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Item 4 (b) (iii) of the provisional agenda*

Technical work: review of notifications of final regulatory action: iprodione

Iprodione: supporting documentation provided by the European Union

Note by the Secretariat

As is mentioned in the note by the Secretariat on iprodione: notifications of final regulatory action (UNEP/FAO/RC/CRC.17/5), the annex to the present note sets out documentation provided by the European Union to support its notification of final regulatory action for iprodione in the pesticide category. The present note, including its annex, has not been formally edited.

* UNEP/FAO/RC/CRC.17/1.

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Annex

Iprodione: supporting documentation provided by the European Union

List of documents:

1. Commission implementing regulation (EU) 2017/2091 of 14 November 2017.

2. Final Renewal report for the active substance iprodione (Iprodione SANTE/10627/2017 rev 21 of 6 October 2017).

3. EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance iprodione. EFSA Journal 2016;14(11):4609, 31 pp.doi:10.2903/j.efsa.2016.4609.

4. Appendix A to: EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance iprodione EFSA Journal 2016;14(11):4609, 145 pp. doi:10.2903/j.efsa.2016.4609.

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2091

of 14 November 2017

concerning the non-renewal of approval of the active substance iprodione, 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 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 2003/31/EC ([2]) included iprodione 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 iprodione, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 October 2018.

(4) An application for the renewal of the approval of iprodione was 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 applicant submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was 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 November 2015.

(7) The Authority communicated the renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.

(8) On 8 June 2016 the Authority communicated to the Commission its conclusion ([6]) on whether iprodione can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority concluded that there is a high potential for the representative uses assessed to result in groundwater exposure above the parametric drinking water limit of 0,1 µg/l by the relevant metabolites of iprodione in situations represented by all pertinent groundwater scenarios; one relevant metabolite is even predicted to exceed 0,75 µg/l in all pertinent groundwater scenarios. In addition, the Authority also concluded that there is a high long-term risk to aquatic organisms.

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

([2]) Commission Directive 2003/31/EC of 11 April 2003 amending Council Directive 91/414/EEC to include 2,4-DB, beta-cyfluthrin, cyfluthrin, iprodione, linuron, maleic hydrazide and pendimethalin as active substances (OJ L 101, 23.4.2003, p. 3).

([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).

([6]) EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance iprodione. EFSA Journal 2016;14(11):4609, 31 pp. doi:10.2903/j.efsa.2016.4609.

(9) Furthermore, in respect of one metabolite, found as a residue in plants and as an impurity in the technical material, the Authority concluded that the genotoxic potential cannot be excluded and therefore the setting of reference values for that metabolite cannot be confirmed based on the information available. Moreover, based on the available information, the dietary risk assessment could not be finalised as it is not possible to establish residue definitions for risk assessment; nevertheless, an acute consumer risk could not be excluded. Finally, the long-term risk assessment for wild mammals for all the relevant routes of exposure could not be finalised, based on the information submitted in the dossier.

(10) Additionally, iprodione is classified as carcinogen category 2 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([1]) while in the conclusion of the Authority it is indicated that iprodione should be classified as carcinogen category 1B and as toxic for reproduction category 2. For the representative uses considered, residue levels exceed the default value as referred to in point (b) of Article 18(1) of Regulation (EC) No 396/2005 of the European Parliament and of the Council ([2]). Consequently, the requirement set out in Points 3.6.3 and 3.6.5 of Annex II to Regulation (EC) No 1107/2009 is not fulfilled.

(11) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with the third paragraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, on the draft renewal report. The applicant submitted its comments, which have been carefully examined.

(12) However, despite the arguments put forward by the applicant, the concerns related to the substance could not be eliminated.

(13) Based on the concerns identified, 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. It is therefore appropriate not to renew the approval of iprodione in accordance with Article 20(1)(b) of that Regulation.

(14) Member States should be given time to withdraw authorisations for plant protection products containing iprodione.

(15) For plant protection products containing iprodione, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should, at the latest, expire on 5 June 2018.

(16) Commission Implementing Regulation (EU) 2017/1511 ([3]) extended the expiry date of iprodione to 31 October 2018 in order to allow the renewal process to be completed before the expiry of the approval of that substance. However, given that a decision has been taken ahead of that extended expiry date, this Regulation should apply as soon as possible.

(17) This Regulation does not prejudice the submission of a further application for the approval of iprodione pursuant to Article 7 of Regulation (EC) No 1107/2009.

(18) 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 approval of active substance

The approval of the active substance iprodione is not renewed.

([1]) 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).
([2]) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).
([3]) Commission Implementing Regulation (EU) 2017/1511 of 30 August 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-methylcyclopropene, beta-cyfluthrin, chlorothalonil, chlorotoluron, cypermethrin, daminozide, deltamethrin, dimethenamid-p, flufenacet, flurtamone, forchlorfenuron, fosthiazate, indoxacarb, iprodione, MCPA, MCPB, silthiofam, thiophanate-methyl and tribenuron (OJ L 224, 31.8.2017, p. 115).

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 50, on iprodione, is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing iprodione as active substance by 5 March 2018 at the latest.

Article 4

Grace Period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire by 5 June 2018 at the latest.

Article 5

Entry into force

This Regulation shall enter into force on the twentieth 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, 14 November 2017.

For the Commission

The President

Jean-Claude JUNCKER

Iprodione
SANTE/10627/2017 rev 2[1]
6 October 2017

Final Renewal report for the active substance **iprodione**

finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 6 October 2017
in view of the non-renewal of the approval of XXX as active substance in accordance with Regulation (EC) No 1107/2009[2]

1. Procedure followed for the re-evaluation process

This renewal report has been established as a result of the evaluation of **iprodione**, in accordance with Regulation (EC) No 1107/2009[3] and Commission Implementing Regulation (EU) No 844/2012[4] following the submission of an application to renew the approval of this active substance expiring in December 2013.

Iprodione 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 2003/31/EC[5]. Iprodione 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[6].

An application for renewal of the approval of iprodione was submitted by BASF Agro BV in accordance with Article 1 of Regulation (EU) No 844/2012.

Commission Implementing Regulation (EU) No 823/2012[7] extended until 31 October 2016 the period of approval of iprodione followed by Commission Implementing Regulation (EU) 2016/950[8] which extended the period of approval until 31 October 2017 to allow the completion of its review.

Commission Implementing Regulation (EU) No 686/2012[9] 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).

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1 Section 3 of the renewal report has been updated to include the toxicological reference values that were finalised as part of the renewal review of iprodione.
2 Renewal report established in accordance with Article 14 of Regulation (EU) No 844/2012; does not necessarily represent the views of the European Commission.
3 OJ L 309, 24.11.2009, p. 1.
4 OJ L 252, 19.9.2012, p. 26.
5 OJ L 101, 23.4.2003, p. 3.
6 OJ L 153, 11.6.2011, p. 1.
7 OJ L 250, 15.9.2012, p. 13.
8 OJ L 159, 16.6.2016, p.3.
9 OJ L 200, 27.7.2012, p. 5.

For iprodione the rapporteur Member State was France and the co-rapporteur Member State was Belgium.

France finalised in November 2015 its examination, in the form of a renewal assessment report. This Report was sent to the Commission and the European Food Safety Authority on 3 November 2015 and included a recommendation concerning the decision to be taken with regard to the renewal of the approval of iprodione for the supported uses.

In accordance with Article 13 of Implementing Regulation (EU) No 844/2012, the EFSA organised an intensive consultation of technical experts from Member States, to review the renewal assessment report and the comments received thereon (peer review).

The EFSA sent to the Commission its conclusion on the risk assessment (Conclusions regarding the peer review of the pesticide risk assessment of the active substance)[10] on 28 November 2016. This conclusion refers to background document A (final revised version of the renewal assessment report) and background document B (EFSA peer review report).

According to the provisions of Article 14 of Implementing Regulation (EU) No 844/2012, the Commission referred a draft renewal report on the renewal of approval to the Standing Committee on Plants, Animals, Food and Feed, for examination on 17 May 2017. The draft renewal report was finalised in the meeting of the Standing Committee on 6 October 2017.

The present renewal report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and the comments and clarifications submitted after the conclusion of the EFSA, these documents are also considered to be part of this renewal report.

2. Purposes of this renewal report

This renewal report, including the background documents and appendices hereto, has been developed and finalised in support of **Commission Implementing Regulation (EU) 2017/2091[11]** concerning the non-renewal of approval of iprodione as 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.

[10] EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active sub stance iprodione. EFSA Jour nal 2016;14(11):4609, 31 pp. doi:10.2903/j.efsa.2016.4609.

[11] OJ L 297, 15.11.2017, p. 25.

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

As part of the updated evaluation of iprodione the following reference values have been finalised:

ADI: 0.02 mg/kg bw per day
ARfD: 0.06 mg/kg bw
AOEL: 0.04 mg/kg bw per day
AAOEL: 0.04 mg/kg bw

To note, the ADI, ARfD and the AOEL have changed compared to the previous EU agreed reference value(s).

The overall conclusion of the evaluation, 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 predicted concentrations in groundwater that exceed 0.1 µg/L for relevant metabolites RP 35606 and RP 30181. Metabolite RP 35606 also exceeds 0.75 µg/L, in acidic soils, and metabolite RP 30181 exceeds 0.75 µg/L in both acidic and slightly acidic to alkaline soils for both intended uses (carrots and lettuce). Iprodione is classified as carcinogen category 2 in accordance with Regulation (EC) No 1272/2008[12] and therefore these metabolites are considered relevant as it has not been demonstrated that they do not share the same intrinsic toxicological properties of iprodione. Furthermore, during the peer review it was proposed that iprodione should be classified as carcinogen category 1B and as toxic for reproduction category 2;

  - the genotoxic potential of metabolite RP 30228 (found as a residue and impurity in the technical material) that cannot be excluded and for which the setting of reference values cannot be confirmed based on the information available. It is noted that metabolite RP 30228 is predicted to occur in groundwater above 0.1 µg/L in one FOCUS GW scenario according to the representative uses;

  - iprodione is classified as carcinogen category 2 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[13] while in the conclusion of the Authority it is indicated that iprodione should be classified as carcinogen category 1B and as toxic for reproduction category 2. For the representative uses considered, residue levels exceed the default value as referred to in point (b) of Article 18(1) of Regulation (EC) No 396/2005. Consequently, the requirement set out in Points 3.6.3 and 3.6.5 of Annex II to Regulation (EC) No 1107/2009 is not fulfilled;

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[12] 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).

[13] 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).

- an acute consumer risk that cannot be excluded based on a preliminary risk assessment. The assessment is likely to underestimate exposure to the metabolite 3,5-dichloroaniline due to instability of the compound in residue sample storage and of residues not fully considered due to different data gaps. Moreover, possible common toxicological effects of 3,5-dichloroaniline and iprodione and similar metabolites have not been considered in the risk assessment;

- the high long-term risk of iprodione to aquatic organisms.

- **the information available is insufficient** to satisfy the requirements set out in Article 4(1) to (3) of Regulation (EC) No 1107/2009, in particular with regard to:

- operator exposure estimates that according to the supported indoor uses in lettuce could not be finalised;
- the dietary consumer risk assessment in terms of food of plant and animal origin that could not be finalised given numerous data gaps identified that do not permit the establishment of final residue definitions for risk assessment;
- the proposed route of degradation in soil that was incomplete since it was based only on phenyl-labelled iprodione studies. Therefore, studies on the fate and behaviour of the hydantoin moiety iprodione in soil are required to demonstrate whether metabolite RP 30181 and/or other degradation/transformation products are formed at amounts requiring further assessment or not;
- the long-term risk assessment for wild mammals for all the relevant routes of exposure that could not be finalised due to the lack of a reliable endpoint.

Given the concerns detailed above, the derogation provided for in Article 4(7) to Regulation (EU) No 1107/2009 does not apply.

In conclusion from the assessments made on the basis of the submitted information, no plant protection products containing the active substance concerned is expected to satisfy in general 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 iprodione in accordance with Regulation (EC) No 1107/2009 should therefore not be renewed.

CONCLUSION ON PESTICIDES PEER REVIEW

EFSA Journal

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Peer review of the pesticide risk assessment of the active substance iprodione

European Food Safety Authority (EFSA)

Abstract

The conclusions of EFSA following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State, France, and co-rapporteur Member State, Belgium, for the pesticide active substance iprodione are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012. The conclusions were reached on the basis of the evaluation of the representative uses of iprodione as a fungicide on carrots and lettuce. The reliable endpoints, appropriate for use in regulatory risk assessment are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

Keywords: iprodione, peer review, risk assessment, pesticide, fungicide

Requestor: European Commission

Question number: EFSA-Q-2014-00814

Correspondence: pesticides.peerreview@efsa.europa.eu

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Summary

Commission Implementing Regulation (EU) No 844/2012 (hereinafter referred to as 'the Regulation') lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012. Iprodione is one of the active substances listed in Regulation (EU) No 686/2012.

In accordance with Article 1 of the Regulation, the rapporteur Member State (RMS), France, and co-rapporteur Member State (co-RMS), Belgium, received an application from BASF Agro BV for the renewal of approval of the active substance iprodione. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS, the European Commission and the European Food Safety Authority (EFSA) about the admissibility.

The RMS provided its initial evaluation of the dossier on iprodione in the renewal assessment report (RAR), which was received by EFSA on 3 November 2015. In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, BASF Agro BV, for comments on 9 December 2015. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 8 February 2016.

Following consideration of the comments received on the RAR, it was concluded that additional information should be requested from the applicant, and that EFSA should conduct an expert consultation in the areas of mammalian toxicology, environmental fate and behaviour and ecotoxicology.

In accordance with Article 13(1) of the Regulation, EFSA should adopt a conclusion on whether iprodione can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of iprodione as a fungicide on field application carrots and lettuce and greenhouse application in lettuce, as proposed by the applicant. Full details of the representative uses can be found in Appendix A of this report.

Data were submitted to conclude that the proposed representative uses of iprodione result in a sufficient fungicidal efficacy against the target organisms.

A data gap was identified for a more detailed assessment of the literature review for relevant metabolites of iprodione in the residue, environmental fate and behaviour and ecotoxicology Sections and published within 10 years before the date of submission of the dossier, to be conducted and reported in accordance with EFSA guidance.

In the area of identity, physical and chemical properties and analytical methods, data gaps were identified for the data generation methods, the assessment of the extraction efficiency of the methods for the determination of residues in plant and animal matrices, for a method of monitoring a metabolite in groundwater and for a method for body fluids and tissues.

In the area of mammalian toxicology and non-dietary exposure, data gaps, issues that could not be finalised and critical area of concerns were identified. The technical specification is not covered by toxicity studies, the genotoxic potential of metabolite RP 30228 cannot be excluded, the peer review classification of iprodione as 'Carc. Cat. 1B (H350)', the potential for endocrine disruption of iprodione and the relevance of groundwater metabolites RP 35606 and RP 30181 were considered critical areas of concern. Operator exposure estimates according to the supported indoor uses in lettuce could not be finalised. Data gaps were identified to support the technical specification and the maximum content of RP 30228 and to address the toxicological profile of metabolites RP 35606, RP 30181, RP 25040, RP 37176, RP 36112, RP 36221 and LS 720942.

In the area of residues, a number of data gaps were identified and only provisional residue definitions for risk assessment could be derived. Based on a preliminary consumer risk assessment, that is likely underestimating exposure to metabolite 3,5-dichloroaniline, acute intake concerns cannot be excluded for the representative uses (carrots and lettuce). Moreover, a genotoxicity concern could not be excluded for the major residue metabolite RP 30228. Both issues have been identified as critical area of concern.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at the European Union (EU) level for the representative uses with some notable exceptions. A data gap was identified for information on the effect of water treatment processes on the nature of residues of both the active substance and its identified

metabolites potentially present in surface and groundwater, when surface water or groundwater are abstracted for drinking water. This gap leads to the consumer risk assessment from the consumption of drinking water being not finalised for all the representative uses. Furthermore, the proposed route of degradation in soil was incomplete since it was based only on phenyl-labelled iprodione studies. This leads to a data gap for investigating the fate and behaviour of the hydantoin moiety iprodione in soil. The potential for groundwater exposure by metabolite RP 35606 (in acidic soils only), and by metabolite RP 30181 is predicted to be high over a wide range of geoclimatic conditions represented by the Forum for the Co-ordination of Pesticide Fate Models and their Use (FOCUS) groundwater scenarios. According to the information available in the mammalian toxicology Section, these metabolites are considered relevant due to the proposed classification for parent compound by the peer review experts as carcinogenic and toxic for the development and reproduction leading to a critical area of concern.

In the area of ecotoxicology, data gaps have been identified for birds, mammals, aquatic organisms, bees and to further address the potential for endocrine disruption of iprodione in fish. The long-term risk assessment for wild mammals could not be finalised due to the lack of a reliable endpoint. Critical areas of concerns have been identified to further address the long-term risk for aquatic organisms to iprodione and for the compliance of the batches used in the ecotoxicity studies with the technical specification.

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Background

Commission Implementing Regulation (EU) No 844/2012[1] (hereinafter referred to as 'the Regulation') lays down the provisions for the procedure of the renewal of the approval of active substances, submitted under Article 14 of Regulation (EC) No 1107/2009[2]. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of the Member States, the applicant(s) and the public on the initial evaluation provided by the rapporteur Member State (RMS) and/or co-rapporteur Member State (co-RMS) in the renewal assessment report (RAR), and the organisation of an expert consultation where appropriate.

In accordance with Article 13 of the Regulation, unless formally informed by the European Commission that a conclusion is not necessary, EFSA is required to adopt a conclusion on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 within 5 months from the end of the period provided for the submission of written comments, subject to an extension of up to 8 months where additional information is required to be submitted by the applicant(s) in accordance with Article 13(3).

In accordance with Article 1 of the Regulation, the RMS France and co-RMS Belgium received an application from BASF Agro BV for the renewal of approval of the active substance iprodione. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS, the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on iprodione in the RAR, which was received by EFSA on 3 November 2015 (France, 2015).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, BASF Agro BV, for consultation and comments on 9 December 2015. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 8 February 2016. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of a reporting table. The applicant was invited to respond to the comments in column 3 of the reporting table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 13(3) of the Regulation were considered in a telephone conference between EFSA, the RMS France and co-RMS Belgium on 25 March 2016. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicant, and that EFSA should conduct an expert consultation in the areas of mammalian toxicology, environmental fate and behaviour and ecotoxicology.

The outcome of the telephone conference, together with EFSA's further consideration of the comments, is reflected in the conclusions set out in column 4 of the reporting table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in an expert consultation, were compiled by EFSA in the format of an evaluation table.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the evaluation table, together with the outcome of the expert consultation and the written consultation on the assessment of additional information, where these took place, were reported in the final column of the evaluation table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with the Member States via a written procedure in September 2016.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the representative formulation, evaluated on the basis of the representative uses of iprodione as a fungicide on carrots and lettuce as proposed by the applicant. A list of the relevant end points for the active substance and the formulation is provided in Appendix A.

In addition, a key supporting document to this conclusion is the peer review report (EFSA, 2016), which is a compilation of the documentation developed to evaluate and address all issues raised in the

[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. 26–32.

[2] Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council 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. 1–50.

peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents, in which all views expressed during the course of the peer review, including minority views, where applicable, can be found:

- the comments received on the RAR;
- the reporting table (25 March 2016);
- the evaluation table (11 October 2016);
- the report(s) of the scientific consultation with the Member State experts;
- the comments received on the assessment of the additional information;
- the comments received on the draft EFSA conclusion.

