichloro-2-pyridinyl) O-sodium phosphorothioate (O-methyl-O-(3,5,6-trichloro-2-pyridinyl) phosphorothoic acid	  C6H5Cl3NO3PS
Trichloropyridinol (TCP), (TCPy) EC 229-405-2 CAS 6515-38-4	3,5,6-trichloro-2-pyridinol [IUPAC and CAS], 3,5,6-trichloro-2-pyridone, 3,5,6-trichloro-2(1H)-pyridone, 3,5,6-trichloro-2(1H)-pyridinone, 3,5,6-trichloropyridin-2-ol	 C5H2Cl3NO
3,5-dichloro-1-methylpyridin-2(1H)-one (3,5 DCMP)	3,5-dichloro-1-methylpyridin-2(1H)-one	
3,6-dichloro-1-methylpyridin-2(1H)-one (3,6 DCMP)	3,6-dichloro-1-methylpyridin-2(1H)-one	

6-chloro-2-pyridinol (MCP) CAS No.: 6515-38-4	6-chloro-2-pyridinol	 C5H4ClNO
*	Sugar conjugates of TCP (no chemical names were established for any of these metabolites)	 (Where R represents sugar conjugates (e.g., glucose and/or glucose plus other natural products).)
*	Conjugates of TCP (no chemical names were established for any of these metabolites)	 (Where R represents conjugates (probably glucuronic acid and sulphate)
Trichloromethoxypyridine (3,5,6-trichloro-6-methoxypyridine) (TMP) CAS 31557-34-3	3,5,6-trichloro-2-methoxypyridine [IUPAC and CAS]	 C6H4Cl3NO
N-methyl pyridinone, N-methyl, N-methyl-3,5,6-trichloro-2(1H)-pyridinone (MTCP), 3,5,6-trichloro-1-methylpyridin-2(1H)-one (N-methyl-TCP) X131419 CAS None	3,5,6-Trichloro-2(N-methyl)-pyridone [IUPAC] 3,5,6-Trichloro-2(N-methyl)-pyridinone [CAS]	 C6H4Cl3NO
3,6-dichloro-2-pyridinol (3,6-DCP)	3,6-dichloro-2-pyridinol	 C5H3Cl2NO
5,6-dichloropyridin-2-ol (5,6-DCP)	5,6-dichloropyridin-2-ol	
2,3,5-trichloro-6-(methylsulfanyl)pyridine (TSP)	2,3,5-trichloro-6-(methylsulfanyl) pyridine	 C6H4Cl3NS

Hydroxy-TCP	3,5,6-trichloro-4-hydroxy-2-pyridinol	 C5H3Cl3NO2

Level 3

Proposed decision with respect to the application

CHLORPYRIFOS-METHYL

3. PROPOSED DECISION WITH RESPECT TO THE APPLICATION

3.1. BACKGROUND TO THE PROPOSED DECISION

3.1.1. Proposal on acceptability against the decision making criteria – Article 4 and annex II of regulation (EC) No 1107/2009

3.1.1.1. Article 4				
		Yes	No	
i)	It is considered that Article 4 of Regulation (EC) No 1107/2009 is complied with. Specifically the RMS considers that authorisation in at least one Member State is expected to be possible for at least one plant protection product containing the active substance for at least one of the representative uses.	X		TOXICOLOGY: GF-1684 The product does no present a risk to human health according to German Model (geomean values) when the appropriate PPE is worn for all supported crops except orchards. Predicted exposures derived from the UK POEM and German model (75^{th} percentile) are all above the AOEL even when PPE (gloves) and RPE are assumed. Predicted exposures from EFSA model, show safe use for low crops when PPE (gloves) is assumed, and for high crops, when PPE (gloves), RPE and closure cab are assumed. No risk is derived of application to grain treatment and structural treatment to cereal stores when the appropriate PPE (coverall, gloves, hood and visor) and RPE are used SAP200CHLORI Exposure assessment not performed since no dermal absorption data are available. ECOTOXICOLOGY *SAP200CHLORI* • ***Birds and mammals****: Exposure of birds and mammals to Chlorpyrifos-methyl according to the GAP shows no unacceptable acute and reproductive risks for all intended uses.* • ***Aquatic organisms****: Assessment not finalised. The applicant should submit information on the rate of release of capsules.*

				• ***Honey bees****: risk mitigation are needed please refer to 3.1.1.3. Restrictions on approval.* • ***Non-target arthropods****: Recovery/Recolonization not demonstrated for all intended uses.* • ***Non-target soil meso- and macrofauna****: Further information to finalise the risk assessment of the following metabolites: TMP, DCP, NMTCP.* • ***Soil nitrogen transformation*** *(microbial processes): the risk for soil microbial processes is acceptable for all proposed uses.* • ***Non-target terrestrial plants:*** *the risk for non-target terrestrial plants is acceptable for all proposed uses.* *GF-1684* • ***Birds:*** No unacceptable risk could be concluded. The approval should be conditioned to a monitoring of mammals populations in areas of continuous use of CPF-M with the submission of the results by 2 years, in order to detect possible effects on population due to application of the active substance. • ***Mammals****:* Unacceptable risk identified for large herbivorous mammal in OSR, Pome and stone fruits, Citrus, Potato, Soybean, Strawberry, Vineyard and the insectivorous mammal 'shrew' in maize. Acceptable risk for mammals could be concluded for cotton and solanaceus vegetables. • ***Aquatic organisms:*** *Risk identified for all FOCUS SW scenarios for the intended uses on citrus. Risk mitigation measures needed for the rest of the intended uses please refer to 3.1.1.3. Restrictions on approval (except cereal grain)* • ***Honey bees****: risk mitigation are needed please refer to 3.1.1.3. Restrictions on approval. Bee brood studies do not cover the application rates in all intended uses (except cereal grain).* • ***Non-target arthropods****: Recovery/Recolonization not demonstrated for all intended uses (except citrus and cereal grain).*