Given the importance of the RAR, including its revisions (France, 2016), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the European Union (EU) for which the applicant has not demonstrated that it has regulatory access to the information on which this conclusion report is based.

The active substance and the formulated product

Iprodione is the ISO common name for 3-(3,5-dichlorophenyl)-*N*-isopropyl-2,4-dioxoimidazolidine-1-carboxamide (IUPAC).

The representative formulated product for the evaluation was 'Rovral WG (BAS 610 06 F)' a water-dispersible granule (WG) containing 750 g/kg iprodione.

The representative uses evaluated were foliar spray field applications for the control of fungal diseases in carrots and lettuce and greenhouse application in lettuce. Full details of the good agricultural practices (GAPs) can be found in the list of end points in Appendix A.

Data were submitted to conclude that the representative uses of iprodione proposed at the EU level result in a sufficient fungicidal efficacy against the target organisms, following the guidance document SANCO/10054/2013-rev. 3 (European Commission, 2013).

A data gap has been identified for a search of the scientific peer-reviewed open literature on metabolites RP 25040, LS 720942 and RP 30181, dealing with side effects on the environment and non-target species and for an updated literature search for 3,5-dichloroaniline for residue Section and published within the 10 years before the date of submission of the dossier, to be conducted and reported in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011).

Conclusions of the evaluation

1. Identity, physical/chemical/technical properties and methods of analysis

The following guidance documents were followed in the production of this conclusion: SANCO/3029/99-rev. 4 (European Commission, 2000a), SANCO/3030/99-rev. 4 (European Commission, 2000b), SANCO/10597/2003-rev. 10.1 (European Commission, 2012), SANCO/825/00-rev. 8.1 (European Commission, 2010).

The reference specification for first approval was updated. The proposed specification is based on batch data from industrial scale production and on quality control data. The minimum purity of the active substance as manufactured is 980 g/kg, meeting the requirements of the FAO specification under the new procedure (FAO, 2006) of min. 960 g/kg. The impurity 3,5-dichloroaniline (RP 32596) was considered relevant with a maximum amount of 0.5 g/kg, while the maximum level of the relevant impurity RP 30228 could not be established (See Section 2).

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of iprodione or the representative formulation. The main data regarding the identity of iprodione and its physical and chemical properties are given in Appendix A.

The methods for the generation of pre-approval data required for the risk assessment, in the physicochemical tests, toxicity and ecotoxicity studies, except residues, were not adequately addressed (data gap). High-pressure/high-performance liquid chromatography-ultraviolet (HPLC-UV) methods are available for the determination of iprodione in the technical material and in the representative formulation, and for the determination of the respective impurities in the technical material.

Iprodione residues can be monitored in food and feed of plant origin by HPLC with tandem mass spectrometry (HPLC–MS/MS) with a limit of quantification (LOQ) of 0.01 mg/kg in all plant commodity groups. Extraction efficiency was, however, demonstrated only for high water content commodities. An adequate HPLC–MS/MS method exists for the determination of RP 32490 in products of animal origin with a LOQ of 0.01 mg/kg in milk, egg, meat, liver, kidney and fat. A data gap was, however, identified for demonstration of the extraction efficiency in animal matrices. Residues of iprodione in soil can be determined by HPLC–MS/MS with a LOQ of 0.005 mg/kg, while in air by gas chromatography-electron capture detector (GC-ECD) with a LOQ of 2 $\mu g/m^3$. Monitoring of the compounds of the residue definition for surface water (iprodione and metabolite RP 35606) can be done by HPLC–MS/MS with LOQs of 0.03 μg/L for each compound. As the residue definition for monitoring in ground water was defined as iprodione and metabolites RP 35606 and RP 30181 (see Sections 2 and 4), a data gap was identified for a method for the determination of metabolite RP 30181 in ground water. A data gap was identified for a method for monitoring iprodione in body fluids and tissues.

2. Mammalian toxicity

The toxicological profile of the active substance iprodione was discussed at the Pesticides Peer Review Experts' Meeting 143 and assessed based on the following guidance documents: SANCO/221/2000-rev. 10-final (European Commission, 2003), SANCO/10597/2003-rev. 10.1 (European Commission, 2012), Guidance on Dermal Absorption (EFSA PPR Panel, 2012) and Guidance on the Application of the CLP Criteria (ECHA, 2015).

To assess the toxicological profile of the **active substance,** the applicant submitted a set of toxicity studies. The toxicity studies, however, were not representative of the proposed technical specification for the active substance and associated impurities leading to a critical area of concern. 3,5-dichloroaniline (RP 32596) is a relevant impurity (maximum content 0.5 g/kg). Impurity RP 30228 is considered potentially relevant based on genotoxic concerns; however, its maximum content from the toxicological point of view cannot be established (data gap, see Section 7).

In the toxicokinetics studies, iprodione was extensively and rapidly absorbed. Oral absorption was estimated to be greater than 60%. There was no evidence for accumulation. Excretion of the active substance was predominantly through the urine but with appreciable amounts excreted in the faeces. The main metabolic pathway identified was hydroxylation of the aromatic ring, degradation of the isopropylcarbamoyl chain and rearrangement followed by cleavage of the hydantoin moiety. Metabolic patterns in rats and humans were similar. No unique human metabolite is expected.

In the acute toxicity studies, the substance has low acute toxicity when administered orally, dermally or by inhalation to rats. It is not a skin or eye irritant or a skin sensitiser. A phototoxicity and photogenotoxicity test are not required for iprodione.

In short-term oral toxicity studies with rats, mice and dogs, the toxicity targets were the adrenals (rats, mice, dogs), liver (mice), haematology (dogs), kidney (dogs), prostate (dogs), uterus and ovary (rats). Non-specific critical effects as reduced body weight gain and food consumption were also observed in rats. Although the dog was considered the most sensitive species during expert consultation some effects were observed in rats at similar dose range than in dogs. It was considered probable (due to dose-dependent increases) that there were some effects in the liver, adrenals and prostate at 500 ppm (30.8 mg/kg body weight (bw) per day) onwards, but the majority of experts considered that these are not adverse (in this study) at 500 ppm. The overall relevant short-term oral no observed adverse effect level (NOAEL) is 17.5 mg/kg bw per day (1-year dog studies). During the expert consultation, it was also discussed whether the adrenals effects (considered effects on a target organ) would give rise to a possible classification as STOT RE 2. These effects were consistent among studies and species and probably related to more than one mechanism. It was concluded that the severity of the effects at the relevant dose levels for classification may be considered as marginal.

Based on available genotoxicity studies, the substance is unlikely to be genotoxic. However, data gaps were identified for a new *in vitro* gene mutation and an Ames test including strain TA102 performed with the representative technical specification.

In long-term toxicity and carcinogenicity studies with rats and mice, the toxicity targets were the liver, adrenals, testes, epidymides, seminal vesicles, prostate and spleen in rats and the liver, testes, non-glandular stomach, uterus, ovaries, spleen, kidney and adrenals in mice. The rat was the most sensitive species. The long-term NOAEL in the 2-year rat study was discussed during the expert's meeting: the experts considered that effects observed at the lowest dose of 6.1 mg/kg bw per day tested were adverse and a NOAEL could not be identified (i.e. NOAEL < 6 mg/kg bw per day). On the basis of the reassessment of long-term toxicity and carcinogenicity studies, new mechanistic data and taking into account guidance on the application of the new classification, labelling and packaging (CLP) Criteria (ECHA, 2015), the carcinogenic potential was also discussed during the experts' meeting: the majority of the experts considered that tumours observed in several organs and in different species (interstitial Leydig cell tumours in rats and ovary luteomas, benign and malignant liver cell tumours in mice), as well as progression to malignancy in liver tumours (and possibly pituitary adenocarcinoma); and a plausible endocrine-mediated (antiandrogenic) mode of action would suggest that classification as 'Carc. Cat. 1B (H350)' would be more appropriate for iprodione than current harmonised classification as 'Carc. Cat. 2 (H351)'[3] leading to a critical area of concern.

In reproductive toxicity studies, fertility and overall reproductive performance was not impaired; however, increased abnormal sperm was observed in F1. Iprodione has been shown to induce developmental toxicity, i.e. delayed onset of male puberty and persistence of areolas in the two-generation study and umbilical hernia in the rabbit developmental toxicity study. Mechanistic studies indicated that iprodione is an antiandrogenic compound. The parental NOAEL is 26.9 mg/kg bw per day, whereas a reproductive and offspring NOAEL could not be identified (i.e. the lowest dose tested of 26.9 mg/kg bw per day was the lowest observable adverse effect level (LOAEL)). In developmental toxicity studies, the maternal NOAEL is 20 mg/kg bw per day for both rats and rabbits, the developmental NOAEL is 20 mg/kg bw per day for the rat, whereas a developmental NOAEL in rabbits could not be identified (i.e. the lowest dose tested of 20 mg/kg per day was the LOAEL). On the basis of the reassessment of reproductive toxicity studies, new mechanistic data and taking into account guidance on the application of the CLP Criteria (ECHA, 2015) the adverse effects observed in the reproductive toxicity studies and adverse effects in reproductive organs in other toxicity studies, *as well as the results of the mechanistic studies*, suggest that classification regarding reproductive toxicity would be required for iprodione as 'toxic for reproduction category 2 (H361df)'[3].

The applicant did not submit neurotoxicity studies; however, no potential for neurotoxicity was observed in the standard toxicity studies.

Iprodione has currently harmonised classification as carcinogenic category 2. During the experts' meeting, the experts considered more appropriate classification as carcinogenic category 1B and toxic for reproduction category 2. On this basis the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting properties are met leading to a critical area of concern. This is supported by the available scientific evidence where iprodione is shown to be antiandrogenic compound and has adverse effects on different endocrine organs at the dose levels triggering the LOAEL in several toxicity studies.

During the first review of iprodione (European Commission, 2002a), the NOAEL of 6 mg/kg bw per day from the 2-year rat study was used for setting the acceptable daily intake (ADI) of 0.06 mg/kg bw per day, applying an uncertainty factor (UF) of 100. The previously considered NOAEL for the 2-year rat study of 6 mg/kg bw per day has been changed to a LOAEL. Therefore, the experts proposed an additional UF of 3. Consequently, the ADI is set at 0.02 mg/kg bw per day instead of the previous one of 0.06 mg/kg bw per day.

An acute reference dose (ARfD) was not set during the first review. The experts agreed that an ARfD was needed for iprodione on the basis of developmental toxicity. The agreed ARfD is 0.06 mg/kg bw based on the LOAEL of 20 mg/kg bw per day for increased incidence of umbilical hernia observed in the developmental toxicity study in rabbits. An additional UF of 3 to the standard 100 considering the use of a LOAEL was applied.

During the first review of iprodione, the systemic acceptable operator exposure level (AOEL) was set at 0.3 mg/kg bw per day based on the results of the 90-day rat study (NOAEL of 31 mg/kg bw per day) and using an UF of 100. The experts considered more appropriate to set the AOEL on the same basis of the ARfD. A correction factor of 60% for oral absorption is needed to derive the AOEL. The agreed AOEL is 0.04 mg/kg bw per day.

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

The experts agreed to set the systemic acute acceptable operator exposure level (AAOEL) on the same basis of the AOEL. The agreed AAOEL is 0.04 mg/kg bw.

The RMS estimated **non-dietary exposure** (i.e. operator, worker, bystander and resident) considering dermal absorption values of iprodione in 'BAS 610 06 F' of 0.2% for the concentrate and of 12% for the dilution as input values.

The intended use with 'BAS 610 06 F' is as a fungicide in lettuce and carrots for open field and lettuce for greenhouse (protected permanent structure). Non-dietary exposure estimates are below the AOEL for the operator (wearing personal protective equipment (PPE)), the bystander, the resident[4] and the worker[5] (wearing PPE) for the intended uses of 'BAS 610 06 F'. However, operator exposure in greenhouse was estimated according to the European Crop Protection Association (ECPA) greenhouse model that it is not an agreed EU model. The applicant was requested to provide non-dietary exposure estimates according to the Dutch model. Nevertheless, the applicant only submitted worker exposure calculation according to the European Predictive Operator Exposure Model (EUROPOEM) II/Dutch model leading to a data gap and issue that could not be finalised for operator exposure estimates for indoor lettuce use.

Available information on **metabolites** RP 32490 and RP 36114 indicated that the reference values for iprodione are applicable to both metabolites.

Metabolite 3,5-dichloroaniline (RP 32596) is unlikely to be genotoxic. The ADI for the metabolite is 0.0005 mg/kg bw per day, based on the NOAEL of 1 mg/kg bw per day for anaemic changes observed in the 90-day study in rats, applying an UF of 2,000. The ARfD is 0.0075 mg/kg bw, based on the NOAEL of 7.5 mg/kg bw per day for haematological changes from the 28-day study in rats applying an UF of 1,000. Reference values of 3,5-dichloroaniline are also applicable to metabolite M 610F007.

Metabolite RP 30228 is predicted to occur in groundwater above 0.1 μg/L in one scenario according to the representative uses (see Section 4). The metabolite is considered relevant due to genotoxic concerns (i.e. positive in the *in vitro* micronucleus (MN) test and equivocal in the *in vivo* MN test) and due to the proposed classification for the parent compound by the peer review experts as carcinogenic and toxic for the development and reproduction. Metabolite RP 30228 is also found on crop metabolism studies (see Section 3). Since there are genotoxicity concerns, the setting of reference values for the metabolite is not possible leading to a critical area of concern.

No conclusion could be reached regarding the genotoxic potential or toxicological profile of RP 25040, RP 37176 and RP 36112.

Metabolites RP 36221 and LS 720942 are unlikely to be genotoxic. However, no conclusion was reached regarding their toxicological profile.

No data on metabolite RP 35606 predicted to occur in groundwater above 0.1 μg/L are available (data gap). The metabolite is considered relevant due to the proposed classification for parent compound by the peer review experts as carcinogenic and toxic for the development and reproduction leading to a critical area of concern.

No data on metabolite RP 30181 proposed to be included in the residue definition for groundwater are available (data gap). The metabolite is considered relevant due to the proposed classification for parent compound by the peer review experts as carcinogenic and toxic for the development and reproduction leading to a critical area of concern.

3. Residues

The assessment in the residue Section is based on the OECD guidance document on overview of residue chemistry studies (OECD, 2009), the OECD publication on MRL calculations (OECD, 2011), the European Commission guideline document on MRL setting (European Commission, 2011) and the Joint Meeting on Pesticide Residues (JMPR) recommendations on livestock burden calculations (JMPR, 2004, 2007)

New summaries of metabolism studies with iprodione in strawberry and wheat from the 1970s and in peach, lettuce, peanut, rice from the early 1980s (all non-good laboratory practice (non-GLP) studies) were submitted and reported to the maximum detail that could be retrieved from the old studies. Most of these studies have minor and the study in strawberry and wheat major shortcomings with regard to the requirements for metabolism data set out in current legislation and guidelines, and

[4] Bystander and resident exposure estimates were done for open field. It is noted that for greenhouse as protected permanent structure potential exposure through ventilation might occur. However, it is not expected to be above bystander and resident exposure in open field uses.

[5] Further considerations considering multiple applications are available in the RAR (France, 2016).

these studies should not be relied on as stand-alone metabolism studies. The old studies were complemented for the renewal submission by a recent study in carrot with spray application and an *in vitro* study in lettuce. The carrot study analysed the roots and the foliage and fully meets modern requirements for metabolism data. In view of the representative uses in root and tuber crops and in leafy crops, the new study in carrot together with the old study in lettuce – supported by the residue trials analysing for parent and the five metabolites – are deemed to provide sufficient information to conclude on the representative uses under peer review. The picture is consistent with the findings in the metabolism studies in peach, peanut and rice, as far as available, and the metabolic pathway of iprodione in primary crops upon foliar application may be considered sufficiently clarified. It is noted that exclusively [^{14}C-phenyl]-iprodione was studied and that the new study summaries were data requirements and not subjected to an expert consultation on whether the deviations from OECD TG 501 (OECD, 2007a) could be acceptable. Since the submission of residue field trials with metabolite analyses is limited to the representative uses, it is proposed to limit the residue definition to root crops and leafy crops for the purpose of this review.

According to metabolism data and the residue trials in carrot and lettuce, iprodione and its rearrangement RP 30228 are the dominant residues accompanied by metabolites RP 32490 and M 610F007 (conjugate of 3,5-dichloroaniline with glutamic acid). Metabolite RP 37176 was present at much lower levels and proportions; however, its genotoxic potential could not be concluded on by the peer review. For RP 32490, the reference values set for iprodione can be used. Due to a genotoxicity concern, no reference values can be derived for RP 30228 (see Section 2). Pending the submission of further data on the toxicological relevance of RP 30228 and RP 37176 and based on considerations of the dietary exposure potential for these metabolites it is proposed to provisionally define the residue definition as sum of iprodione, RP 30228 and RP 32490 expressed as iprodione for risk assessment purposes.

3,5-dichloroaniline in its free form was not recovered in primary crop metabolism studies but is known as a soil metabolite and was also occasionally detected above LOQ level in the residue trials. It was found that 3,5-dichloroaniline is taken up by the roots. In carrots and lettuce 3,5-dichloroaniline is conjugated with glutamic acid to form M 610F007. Moreover, in the hydrolysis studies to investigate the effect of processing on the nature of residues, iprodione was found to be almost stable at conditions simulating pasteurisation, but degraded notably at conditions representative of baking, brewing, boiling and sterilisation under formation of RP 30228, RP 37176 and 3,5-dichloroaniline. The behaviour of metabolite RP 32490 – included in the risk assessment definition for plant and livestock and occurring at levels above 0.01 mg/kg – was not studied under processing conditions (data gap).

3,5-dichloroaniline has a greater toxicity than iprodione. It was therefore proposed to set separately another residue definition for risk assessment as sum of 3,5-dichloroaniline and its conjugates expressed as 3,5-dichloroaniline.

For enforcement purposes, iprodione is a good marker and it is proposed that the monitoring residue definition for plant commodities is iprodione only. It is noted that the Art. 12 MRL review (EFSA, 2013b) was conducted with a residue definition for enforcement and also for risk assessment in all plant commodities defined on a tentative basis as iprodione only. In addition, the toxicological reference values have become more critical. In the light of significant changes impacting on the risk assessment, a review of the safety of all maximum residue levels (MRLs) is therefore recommended.

Residue trials in carrot and lettuce were sufficient to support the critical GAP for the representative uses in view of number, representativeness, the compounds determined, the analytical method validation, and storage stability of analytes with the exceptions of 3,5-dichloroaniline. Processing residue trials in carrot and spinach are also available. The stability of 3,5-dichloroaniline in high water and high starch matrices could not be demonstrated. Residues levels of 3,5-dichloroaniline measured in raw and processed commodities in primary and also rotational crops may therefore have been underestimated, and actual values still need to be ascertained following further investigation of the issue.