				• ***Non-target soil meso- and macrofauna****: Further information to finalise the risk assessment of the following metabolites: TMP, DCP, NMTCP.* • ***Soil nitrogen transformation*** *(microbial processes): Further information to finalise the risk assessment of the following metabolite DCP* • ***Non-target terrestrial plants:*** *the risk for non-target terrestrial plants is acceptable for all proposed uses*
3.1.1.2. Submission of further information				
		Yes	No	
i)	It is considered that a complete dossier has been submitted		X	*[If no go to ii immediately below]*
ii)	It is considered that in the absence of a full dossier the active substance may be approved even though certain information is still to be submitted because: (a) the data requirements have been amended or refined after the submission of the dossier; or (b) the information is considered to be confirmatory in nature, as required to increase confidence in the decision.	X		**<u>The information is considered to be confirmatory in nature, as required to increase confidence in the decision.</u>** <u>TOXICOLOGY:</u> Dermal absorption data of SAP200CHLORI is required. The conclusions of more of in vitro studies are considered as provisional until Laboratories proficiency can be confirmed <u>RESIDUES</u>: See data gap <u>ECOTOXICOLOGY</u> See point 3.1.4.
3.1.1.3. Restrictions on approval				
		Yes	No	
	It is considered that in line with Article 6 of Regulation (EC) No 1107/2009 approval should be subject to conditions and restrictions.	X		<u>ECOTOXICOLOGY</u> Risk managers to consider the potential risk on B&M. Aproval should

				be conditioned to a monitoring of birds and mammals populations in areas of continuous use of CPF-M with the submission of the results by 2 years, in order to detect possible effects on population due to application of the active substance. Risk mitigation measures are needed to reduce drift and runoff entries in aquatic systems. Risk assessment conducted with 20 m VBS +95% DRN. Risk managers to decide wether or not these mitigation measures are reliable or not Applicants proposed to use VFMOD model to reduce VBS . The use of this tool is not adopted yet at EU level and not considered in the risk assessment In any case it could be included in LoEP by request formulatios Spe8: Dangerous to bees/To protect bees and pollinating insects do not apply to crop plants when in flower/Do not use where bees are actively foraging/Remove or cover beehives during application and for 14 d after treatment/Do not apply when flowering weeds are present/Remove weeds before application. Risk managers to consider the potential risk on NTA. Recovery/Recolonization not demonstrated for all intended uses (Except citrus and cereal grain).
3.1.1.4. Criteria for the approval of an active substance				
Dossier				
		Yes	No	
	It is considered the dossier contains the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL) and Acute Reference Dose (ARfD).	X		
	It is considered that the dossier contains the information necessary to carry out a risk assessment and for enforcement purposes (relevant for substances for which one or more representative uses includes use on feed or food crops or leads indirectly to residues in food or feed). In particular it is considered that the dossier: (a) permits any residue of concern to be defined; (b) reliably predicts the residues in food and feed, including succeeding	X		*RESIDUES:* *Metabolism studies conducted using chlorpyrifos–methyl and the structurally related active substance chlorpyrifos demonstrated that the parent compound is a good marker for monitoring and confirmed that the polar metabolites represent a major component of the residue at harvest. The metabolic pattern after foliar application included the hydroxilation of the phosphate ester to form TCP and polar residues, mainly TCP*

	crops (c) reliably predicts, where relevant, the corresponding residue level reflecting the effects of processing and/or mixing; (d) permits a maximum residue level to be defined and to be determined by appropriate methods in general use for the commodity and, where appropriate, for products of animal origin where the commodity or parts of it is fed to animals; (e) permits, where relevant, concentration or dilution factors due to processing and/or mixing to be defined.			*conjugates. From these studies, the residue of greatest toxicological significance is the unchanged parent test material (chlorpyrifos or chlorpyrifos-methyl), while the only other residue of significance is TCP (free and conjugated).* *The main metabolites found in the stored grain metabolism study (post-harvest application) are TCP and the DEM, although parent chlorpyrifos methyl predominated in stored grain, especially at earlier time intervals where less degradation had occurred.* *The residue definition derived from these studies is proposed as Chlorpyrifos-methyl for monitoring for plant and animal products. For risk assessment, Chlorpyrifos-methyl + 3,5,6-trichloropyridinol (TCP) and its conjugates, expressed as chlorpyrifos-methyl, except for* ***Post-harvest use in stored grain:*** *Chlorpyrifos-methyl + des-methyl chlorpyrifos-methyl, expressed as chlorpyrifos-methyl.* *Supervised residue trials for several representative uses are available compliant the proposed GAPs, except on citrus and cherry, where GAPs compliant data are not available.* *For processed commodities the following residue definition for risk assessment is proposed : Chlorpyrifos-methyl + 3,5,6-trichloropyridinol (TCP) and its conjugates + des-methyl chlorpyrifos-methyl, expressed as chlorpyrifos-methyl.* *Reliable processing factors are derived from studies on several processed commodities.*
	It is considered that the dossier submitted is sufficient to permit, where relevant, an estimate of the fate and distribution of the active substance in the environment, and its impact on non-target species.		X	<u>ENVIRONMENTAL FATE AND BEHAVIOUR</u> SAP200CHLORI and GF 1684 1.- Data on DT50 and Koc for metabolite N-methyl TCP 2.- GW modelling for N-methyl TCP for all intended uses considering the input data selected by RMS in for parent compound (see LoEP for details) <u>ECOTOXICOLOGY</u> GF 1684: Further refined risk assessment large herbivorous mammal in OSR, Pome and stone fruits, Citrus, Potato, Soybean, Strawberry, Vineyard