Metabolism in lactating ruminant (cow and goat) and laying hens was investigated in studies from the early 1980s (all non-GLP studies). The newly submitted study summaries are deemed to report the available information to the maximum detail that could be retrieved from these old studies. Regarding different aspects, the ruminant metabolism studies do not fully correspond to the requirements of current legislation and guidelines, and show some shortcomings. However, taken the information of both studies on cow and goat together, a pathway can be proposed in ruminants but uncertainty remains over its completeness. The study in poultry can be considered sufficient regarding the extractability of residues and the identification rate achieved. As for residues of 3,5-dichloroaniline (free and conjugated), the livestock dietary burden was significant; however, the data available are insufficient to adequately address the residue behaviour and levels of 3,5-dichloroaniline in animal commodities (data gap). In the feeding studies with cattle and poultry, iprodione was administered and residues in animal commodities were determined as the sum of iprodione and all metabolites containing the 3,5-dichloroaniline and 3,5-dichloro-4-hydroxyaniline moieties expressed as iprodione.

Based on the findings in the livestock metabolism studies, it was proposed to define the residue for enforcement in animal commodities as RP 32490 only.

For risk assessment, considering the uncertainties related to the metabolism studies and livestock feeding studies and the lack of data on the toxicity of several metabolites occurring in metabolism studies, the RMS proposed to define the residue definition as the sum of iprodione and all metabolites containing the 3,5-dichloroaniline moiety expressed as iprodione. For the mammalian kidney and milk, a separate residue definition for risk assessment is proposed as the sum of iprodione and all metabolites containing the 3,5-dichloroaniline or the 3,5-dichloro-4-hydroxyaniline moieties expressed as iprodione. Given the differences in the toxicity profile and/or the potency of the different metabolites and parent, it is EFSA's position that the common moiety definition is not deemed adequate to conduct a reasonable consumer risk assessment for livestock commodities. Without an agreed and peer-reviewed livestock residue definition, and among other things a genotoxicity concern for RP 30228 that is also a livestock metabolite and a lack of information on the residue behaviour of 3,5-dichloroaniline upon dietary exposure of the animals to this compound, the consumer risk assessment in terms of food of animal origin cannot be concluded. Since the available feeding studies in poultry and ruminants were using a total residue method, it is currently not possible to confirm their adequacy for the purpose of the risk assessment and further considerations will be necessary in this regard.

Rotational crops metabolism studies were submitted with [^{14}C-phenyl]-iprodione in cereals, root and tuber vegetables, pulses and oilseeds, fruit and fruiting vegetables. New summaries were made available for the old studies (1970s and 1980s, all non-GLP) and shortcomings with regard to current standards were identified. Based on the information available from the studies, iprodione was the predominant residue followed by RP 30228, RP 25040 and RP 32490. It could not be assessed if the study design of the rotational crop studies was sufficient in perspective to the likely soil residue pattern after years of continuous use of iprodione, given the persistency of some of its metabolites (e.g. RP 36221 with a period required for 90% dissipation (DT_{90}) > 1,000 days). An assessment is required, taking into account the full picture of findings on soil metabolism and degradation in the section of environmental fate and behaviour upon availability of the requested new soil metabolism study (see Section 4) (data gap). It could also not be reasoned why 3,5-dichloroaniline or M 610F007, respectively, was not identified in rotational crops, given its presence and its moderate to high persistence in soil plus the findings above LOQ in some of the residue field trials. Further investigations in rotational crops regarding the uptake of 3,5-dichloroaniline are required (data gap). Moreover, data are required to clearly explain the behaviour of 3,5-dichloroaniline observed in the studies on storage stability, primary and rotational crops, and hydrolysis, and to consider the potential for dechlorination under conditions potentially relevant for humans. Any confirmation of a residue definition in rotational crops is pending the availability of all the requested data and information in this field including consideration of the toxicity of rotational crop metabolites where this information is pending (see Section 2).

Consequently, pending the rotational crop investigations, the potential relevance of residues in the fish diet and information against the residues data requirements on fish are required (data gap). In the same context, a data gap was also identified on residue levels in pollen and in bee products for human consumption resulting from residues taken up by honeybees from crops at blossom. Considerations should include metabolite 3,5-dichloroaniline (free and conjugated).

Considering all uncertainties and data gaps in the residue section, and pending submission of toxicological clarification for major residue compounds, the consumer risk assessment has to be considered as provisional. Only very rough indications regarding a potential consumer risk can be given.

Two separate consumer risk assessments were conducted by the RMS; for the sum of iprodione, RP 30228 and RP 32490 expressed as iprodione, and for the sum of 3,5-dichloroaniline and its conjugates expressed as 3,5-dichloroaniline. EFSA reminds, that this approach is disregarding the genotoxicity issue on RP 30228 and any potential common effects of iprodione and 3,5-dichloroaniline.

For the sum of iprodione, RP 30228 and RP 32490 expressed as iprodione, the theoretical maximum daily intake (TMDI), calculated with the MRL reaches a maximum of 146% of the ADI, and the higher tier international estimated daily intake (IEDI), using median residues (STMR), reaches a maximum of 28% of the ADI. The international estimated short term intake (IESTI) reaches a maximum of 2205% of the ARfD for scarole (indoor use) and 255% for scarole (outdoor use).

For the sum of 3,5-dichloroaniline and its conjugates expressed as 3,5-dichloroaniline, the IEDI reaches a maximum of 80% of the ADI, and the IESTI reaches a maximum of 186% of the ARfD for carrot.

An acute consumer risk can therefore not be excluded for neither of the representative uses (carrots, lettuce) requested by the applicant (critical area of concern).

4. Environmental fate and behaviour

Iprodione was discussed at the Pesticides Peer Review TC 136 in July 2016.

The rates of dissipation and degradation in the environmental matrices investigated were estimated using FOCUS (2006) kinetics guidance. In soil laboratory incubations under aerobic conditions in the dark, iprodione exhibited moderate to high persistence, forming the major (> 10% applied radioactivity (AR)) metabolite RP 35606 (max. 25.5% AR after 7 days) which exhibited low to moderate persistence, the metabolite RP 30228, a constitutional isomer of iprodione, (max. 29.5% AR after 30 days) which exhibited moderate to medium persistence, the metabolite RP 36221 (max. 12.7% AR after 100 days), which exhibited high to very high persistence, and the metabolite RP 32596 (max. 12.6% AR after 120 days), which exhibited moderate to high persistence.

A data gap was identified (see Section 7) because the proposed route of degradation was incomplete since it was based only on phenyl-labelled iprodione studies. Metabolite RP 30181 was included in the exposure assessment because it was assumed to be formed in similar amounts as RP 32596. Therefore, studies on the fate and behaviour of the hydantoin moiety iprodione in soil are required to demonstrate whether metabolite RP 30181 and/or other degradation/transformation products are formed at amounts requiring further assessment or not. In case RP 30181 and/or other metabolite(s) resulted to be triggered for further assessment, a GLP-study on aerobic transformation in soil conducted according to the OECD Test guideline 307 (OECD, 2002) and an adsorption batch study conducted following the OECD Test guideline 106 (OECD, 2000) should be provided as required by Commission Regulation (EU) No 283/2013[6].

Mineralisation of the phenyl ring ^{14}C radiolabel to carbon dioxide accounted for 0.6–1.9% AR after 120 days. The formation of unextractable residues (not extracted by acetonitrile/water) for this radiolabel accounted for 40.4–67.9% AR after 120 days.

A pH dependency of degradation rates was found for iprodione, with slower degradation in acidic soils (pH_{CaCl2} < 5.9), and for metabolite RP 25040, with slower degradation when pH decreases.

In reliable field soil dissipation studies, iprodione exhibited low to medium persistence. According to the data requirements, field soil dissipation investigations should be made for metabolites when laboratory DT_{90} are greater than 200 days. Field dissipation studies were carried out for metabolite RP 30228; however, a data gap was identified (see Section 7) because a kinetic assessment of the field dissipation data should be performed according to the new data requirements. Field dissipation studies were triggered for metabolite RP 36221, but a data gap was set (see Section 7) because soil dissipation studies under field conditions for metabolite RP 36221 were not performed. However, the exposure assessment for the EU representative uses was completed using the available laboratory kinetic endpoints.

In anaerobic soil incubations, only 13% AR remained as iprodione at the beginning of the anaerobic phase, and then the study did not allow describing properly degradation of iprodione under anaerobic conditions. A more robust anaerobic degradation study might be needed at national level in case of further uses where anaerobic conditions are relevant.

Iprodione is not significantly photodegraded on the soil surface; however, a mixture of metabolites RP 25040 and LS 720942 reaches more than 10% AR under irradiated conditions (max. 13.8% AR after 7 days). Metabolite RP 25040, which was also formed at max. 7.8% AR under laboratory aerobic conditions, exhibited very low to medium persistence in soil.

Iprodione exhibited medium to low mobility in soil. However, a data gap was set for a batch adsorption study in at least one further soil in order to comply with the data requirements. It was concluded that the adsorption of iprodione was not pH dependent. Metabolite RP 25040 exhibited high to medium soil mobility, metabolite RP 36221 was immobile, metabolite RP 30228 exhibited low mobility to immobile, metabolite RP 32596 exhibited medium to low mobility, and metabolite LS 720942 exhibited medium mobility. It was concluded that the adsorption of these metabolites was not pH dependent. Metabolite RP 35606 exhibited very high mobility; for this metabolite, only an

[6] Regulation (EU) No 283/2013 of the European Parliament and of the Council of 1 March 2013 setting out the data requirements for active substances in accordance with Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market. OJ L 93, 3.4.2013, p. 1–84.

alkaline pH range was investigated due to the difficulties of carrying out studies under acidic conditions. Experts agreed with the proposed approach, and therefore, it was concluded that adsorption of metabolite RP 35606 is expected to be pH-dependent due to the nature of the compound. The potential metabolite RP 30181 exhibited a very high mobility; however, for this metabolite, adsorption values were obtained via QSAR calculation. This approach was not considered acceptable and a data gap for conducting a laboratory batch adsorption study following the OECD Test guideline 106 was set. This data gap depends on whether the data gap on studies regarding the investigation of the hydantoin moiety iprodione in soil confirms that RP 30181 reaches amounts triggering a risk assessment.

A column leaching study and an aged column leaching study were carried out for iprodione and its metabolites. Radioactivity in the leachates was very low (< 1.9% AR), except in one sandy soil representing worst-case conditions in which it reached 52.2% AR. The main compounds found were iprodione (6.3%), RP 35606 (27.1%), RP 30228 (13.1%), RP 25040 (2.0%) and RP 32596 (3.2%).

In laboratory incubations in dark aerobic natural sediment water systems, iprodione exhibited low persistence, forming metabolites RP 35606 (max. 73.3% AR in water but only max. 4.0% in sediment), and metabolite RP 30228 (max. 10.3% in water and max. 79.2% in sediment). The unextractable sediment fraction (not extracted by acetonitrile/water) accounted for 9.0–10.1% AR at study end (100 days) for phenyl ring ^{14}C radiolabel. Mineralisation was < 1% AR for phenyl ring ^{14}C radiolabel at study end (100 days).

The rate of decline of iprodione in a laboratory sterile aqueous photolysis experiment was slow relative to that occurred in the aerobic sediment water incubations. No chromatographically resolved component (excluding iprodione) accounted for > 5% AR. Irradiation of phenyl-labelled iprodione in sterile natural water did not result in the formation of any photodegradation products.

The necessary surface water and sediment exposure assessments (predicted environmental concentrations (PEC) calculations) were carried out for iprodione and for its metabolites RP 25040, RP 35606, RP 30228, RP 36221, RP 32596, RP 30181 and LS 720942 using the FOCUS (FOCUS, 2001) Step 1 and Step 2 approach (version 2.1 of the Steps 1 and 2 in FOCUS calculator). However, during the peer review process the adsorption data for iprodione, RP 35606, RP 36221, RP 25040 and LS 720942 were re-analysed and the new values resulted to be lower than the initial ones. The new Freundlich organic carbon adsorption coefficient (K_{Foc}) values were not used for the PEC_{sw} calculations, and it is expected that PEC_{sw} values presented are underestimated. Therefore, a data gap was set for new PEC_{sw} calculations. For metabolite RP 35606, PEC_{sw} calculations should be performed using both K_{Foc} values.

For the glasshouse use, specific calculations were performed for PEC_{sw}. Experts agreed on considering an overall emission of 0.1% of the application rate as an assumption that can be used in the EU level surface water exposure assessments for greenhouse uses and is referred in FOCUS (2008) guidance as being appropriate, except when applications are made with ultralow volume application techniques when 0.2% emission is assumed. No specific calculations were performed for groundwater, and thus the PEC_{gw} obtained for field used will be applied to the glasshouse use.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (European Commission, 2014) scenarios and the models PEARL 4.4.4 and PELMO 5.5.3[7] for the active substance iprodione and its metabolites RP 25040, RP 35606, RP 30228, RP 36221, RP 32596, and RP 30181. Two sets of calculations were performed due to pH-dependence of the degradation rate of iprodione: one for acidic soils (pH_{CaCl2} < 5.9) and one for slightly acidic to alkaline soils ($pH_{CaCl2} \geq 5.9$). The same approach was used for metabolite RP 25040. Furthermore, the pH dependency of adsorption for metabolite RP 35606 was taken into account performing simulations using both the lowest and the highest K_{Foc} values. Results for RP 30181 were considered indicative only because the input parameters used have to be confirmed by additional data on degradation rate and adsorption (see data gaps in Section 7). PECgw calculations for the photometabolites LS 720942 and RP 25040 were conducted separately. The potential for groundwater exposure from the representative uses by iprodione above the parametric drinking water limit of 0.1 μg/L was concluded to be low in all geoclimatic situations that are represented by all FOCUS groundwater scenarios on soils with $pH_{CaCl2} \geq 5.9$; the limit was exceeded in three out of six carrots scenarios and in two out of seven lettuce scenarios on soils with $pH_{CaCl2} < 5.9$ PECgw.

For metabolites RP 25040, RP 36221, RP 32596 and LS 720942, the potential for groundwater exposure above the parametric drinking water limit of 0.1 μg/L was concluded to be low in all

[7] Simulations utilised the agreed Q10 of 2.58 (following EFSA, 2008) and Walker equation coefficient of 0.7.

geoclimatic situations that are represented by all the relevant FOCUS groundwater scenarios in both acidic and slightly acidic to alkaline soils.

For the representative use on carrots in acidic soils, the 80th percentile annual average recharge concentrations leaving the top 1 m soil layer were estimated to be > 0.1 μg/L at four out of six scenarios (using the lowest K_{Foc} value) and at all scenarios (using the highest K_{Foc} value) for metabolite RP 35606. While for the representative use on carrots in slightly acidic to alkaline soils, concentrations expressed on this basis were estimated to be > 0.1 μg/L at one out of six scenarios (using the lowest K_{Foc} value) and at four out of six scenarios (using the highest K_{Foc} value) for metabolite RP 35606.

For the representative use on carrots, concentrations expressed on this basis were estimated to be > 0.1 μg/L at one out of six scenarios in acidic soils and < 0.1 μg/L at all scenarios in slightly acidic to alkaline soils for metabolite RP 30228. For the representative use on carrots, concentrations expressed on this basis were estimated to be > 0.1 μg/L at all scenarios for metabolite RP 30181 in both acid and acidic to alkaline soils.

For the representative use on lettuce in acidic soils, concentrations expressed on this basis were estimated to be > 0.1 μg/L at five out of seven scenarios (using the lowest K_{Foc} value) and at all scenarios (using the highest K_{Foc} value) for metabolite RP 35606. For the representative use on lettuce in slightly acidic to alkaline soils, concentrations expressed on this basis were estimated to be > 0.1 μg/L at three out of seven scenarios (using the lowest K_{Foc} value) and at five out of seven scenarios (using the highest K_{Foc} value) for metabolite RP 35606.

For the representative use on lettuce, concentrations expressed on this basis were estimated to be > 0.1 μg/L at one out of seven scenarios in acidic soils and < 0.1 μg/L at all scenarios in slightly acidic to alkaline soils for metabolite RP 30228. For the representative use on lettuce, concentrations expressed on this basis were estimated to be > 0.1 μg/L at all scenarios for metabolite RP 30181 in both acid and acidic to alkaline soils.

Predicted metabolite concentrations were > 0.75 μg/L for metabolite RP 35606, only in acidic soils, and for metabolite RP 30181, in both acidic and slightly acidic to alkaline soils. According to the information available in the mammalian toxicology section, these metabolites are considered relevant due to the proposed classification for parent compound by the peer review experts as carcinogenic and toxic for the development and reproduction leading to a critical area of concern (see Section 2).

The PEC in soil, surface water, sediment and groundwater covering the representative uses assessed can be found in Appendix A of this conclusion.

The applicant did not provide appropriate information to address the effect of water treatments processes on the nature of the residues that might be present in surface water and groundwater, when surface water or groundwater are abstracted for drinking water. This led to the identification of a data gap (see Section 7) and results in the consumer risk assessment not being finalised (see Section 9).

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002b,c), SETAC (2001) and EFSA (2009, 2013a). According to Regulation (EU) No 283/2013, data should be provided regarding the acute and chronic toxicity to honeybees and data to address the development of honeybee brood and larvae. As the European Commission (2002b) does not provide a risk assessment scheme which is able to use the chronic toxicity data for adult honeybees and the honeybee brood, when performing the risk assessment according to the European Commission (2002b), the risk to adult honeybees from chronic toxicity and the risk to bee brood, could not be finalised due to the lack of a risk assessment scheme. Therefore, EFSA (2013a) was used for risk assessment in order to reach a conclusion for the representative uses.

For the representative use in greenhouse (permanent protected structure), only the risk assessment for aquatic organisms is triggered.

Iprodione was discussed at the Pesticides Peer Review Experts' Meeting 147.

It had not been demonstrated that the batches used in the ecotoxicity studies were in compliance with the technical specification (data gap).

The acute risk to birds and to wild mammals via dietary exposure resulted as low at the screening level assessment for all the representative uses.

A high long-term risk to birds was identified on the basis of the available first tier risk assessments for all the relevant scenarios and representative field uses. Available refinements of the risk based on identification of focal species, more realistic ecological data (proportion of different food types (PD), proportion of diet obtained in the treated area (PT)), residue dissipation data in plants and arthropods were discussed at the Pesticides Peer-review Experts' Meeting 147. The experts agreed with the selection of the focal species and PD refinement. For the wood pigeon (medium herbivorous), it was agreed to use the highest available PT value instead of the 90th percentile PT due to uncertainties identified in the available study. The use of refined residue per unit dose (RUD) values for ground dwelling arthropods was not accepted as it was considered not justified to replace the generic RUD value with one resulting from a small data set of measured residue data. Furthermore, it was agreed to use the geometric mean period required for 50% dissipation (DT_{50}) calculated by pooling all available residue decline data on foliage which were consistent despite the geographical location of the studies (north EU or south EU) and the type of crop (monocot or dicot). Overall, based on the available data and risk assessment, a high risk was still identified for the medium herbivorous birds and the small granivorous birds in lettuce (field use) and for the small omnivorous and granivorous birds in carrot (field use) (data gap).

The long-term endpoint for wild mammals for use in the risk assessment was discussed at the Pesticides Peer-review Experts' Meeting 147. Two 2-generation toxicity studies with rats were available. However, one was dismissed because there were not enough biological measurements while from the second available study no NOAEL could be set. Therefore, since no valid reproductive endpoint was available for wild mammals the long-term risk assessment for all the relevant routes of exposure could not be finalised (data gap).

The risk for birds and wild mammals through dietary exposure to the metabolite RP 32596 was discussed at the Pesticides Peer-review Experts' Meeting 147. It was agreed that the exposure to this metabolite via dietary exposure is sufficiently low to exclude any potential high risk.

Based on the log P_{ow}, an assessment of the risk of secondary poisoning was triggered for the parent compound. A low risk to earthworm- and fish-eating birds could be concluded for all the representative uses. The risk to birds from consumption of contaminated water was considered as low.

For aquatic organisms and the parent compound, based on the available tier 1 data and risk assessment, a high chronic risk to fish and a high acute risk to aquatic invertebrates was identified using the FOCUS Step 4 PEC_{sw} in situations represented by the scenario D6 when mitigation measures of up to 20 m non-spray buffer zone and 20 m vegetated buffer strip are applied and for all the representative field uses. However, for the uses on carrot and when acidic soils only are considered as a source of entry in aquatic systems, a low chronic risk to fish and acute risk to aquatic invertebrates could be concluded using the FOCUS Step 4 PEC_{sw} and when the same mitigation measures are implemented. By applying the same mitigation measures, a high chronic risk to aquatic invertebrates was identified at the FOCUS Step 4 PEC_{sw} in several scenarios (6/7 for the field use on lettuce and 5/6 for the use on carrot). A low risk was identified for fish (acute), algae and higher aquatic plants for all the representative uses and scenarios at the FOCUS Step 1/3 PEC_{sw}.

For the indoor use on lettuce, based on the available exposure estimate, a high chronic risk to aquatic invertebrates was identified (data gap).

A high risk to aquatic organisms to the metabolite RP 35606 could not be excluded based on a screening assessment for the most sensitive species (*Americamysis bahia*) for all the FOCUS Step 4 scenarios and for all the representative field uses when mitigation measures of 20 m non-spray buffer zone and 20 m vegetated buffer strip are applied.

For RP 32596, RP 30228 and RP 36221, a high chronic risk to aquatic invertebrates could not be excluded at the FOCUS PEC_{sw} Step 2/3 for all the representative field uses. For RP 32596, a high chronic risk to aquatic invertebrates could not be excluded also for the indoor use. The risk to RP36221 was assessed as low at the FOCUS Step 4 when mitigation measures of up to 20 m non-spray buffer zone and 20 m vegetated buffer strip are implemented.

For RP 25040, LS 720942 and RP 30181, a high risk to fish (chronic) and aquatic invertebrates (both acute and chronic) could not be excluded for all the representative field uses.

With regard to the assessment of the risk to aquatic organisms, it should be considered that the exposure assessment is likely to be underestimated (see Section 4).

The risk assessment for bees was conducted by EFSA in accordance with (EFSA, 2013a).

For the honeybee and the solitary bee *Osmia lignaria*, acute oral and contact toxicity studies were available with the parent and the representative formulation. Chronic toxicity studies on adult honeybees as well as a toxicity study on larvae with the formulation were also available. However, the latter was a single exposure study and it could not be considered suitable for the risk assessment according to EFSA, 2013a. Nonetheless, an illustrative risk assessment for larvae was performed using the endpoint from the single exposure test as surrogate. On the basis of the tier 1 data, a low acute contact and oral risk to honeybees and solitary bees could be concluded at the screening level. A high chronic risk to adults and a high risk to larvae could not be excluded on the basis of the screening level assessment. The first tier oral assessment indicated a high chronic risk to adults for the weed scenario and applications at growth stages of mono- and dicotyledonous plants (BBCH) 10-49 for all the representative uses. However, the chronic risk to adults could be considered low as long as mitigation measures are implemented (i.e. to remove flowering weeds before applications).

The available higher tier studies performed according to OECD 75 (OECD, 2007b) were discussed at the Pesticides Peer-Review Experts' Meeting 147. Effects bee on brood could not be excluded in two of the three available studies, while in the third one, which included an assessment of the overwintering clear effects on brood were not observed. Overall, as far as the exposure would be via flowering weeds and taking into account the possibility of mitigation measures at the Member State level, the majority of experts agreed to conclude a low risk to larvae. Additionally, the illustrative Tier 1 risk assessment indicated a low risk to larvae for all the relevant Tier 1 scenarios and all the representative uses.

Low risk to adults was concluded on the basis of the screening level assessment for exposure via surface water and via residues in guttation fluids. No specific assessment was performed for the puddle scenario; however, it can be considered covered by the guttation assessment.

No assessment was available for sublethal effects (i.e. hypopharyngeal glands (HPG)) on honeybees (data gap) or for accumulative effects. Further information regarding metabolites occurring in pollen and nectar of succeeding crops could be needed pending the data gap in Section 3 (data gap). Data were not available to perform a risk assessment for bumble bees.

Based on the available data and risk assessment, a low in-field and off-field risk to non-target arthropods other than bees could be concluded. Furthermore, the risk to soil micro- and macroorganisms, non-target terrestrial plants and to organisms involved in biological methods for sewage treatment could be concluded as low for all the representative uses. For metabolite RP 30181, further data could be required, pending on the data gap in Section 4.

With regard to the endocrine disruption potential, as discussed in Section 2, iprodione meet the interim criteria on the basis of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009. The endocrine disrupting potential of iprodione to fish was also discussed at the Pesticides Peer-review Experts' Meeting 147. The experts agreed that based on the effects observed on the concentration of male vitellogenin and increased incidence of interstitial cell hyperplasia in fish, further information would be needed to address the potential for endocrine disruption of iprodione in fish as it is unclear whether the chronic endpoint used in the risk assessment would cover the potential endocrine activity of iprodione on fish. No firm conclusion can be drawn to that respect on birds.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (Tables 1–4)

Table 1: Soil*

Compound (name and/or code)	Persistence	Ecotoxicology
Iprodione	Moderate to high persistence single first order and biphasic kinetics DT_{50} 6.3–89.4 days (DT_{90} 53.9–344.5 days; laboratory conditions at 20°C, 40–75% MWHC soil moisture) European field dissipation studies single first order DT_{50} 8.7–59.3 days	Low risk to soil organisms
RP 25040	Very low to medium persistence single first order and biphasic kinetics DT_{50} 0.38–22.5 days (DT_{90} 2.5–74.7 days; laboratory conditions at 20°C, 40% MWHC soil moisture)	Low risk to soil organisms
RP 36221	High to very high persistence single first order and biphasic kinetics DT_{50} 180.4–> 1,000 days (DT_{90} 599.3–> 1,000 days; laboratory conditions at 20°C, 40 MWHC soil moisture)	Low risk to soil organisms
RP 30228	Moderate to medium persistence single first order kinetics DT_{50} 22.7–83.8 days (DT_{90} 75.3–278.3 days; laboratory conditions at 20°C, 40% MWHC soil moisture)	Low risk to soil organisms
RP 35606	Low to moderate persistence single first order kinetics DT_{50} 3.2–33.1 days (DT_{90} 10.5–110 days; laboratory conditions at 20°C, 40% MWHC soil moisture)	Low risk to soil organisms
RP 32596	Moderate to high persistence single first order and biphasic kinetics DT_{50} 2.7–39.6 days (DT_{90} 51.7–197.8 days; laboratory conditions at 20–25°C, 40–75% MWHC soil moisture)	Low risk to soil organisms
LS 720942	Low to moderate persistence single first order kinetics DT_{50} 4.2–11.1 days (DT_{90} 14.0–36.9 days; laboratory conditions at 20°C, 40% MWHC soil moisture)	Low risk to soil organisms
RP 30181	No reliable data, assumed to show low persistence in preliminary risk assessment Data gap identified for soil degradation studies with hydantoin-labelled iprodione	Data gap

DT_{50}: period required for 50% dissipation; DT_{90}: period required for 90% dissipation; MWHC: maximum water-holding capacity.
*: The residue definition is provisional because of the lack of information on the route of degradation of iprodione radiolabelled in the hydantoin position.

Table 2: Groundwater*

Compound (name and/or code)	Mobility in soil	> 0.1 μg/L at 1 m depth for the representative uses[(a)]	Pesticidal activity	Toxicological relevance
Iprodione	Medium to low mobility K_{Foc} 223–543 mL/g	Yes Carrots: 3/6 FOCUS scenarios (< 0.001–0.301 μg/L, acidic conditions) Lettuce: 2/7 FOCUS scenarios (< 0.001–0.28 μg/L, acidic conditions)	Yes	Yes
RP 25040	High to medium mobility K_{Foc} 118–233 mL/g	No	No data	Assessment not triggered (No conclusion on the genotoxic potential)
RP 36221	Immobile K_{Foc} 6,213–8,109 mL/g	No	No data	Assessment not triggered (Unlikely to be genotoxic)
RP 30228	Low mobility to immobile K_{Foc} 1,864–7,575 mL/g	Yes Carrots: 1/6 FOCUS scenarios (< 0.001–0.233 μg/L, acidic conditions, highest K_{Foc} for RP 35606) Lettuce: 1/7 FOCUS scenarios (0.001–0.222 μg/L, acidic conditions)	No	Yes (genotoxic concerns; it cannot be excluded that they share the carcinogenic and reproductive toxicity potential of iprodione)
RP 35606	Very high mobility K_{Foc} 15.4–49.6 mL/g (pH dependency, highest and lowest K_{Foc} values used)	Yes Carrots: 6/6 FOCUS scenarios (0.083–2.245 μg/L, acidic conditions, highest K_{Foc}) Lettuce: 7/7 FOCUS scenarios (0.105–2.153 μg/L, acidic conditions, highest K_{Foc})	No data	Yes (it cannot be excluded that they share the carcinogenic and reproductive toxicity potential of iprodione; no data on genotoxicity)
RP 32596	Medium to low mobility K_{Foc} 380–932 mL/g	No	No data	Assessment not triggered (Unlikely to be genotoxic)
LS 720942	Medium mobility K_{Foc} 362–475 mL/g	No	No data	Assessment not triggered (Unlikely to be genotoxic)
RP 30181	No reliable data, assumed to be very high mobile (based on QSAR) in preliminary risk assessment	Yes (based on preliminary assessment with available information) Carrots 6/6 FOCUS scenarios (0.23–6.44 μg/L) Lettuce: 7/7 FOCUS scenarios 0.21–6.30 μg/L)	No data	Yes (it cannot be excluded that they share the carcinogenic and reproductive toxicity potential of iprodione; no data on genotoxicity)

K_{Foc}: Freundlich organic carbon adsorption coefficient; FOCUS: Forum for the Co-ordination of Pesticide Fate Models and their Use; QSAR: quantitative structure–activity relationship.
(a): At least one FOCUS scenario or relevant lysimeter.
*: The residue definition is provisional because of the lack of information on the route of degradation of iprodione radiolabelled in the hydantoin position.

Table 3: Surface water and sediment*

Compound (name and/or code)	Ecotoxicology
Iprodione	High risk to aquatic organisms in surface water
RP 25040	High risk to aquatic organisms in surface water
RP 36221	Low risk to aquatic organisms in surface water when mitigation measures are implemented
RP 30228	High risk to aquatic organisms in surface water
RP 35606	High risk to aquatic organisms in surface water
RP 32596	High risk to aquatic organisms in surface water
LS 720942	High risk to aquatic organisms in surface water
RP 30181	High risk to aquatic organisms in surface water

*: The residue definition is provisional because of the lack of information on the route of degradation of iprodione radiolabelled in the hydantoin position.

Table 4: Air

Compound (name and/or code)	Toxicology
Iprodione	Not acutely toxic by inhalation to rat (LC_{50} > 5.16 mg/L air/4 h; whole body)

LC_{50}: lethal concentration, median.

7. Data gaps

This is a list of data gaps identified during the peer review process, including those areas in which a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 56 of Regulation (EC) No 1107/2009 concerning information on potentially harmful effects).

- A data gap has been identified for a search of the scientific peer-reviewed open literature on metabolites RP 25040, LS 720942 and RP 30181, dealing with side effects on environment and non-target species and an updated literature search for DCAs and review of relevance/exclusion criteria for already retrieved studies should be included, published within the 10 years before the date of submission of the dossier, to be conducted and reported in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011).
- Information about the data generation methods used in the physicochemical tests, toxicity and ecotoxicity studies (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Sections 1, 2 and 5).
- Assessment of the extraction efficiency for all plant matrix groups (except high water content commodities) (not relevant for the representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1).
- Assessment of the extraction efficiency in animal matrices (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Sections 1 and 3).
- Method for the determination of metabolite RP 30181 in ground water (relevant for all uses evaluated; submission date proposed by the applicant: unknown; see Sections 1, 2 and 4).
- Method for the determination of iprodione in body fluids and tissues (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Sections 1 and 2).
- Operator exposure estimates in greenhouse according to the Dutch Model (relevant for greenhouse uses in lettuce; submission date proposed by the applicant: unknown; see Section 2).
- Further data to support the technical specification including Ames test and an *in vitro* gene mutation with the representative technical specification and further information to demonstrate the compliance of the batches used in the ecotoxicity studies with the technical specification (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Sections 2 and 5).
- Further data to support the maximum content of impurity RP 30228 (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2).
- Further data to address the toxicological profile of metabolites RP 30181, RP 35606, RP 25040, RP 37176, and RP 36112 including its genotoxic potential (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2).
- Further data to address the toxicological profile of metabolites RP 36221 and LS 720942 (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2).
- Further information on the behaviour of metabolite 3,5-dichloroaniline in the storage stability study, primary and rotational crops study and hydrolysis study, considering the instability observed under storage conditions and the potential for dechlorination under conditions potentially relevant for humans (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).
- Data that adequately address the residue behaviour and levels of 3,5-dichloroaniline in animal commodities (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).
- Taking into account rotational crops, the potential relevance of residues in the fish diet and information against the residues data requirements on fish are required (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).
- Taking into account rotational crops, residue levels in pollen and in bee products for human consumption resulting from residues taken up by honeybees from crops at blossom.

Considerations should include metabolite 3,5-dichloroaniline (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).

- Data to address the behaviour of RP 32490 under conditions simulating food processing (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).
- An assessment is required, taking into account the full picture of findings in soil metabolism (new study) and whether available rotational crop data are sufficient in respect to the likely soil residue pattern after years of continuous use of iprodione, given the persistency of some of its metabolites (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).
- Further investigations of residues in rotational crops regarding the uptake of 3,5-dichloroaniline from soil (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).
- Studies on the fate and behaviour of the hydantoin moiety iprodione in soil are required to demonstrate whether metabolite RP 30181 and/or other degradation/transformation products are formed at amounts requiring further assessment or not. In case RP 30181 and/or other metabolite(s) resulted to be triggered for further assessment, a GLP-study on aerobic transformation in soil conducted according to the OECD Test guideline 307 and an adsorption batch study conducted following the OECD Test guidelines 106 should be provided as required by Commission Regulation (EU) No 283/2012 (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Sections 4 and 5).
- Applicant to submit a kinetic assessment of the field dissipation data for metabolite RP 30228 (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 4).
- Applicant to submit soil dissipation studies for metabolites RP 36221 as field studies are triggered according to the new data requirements for active substance (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 4).
- A batch adsorption study in at least one further soil for iprodione is necessary to comply with the data requirements (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 4).
- New K_{Foc} values provided for iprodione and metabolites RP 35606, RP 36221, RP 25040 and LS 720942 resulted to be lower than the ones calculated initially and used in the modelling. PEC_{sw} calculations were not updated using the new K_{Foc} values. Therefore, it is expected that PEC_{sw} values presented are underestimated and a data gap is identified for new PEC_{sw} calculations. For metabolite RP 35606, PEC_{sw} calculations should be performed using both K_{Foc} values (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 4).
- The effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water (Article 4 (approval criteria for active substances) 3. (b) of Regulation (EC) No 1107/2009) has not been assessed. In the first instance, a consideration of the processes of ozonation and chlorination may be considered appropriate. If an argumentation is made that concentrations at the point of extraction for drinking water purposes will be low, this argumentation should cover metabolites predicted to be in groundwater and surface water, as well as the active substance (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 4).
- Further information is required to address the long-term risk for medium herbivorous birds in lettuce (field use), for small omnivorous birds in carrot (field use) and for small granivorous birds in both carrot and lettuce (field use) (relevant for the field representative uses; submission date proposed by the applicant: unknown; see Section 5).
- Further information is required to address the long-term risk for wild mammals for all the routes of exposure (relevant for the field representative uses; submission date proposed by the applicant: unknown see Section 5).
- Further information is required to address the long-term risk for aquatic organisms (especially aquatic invertebrates) to iprodione (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5) and to further address the long-term

to fish in situations represented by the FOCUS scenario D6 (relevant for the representative use on lettuce; submission date proposed by the applicant: unknown; see Section 5).
- The risk to aquatic organisms for RP 35606, RP 25040, LS 720942 and RP 30181 should be further addressed (relevant for the field uses on carrot and lettuce) and for metabolite RP 32596 for all the representative uses (submission date proposed by the applicant: unknown; see Section 5).
- The risk to aquatic organisms for RP 30228 should be further addressed (relevant for the uses evaluated; submission date proposed by the applicant: unknown; see Section 5).
- Suitable data to address the risk of sublethal effects (i.e. HPG development effects) to honeybees (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5).
- Information to assess the risk to honeybees due to relevant plant metabolites occurring in pollen and nectar (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5).
- Further information would be needed to address the potential for endocrine disruption of iprodione in fish (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5).

8. Particular conditions proposed to be taken into account to manage the risk(s) identified

- Non-dietary exposure estimates are only below the AOEL for the operator (open field application; greenhouse application inconclusive) and worker (all uses) if wearing PPE (see Section 2).
- For the field representative uses, mitigation measures up to 20 m no-spray buffer zones and up to 20 m vegetated buffer strips are needed to conclude low risk on aquatic organisms (especially fish) for the parent compound and metabolite RP 36221 (especially for aquatic invertebrates) for the field representative uses on lettuce (see Section 5).
- Flowering weeds in the field should be removed before iprodione is applied to exclude a high risk to bees.

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as 'could not be finalised' if 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 in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011[8] and if 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).

An issue is also listed as 'could not be finalised' if the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

1) Operator exposure estimates according to the supported indoor uses in lettuce could not be finalised (see Section 2).
2) The dietary consumer risk assessment in terms of food of plant and animal origin could not be finalised given numerous data gaps identified that do not permit the establishment of final residue definitions for risk assessment (see Section 3).
3) The consumer risk assessment from the consumption of water could not be finalised, while satisfactory information was not available to address the effect of water treatment processes on the nature of the residues that might be present in surface water and groundwater, when surface water or groundwater are abstracted for drinking water (see Section 4).

[8] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

4) The proposed route of degradation in soil was incomplete since it was based only on phenyl-labelled iprodione studies. Therefore, studies on the fate and behaviour of the hydantoin moiety iprodione in soil are required to demonstrate whether metabolite RP 30181 and/or other degradation/transformation products are formed at amounts requiring further assessment or not (see Section 4).
5) The long-term risk assessment for wild mammals for all the relevant routes of exposure could not be finalised due to the lack of a reliable endpoint (see Section 5).