				and the insectivorous mammal ‘shrew’ in maize The bee brood studies do not cover the intended application rates. Further information needed (except for cereal grain). SAP200CHLORI: applicant to submit further information on the release rate of capsules in order to support their statement the toxicity data of the active substance covers the toxicity of the plant protection product. SAP200CHLORI and GF-1684: toxicity data of NMTCP, TMP and DCP on Folsomia and Hypoaspys and toxicity data of DCP on nitrification transformation in order to finalise the risk assessment. GF-1684 and SAP200CHLORI: further information needed to conclude on recovery/recolonization of NTA in every intended uses except cereal grain.
Efficacy				
		Yes	No	
	It is considered that it has been established for one or more representative uses that the plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use is sufficiently effective.	X		*Chlorpyrifos-methyl is an insecticide used in agriculture to control a wide range of chewing and sucking pests in a range of crops such as grape, citrus, top fruit, vegetable crops, cereals, oilseed rape, corn, cotton, potato, soybean and strawberry. In cereals, stored grain pests are controlled in storehouses, while in the other crops open field broadcast applications are registered. Chlorpyrifos is effective by contact, ingestion and vapour phase to control insect pests.* *Chlorpyrifos-methyl is a well known contact and ingested insecticide that has demonstrated effective control of key sucking and chewing pests, representatives of the classes Coleoptera, Diptera, Homoptera and Lepidoptera in a wide range of crops and situations. It has been long established as an effective broad spectrum insect management tool for growers across Europe for use in both major and minor crops. Chlorpyrifos-methyl also control some mite pests in store houses.* *Where there is a general resistance in the pest population to organophosphates there could be cross resistance to chlorpyrifos-methyl. One specific case of resistance to this molecule have been reported in Europe (Czech Republic) on Phorodon humuli as agricultural pest species according to the Arthropod Pesticide Resistance Database of Michigan University and IRAC (Insecticide Resistance Action Committee).*

				It is recommended that chlorpyrifos-methyl should be applied according to basic IRAC principles and used in programmes alternating with products that have different modes of action. As in most uses chlorpyrifos-methyl can be applied only once per year and very few other IRAC Group 1B insecticides are used in the practice, the chance to develop resistance is low.
Relevance of metabolites				
		Yes	No	
	It is considered that the documentation submitted is sufficient to permit the establishment of the toxicological, ecotoxicological or environmental relevance of metabolites.		X	*ENVIRONMENTAL FATE AND BEHAVIOUR* *Data on DT50 and Koc for metabolite N-methyl TCP are required to finalise the GW modelling* *ECOTOXICOLOGY* *toxicity data of NMTCP , TMP and DCP on Folsomia and Hypoaspys and toxicity data of DCP on nitrification transformationare required in order to finalise the risk assessment*
Composition				
		Yes	No	
	It is considered that the specification defines the minimum degree of purity, the identity and maximum content of impurities and, where relevant, of isomers/diastereo-isomers and additives, and the content of impurities of toxicological, ecotoxicological or environmental concern within acceptable limits.	X		*See for data and the specification regarding Chlorpyirifos-methyl, and possible isomers, impurities, plant scale details the confidential Annex C/Volume 4. The minimum purity of Chlorpyirifos-methyl is 960 g/kg.*
	It is considered that the specification is in compliance with the relevant Food and Agriculture Organisation specification, where such specification exists.	X		
	It is considered for reasons of protection of human or animal health or the environment, stricter specifications than that provided for by the FAO specification should be adopted		X	
Methods of analysis				
		Yes	No	
	It is considered that the methods of analysis of the active substance, safener or synergist as manufactured and of determination of impurities of toxicological, ecotoxicological or environmental concern or which are present in quantities greater than 1 g/kg in the active substance, safener or synergist as manufactured, have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise.		X	***SAP**: Sulfotemp and Sulfotemp ester in technical chlorpyrifos-methyl were preliminary screened by LC-MS. Accurately validated method is required (see level 2, 2.5.1.1). Validation of the method for the determination of free chlorpyrifos-methyl in the preparation SAP200CHLORI (Chlorpyrifos-methyl 200 g/L CS) is required (see level 2, 2.5.1.2)*