9.2. Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29 (6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion 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 if the assessment at a higher tier level could not be finalised due to lack of information, and if the assessment performed at the lower tier level does not permit the conclusion 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 if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

6) The toxicity studies were not representative of the proposed technical specification for the active substance and associated impurities (see Sections 2 and 5).
7) Iprodione has harmonised classification and labelling as carcinogen category 2. During the Pesticide peer review, the experts proposed iprodione to be classified as carcinogen category 1B and a critical area of concern is identified with regard to the approval criteria, Annex II, Point 3.6.3 of Regulation (EC) No 1107/2009 (see Section 2).
8) During the pesticide peer review, the experts proposed iprodione to be classified as carcinogen category 1B and as toxic for reproduction category 2 in accordance with the provisions of Regulation (EC) No 1272/2008[3], and therefore, the first interim provision of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 indicates that iprodione shall be considered to have endocrine disrupting properties (see Sections 2 and 5). Iprodione is considered to have endocrine disruption properties (see Sections 2 and 5).
9) The genotoxic potential of metabolite RP 30228 found as a residue and impurity cannot be excluded and setting of reference values cannot be done (see Sections 2 and 3). It is noted that metabolite RP 30228 is predicted to occur in groundwater above 0.1 μg/L in one FOCUS GW scenario according to the representative uses (see Section 4).
10) For both intended uses, PEC_{gw} were > 0.75 μg/L for metabolite RP 35606, only in acidic soils, and for metabolite RP 30181, in both acidic and slightly acidic to alkaline soils. Both metabolites are considered relevant because it cannot be excluded that they share the carcinogenic and reproductive toxicity potential of iprodione (no toxicity and genotoxicity data on these two metabolites are available, see Sections 2 and 4).
11) An acute consumer risk cannot be excluded based on a preliminary risk assessment. The assessment is likely to underestimate exposure to the metabolite 3,5-dichloroaniline due to instability of the compound in residue sample storage and of residues not fully considered due to different data gaps. Moreover, possible common toxicological effects of 3,5-dichloroaniline and iprodione and similar metabolites have not been considered in the risk assessment.
12) A high long-term risk of iprodione to aquatic organisms was identified.

9.3. Overview 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 Section 8, has been evaluated as being effective, then 'risk identified' is not indicated in Table 5.)

All columns are grey, as the technical material specification proposed was not comparable to the material used in the testing that was used to derive the (eco) toxicological reference values.

Table 5: Overview of concerns

Representative use		Carrots	Lettuce (field)	Lettuce (greenhouse)
Operator risk	Risk identified			
	Assessment not finalised			X[1]
Worker risk	Risk identified			
	Assessment not finalised			
Resident/bystander risk	Risk identified			
	Assessment not finalised			
Consumer risk	Risk identified	X[11]	X[11]	X[11]
	Assessment not finalised	X[2,3]	X[2,3]	X[2,3]
Risk to wild non-target terrestrial vertebrates	Risk identified	X	X	
	Assessment not finalised	X[4,5]	X[4,5]	
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified			
	Assessment not finalised			
Risk to aquatic organisms	Risk identified	X[12] 5/6 FOCUS scenarios	X[12] 6/7 FOCUS scenarios	X[12]
	Assessment not finalised			
Groundwater exposure to active substance	Legal parametric value breached	3/6 FOCUS scenarios	2/7 FOCUS scenarios	2/7 FOCUS scenarios
	Assessment not finalised			
Groundwater exposure to metabolites	Legal parametric value breached[(a)]	X[10]	X[10]	X[10]
	Parametric value of 10 μg/L[(b)] breached			
	Assessment not finalised	X[4]	X[4]	X[4]

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Columns are grey if no safe use can be identified. The superscript numbers relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number, see Sections 2–6 for further information.

(a): When the consideration for classification made in the context of this evaluation under Regulation (EC) No 1107/2009 is confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008.

(b): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission (2003).

References

ECHA (European Chemicals Agency), 2015. Guidance on the Application of the CLP Criteria; Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures. Version 4.1, June 2015. Reference: ECHA-15-G-05-EN; ISBN: 978-92-9247-413-3. Available online: http://echa.europa.eu/documents/10162/13562/clp_en.pdf

EFSA (European Food Safety Authority), 2008. Opinion on a request from EFSA related to the default Q10 value used to describe the temperature effect on transformation rates of pesticides in soil. EFSA Journal 2008;6(1):622, 32 pp. doi:10.2903/j.efsa.2008.622

EFSA (European Food Safety Authority), 2009. Guidance 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

EFSA (European Food Safety Authority), 2011. Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009. EFSA Journal 2011;9(2):2092, 49 pp. doi:10.2903/j.efsa.2011.2092

EFSA (European Food Safety Authority), 2013a. 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

EFSA (European Food Safety Authority), 2013b. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for iprodione according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013; 11(10):3438, 94 pp. doi:10.2903/j.efsa.2013.3438

EFSA (European Food Safety Authority), 2016. Peer review report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance iprodione. Available online: www.efsa.europa.eu

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2012. Guidance on dermal absorption. EFSA Journal 2012;10(4):2665, 30 pp. doi:10.2903/j.efsa.2012.2665

European Commission, 2000a. Residues: guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (Part A, Section 4) and Annex III (Part A, Section 5) of Directive 91/414. SANCO/3029/99-rev. 4, 11 July 2000.

European Commission, 2000b. Technical material and preparations: guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (Part A, Section 4) and Annex III (Part A, Section 5) of Directive 91/414. SANCO/3030/99-rev. 4, 11 July 2000.

European Commission, 2002a. Review report for the active substance iprodione. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 3 December 2002 DD Month YYYY in view of the inclusion of iprodione in Annex I of Council Directive 91/414/EEC. SANCO/5036/VI/98-final, 3 December 2002, 47 pp.

European Commission, 2002b. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002-rev. 2 final, 17 October 2002.

European Commission, 2002c. Guidance Document on Aquatic Ecotoxicology Under Council Directive 91/414/EEC. SANCO/3268/2001-rev. 4 final, 17 October 2002.

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.

European Commission, 2010. Guidance Document on residue analytical methods. SANCO/825/00-rev. 8.1, 16 November 2010.

European Commission, 2011. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. SANCO 7525/VI/95-rev. 9. March 2011. p. 1–46.

European Commission, 2012. Guidance document on the assessment of the equivalence of technical materials of substances regulated under Regulation (EC) No 1107/2009. SANCO/10597/2003-rev. 10.1, 13 July 2012.

European Commission, 2013. Guidance document on data requirements on efficacy for the dossier to be submitted for the approval of new active substances contained in plant protection products. SANCO/10054/2013-rev. 3, 11 July 2013.

European Commission, 2014. Assessing potential for movement of active substances and their metabolites to ground water in the EU. Report of the FOCUS Workgroup. EC Document Reference SANCO/13144/2010-v. 3, 613 pp. as outlined in Generic guidance for tier 1 FOCUS groundwater assessment, v. 2.2, May 2014.

FAO (Food and Agriculture Organisation of the United Nations), 2006. FAO specification for Agricultural Pesticides in agriculture. Iprodione 287/TC. FAO Specifications, 30 pp.

FAO (Food and Agriculture Organization of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Edition. FAO Plant Production and Protection Paper 197, 264 pp.

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 Generic guidance for FOCUS surface water scenarios, v. 1.1, March 2012.

FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use), 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-v. 2.0, 434 pp.

FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use), 2008. Pesticides in air: considerations for exposure assessment. Report of the FOCUS Working Group on Pesticides in Air. EC Document Reference SANCO/10553/2006-rev. 2, June 2008.

France, 2015. Renewal Draft Assessment Report (RAR) on iprodione prepared by the rapporteur Member State France in the framework of Regulation (EC) No 844/2012, October 2015. Available online: www.efsa.europa.eu

France, 2016. Revised renewal assessment report (RAR) on iprodione, August 2016. Available online: www.efsa.europa.eu

JMPR (Joint Meeting on Pesticide Residues), 2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues, Rome, Italy, 20–29 September 2004, 383 pp.

JMPR (Joint Meeting on Pesticide Residues), 2007. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues, Geneva, Switzerland, 18–27 September 2007, 164 pp.

OECD (Organisation for Economic Co-operation and Development), 2000. Test No. 106: adsorption – Desorption Using a Batch Equilibrium Method, OECD Publishing, Paris, 21 January 2000. doi: http://dx.doi.org/10.1787/9789264069602-en

OECD (Organisation for Economic Co-operation and Development), 2002. Test No. 307: aerobic and Anaerobic Transformation in Soil, OECD Publishing, Paris, 24 April 2012. doi: http://dx.doi.org/10.1787/9789264070509-en

OECD (Organisation for Economic Co-operation and Development), 2007a. Test No. 501: metabolism in Crops, OECD Publishing, Paris, 25 January 2007. doi: http://dx.doi.org/10.1787/9789264061835-en

OECD (Organisation for Economic Co-operation and Development), 2007b. Test No. 75: Guidance document on the honey bee (*Apis mellifera* L.) brood test under semi-field conditions. ENV/JM/MONO(2007)22, 31 August 2007.

OECD (Organisation for Economic Co-operation and Development), 2009. Guidance document on overview of residue chemistry studies. ENV/JM/MONO(2009)31, 28 July 2009.

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: www.oecd.org

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.

Abbreviations

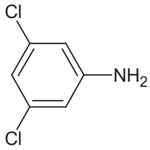
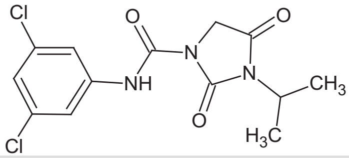
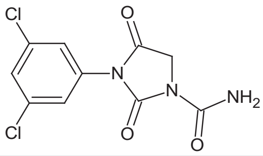
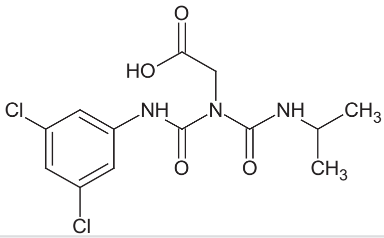
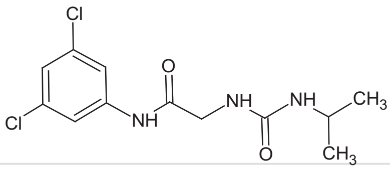
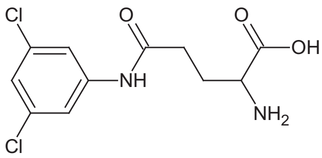
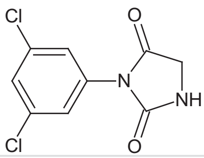
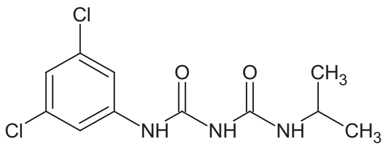
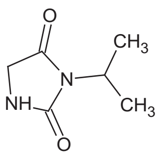
AAOEL	acute acceptable operator exposure level
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAS	Chemical Abstracts Service
CLP	classification, labelling and packaging
DCA	dichloroaniline
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
ECHA	European Chemicals Agency
ECPA	European Crop Protection Association
EEC	European Economic Community
ETR	exposure toxicity ratio
EUROPOEM	European Predictive Operator Exposure Model
FAO	Food and Agriculture Organization of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GLP	good laboratory practice
GC-ECD	gas chromatography-electron capture detector
HPLC	high-pressure liquid chromatography or high-performance liquid chromatography
HPLC–MS	high-pressure liquid chromatography–mass spectrometry
HPG	hypopharyngeal glands
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{Foc}	Freundlich organic carbon adsorption coefficient
LC_{50}	lethal concentration, median
LC–MS	liquid chromatography–mass spectrometry
LC–MS/MS	liquid chromatography with tandem mass spectrometry
LOAEL	lowest observable adverse effect level
LOQ	limit of quantification

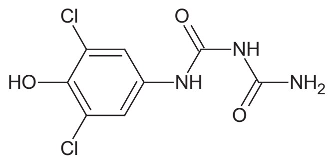
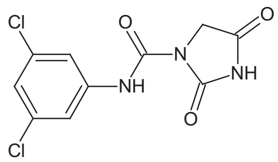
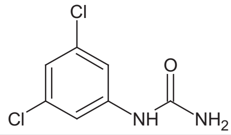
MN	micronucleus
MRL	maximum residue level
MS	mass spectrometry
MWHC	maximum water-holding capacity
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PD	proportion of different food types
PEC	predicted environmental concentration
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
PT	proportion of diet obtained in the treated area
QSAR	quantitative structure–activity relationship
RAR	renewal assessment report
RMS	rapporteur Member State
RUD	residue per unit dose
SMILES	simplified molecular-input line-entry system
TMDI	theoretical maximum daily intake
UF	uncertainty factor
UV	ultraviolet
WG	water-dispersible granule
WHO	World Health Organization

Appendix A – List of end points for the active substance and the representative formulation

Appendix A can be found in the online version of this output ('Supporting information' section): http://dx.doi.org/10.2903/j.efsa.2016.4609

Appendix B – Used compound codes

Code/trivial name[(a)]	Chemical name/SMILES notation	Structural formula
Impurity RP 32596 **3,5-dichloroaniline**	3,5-Dichloroaniline Nc1cc(Cl)cc(Cl)c1	
Impurity RP 30228	*N*-(3,5-Dichlorophenyl)-3-isopropyl-2,4-dioxoimidazolidine-1-carboxamide O=C2CN(C(=O)Nc1cc(Cl)cc(Cl)c1)C(=O)N2C(C)C	
RP 32490 Reg. No. 5079628	3-(3,5-Dichlorophenyl)-2,4-dioxoimidazolidine-1-carboxamide O=C2CN(C(=O)N)C(=O)N2c1cc(Cl)cc(Cl)c1	
RP 35606 M 610F014 Reg. No. 5079626	*N*-[(3,5-Dichlorophenyl)carbamoyl]-*N*-(isopropylcarbamoyl)glycine Clc1cc(NC(=O)N(CC(=O)O)C(=O)NC(C)C)cc(Cl)c1	
RP 37176	*N*-(3,5-Dichlorophenyl)-N^2-(isopropylcarbamoyl)glycinamide Clc1cc(NC(=O)CNC(=O)NC(C)C)cc(Cl)c1	
M 610F007	*N*-(3,5-Dichlorophenyl)glutamine Clc1cc(NC(=O)CCC(N)C(=O)O)cc(Cl)c1	
RP 25040	3-(3,5-Dichlorophenyl)imidazolidine-2,4-dione Clc1cc(Cl)cc(c1)N2C(=O)CNC2=O	
RP 36221	*N*-(3,5-Dichlorophenyl)-*N*′-isopropyl-2-imidodicarbonic diamide Clc1cc(NC(=O)NC(=O)NC(C)C)cc(Cl)c1	
RP 30181	3-Isopropylimidazolidine-2,4-dione O=C1CNC(=O)N1C(C)C	

Code/trivial name[(a)]	Chemical name/SMILES notation	Structural formula
RP 36114	*N*-(3,5-Dichloro-4-hydroxyphenyl)-2-imidodicarbonic diamide Clc1cc(cc(Cl)c1O)NC(=O)NC(N)=O	
RP 36112	*N*-(3,5-Dichlorophenyl)-2,4-dioxoimidazolidine-1-carboxamide O=C2NC(=O)CN2C(=O)Nc1cc(Cl)cc(Cl)c1	
LS 720942 RP 44247	1-(3,5-Dichlorophenyl)urea Clc1cc(NC(N)=O)cc(Cl)c1	

SMILES: simplified molecular-input line-entry system.
(a): The compound name in bold is the name used in the conclusion.

Appendix to:

EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance iprodione EFSA Journal 2016;14(11):4609, 145 pp. doi:10.2903/j.efsa.2016.4609

Appendix A – List of end points for the active substance and the representative formulation

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2)

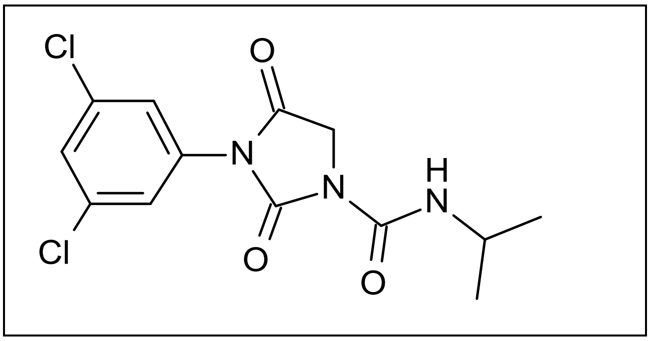
Active substance (ISO Common Name)	Iprodione
Function (*e.g.* fungicide)	fungicide

Rapporteur Member State	France
Co-rapporteur Member State	Belgium

Identity (Regulation (EU) N° 283/2013, Annex Part A, point 1)

Chemical name (IUPAC)	3-(3,5-dichlorophenyl)-*N*-isopropyl-2,4-dioxoimidazolidine-1-carboxamide
Chemical name (CA)	3-(3,5-dichlorophenyl)-*N*-(1methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide
CIPAC No	278
CAS No	36734-19-7
EC No (EINECS or ELINCS)	253-178-9
FAO Specification (including year of publication)	960 g/kg (FAO specification 278/TC (July 2006))
Minimum purity of the active substance as manufactured	980 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	3,5-dichloroaniline (RP 32596) (maximum level: 0.5 g/kg) RP 30228 max. open
Molecular formula	$C_{13}H_{13}Cl_2N_3O_3$
Molar mass	330.17 g/mol

Structural formula



Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)

Melting point (state purity)	134 °C (99.9%)
Boiling point (state purity)	Not determined, higher than the decomposition point.
Temperature of decomposition (state purity)	164.5 °C (99.7%)
Appearance (state purity)	White crystalline powder (99.9%) White powder (95.5%)
Vapour pressure (state temperature, state purity)	5.10^{-7} Pa at 25 °C (99.7%)
Henry's law constant (state temperature)	$0.7x10^{-5}$ Pa m^3 mol^{-1} (20°C)
Solubility in water (state temperature, state purity and pH)	8.9 mg/L at 20°C (pH 5) (99.8%) 6.8 mg/L at 20°C (pH 7) (99.8%) 9.0 mg/L at 30°C (pure water, pH 6.1) (99.8%)
Solubility in organic solvents (state temperature, state purity)	hexane 590 mg/L (96.1%) acetonitrile 168 g/L (96.1%) dichloromethane 450 g/L (96.1%) ethylacetate 22.5 g/L (96.1%) acetone 342 g/L (96.1%) toluene 147 g/L (96.1%) 1-octanol 10 g/L (96.1%) (temperature not provided)
Surface tension (state concentration and temperature, state purity)	73 mN/m at 20°C (6 mg/L) (97.7%)
Partition coefficient (state temperature, pH and purity)	log P_{OW} = 2.99 at 25°C (pH 3) (99.7%) log P_{OW} = 3.00 at 25°C (pH 5) (99.7%)
Dissociation constant (state purity)	No dissociation
UV/VIS absorption (max.) incl. ε (state purity, pH)	solution: water λ_{max} (204.5 nm); ε (44333 L mol^{-1} cm^{-1}) No λ max between 205 and 400 nm, no absorption above 330 nm. No significant modification of the spectrum was observed in acidic medium (pH = 1) (99.9 %)
Flammability (state purity)	Not flammable (97.8 %)
Explosive properties (state purity)	Not explosive (97.8 %)
Oxidising properties (state purity)	No oxidising properties (97.8 %)

Summary of representative uses evaluated, for which all risk assessments needed to be completed (*name of active substance or the respective variant*)

(Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

Crop and/or situation (a)	**Member State**	**Product Name**	**F G 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.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	g a.i./hL min max (g/hL)	Water L/ha min max	g a.i./ha min max (*) (g/ha)		
Carrots	CEU (BE) SEU (GR, CY, IT, ES, FR)	BAS 61006 F (ROVRAL WG)	F	*Alternaria, Stemphylium, Botrytis*	WG	750 g/kg	Spraying	BBCH 13-49	1-4	10		200-800	750	27	Risk of groundwater contamination Consumer acute risk identified
Lettuce and similar	CEU (BE, DE, AT, UK, IE) SEU (GR, CY, IT, ES, FR)	BAS 61006 F (ROVRAL WG)	F	*Botrytis, Rhizoctonia, Sclerotinia*	WG	750 g/kg	Spraying	BBCH 10-49	1-3	14		200-1000	488 - 750	21	Rate range: 0,65 – 1,0 kg/ha Risk of groundwater contamination Consumer acute risk identified for scarole
Lettuce and similar	CEU (BE, DE, AT, UK, IE) SEU (GR, CY, IT, ES, FR)	BAS 61006 F (ROVRAL WG)	G	*Botrytis, Rhizoctonia, Sclerotinia*	WG	750 g/kg	Spraying	BBCH 10-49	1-3	14		200-1000	488 - 750	14	Rate range: 0,65 – 1,0 kg/ha Risk of groundwater contamination Consumer acute risk identified for lettuce and scarole

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(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 plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage range from first to 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) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Further information, Efficacy

Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

	Considering that the substance is approved and authorisations of plant protection products containing the substance have already been evaluated according to Uniform Principles (Regulation (EC) No 546/2011), no other efficacy documentation is deemed to be necessary at this stage.

Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

	Considering that the substance is approved and authorisations of plant protection products containing the substance have already been evaluated according to Uniform Principles (Regulation (EC) No 546/2011), no other selectivity documentation is deemed to be necessary at this stage.

Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

	Considering that the substance is approved and authorisations of plant protection products containing the substance have already been evaluated according to Uniform Principles (Regulation (EC) No 546/2011), no other documentation is deemed to be necessary at this stage.

Groundwater metabolites: Screening for biological activity (SANCO/221/2000-rev.10-final Step 3 a Stage 1)

	RP 30228	RP 35606	RP 30181
Activity against target organism	No	No data available	

Methods of Analysis

Analytical methods for the active substance (Regulation (EU) N° 283/2013, Annex Part A, point 4.1 and Regulation (EU) N° 284/2013, Annex Part A, point 5.2)

Technical a.s. (analytical technique)	HPLC-UV (220 nm)
Impurities in technical a.s. (analytical technique)	HPLC-UV (205 and 220 nm)
Plant protection product (analytical technique)	HPLC-UV (220 nm)

Analytical methods for residues (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 & point 7.4.2)

Residue definitions for monitoring purposes

Food of plant origin		Iprodione
Food of animal origin		RP32490 (Reg. No. 5079628)
Soil		Iprodione
Sediment		Iprodione
Water	surface	Iprodione + RP35606 (Reg.No. 5079626)
	drinking/ground	Iprodione + RP35606 + RP 30181
Air		Iprodione
Body fluids and tissues		Iprodione

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-MS/MS and its ILV validated and confirmed for iprodione with LOQ=0.01 mg/kg in plants with high water, high acid, high oil content and in dry crops. Extraction efficiency demonstrated for high water content commodities. Demonstration of the extraction efficiency in high acid, high oil content and in dry crops is required.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-MS/MS and its ILV validated and confirmed for RP 32490 (Reg. No 5079628) with LOQ=0.01 mg/kg in Milk, Egg, Meat, Liver, Kidney, Fat. Demonstration of the extraction efficiency in animal matrices is required.
Soil (analytical technique and LOQ)	HPLC-MS/MS validated and confirmed for iprodione with LOQ=0.005 mg/kg in soil

Water (analytical technique and LOQ)	HPLC-MS/MS and its ILV validated and confirmed for iprodione and Reg.No. 5079626 (RP35606) with LOQ=0.03 µg/L in drinking, ground and surface water Data gap for method for RP 30181 in groundwater
Air (analytical technique and LOQ)	GC-ECD LOQ = 2.0 µg/m3
Body fluids and tissues (analytical technique and LOQ)	Data required

Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 10)

Substance	Iprodione
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][1]:	Not explosive, not oxidizing, not flammable
Peer review proposal [2] for harmonised classification according to Regulation (EC) No 1272/2008:	Not explosive, not oxidizing, not flammable

[1] 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.

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

Section 2 Impact on Human and Animal Health

Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)

Rate and extent of oral absorption/systemic bioavailability	60% based on urinary excretion
Toxicokinetics	Tmax = 2 (males) - 4 (females) hours (low dose)/ 6 hours (high dose)
Distribution	Widely distributed (GI tract, liver, skin)
Potential for bioaccumulation	No evidence for accumulation
Rate and extent of excretion	Rapid and extensive (98 % within 96 h), mainly via urine (62 %, 36 % via faeces)
Metabolism in animals	Extensively metabolised (approximately 95 % of absorbed dose, 20 metabolites); hydroxylation of the aromatic ring, degradation of the isopropylcarbamoyl chain and rearrangement followed by cleavage of the hydantoin moiety
In vitro metabolism	Rat and human liver microsomes study: no unique human metabolite detected
Toxicologically relevant compounds (animals and plants)	Parent compound, 3,5-dichloroaniline, M610F007. Toxicity of metabolites found in livestock not determined.
Toxicologically relevant compounds (environment)	RP30228, RP 35606 and RP30181

Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

Rat LD_{50} oral	> 2000 mg/kg bw	
Rat LD_{50} dermal	> 2000 mg/kg bw	
Rat LC_{50} inhalation	> 5.16 mg/L air /4h (whole body)	
Skin irritation	Non-irritant	
Eye irritation	Non-irritant	
Skin sensitisation	Non-sensitising (Buehler 9 applications and Maximisation test)	
Phototoxicity	Not required	

Short-term toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.3)

Target organ / critical effect	Rat: decreased body weight and food consumption, adrenals, ovary, uterus Mouse: liver, adrenals Dog: liver, adrenals, haematology, prostate, kidney	
Relevant oral NOAEL	1-year, dog: 17.5 mg/kg bw per day (400 ppm) 90-day, rat: 30.8 mg/kg bw per day (500	

	ppm) 90-day, mouse: 260 mg/kg bw per day.	
Relevant dermal NOAEL	28-day, rabbit: 1000 mg/kg bw per day	
Relevant inhalation NOAEL	No data - not required	

Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)

In vitro studies	Ames tests (*S. typhimurium*), DNA repair assays (*E. coli*), Sister chromatid exchange assay (CHO cells), CHO/HGPRT mutation assay (CHO cells), chromosome aberration assay (CHO cells), induct test (*E. coli*), yeast test (*S. cerevisiae*): negative DNA damage assay *(B. subtilis*): positive	
In vivo studies	Micronucleus assay (mice): negative	
Photomutagenicity	Not required	
Potential for genotoxicity	Iprodione is unlikely to be genotoxic	

Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

Long-term effects (target organ/critical effect)	Rat: liver, adrenals, testes, epididymides, seminal vesicles, prostate, spleen Mouse : liver, testes, non-glandular stomach, uterus, ovaries, spleen, kidney, adrenals	
Relevant long-term NOAEL	2-year, rat: LOAEL = 6.1 mg/kg bw per day (150 ppm). No NOAEL was determined. 18-month, mouse: 23 mg/kg bw per day (160 ppm)	
Carcinogenicity (target organ, tumour type)	Rat: interstitial Leydig cell tumours Mouse: ovary luteomas, benign and malignant liver cell tumours	Cat. 1B H350
Relevant NOAEL for carcinogenicity	2-year, rat: LOAEL = 6.1 mg/kg bw per day (150 ppm). No NOAEL was determined; 18-month, mouse: 115 mg/kg bw per day (800 ppm)	

Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)

Reproduction toxicity

Reproduction target / critical effect	In a new 2-generation study: Parental toxicity: effects on adrenals. Highest dose level: decreased body weight gain and food consumption Reproductive toxicity: sperm abnormalitie Offspring's toxicity: sperm abnormalities F1 and marginal delay in preputial separation. Highest dose levels: persistence of areolas/nipples F1/F2, decreased bodyweight gain, decreased male anogenital distances F1/F2 In an older 2-generation study: Parental toxicity: decreased body weight gain and food consumption Reproductive toxicity: decreased mean number of pups per litter Offspring's toxicity: clinical signs, decreased number of live/dead pups delivered, decreased pup survival and pup bodyweight during lactation	Repr 2 H361df
Relevant parental NOAEL	26.9 mg/kg bw per day	
Relevant reproductive NOAEL	LOAEL = 26.9 mg/kg bw per day. No NOAEL was determined.	
Relevant offspring NOAEL	LOAEL = 26.9 mg/kg bw per day. No NOAEL was determined.	

Developmental toxicity

Developmental target / critical effect	Rat: Maternal toxicity: effects on adrenals, decreased bodyweight gain Developmental toxicity: slight effect on male anogenital distance, delayed fetal development (bodyweight and increased space between the body wall and organs) Rabbit: Maternal toxicity: slight decreased maternal bodyweight gain. Highest dose level: bodyweight losses, abortions, post-implantation losses Developmental toxicity : umbilical hernia	Repr 2 H361d
Relevant maternal NOAEL	Rat: 20 mg/kg bw per day Rabbit: 20 mg/kg bw per day	
Relevant developmental NOAEL	Rat: 20 mg/kg bw per day Rabbit: < 20 mg/kg bw per day. No NOAEL was determined.	

Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)

Acute neurotoxicity	Study not required	
Repeated neurotoxicity	Study not required	
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	Study not required	

Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

Supplementary studies on the active substance	Hepatotoxicity in the mouse: - proliferative response in centrilobular hepatocytes at 4000 ppm for 13 or 90 days - dose-related increase in total cytochrome P450 content and in staining of the isoforms CYP2B and CYP3A on Western blots after 3- and 14-day exposure at 4000 and 12000 ppm. Quantification of iprodione in the plasma and testes of the rat following single oral adminsitration (70 mg/kg bw): tissue levels of iprodione in the testes mirrored those in the whole blood and plasma, but were slightly lower than plasma levels. Iprodione in the plasma was largely protein-bound. 15- and 30-day gavage rat studies: at 600 mg/kg bw per day: decreased weight of sex organs, marked increased adrenal weight and vacuolisation, higher proliferation index of iprodione treated Leydig cells, increased FSH and LH level 14-day dietary rat study: no changes in testicular function, increased LH level, dose-dependant decreased testosterone secretion in testicular sections from treated or untreated animals by addition of iprodione to the media Hormonal measurements in male rats: at 70 and 300 mg/kg bw per day by gavage, single dose or 14-day exposure: transient reduction in circulating testosterone levels and consequent homeostatic increase in the levels of circulating LH Measurement of Leydig cell proliferation in male rats: 14-day exposure by gavage: dose-related significant increase in Leydig cell proliferation at 70 and 300 mg/kg bw per day, not statistically significant at 6 mg/kg bw per day Inhibition of testosterone secretion in cultured porcine Leydig cells, reversible at the withdrawal of iprodione. Iprodione appears to modulate Leydig cell steroidogenesis at the level of cholesterol

	transport into mitochondria No clear evidence of competitive binding to androgen receptors isolated from rat ventral prostate No competition with the human androgen receptor in T47D cell line Binding to the human androgen receptor expressed within COS-1 cells: IC_{50} = 86 µM (literature data) Inhibition of androgen-dependent gene expression in the hAR-expressing MDA-kb2 cell line after DHT stimulation: IC50 = 245.9 µM, insolubility of iprodione at 300 µM (literature data) Negative response in a transactivation assay using Chinese Hamster Ovary cells transfected with hERα and hERβ and lack of activity in the MCF7 cell proliferation assay and the Yeast Oestrogen Screen (literature data) **US-EPA EDSP Tier 1 studies**: - Aromatase assay (human recombinant): no inhibition of aromatase - Estrogen receptor binding: no interaction of the rat uterine cytosol oestrogen receptors - Estrogen receptor transcriptional activation (Human cell line HeLa-9903): iprodione is not an agonist of hERα - Female pubertal assay (rat): delayed initiation and completion of vaginal opening and time to first oestrus at 300 mg/kg bw per day, decreased uterine weights and altered uterine histopathology from 150 mg/kg bw per day - Uterotrophic assay (rat): no evidence of oestrogenic activity - Steroidogenesis assay (human cell line H295R): inhibition of androgen steroidogenesis at 30 and 100 µM - Androgen receptor binding (rat prostate): not performed according to OPPTS Guideline but low affinity for AR binding in the available studies (see above) - Hershberger assay (rat): not performed according

	to OPPTS Guideline but available in the literature: decreased androgen-sensitive tissue weights at 100 and 200 mg/kg bw per day - Male pubertal assay (rat): not performed according to OPPTS Guideline but available in the literature: delayed preputial separation from 100 mg/kg bw per day, decreased weights of seminal vesicles and epididymides, increased adrenals and liver weights at 200 mg/kg bw per day, decreased testosterone level at all dose level (LOAEL = 50 mg/kg bw per day) and 17α-hydroxyprogesterone and androstenedione from 100 mg/kg bw per day
Endocrine disrupting properties	Iprodione showed endocrine disrupting properties, particularly anti-androgenic effects. Iprodione may interfere with steroidogenesis at the level of cholesterol transport but another mode of action, implying its metabolites, cannot be totally excluded.
Studies performed on metabolites or impurities	RP30228 (Reg. No. 5079647) Minor rat metabolite (TK rat study on iprodione). Mice: oral LD50 >10000 mg/kg bw Rats: oral LD50 >2500 mg/kg bw; dermal LD50 >2500 mg/kg bw Not irritating to skin and eyes of rabbits. Ames test: negative MNT in vitro: positive MNT in vivo: equivocal/marginally positive 13-week oral toxicity study in rats: LOAEL of 58/64 mg/kg bw/d (M/F) (reduced body weight gain in females). RP36112 (Reg. No. 5079623) Minor rat metabolite (TK rat study on iprodione). In vitro assays: Inhibition of testosterone secretion in cultured porcine Leydig cells at the level of steroidogenic enzymes No androgen receptor binding in human mammary gland cancer cells Androgen receptor binding in rat ventral prostate RP32490 (Reg. No. 5079628) Major rat metabolite (20% in urine) (TK rat study on iprodione).. In vitro assays: No inhibition of testosterone secretion in cultured porcine Leydig cells No androgen receptor binding in human mammary gland cancer cells

	No androgen receptor binding in rat ventral prostate Toxicological profile covered by iprodione. RP25040 (Reg. No. 207099) Minor rat metabolite (TK rat study on iprodione). Mice: oral LD50: 1125 mg/kg bw No skin irritation effects in rabbits. Ames test (not acceptable): negative In vitro assays: No inhibition of testosterone secretion in cultured porcine Leydig cells Androgen receptor binding in human mammary gland cancer cells Androgen receptor binding in rat ventral prostate RP37176 (Reg. No. 5079612) No rat metabolite (TK rat study on iprodione). Mice: oral LD50 >1125 mg/kg bw Ames test (not acceptable): negative MNT in vitro: negative M610F007 (Reg. No. 5916256) Ames test: negative MNT in vitro: negative Toxicological profile covered by 3,5-DCA. RP36221 (Reg. No. 5079618) No rat metabolite (TK rat study on iprodione).. Rats: oral LD50 >2000 mg/kg Ames test: negative MNT in vitro: negative MLA: negative RP36115 (Reg. No. 5079624) Rat metabolite (8% in urine) (TK rat study on iprodione). In vitro assays: Inhibition of testosterone secretion in cultured porcine Leydig cells at the level of cholesterol transport No androgen receptor binding in human mammary gland cancer cells Androgen receptor binding in rat ventral prostate RP36114 (Reg. No. 5079627) Major rat metabolite (11% in urine) (TK rat study on iprodione).

	In vitro assays: No androgen receptor binding in human mammary gland cancer cells No androgen receptor binding in rat ventral prostate RP44247 (Reg. No. 89517) No rat metabolite (TK rat study on iprodione). Ames test: negative MNT in vitro: negative RP32596 (3,5-DCA, Reg. No. 85831) No rat metabolite (TK rat study on iprodione).. Ames test: negative MLA: negative MNT in vivo in mice: negative MNT in vivo in rats (limited validity): negative 28-day oral gavage study in Wistar rats: NOAEL of 7.5 mg/kg bw/d 90-day oral gavage study in SD rats: NOAEL of 1.0 mg/kg bw/d (LOAEL of 3 mg/kg bw per day, haemotoxicity).

Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

	No reported adverse effects in workers or poisoning indicents

Summary[3] (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6) Iprodione	Value (mg/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI) [(a),(b)]	0.02	rat, 2-year	300[(d)]
Acute Reference Dose (ARfD) [(a),(b)]	0.06	rabbit, developmental	300[(d)]
Acceptable Operator Exposure Level (AOEL) [(b)]	0.04[(c)]	rabbit, developmental	300[(d)]
Acute Acceptable Operator Exposure Level (AAOEL)	0.04 [(c)]	rabbit, developmental	300[(d)]

(a) Applicable also to metabolites RP 32490 and RP 36114.
(b) The proposed reference values are different than those mentioned in the review report 5036/VI/98-final. 3 (European Commission, 2002a).
(c) Including correction for for limited oral absorption of 60%.
(d) Including additional uncertainty factor of 3 for the use of a LOAEL.

Summary[4] (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6) 3,5-dichloroaniline	Value (mg/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI) **[(a)]**	0.0005	90-day, rat	2000 [(b)]
Acute Reference Dose (ARfD) **[(a)]**	0.0075	28-day, rat	1000 [(c)]

(a) Applicable also to metabolite M610F007.
(b) Additional UF of 2 for sub-chronic to chronic extrapolation and an additional 10 for covering lack of complete data package.
(c) Additional UF of 10 for covering lack of complete data package.

Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)

Representative formulation (BAS 610 06 F, WG, 750 g/kg)	*In vitro* human skin study on the representative formulation: Concentrate (375 g/L): 0.2 % Spray dilution (0.9 g/L): 12 % Spray dilution (0.5 g/L): 3%

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

Operators	Use: carrots and lettuce, tractor mounted equipment, application rate 0.75 kg a.s./ha Exposure estimates (model): % of AOEL UK POEM Without PPE: 862 % PPE (gloves M/L/application): 186 % German model

[3] If available include also reference values for metabolites
[4] If available include also reference values for metabolites

	Without PPE: 138 % PPE (gloves M/L/application and coverall): 14 %
	Use: lettuce (indoor), spray lance, application rate 0.75 kg a.s./ha : inconclusive.
Workers	Exposure estimates: % of AOEL EUROPOEM II *1 application (worst-case : lettuce in greenhouses)* Without PPE: 475% PPE (coverall): 70 %
Bystanders and residents	EUROPOEM II: Bystander: 1.9% of AOEL Martin *et al.*: Bystander: 1.0% of AOEL for adults / 0.9% of AOEL for children Resident: 0.125% of AOEL for adults / 0.25% of AOEL for children

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

Substance:	Iprodione
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][5] :	Carc 2 H351- Suspected of causing cancer
Peer review proposal [6] for harmonised classification according to Regulation (EC) No 1272/2008:	Carc 1B H350 – May cause cancer Repr 2 H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.

[5] 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.

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

Section 3 Residues in or on treated products food and feed

Metabolism in plants (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

Primary crops (Plant groups covered) **OECD Guideline 501**	**Crop groups**	**Crop(s)**	**Application(s)**	**DAT** (days)
	Fruit crops	Peach[(a)]	Foliar	64 (pre-final appl.), 8
	Root crops	Carrot	Foliar	28
	Leafy crops	Lettuce[(a)]	Foliar and soil spray	0, 16, 25, 38
	Cereals/grass crops	Rice[(a)]	Foliar	40
	Pulses/Oilseeds	Peanut[(a)]	Foliar	0, 10
	Miscellaneous	-	-	-
	(a) No stand-alone OECD guideline study; deficiencies noted. Performed before GLP. Only the metabolism study on carrot was conducted under GLP and according to OECD guidelines. For information only: - Wheat and strawberry data not acceptable. - One in vitro study on lettuce available. - Literature data provided two studies conducted with 3,5-dichloroaniline on duckweed, seed of cabbage and tomato.			