				DOW: *Validation of the method for the determination of the relevant impurity sulfotemp-ester in the formulation GF-1684 is required (see level 2, 2.5.1.2).*
	It is considered that the methods of residue analysis for the active substance and relevant metabolites in plant, animal and environmental matrices and drinking water, as appropriate, shall have been validated and shown to be sufficiently sensitive with respect to the levels of concern.		X	***SAP****: Analytical method is required for the monitoring of active substance and relevant metabolites in body fluids according with Regulation 283_2013 (see level 2, 2.5.2).*
	It is confirmed that the evaluation has been carried out in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009.	X		
Impact on human health				
Impact on human health - ADI, AOEL, ARfD				
		Yes	No	
	It is confirmed that (where relevant) an ADI, AOEL and ARfD can be established with an appropriate safety margin of at least 100 taking into account the type and severity of effects and the vulnerability of specific groups of the population.	X		*ADI = 0.01 mg/kg bw/day based on the 2-year rat study (NOAEL = 1mg/kg/d), with a safety factor of 100.* *AOEL = 0.01 mg/kg bw/day based on the 13-week rat study (NOAEL = 1 mg/kg/d), with a safety factor of 100.* *ARfD = 0.1 mg/kg bw/day based on acute oral neurobehavioral and cholinesterase inhibition study (NOAEL = 10 mg/kg/d), with a safety factor of 100.*
Impact on human health – proposed genotoxicity classification				
		Yes	No	
	It is considered that, on the basis of assessment of higher tier genotoxicity testing carried out in accordance with the data requirements and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as mutagen category 1A or 1B.**		X	*The genotoxic potential of Chlorpyrifos methyl has been investigated in a comprehensive range of in vitro and in vivo assays. The overall weight of evidence from the in vitro and in vivo studies is that Chlorpyrifos methyl is not genotoxic (see level 2).*
Impact on human health – proposed carcinogenicity classification				
		Yes	No	
i)	It is considered that, on the basis of assessment of the carcinogenicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data and		X	*The chronic toxicity and/or carcinogenicity of Chlorpyrifos-Methyl were evaluated in rats, mice and dogs. No evidence of carcinogenicity was observed in long term studies of toxicity/carcinogenicity with Chlorpyrifos-Methyl (see level2).*

	information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as carcinogen category 1A or 1B.**			
ii)	Linked to above classification proposal. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			*[if no provide a brief explanation of conditions of use and cross refer to the section containing full details to support the contention of negligible exposure]*
Impact on human health – proposed reproductive toxicity classification				
		Yes	No	
i)	It is considered that, on the basis of assessment of the reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as toxic for reproduction category 1A or 1B.**		X	*Reproductive toxicity of Chlorpyrifos methyl was studied in a two-generation study in rat, teratology studies in the rat and rabbit and a developmental neurotoxicity study. A published study was also taken into account for risk assessment. Chlorpyrifos methyl showed no potential to adversely affect reproductive outcome, fertility or produce teratogenicity.* *(see level 2).*
ii)	Linked to above classification proposal. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			*[if yes provide a brief explanation of conditions of use and cross refer to the section containing full details to support the contention of negligible exposure]*
Impact on human health – proposed endocrine disrupting properties classification				
		Yes	No	
i)	It is considered that **the substance SHOULD BE classified or proposed for classification** in accordance with the provisions of Regulation (EC) No 1272/2008, as **carcinogenic category 2 and toxic**		X	

	for reproduction category 2 and on that basis shall be considered to have endocrine disrupting properties			
ii)	It is considered that **the substance SHOULD BE classified or proposed for classification** in accordance with the provisions of Regulation (EC) No 1272/2008, as **toxic for reproduction category 2 and** in addition the RMS considers the substance **has toxic effects on the endocrine organs and on that basis shall be considered to have endocrine disrupting properties**		X	*With the available information it can conclude that Chlorpyrifos methyl seems to be no potential to interact with the estrogen pathway, while hipotiroidism and antiandrogenic effects cannot be discarded.* *Effects on Non-EAT pathways, atypical EAT pathways and neuroendocrine pathways were not assessed.* *(See level 2)*
iii)	Linked to either i) or ii) immediately above. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.		X	
Fate and behaviour in the environment				
Persistent organic pollutant (POP)				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a persistent organic pollutant (POP) as laid out in Regulation 1107/2009 Annex II Section 3.7.1.		X	*1.- Persistence criterion* *Soil system: The aerobic and anaerobic degradation of Chlorpyrifos-methyl was studied in 12 soils under laboratory conditions. The persistence criterion was not fulfilled in any soil. In aerobic soils, the degradation half-lives ranged from 0.94 days to 8.4 days (20 ºC). Photodegradation is a significant environmental degradation route.* *Aquatic system:* *Hydrolysis of Chlorpyrifos-methyl in sterilized water is pH dependent.* *Chlorpyrifos-methyl is hydrolytically unstable in sterile aqueous buffers between pH 4 and pH 9. DT50 values at 25ºC are 27, 21 and 13 days at pH 4, 7 and 9, respectively.* *Photodegradation is not a significant environmental degradation route, but it could have an influence on the degradation.* *Chlorpyrifos-methyl is considered as not ready biodegradable.* *In water/sediment systems, DT50 for the whole system for Chlorpyrifos-*

				methyl was estimated ranged from 2 to 7.17 days. *Two studies have been conducted to investigate the aerobic mineralization in surface water. Chloprpyrifos-methyl dissipates rapidly in natural water systems(DT50=5-9 days)* *2.- Bioaccumulation criterion* *Rainbow trout (Oncorhynchus mykiss) were exposed to two concentrations of 14C-chlorpyrifos-methyl (1.0 and 10.0 µg/l) for 13 days and the depuration was studied during 10 days after the exposure phase. BCFs were estimated at different times throughout the exposure period of the study (for the two concentrations) based on whole fish and steady-state concentration ratio. At EU level, a BCF = 1800 was agreed corresponding to exposure for 13 days at 10 µg/l. RMS considers the steady-state could not be reached and this value could entail uncertainties. Consequently, and following the recommendations of the OECD GD 305 (2012), RMS has estimated the kinetic BCF (BCFK) as the ratio of the rate constant of uptake (k1) and depuration (k2) assuming first order kinetic. In Appendix I are included the details of calculations performed for estimating the kinetic rate constants and BCFKs. A geomean of two BCFK (from exposure at 1 and 10) was calculated obtaining a BCFK = 1581, which is below the threshold value of 2000* *3.- Toxicity criterion* *A wide database from laboratory studies on aquatic organisms are available for chlorpyrifos-methyl and its metabolites at tier 1 level. These studies revealed invertebrates as the most sensitive taxonomic group being critical endpoints for chlorpyrifos-methyl the EC50 = 0.29 µg a.s./L for Chironomus riparius (Hartgers and Roessink, 2015) and the NOEC = 0.01 µg a.s./L for Daphnia (Douglas, M.T., 1992).* *A higher-tier endpoint is also available for chlorpyrifos (which can be used for chlorpyrifos-methyl), based on the threshold option and several micro- and mesocosm studies, resulting in an overall regulatory acceptable concentration (ETO-RAC) of 0.015 µg a.s./L* *Therefore, it can be concluded that chlorpyrifos-methyl fulfills the criterion of toxicity to aquatic organisms set out in the Annex II of the Regulation 1107/2009.*

				4.- Atmospheric Long range transport *Under FOCUS Air Guidance (SANCO/10553/2006 Rev 2 June 2008), substances with a DT50 air > 2 days must be modelled using air dispersion simulations.* *An atmospheric half-life of 2.11 hours has been calculated for the photochemical oxidation of Chlorpyrifos-methyl.*
Persistent, bioaccumulative and toxic substance (PBT)				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a persistent, bioaccumulative and toxic (PBT) substance as laid out in Regulation 1107/2009 Annex II Section 3.7.2.		X	*See previous paragraph*
Very persistent and very bioaccumulative substance (vPvB).				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a a very persistent and very bioaccumulative substance (vPvB) as laid out in Regulation 1107/2009 Annex II Section 3.7.3.		X	*See previous paragraph*
Ecotoxicology				
		Yes	No	
	It is considered that the risk assessment demonstrates risks to be acceptable in accordance with the criteria laid down in the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) under realistic proposed conditions of use of a plant protection product containing the active substance, safener or synergist. The RMS is content that the assessment takes into account the severity of effects, the uncertainty of the data, and the number of organism groups which the active substance, safener or synergist is expected to affect adversely by the intended use.		X	*For overall summaries of risk assessment and endpoints for section ecotoxicology: refer to Volume 2, section 2.9. For overall conclusions:* *Overall conclusions ecotox:* *SAP200CHLORI* • ***Birds and mammals**: Exposure of birds and mammals to Chlorpyrifos-methyl according to the GAP shows no unacceptable acute and reproductive risks for all intended uses.* • ***Aquatic organisms**: Assessment not finalised. The applicant should submit information on the rate of release of capsules.* • ***Honey bees**: risk mitigation are needed please refer to 3.1.1.3. Restrictions on approval.* • ***Non-target arthropods**: Recovery/Recolonization not demonstrated for all intended uses.*

				• ***Non-target soil meso- and macrofauna****: Further information to finalise the risk assessment of the following metabolites: TMP, DCP, NMTCP.* • ***Soil nitrogen transformation*** *(microbial processes): the risk for soil microbial processes is acceptable for all proposed uses.* • ***Non-target terrestrial plants:*** *the risk for non-target terrestrial plants is acceptable for all proposed uses.* *GF-1684* • ***Birds:*** No unacceptable risk could be concluded. The approval should be conditioned to a monitoring of mammals populations in areas of continuous use of CPF-M with the submission of the results by 2 years, in order to detect possible effects on population due to application of the active substance. • ***Mammals****:* Unacceptable risk identified for large herbivorous mammal in OSR, Pome and stone fruits, Citrus, Potato, Soybean, Strawberry, Vineyard and the insectivorous mammal 'shrew' in maize. Acceptable risk for mammals could be concluded for cotton and solanaceus vegetables. • ***Aquatic organisms:*** *Risk identified for all FOCUS SW scenarios for the intended uses on citrus Risk mitigation measures needed for the rest of the intended uses please refer to 3.1.1.3. Restrictions on approval (except cereal grain)* • ***Honey bees****: risk mitigation are needed please refer to 3.1.1.3. Restrictions on approval. Bee brood studies do not cover the application rates in all intended uses (except cereal grain).* • ***Non-target arthropods****: Recovery/Recolonization not demonstrated for all intended uses (except citrus and cereal grain).* • ***Non-target soil meso- and macrofauna****: Further information to finalise the risk assessment of the following metabolites: TMP, DCP, NMTCP.* • ***Soil nitrogen transformation*** *(microbial processes): Further information to finalise the risk assessment of the following metabolite DCP*