Rotational crops (metabolic pattern) **OECD Guideline 502**	**Crop groups**	**Crop(s)**	**PBI** (days)	**Comments**
	Root/tuber crops	Turnip, radish	30, 120, 240, 365	Studies were performed before GLP and OECD guidelines. Some shortcomings with regard to current testing standards were identified. Further information necessary to conclude (data gap). Additional study in wheat, beans & sugar beet not acceptable.
	Leafy crops	Spinach	30, 120, 365	
	Cereal (small grain)	Oats, wheat, maize	30, 120, 240, 365	
	Other	Peanut, soybean	120, 240, 365	
Rotational crop and primary crop metabolism similar?	Residue pattern is expected to be qualitatively similar based on indication from available data. However, any confirmation of a residue definition in rotational crops is pending the availability of requested data and information on the residue behaviour and further consideration of the genotoxic potential or toxicological profile of major rotational crop metabolites (e.g. RP 25040)			

Processed commodities (standard hydrolysis study) **OECD Guideline 507**	**Conditions**	Iprodione	RP 30228	RP 37176	RP 32596 (3,5-DCA)
	20 min, 90°C, pH 4	94.5	3.0	1.6	1.3
	30 min, 70°C, pH 4	94.3	0.29	0.37	0.00
	30 min, 130°C, pH 4	78.9	10.9	2.1	0.5
	60 min, 100°C, pH 5	66.6	30.3	3.3	1.2
	20 min, 120°C, pH 6	53.0	24.8	20.5	5.5
	30 min, 70°C, pH 6	86.3	5.9	3.4	0.00
	30 min, 130°C, pH 6	2.2	17.5	15	41.9
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Depending on the hydrolysis conditions, iprodione was found to be relatively stable or degraded almost completely with the formation of RP 30228, RP 37176 and RP 32596 RP 37176 and RP 32596 were found in very limited amounts in raw commodities. RP 32490 not studied (data gap).				

Plant residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	Iprodione
Plant residue definition for risk assessment (RD-RA)	1) Sum of iprodione, RP 30228 and RP 32490 expressed as iprodione

	and separately (pending further considerations of any potential common effects of 3,5-dichloroaniline with compounds in part 1) of the residue definition) 2) Sum of 3,5-dichloroaniline and its conjugates expressed as 3,5-dichloroaniline The residue definition is provisional pending the submission of further data on the toxicological relevance of metabolites of iprodione, in particular data on their genotoxic potential, especially for RP 30228.
Conversion factor (monitoring to risk assessment)	1.20 for carrot 1.30 for lettuce

Metabolism in livestock (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1)

OECD Guideline 503 and SANCO/11187/2013 rev. 3 (fish)	**Animal**	**Dose** (mg/kg bw/d)	**Duration** (days)	**N rate/comment**
Animals covered	Laying hen Goat Cow	0.70 2 2	15 5 5	Studies were performed before GLP and OECD guidelines. Some shortcomings with regard to current testing standards were identified.
	Pig	Not required	-	
	Fish	-	-	
	Data in fish are pending further assessment (data gap).			

Time needed to reach a plateau concentration in milk and eggs (days)	10 in eggs 5 in milk
Animal residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	RP 32490
Animal residue definition for risk assessment (RD-RA)	The residue definition cannot be concluded and is pending the submission of further data on toxicological relevance of metabolites, on the behavior in livestock of 3,5 dichloroaniline and possibly of a new feeding study investigating residues of iprodione in ruminants and poultry performed according to OECD guidelines and taking into account the appropriate livestock residue definitions.
Conversion factor (monitoring to risk assessment)	Pending
Metabolism in rat and ruminant similar (Yes/No)	Yes
Fat soluble residues (Yes/No) (FAO, 2009)	Conclusion pending finalisation of RD-RA

Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)

Confined rotational crop study (Quantitative aspect) **OECD Guideline 502**	Parent iprodione was the major component in all commodities. Main metabolites (>10% TRR) were RP 32490, RP 25040 and RP 30228. In addition to these, RP 36221 and RP 36112 were found in lower and varying ratios.
Field rotational crop study **OECD Guideline 504**	Data gaps were identified with regard to rotational crops residues. Field studies performed at exaggerated application rates were available in the initial DAR. Quantifiable residues were detected above LOQ (0.05 mg/kg) for iprodione, RP 30228 and RP 32490 in peas, radish roots, carrot roots, mustard greens, any several forage and feed items. In a new study performed under the conditions of the intended uses (single application), residues of iprodione, RP 30228, RP 32490, 3,5-dichloroaniline and its glutamic acid conjugate were below the LOQ (individually 0.01 mg/kg) in part of crops for human consumption when planted after a short re-plant interval of 30 days. Data for longer PBI than 30 d not available An assessment multi-annual application of iprodione considering the soil plateau concentration for iprodione and pertinent metabolites was not conducted. Finalisation of rotational crop residue assessment is pending.

Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1) OECD Guideline 506

Plant products (Category)	**Commodity**	**T** (°C)	**Stability** (Months)					
			Iprodione	RP 30228	RP 32490	RP 37176	RP 32596	M610 F007
High water content	Apples	-10°C	**12**	**N/A**	**3**			
	Broccoli	-10°C	12	12	12			
	Cucumber	-10°C	21	21	21			
	Garlic	-10°C	12	3	12			
	Lettuce	-10°C -18°C	**35**	**35**	**35**	**24**	**<28 days**	**6**
	Onion	-10°C	12	12	12			
	Peach	-10°C	12	12	12			
	Pepper	-10°C	12	12	12			
	Tomato	-10°C	24	24	24			
High oil content	Almond	-10°C -18°C	31	31	31	**24**	**11**	**6**
	Canola	-10°C	9	9	12			
	Cotton	-10°C	31	9	31			
	Peanut	-10°C	12	12	12			
High protein content	Dried bean	-18°C	-	-	-	**24**	**18**	**6**
High starch content	Corn grain	-10°C	**34**	**34**	N/A			
	Rice grain	-10°C	12	12	**12**			
	Carrot	-10°C -18°C	28	9	28	**24**	**<28 days**	6
High acid content	Blueberry	-10°C	12	12	12			
	Grapes	-10°C	**15**	**15**	**15**			
	Strawberry	-10°C	12	12	12	**24**	**3**	**6**

		-18°C						
Processed products	Canola crude oil	-10°C	12	12	12			
	Canola presscake	-10°C	12	12	12			
	Canola refined oil	-10°C	12	12	12			
	Grape dried pomace	-10°C	12	12	12			
	Grape wet pomace	-10°C	12	12	12			
	Grape raisin	-10°C	12	70	12			
	Grape juice	-10°C	12	12	12			
	peanut hay	-10°C	12	9	12			
	peanut meal	-10°C	12	12	12			
	peanut vines	-10°C	N/A	12	12			
	potato chips	-10°C	12	12	12			
	potatoes granules	-10°C	12	12	12			
	rice bran	-10°C	12	3	12			
	rice hulls	-10°C	N/A	12	12			
	rice polished	-10°C	12	12	12			
Other	Almond hulls	-10°C	30	30	30			
	Ginseng root	-10°C	12	12	12			
	Rice straw	-10°C	9	6	12			
	Tobacco leaf	-10°C	2 and 1/2	2 and 1/2	2 and 1/2			

Stability of 3,5-dichloroaniline in high water and high starch matrix cannot be totally proved. Residues levels of 3,5-dichloroaniline measured in raw and processed commodities in primary and rotational crops may be underestimated.

Animal	**Animal commodity**	**T** (°C)	**Stability** (Month/Year)					
-	Muscle	-	-	-	-	-	-	
	Liver							
	Kidney							
	Milk							
	Egg							

A non-GLP study was available to demonstrate stability iprodione and metabolites containing 3,5-dichloroaniline moiety and metabolites containing 3,5-dichloro-4-hydroxyaniline moiety in liver and milk after storage below 0°C.

Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3) OECD Guideline 509, OECD Guidance, series on pesticides No 66 and OECD MRL calculator

Crop	**Region/ Indoor** (a)	**Residue levels** (mg/kg) **observed in the supervised residue trials relevant to the supported GAPs** (b)	**Recommendations/comments** (OECD calculations)	**MRL** proposals (mg/kg)	**HR** (mg/kg) (c)	**STMR** (mg/kg) (d)
Representative uses : carrot and lettuce **Residue definition for monitoring (M):** Iprodione **Residue definition for risk assessment 1 (RA1):** sum of iprodione, RP 30228 and RP 32490 expressed as iprodione* (provisionally) **Residue definition for risk assessment 2 (RA2):** sum of 3,5-dichloroaniline and its conjugates expressed as 3,5-dichloroaniline*+						
Carrot root	NEU	**M:** 0.06; 0.08; 0.08; 0.08; 0.09; 0.09; 0.12; 0.20 **RA1:** 0,08; 0,1; 0,1; 0,1; 0,11; 0,11; 0,14; 0,22 **RA2:** 0.04: 0.05; 0.07; 0.12; 0.17; 0.19; 0.20; 0.22	MRL_{OECD}= 0.30	0.30	M:0.20 RA1:0.22 RA2: **0.22**	M:0.09 RA1:0.10 RA2: **0.15**
	SEU	**M:** 0.04; 0.11; 0.11; 0.12; 0.15; 0.15; 0.15; 0.23; 0.31; 0.33; 0.36; 0.40; 0.46 **RA1:** 0.13; 0.15; 0.17; 0.18; 0.34; 0.37; 0.41; 0.56 **RA2:** 0.02; 0.02; 0.05; 0.05; 0.14; 0.15	MRL_{OECD}= 0.755	0.80	M: 0.46 RA1: **0.56** RA2: 0.15	M: 0.15 RA1:**0.26** RA2: 0.05
Lettuce and other salads	NEU	**M:** <0.01; 0.01; 0.04; 0.05; 0.06; 0.08; 0.48; 1.60 **RA1:** 0.03; 0.03; 0.06; 0.07; 0.08; 0.10; 0.53; 1.75 **RA2:** 7x <0.02; 0.02	MRL_{OECD}= 2.496	3.00	M: 1.60 RA1: 1.75 RA2: 0.02	M: 0.05 RA1: 0.08 RA2: 0.02
	SEU	**M:** <0.01; <0.01, 0.02; 0.04; 0.06; 0.23; 0.24; 0.30 **RA1: <**0.03; 0.03; 0.04; 0.06; 0.08; 0.30; 0.33; 0.33 **RA2:** 8x <0.02	MRL_{OECD}= 0.599	0.60	M: 0.30 RA1: 0.33 RA2: 0.02	M: 0.05 RA1: 0.07 RA2: 0.02
	Indoor	**M:** 0.53; 4.10; 4.60; 7.80; 11.00; 14.00; 15.00; 15.00 **RA1:** 0.67; 4.44; 5.63; 7.99; 11.63; 14.22; 15.12; 15.13 **RA2:** 6x<0.02; 0.02; 0.05	MRL_{OECD}= 31.303	40	M: 15.00 RA1: **15.13** RA2: **0.05**	M: 9.40 RA1: **9.81** RA2: **0.02**
Crop	**Region**	**Residue data** (mg/kg)	**Recommendations/comments**			
-	-	-	-			
Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1)						
Product(s)	**Region**	**Residue data** (mg/kg)	**Recommendations/comments**			
-	-	-	-			

(a): **NEU** or **SEU** for northern or southern **outdoor** trials in EU member states (**N+SEU** if both zones), **Indoor** for glasshouse/protected crops, **Country** if non-EU location.
(b): Residue levels in trials conducted according to GAP reported in ascending order (*e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differs, use **Mo/RA** to differentiate data expressed according to the residue definition for **Mo**nitoring and **R**isk **A**ssessment.
(c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HR_{Mo}).
(d): **STMR:** Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets ($STMR_{Mo}$).

+Further data on levels of 3,5-dichloroaniline conjugates other than M610B007 are required

*In a worst case scenario approach values below LOQ were set at LOQ for sum of iprodione, RP 30228 and RP 32490 and for sum of 3,5-dichloroaniline and its conjugates expressed as 3,5-dichloroaniline

Stability of 3,5-dichloroaniline in high water matrix cannot be totally proved. Residues levels of 3,5-dichloroaniline measured in raw and processed commodities in primary and rotational crops could be underestimated.

For M610F007, interim results of a new freezer storage stability study in plant matrices show that metabolite M610F007 is stable when stored at -18 °C for at least up to 180 days in high water. Final report is attended to confirm that levels of M610F007 observed in residue trials were not underestimated.

Underlines values correspond to trials conducted on closed lettuce.

Bold values correspond to the critical HR and STMR.

Inputs for animal burden calculations for RA 1 (Sum of iprodione, RP 30228 and RP 32490 expressed as iprodione)

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	**Comment**	(mg/kg)	**Comment**
Representative uses				
Carrot culls	0.26	Southern Europe	0.56	Southern Europe

Inputs for animal burden calculations for RA 2 (Sum of 3,5-dichloroaniline and its conjugates expressed as 3,5-dichloroaniline)

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	**Comment**	(mg/kg)	**Comment**
Representative uses				
Carrot culls	0.15	Southern Europe	0.22	Southern Europe

Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)
OECD Guideline 505 and OECD Guidance, series on pesticides No 73
Assessment part 1

MRL calculations	**Ruminant**				**Pig/Swine**		**Poultry**		**Fish**	
Highest expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	0.027	Ram/Ewe	0.031	Breeding	0.027	Broiler	0.033	Carp	-
	Dairy cattle	0.017	Lamb	0.040	Finishing	0.035	Layer	0.032	Trout	-
							Turkey	0.033		
Intake >0.004 mg/kg bw (>0.1 mg/kg DM for fish)	Yes		Yes		Yes		Yes		Assessment pending	
Feeding study submitted	Residue analysis in feedng study (common moiety) not in line with RD-Mo. RD-RA not finalised. Common moiety residues not suitable in light of different toxicity profile and/or potency of iprodione and metabolites. Residues in livestock not further investigated at this point.		Residue analysis in feedng study (common moiety) not in line with RD-Mo. RD-RA not finalised. Common moiety residues not suitable in light of different toxicity profile and/or potency of iprodione and metabolites. Residues in livestock not further investigated at this point.		Residue analysis in feedng study (common moiety) not in line with RD-Mo. RD-RA not finalised. Common moiety residues not suitable in light of different toxicity profile and/or potency of iprodione and metabolites. Residues in livestock not further investigated at this point.		Residue analysis in feedng study (common moiety) not in line with RD-Mo. RD-RA not finalised. Common moiety residues not suitable in light of different toxicity profile and/or potency of iprodione and metabolites. Residues in livestock not further investigated at this point.		-	
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level	Beef: N Dairy: N	Level	Lamb: N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals
Muscle										
Fat										
Meat[(b)]										
Liver										
Kidney										
Milk[(a)]										
Eggs										
Method of calculation[(c)]										

[(a)]: Estimated HR calculated at 1N level (**estimated mean level for milk**).
[(b)]: HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry
[(c)]: The OECD guidance document on residues in livestock (series on pesticides 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

STMR calculations	Ruminant				Pig/Swine		Poultry		Fish	
Median expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	0.013	Ram/Ewe	0.014	Breeding	0.013	Broiler	0.015	Carp	-
	Dairy cattle	0.008	Lamb	0.018	Finishing	0.016	Layer	0.015	Trout	-
							Turkey	0.015		
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level	Beef: N Dairy: N	Level	Lamb : N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N
Muscle										
Fat										
Meat[(a)]										
Liver										
Kidney										
Milk										
Eggs										
Method of calculation[(c)]										

[(a)]: STMR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry

[(b)]: When the mean level is set at the LOQ, the STMR is set at the LOQ.

[(c)]: The OECD guidance document on residues in livestock (series on pesticide 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)

OECD Guideline 505 and OECD Guidance, series on pesticides No 73

Assessment part 2

MRL calculations	Ruminant				Pig/Swine		Poultry		Fish	
Highest expected intake	Beef cattle	0.011	Ram/Ewe	0.012	Breeding	0.011	Broiler	0.013	Carp	-
(mg/kg bw/d)	Dairy cattle	0.007	Lamb	0.016	Finishing	0.014	Layer	0.013	Trout	-
(mg/kg DM for fish)							Turkey	0.013		
Intake >0.004 mg/kg bw (>0.1 mg/kg DM for fish)	Yes		Yes		Yes		Yes		Assessment pending	
Feeding study submitted	No		No		No		No		No	
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level	Beef: N Dairy: N	Level	Lamb: N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals
Muscle										
Fat										
Meat[(b)]										
Liver										
Kidney										
Milk[(a)]										
Eggs										
Method of calculation[(c)]										

(a): Estimated HR calculated at 1N level (**estimated mean level for milk**).

(b): HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry

(c): The OECD guidance document on residues in livestock (series on pesticides 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

STMR calculations	Ruminant				Pig/Swine		Poultry		Fish	
Median expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	0.007	Ram/Ewe	0.008	Breeding	0.007	Broiler	0.009	Carp	-
	Dairy cattle	0.005	Lamb	0.011	Finishing	0.009	Layer	0.009	Trout	-
							Turkey	0.009		
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level	Beef: N Dairy: N	Level	Lamb : N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Mean level in feeding level	Estimated **STMR**[b] at 1N	Mean level in feeding level	Estimated **STMR**[b] at 1N	Mean level in feeding level	Estimated **STMR**[b] at 1N	Mean level in feeding level	Estimated **STMR**[b] at 1N	Mean level in feeding level	Estimated **STMR**[b] at 1N
Muscle										
Fat										
Meat[a]										
Liver										
Kidney										
Milk										
Eggs										
Method of calculation[c]										

(a): STMR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry

(b): When the mean level is set at the LOQ, the STMR is set at the LOQ.