				• ***Non-target terrestrial plants:*** *the risk for non-target terrestrial plants is acceptable for all proposed uses*
	It is considered that, on the basis of the assessment of Community or internationally agreed test guidelines, the substance **HAS** endocrine disrupting properties that may cause adverse effects on non-target organisms.		X	
	Linked to the consideration of the endocrine properties immediately above. It is considered that the exposure of non-target organisms to the active substance in a plant protection product under realistic proposed conditions of use is negligible.			
	It is considered that it is established following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist: — will result in a negligible exposure of honeybees, or — has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour.	X		*Honey bees: risk mitigation are needed please refer to 3.1.1.3. Restrictions on approval.* *Bee brood studies do not cover the application rates in all intended uses of PPP GF 1684*
Residue definition				
		Yes	No	
	It is considered that, where relevant, a residue definition can be established for the purposes of risk assessment and for enforcement purposes.	X		*The residue definition derived from the metabolism studies is proposed as Chlorpyrifos-methyl for monitoring for plant and animal products. For risk assessment, Chlorpyrifos-methyl + 3,5,6-trichloropyridinol (TCP) and its conjugates, expressed as chlorpyrifos-methyl, except for* ***Post-harvest use in stored grain:*** *Chlorpyrifos-methyl + des-methyl chlorpyrifos-methyl, expressed as chlorpyrifos-methyl.* *For processed commodities the following residue definition for risk assessment is proposed : Chlorpyrifos-methyl + 3,5,6-trichloropyridinol (TCP) and its conjugates + des-methyl chlorpyrifos-methyl, expressed as*

				chlorpyrifos-methyl.
Fate and behaviour concerning groundwater				
		Yes	No	
	It is considered that it has been established for one or more representative uses, that consequently after application of the plant protection product consistent with realistic conditions on use, the predicted concentration of the active substance or of metabolites, degradation or reaction products in groundwater complies with the respective criteria of the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009.		X	*Further information needed to finalise the risk assessment of the metabolite NMTCP.*

3.1.2. Proposal – Candidate for substitution

Candidate for substitution				
		Yes	No	
	It is considered that the active substance shall be approved as a candidate for substitution		X	

3.1.3. Proposal – Low risk active substance

Low-risk active substances				
		Yes	No	
	It is considered that the active substance **shall be considered of low risk.** In particular it is considered that the substance **should NOT be classified or proposed for classification** in accordance with Regulation (EC) No 1272/2008 as at least one of the following: — carcinogenic, — mutagenic, — toxic to reproduction, — sensitising chemicals, — very toxic or toxic, — explosive, — corrosive. In addition it is considered that **the substance is NOT**: — persistent (half-life in soil more than 60 days), — has a bioconcentration factor higher than 100, — is deemed to be an endocrine disrupter, or — has neurotoxic or immunotoxic effects.		X	Very toxic for aquatic organism BCF>100

3.1.4. List of studies to be generated, still ongoing or available but not peer reviewed

Data gap	Relevance in relation to representative use(s)	Study status		
		No confirmation that study available or on-going.	**Study on-going and anticipated date of completion**	**Study available but not peer-reviewed**
3.1.4.1. Identity of the active substance or formulation				
3.1.4.2. Physical and chemical properties of the active substance and physical, chemical and technical properties of the formulation				
SAP200CHLORI: shelf life of 2 years at ambient temperature - the results after 24 months at ambient temperature are required			Final report is scheduled by April 2017	
3.1.4.3. Data on uses and efficacy				
3.1.4.4. Data on handling, storage, transport, packaging and labelling				
3.1.4.5. Methods of analysis				
DOW: Validation of the method for the determination of the relevant impurity sulfotemp-ester in the formulation GF-1684 is required		X		
SAP: Sulfotemp and Sulfotemp ester in technical chlorpyrifos-methyl were preliminary screened by LC-MS. Accurately validated method is required		X		

Data gap	**Relevance in relation to representative use(s)**	**Study status**		
		No confirmation that study available or on-going.	**Study on-going and anticipated date of completion**	**Study available but not peer-reviewed**
SAP: Validation of the method for the determination of free chlorpyrifos-methyl in the preparation SAP200CHLORI (Chlorpyrifos-methyl 200 g/L CS) is required		X		
SAP: Analytical method is required for the monitoring of active substance and relevant metabolites in body fluids according with Regulation 283_2013.		X		
3.1.4.6. Toxicology and metabolism				
3.1.4.7. Residue data				
(DAS): The Applicant is requested to provide residue data complying with the dose rate of 3 mg/kg on stored cereals.	A potential chronic consumer risk concern cannot be excluded with the proposed MRL of 5 mg/kg for stored cereals, being rye and wheat the main contributors.	X		
(DAS): Further studies investigating the nature and magnitude of the metabolite TCP uptake in rotational crops are required, because of the moderate degradation of this compound (DT90 up to 319 days). According to the Notifier, a further study investigating the residues of chlorpyrifos-methyl and TCP in radish, leaf lettuce, oilseed rape and			X	

Data gap	**Relevance in relation to representative use(s)**	**Study status**		
		No confirmation that study available or on-going.	**Study on-going and anticipated date of completion**	**Study available but not peer-reviewed**
wheat grown as rotational crops is still ongoing.				
3.1.4.8. Environmental fate and behaviour				
(DAS and SAP): Data on DT50 and Koc for metabolite N-methyl TCPin three European agricultural soils are required to finalise the risk assessment to GW		X		
(DAS and SAP): GW modelling for N-methyl TCP for all intended uses considering the input data selected by RMS in for parent compound (see LoEP for details)		X		
3.1.4.9. Ecotoxicology				
(DAS and SAP): toxicity data of NMTCP, TMP and DCP on Folsomia and Hypoaspys. **(DAS):** toxicity data of DCP on nitrification transformation in order to finalise the risk assessment		X		
(DAS) : Further Refined risk assessment for median large mammals in OSR, Pome and stone fruits, Citrus, Potato, Soybean, Strawberry, Vineyard and the insectivorous mammal ‘shrew’ in maize.		X		
(DAS): bee brood studies do not cover the intended application rates. Further information needed .		X		

Data gap	Relevance in relation to representative use(s)	Study status		
		No confirmation that study available or on-going.	Study on-going and anticipated date of completion	Study available but not peer-reviewed
(SAP) : applicant to submit further information on the reralse rate of capsules in order to support their statement the toxicity data of the active substance covers the toxicity of the plant protection product		X		

3.1.5. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles, as laid out in Commission Regulation (EU) No 546/2011, and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

Area of the risk assessment that could not be finalised on the basis of the available data	**Relevance in relation to representative use(s)**
(1) Dermal absorption data of SAP200CHLORI CS, 200 g/L	Operator, bystander, resident and worker exposure assessment for the representative formulation (SAP200CHLORI CS, 200 g/L will be carried out with appropriate absorption data). Risk assessment cannot be performed.
(6) further information needed to cover the beebrood	All intended uses (GF 1684) see table 2.9.9.3-1 for details
(8) toxicity data of NMTCP, TMP and DCP on *Folsomia* and *Hypoaspys*	All intended uses of SAP200CHLORI CS, 200 g/L and GF-1684.
(9) toxicity data of DCP on nitrification transformation	All intended uses (except OSR and Grapes) for GF 1684
(11) further information on persistence and mobility of the metabolite N-methyl TCP to finalise GW modelling	All intended uses for SAP200CHLORI CS, 200 g/L, GF 1684
(12) risk assessment on aquatic orgqanisms: The applicant should submit information on the rate of release of capsules	All intended uses on SAP200CHLORI CS, 200 g/L
(13) Risk assessment on *Hypoaspis aculeifer*	All intended uses on SAP200CHLORI: EC10 and EC20 calculations should be provided.

3.1.6. Critical areas of concern

An issue is listed as a critical area of concern:
(a) where the substance does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II of Regulation (EC) No 1107/2009 and the applicant has not provided detailed evidence that the active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, taking into account risk mitigation measures to ensure that exposure of humans and the environment is minimised, or
(b) where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles, as laid out in Commission Regulation (EU) 546/2011, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

Critical area of concern identified	**Relevance in relation to representative use(s)**
(4) Risk identified for medium-large mammals and insectivorous mammal 'shrew'	GF-1684 Medium/large herbivorous mammal (lagomomorph): OSR, Pome and stone fruits, Citrus, Potato, Soybean, Strawberry, Vineyard Insectivorous mammal 'shrew': maize.
(5) Aquatic Risk identified for all FOCUS SW scenarios.	GF 1684: For the following intended uses: citrus, ~~grapes late application at 1 x 608 g as/ha and pomes~~ (considering 20 m VBS (reduction factor according to FOCUS L&M) + 95% DRN).
(7) Risk identified for in-field and off-field NTA. No recovery/recolonization demonstrated.	All intended uses for SAP200CHLORICS (200 g/L) and GF-1684 (except citrus and cereal grain).
(10) risk indentified on soil nitrification	GF-1684: Intended use on maize.

3.1.7. Overview table of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in 3.3.1, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)
All columns are grey as the material tested in the toxicological studies has not been demonstrated to be representative of the technical specification.

SAP200CHLORI

Representative use (X[1])		ORS	Grapes
Operator risk	Risk identified		
	Assessment not finalised	X[1]	X[1]
Worker risk	Risk identified		
	Assessment not finalised		
Bystander risk	Risk identified		
	Assessment not finalised		

Representative use (X[1])		ORS	Grapes
Consumer risk	Risk identified		
	Assessment not finalised		
Risk to wild non target terrestrial vertebrates	Risk identified		
	Assessment not finalised		
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	X[7]	X[7]
	Assessment not finalised	X[8], X[13]	X[8], X[13]
Risk to aquatic organisms	Risk identified		
	Assessment not finalised	X[12]	X[12]
Groundwater exposure active substance	Legal parametric value breached		
	Assessment not finalised		
Groundwater exposure metabolites	Legal parametric value breached		
	Parametric value of 10µg/L[(a)] breached		
	Assessment not finalised	X[11]	X[11]
Comments/Remarks			

The superscript numbers in this table relate to the numbered points indicated within chapter 3.1.5 and 3.1.6. Where there is no superscript number, see level 2 for more explanation.
(a): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

GF 1684

Representative use (X[1])		Cotton	Solanaceous vegetables	Maize	ORS	Orchards	Citrus	Potatoes	Soybean	Strawberry	Grapes	Cereal grain
Operator risk	Risk identified											
	Assessment not finalised											
Worker risk	Risk identified											
	Assessment not finalised											
Bystander risk	Risk identified											
	Assessment not finalised											
Consumer risk	Risk identified											
	Assessment not finalised											
Risk to wild non target terrestrial vertebrates	Risk identified			X[4]	X[4]	X[4]	X[4]	X[4]	X[4]	X[4]	X[4]	
	Assessment not finalised											
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	X[7]	X[7]	X[7,10]	X[7]	X[7]		X[7]	X[7]	X[7]	X[7]	
	Assessment not finalised	X[6,8,9]	X[6,8,9]	X[6,8,9]	X[6,8]	X[6,8,9]	X[6,8,9]	X[6,8,9]	X[6,8,9]	X[6,8,9]	X[6,8]	
Risk to aquatic organisms	Risk identified						X[5]					
	Assessment not finalised											
Groundwater exposure active substance	Legal parametric value breached											
	Assessment not finalised											X[2]

Representative use (X[1])		Cotton	Solanaceous vegetables	Maize	ORS	Orchards	Citrus	Potatoes	Soybean	Strawberry	Grapes	Cereal grain
Groundwater exposure metabolites	Legal parametric value breached											
	Parametric value of 10µg/L[(a)] breached											
	Assessment not finalised	X[11]	X[11]	X[11]	X[11]	X[11]	X[11]	X[11]	X[11]	X[11]	X[11]	X[11]
Comments/Remarks												

The superscript numbers in this table relate to the numbered points indicated within chapter 3.1.5 and 3.1.6. Where there is no superscript number, see level 2 for more explanation.
(a): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

3.1.8. Area(s) where expert consultation is considered necessary

It is recommended to organise a consultation of experts on the following parts of the assessment report:

Area(s) where expert consultation is considered necessary	**Justification**
NTA	In this point, during the CoRMS and the applicants' consultation period, the applicant DAS pointed out that each specific crop does not have its own individual range of non-target arthropod species and hence, extrapolation is possible between broadly similar (from an arthropod habitat perspective) crops. For example, the applicant defended the use of cereals as a representative crop and considered to adequately demonstrate effects in other broad acre crops (vegetables). However, the RMS respectfully disagrees with the applicant's argument: the arthropod communities are different from one specific crop to another and though some generalist species are common to many environments, factors like the crop physiology, the management calendar or the pesticides application regimes, among others, are continuously selecting the species inhabiting a particular crop. The RMS is of the opinion that to discard any field effect in a specific crop, no extrapolated results from a different one can be used. However, this point could be discussed during the peer-review.

3.1.9. Critical issues on which the Co RMS did not agree with the assessment by the RMS

Points on which the co-rapporteur Member State did not agree with the assessment by the rapporteur member state. Only the points relevant for the decision making process should be listed.

Issue on which Co-RMS disagrees with RMS	**Opinion of Co-RMS**	**Opinion of RMS**

3.2. PROPOSED DECISION

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

3.3. RATIONAL FOR THE CONDITIONS AND RESTRICTIONS TO BE ASSOCIATED WITH THE APPORVAL OR AUTHORISATION(S), AS APPROPRIATE

3.3.1. Particular conditions proposed to be taken into account to manage the risks identified

[redacted]	[redacted]
[redacted]	[redacted]
[redacted] [redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

3.4. APPENDICES

GUIDANCE DOCUMENTS USED IN THIS ASSESSEMENT

- EFSA (European Food Safety Authority), 2009. Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA. EFSA Journal 2009;7(12):1438, 358 pp. doi:10.2903/j.efsa.2009.1438
- European Commission, 2002a. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002 rev.2 final, 17 October 2002
- European Food Safety Authority, 2014. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 37 pp., doi:10.2903/j.efsa.2014.3662
- EFSA (European Food Safety Authority), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013; 11(7):3290.
- European Food Safety Authority, 2013. EFSA Guidance Document on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees). EFSA Journal 2013;11(7):3295, 268 pp., doi:10.2903/j.efsa.2013.3295
- European Commission, 2003. Guidance Document on Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC. SANCO/221/2000-rev. 10 - final, 25 February 2003
- FOCUS (2000) “FOCUS groundwater scenarios in the EU review of active substances” Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference Sanco/321/2000 rev.2, 202pp
- FOCUS (Forum for the co-ordination of pesticide fate models and their use), 2001. FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp., as updated by the Generic Guidance for FOCUS surface water scenarios, version 1.3 dated December 2014.
- FOCUS (2006) “Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration” Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp, as updated by the Generic guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, version 1.1 dated December 2014.
- FOCUS (Forum for the co-ordination of pesticide fate models and their use), 2007. Landscape and Mitigation Factors In Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations. Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 169 pp
- SETAC (Society of Environmental Toxicology and Chemistry), 2001. Guidance Document on Regulatory Testing and Risk Assessment procedures for Plant Protection Products with Non-Target Arthropods. ESCORT 2.
- SETAC (Society of Environmental Toxicology and Chemistry), 2012. Linking Non-Target Arthropod and risk assessment with protection goals. ESCORT 3.

3.5. REFERENCE LIST

Not applicable