(c): The OECD guidance document on residues in livestock (series on pesticide 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals

Conversion factors (CF) for monitoring to risk assessment

Plant products

Mean Conversion Factors (CF) calculated at the different PHIs in the supervised residues trials[(a)] OECD Guidance, series on Pesticides No 66							
PHI[(b)] (days)	**0**	**7**	**14**	**21**	**28**	**35**	**Comments**
Representative uses							
Carrot NEU	Not relevant	NA	NA	1.2	1.2	1.2	Only one trial with metabolites detected above the LOQ
Carrot SEU	Not relevant	NA	NA	1.1	1.1	1.2	
Carrot (all zones)	Not relevant	NA	NA	1.2	1.2	1.2	
Lettuce indoor	1.0	1.0	1.0	1.0	1.0	NA	
Lettuce NEU	1.0	NA	1.2	1.3	1.6	NA	
Lettuce SEU	1.0	NA	1.3	1.5	1.4	NA	
Lettuce (all zones)	1.0	1.0	1.1	1.3	1.2	NA	

Comments:
Conversion factors were derived based on the ratio between residues levels of sum of iprodione, RP 30228 and RP 32490 expressed as iprodione and residue levels of iprodione.
The reported values correspond to the median conversion factor derived from the overall data set for each crop
No conversion factor was derived from monitoring to RA2

[(a)]: CF calculated at the supported PHI are underlined.
[(b)]: 0-/0+ for samples collected just before/after the last application

Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)

OECD Guideline 508 and OECD Guidance, series on testing and assessment No 96

Crop (RAC)/Edible part or Crop (RAC)/Processed product	**Number of studies[(a)]**	**Processing Factor** (PF)		**Conversion Factor** (CF_P) **for RA1[(b)]**
		Individual values	Median PF for iprodione	
Representative uses				
washed carrots	4	0,9; 0,67; 0,84; 0,9	0,87	1,06
wash water	4	0,05; 0,03; 0,03; 0,01	0,03	1,67
peeled carrots	4	0,29; 0,34; 0,25; 0,35	0,31	1,07
peel	4	2,81; 3,5; 5,03; 3,09	3,29	1,05
cooked carrots	4	0,19; 0,16; 0,13; 0,27	0,18	1,79
cooking liquid	4	0,03; 0,02; 0,03; 0,03	0,03	2,33
blanching water	4	0,01; 0,01; 0,03; 0,02	0,01	2,5
canned carrots	4	0,04; 0,03; 0,03; 0,03	0,03	9,33
vegetable stock	4	0,005; 0,01; 0,03; 0,01	0,01	2
wet pomace	4	0,9; 0,9; 0,88; 0,87	0,89	1,05
juice	4	0,31; 0,34; 0,28; 0,28	0,3	1,11

[(a)]: Studies with residues in the RAC at or close to the LOQ should be disregarded (unless concentration)
[(b)]: When the residue definition for risk assessment differs from the residue definition for monitoring

Crop (RAC)/Edible part or Crop (RAC)/Processed product	Number of studies[(a)]	Processing Factor (PF)		Conversion Factor (CF_P) for RA1[(b)]
		Individual values	Median PF for sum of 3,5-DCA and M610F007	
Representative uses				
washed carrots	4	1,25; 1,01; 0,58; 0,75	0,879	-
wash water	4	0,06; 0,04; 0,05; 0,02	0,043	-
peeled carrots	4	0,41; 0,68; 1,09; 0,34	0,545	-
peel	4	1,59; 2,64; 1,8; 2,61	2,207	-
cooked carrots	4	0,34; 0,54; 0,6; 0,37	0,455	-
cooking liquid	4	0,23; 0,35; 0,14; 0,23	0,230	-
blanching water	4	0,09; 0,15; 0,08; 0,1	0,094	-
canned carrots	4	0,2; 0,45; 0,35; 0,25	0,298	-
vegetable stock	4	0,08; 0,07; 0,11; 0,05	0,076	-
wet pomace	4	1,04; 1,37; 0,79; 0,89	0,968	-
juice	4	0,69; 0,97; 0,5; 0,74	0,718	-

Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9) Including all uses (representative uses and uses related to an MRL application)

ADI	Iprodione: 0.02 mg/kg bw per day 3,5-dichloroaniline: 0.0005 mg/kg bw per day
TMDI according to EFSA PRIMo	Highest TMDI 1: 146 % ADI (IT, adult) Highest TMDI 2: NA
NTMDI, according to (to be specified)	Not provided, not required
IEDI (% ADI), according to EFSA PRIMo	Highest IEDI 1: 28 % ADI (IT, adult) Highest IEDI 2: 80 % ADI (FR, infant)
NEDI (% ADI), according to (to be specified)	Not provided, not required
Factors included in the calculations	CF= 1.20 for carrot and CF=1.30 for lettuce for TMDI calculation
ARfD	Iprodione: 0.06 mg/kg bw 3,5-dichloroaniline: 0.0075 mg/kg bw
IESTI (% ARfD), according to EFSA PRIMo	Highest IESTI 1: 2205 % ARfD (Scarole indoor) 678 % ARfD (Lettuce indoor) 255 % ARfD (Scarole outdoor) 79 % ARfD (Lettuce north Europe) 78 % ARfD (rocket, rucola, indoor) 71 % ARfD (lamb's lett., indoor) 59 % ARfD (Carrot) 9.0% ARfD (rocket rucola outdoor) 8.2% ARfD (lamb's let. outdoor) 3.6% ARfD (Carrot juice) Highest IESTI 2: 186 % ARfD (Carrots) 62% ARfD (Carrot juice) 58% ARfD (Scarole indoor) 23% ARfD (Scarole outdoor) 18% ARfD (Lettuce indoor) 7.2% ARfD (Lettuce outdoor) 2.1% ARfD(Rocket ruccola indoor)

	1.9% ARfD (Lamb's lettuce indoor) 0.8% ARfD (rocket rucola outdoor) 0.7% ARfD (Lamb's let. outdoor)
NESTI (% ARfD), according to (to be specified)	Not provided, not required
Factors included in IESTI and NESTI	PF (0.30) and CF (1.11) for carrot juice (RA1) PF (0.72) for carrot juice (RA2)

Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)

Some of the in force MRL and CXL may not be safe anymore for the consumer. A rapid review of the iprodione MRLs is recommended.

Section 4 Environmental fate and behaviour

Route of degradation (aerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.1)

Mineralisation after 100 days	0.6-1.9 % after 120 d, [^{14}C-phenyl]-label (n[7]= 5)
Non-extractable residues after 100 days	40.4-67.9 % after 120 d, [^{14}C-phenyl]-label (n= 5)
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	From n=6: RP 35606: max. 25.5 % at 7 d [^{14}C-phenyl] label RP 30228[8]: max. 29.5 % at 30 d [^{14}C-phenyl] label RP 36221: max. 12.7 % at 100 d [^{14}C-phenyl] label RP 32596: max. 12.6 % at 120 d [^{14}C-phenyl] label RP 25040: max. 7.8 %[9] at 30 d [^{14}C-phenyl] label RP 30181: assumed to be formed in similar amounts as RP 32596 (12.6%)(Data gap for hydantoin label)

Route of degradation (anaerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.2)

Mineralisation after 100 days	1.4 % after 119 d, [^{14}C-phenyl]-label (n= 1)
Non-extractable residues after 100 days	53.6 % after 119 d, [^{14}C-phenyl]-label (n= 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Remark: only 13% remained as iprodione at the beginning of the anaerobic phase (15 days). The study is therefore not fully satisfactory to describe degradation under anaerobic conditions. RP 30228: max. 7.5 % at 70 d [^{14}C-phenyl] label (already formed in the aerobic phase of the study) RP 32596: max. 29.8 % at 41 d [^{14}C-phenyl] label (already formed in the aerobic phase of the study)

Route of degradation (photolysis) on soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Artificial light simulating summer sunlight in UK, 50°N (Xenon irradiation source, using a 8.8 h light / 15.2 h dark cycle, average intensity 470 W/m^2) RP 32596: max. 27.9 % at 14 d [^{14}C-phenyl] label (37.2% at 21 days in dark control) Mixture of RP 25040 + LS 720942: max. 13.8 % at 7 d [^{14}C-phenyl] label (2.7% at 21 days in dark control)

[7] n corresponds to the number of soils.
[8] RP 30228 is a constitutional isomer of parent iprodione
[9] Under laboratory aerobic conditions, RP 25040 does not reach amounts triggering an environmental risk assessment. It is major by photodegradation. It is reported here for information to indicate that it can be formed both via microbial and photodegradation processes.

Mineralisation at study end	23.3 % after 30 d, [^{14}C-phenyl]-label (n= 1) (2.1% in dark control)
Non-extractable residues at study end	52.6 % after 30 d, [^{14}C-phenyl]-label (n= 1) (54.4% in dark control)

Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Parent	**Dark aerobic conditions**					
Soil type	pH[a)]	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
LUFA 2.2 (Hartman 2014a)	5.5 ($CaCl_2$)	20°C / 40% MWHC	89.4/344.5	94.1[c)]	2.5	DFOP k_1: 0.2425, k_2: 0.0063, g: 0.121
Li 10 (Hartman 2014a)	6.2 ($CaCl_2$)	20°C / 40% MWHC	38.6/128.4	36.1	7.3	SFO
LUFA 2.3 (Hartman 2014a)	6.7 ($CaCl_2$)	20°C / 40% MWHC	9.7/99.0	22.9 [c)]	3.2	FOMC α: 0.9026, β: 8.3730
LUFA 5M (Hartman 2014a)	7.3 ($CaCl_2$)	20°C / 40% MWHC	6.3/73.3	21.5 [c)]	2.2	DFOP k_1: 0.2703 k_2: 0.0207, g: 0.544
Bondhay (Waring 1993b)	6.8 (KCl)	25°C / pF2.5	18.5/61.4	29.0	7.6	SFO
Sandy loam (Waring 1993a)	5.75 (KCl)	25°C / 75% pF2.5	16.2/53.9	13.4	17.0	SFO
Geometric mean (if not pH dependent)				Not relevant		
pH dependence				Yes, degradation is slower in soils with pH_{CaCl2} < 5.9		

[a)] Measured in calcium chloride / KCl solution
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
[c)] For biphasic models, DT_{50} value for modelling was obtained from ln/k_{2_DFOP} or DT_{90_FOMC}/3.32 and was then normalised to reference conditions

Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Metabolite RP 25040	**Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was iprodione**						
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
LUFA 2.2 (Hartman 2014a)	5.5	20°C / 40% MWHC	22.5/74.7	0.17	19.2	18.1	SFO
Li 10 (Hartman 2014a)	6.2	20°C / 40% MWHC	12.0/39.8	0.185	11.2	37.6	SFO
Li 10 (Class 2013b)	6.3	20°C / 40% MWHC	2.8/13.7	-	3.9[c)]	3.5	FOMC α=2.3088, β=192.0763
LUFA 5M (Class 2013b)	7.4	20°C / 40% MWHC	0.38/2.5	-	0.6 [c)]	1.8	FOMC α=1.4040, β=14.4581
LUFA 2.3 (Class 2013b)	7.0	20°C / 40% MWHC	0.44/5.6	-	1.4 [c)]	4.8	FOMC α=0.7726, β=7.2479
Geometric mean (if not pH dependent)					Not relevant		
Arithmetic mean				0.178			
pH dependence					Yes, degradation is slower when pH decreases		

[a)] Measured in calcium chloride solution
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
[c)] For biphasic models, DT_{50} value for modelling was obtained from DT_{90_FOMC}/3.32 and was then normalised to reference conditions

Metabolite RP 36221	**Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was RP 35606**						
Soil type	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d) (P)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10kPa[b)] (M)	St. (χ^2)	Method of calculation
LUFA 2.2 (Hartman 2014a)	5.5	20°C / 40% MWHC	180.4/599.3	0.15	154.2	11.5	SFO
Li 10 (Hartman 2014a)	6.2	20°C / 40% MWHC	> 1000	0.074	1000	15.1	SFO
LUFA 2.3 (Hartman 2014a)	6.7	20°C / 40% MWHC	> 1000	0.08	1000	14.7	SFO
LUFA 5M (Hartman 2014a)	7.3	20°C / 40% MWHC	> 1000	0.08	1000	14.4	SFO
Li 10 (Class 2013a)	6.3	20°C / 40% MWHC	> 1000	-	1000	2.1	FOMC α=0.0144, β=2.3540
LUFA 5M (Class 2013a)	7.4	20°C / 40% MWHC	715 / >1000	-	536	3.2	SFO
LUFA 2.3 (Class 2013a)	7.0	20°C / 40% MWHC	> 1000 (P)	-	342 (M)	1.8 [c)] (P) 3.1 [d)] (M)	FOMC (P) α=0.0692, β=6.3918 SFO (M)
Geometric mean (if not pH dependent)					601		
Arithmetic mean				0.10			
pH dependence					No		

[a)] Measured in calcium chloride solution
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
(P): Persistence endpoint / (M): Modelling endpoint

Metabolite RP 30228	**Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was RP 35606**						
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
LUFA 2.2 (Hartman 2014a)	5.5	20°C / 40% MWHC	43.1/143.1	0.21	36.9	12.1	SFO
Li 10 (Hartman 2014a)	6.2	20°C / 40% MWHC	48.7/161.7	0.283	45.6	11.2	SFO
LUFA 2.3 (Hartman 2014a)	6.7	20°C / 40% MWHC	83.8/278.3	0.227	64.5	10.3	SFO
LUFA 5M (Hartman 2014a)	7.3	20°C / 40% MWHC	22.7/75.3	0.923	14.6	15.5	SFO
Geometric mean (if not pH dependent)					35.5		
Arithmetic mean				0.41			
pH dependence					No		

a) Measured in calcium chloride solution
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

Metabolite RP 35606	**Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was parent iprodione**						
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
LUFA 2.2 (Hartman 2014a)	5.5	20°C / 40% MWHC	3.2/10.5	0.52	2.7	14.2	SFO
Li 10 (Hartman 2014a)	6.2	20°C / 40% MWHC	3.2/10.8	0.815	3.0	22.8	SFO
LUFA 2.3 (Hartman 2014a)	6.7	20°C / 40% MWHC	33.1/110.0 c)	-	25.5 c)	8.2	SFO
LUFA 5M (Hartman 2014a)	7.3	20°C / 40% MWHC	10.4/34.6	0.759	6.7	16.7	SFO
Geometric mean (if not pH dependent)					6.1		
Arithmetic mean				0.70			
pH dependence					No		

a) Measured in calcium chloride solution
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
c) Calculated from maximum occurrence

Metabolite RP 32596	**Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was RP 25040 or RP 30228 or RP 36221**						
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
LUFA 2.2 (Hartman 2014a)	5.5 ($CaCl_2$)	20°C / 40% MWHC	37.7/125.4	1 (RP 25040)	32.2	28.6	SFO
LUFA 2.3 (Hartman 2014a)	6.7 ($CaCl_2$)	20°C / 40% MWHC	39.6/131.4	1 (RP 25040 & RP 30228)	30.5	13.0	SFO
LUFA 5M (Hartman 2014a)	7.3 ($CaCl_2$)	20°C / 40% MWHC	15.5/51.7	0.536 (RP 30228) 0.213 (RP 36221)	10.0	12.9	SFO
Sandy loam (Gouot 1981)	6.6 (H_2O)	25°C / 75% pF2.5	15.5/144.4	-	63.7	5.3	DFOP k_1=1.054, k_2=0.0125, g=0.39
Columbia (Quarmby 2000)	6.9 (H_2O)	25°C / 75% pF2.5	2.7/74.9	-	35.5	8.1	FOMC α=0.5361, β=1.0353
Madera (Quarmby 2000)	7.3 (H_2O)	25°C / 75% pF2.5	8.6/197.8	-	38.0	4.2	FOMC α=0.5763, β=3.7082
Geometric mean (if not pH dependent)					30.7		
Arithmetic mean				-			
pH dependence					No		

[a)] Measured in calcium chloride solution or water
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
[c)] For biphasic models, DT_{50} value for modelling was obtained from $\ln/k_{2\_DFOP}$ or $DT_{90\_FOMC}/3.32$ and was then normalised to reference conditions

Metabolite LS720942	**Dark aerobic conditions Metabolite dosed**						
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
LUFA 2.3 (Wadim 2014)	5.9	20°C / 40% MWHC	8.0/26.7	-	6.3	8.8	SFO
LUFA 5M (Wadim 2014)	7.2	20°C / 40% MWHC	4.2/14.0	-	2.7	4.9	SFO
Li 10 (Wadim 2014)	6.1	20°C / 40% MWHC	11.1/36.9	-	11.1	3.2	SFO
Geometric mean (if not pH dependent)					5.7		
Arithmetic mean				-			
pH dependence					No		

[a)] Measured calcium chloride solution
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

Parent	**Aerobic conditions**								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	pH[a)]	Depth (cm) [c)]	DT_{50} (d) actual	DT_{90}(d) actual	St. (χ^2)	DT_{50} (d) Norm[b)]	St. (χ^2)	Method of calculation
Bare soil	Goch, Germany	6.1	0-60	19.0	63.1	19.2	3.5	3.7	SFO
Bare soil	Lyon, France	6.9	0-10	13.5	44.8	15.6	4.6	3.2	SFO
Bare soil	Manningtree, UK	6.4	0-30	9.6	32.0	7.9	3.5	7.5	SFO
Bare soil	Sevilla, Spain	7.0	0-10	8.7	29.0	15.4	11.5	15.3	SFO
Bare soil	Luigné, France	4.3	0-10	59.3	196.9	7.7	35.3	8.6	SFO
Geometric mean (excluding last site with pH 4.3 due to pH-dependence)							5.0		
pH dependence				Yes, degradation is slower in the very acidic soil (pH_{CaCl2} = 4.3)					

a) Measured in calcium chloride solution
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix
c) Layers were the > LOQ residues were considered for calculation of DT50

RP 30228		**Field DT50 values are required**

RP 36221		**Field DT50 values are required**

Combined laboratory and field kinetic endpoints for modelling (when not from different populations)*

Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent)	Not relevant (laboratory and field DT50 are from different populations)
Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent)	Not applicable (only laboratory DT50 are available for metabolites)
Kinetic formation fraction (f. f. k_f / k_{dp}) of transformation products, arithmetic mean	Not applicable

* Only relevant after implementation of the published EFSA guidance describing how to amalgamate laboratory and field endpoints.

Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

Soil accumulation and plateau concentration	Iprodione: Plateau concentration of 0.061 mg/kg for carrots and 0.056 mg/kg for lettuce reached after 4 years (based on calculation in 20 cm) RP 36221: Plateau concentration of 0.225 mg/kg for carrots and 0.205 mg/kg for lettuce reached after 24 years (based on calculation in 20 cm)

Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Parent	**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
Loamy sand	6.6	20°C, flooded soil from day 15	32.2/107.1	-	6.6	Slow phase of HS (corresponding to anaerobic phase)

[a)] Measured in calcium chloride solution
[b)] Normalised using a Q10 of 2.58

Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3

Parent	**Soil photolysis**				
Soil type	pH[a)]	t. °C / % MWHC	DT_{50} / DT_{90} (d) calculated at ??ºN	St. (χ^2)	Method of calculation
Sandy loam	6.7	25°C / 75% of pF2.5	Irradiated: 6.2/20.5 (50°N) Dark: 10.6/35.1	15.1 19.0	SFO

[a)] Measured in calcium chloride solution

Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Parent Iprodione							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
94/6/2 (sandy loam)	1.1	5.97	-	-	2.45	223	0.905
94/14/2 (loamy sand)	0.5	6.13	-	-	2.16	431	0.858
94/15/2 (clay)	1.2	6.01	-	-	6.52	543	0.891
Data gap for adsorption investigation in a fourth soil							
Geometric mean (if not pH dependent)*					3.26	374	-
Arithmetic mean (if not pH dependent)					3.71	399	0.885
pH dependence			No				

[a)] Measured in calcium chloride solution
* Only relevant after implementation of the published EFSA guidance.

Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Metabolite RP 35606							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
LUFA 5M (loamy sand)	2.03	7.2	-	-	0.313	15.4	0.781
La Gironda (sandy clay loam)	1.22	7.4	-	-	0.605	49.6	1.063
pH dependence			pH-dependence is expected due to the nature of the compound (carboxylic acid) but it cannot be identified based on the available data				

[a)] Measured in calcium chloride solution
* Only relevant after implementation of the published EFSA guidance.

Metabolite RP 30228							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
LUFA 2.1 (sand)	0.52	5.2	-	-	14.16	2723	0.884
LUFA 2.3 (sandy loam)	1.09	6.9	-	-	27.14	2490	0.868
Nierswalde (silt loam)	1.63	6.5	-	-	123.48	7575	0.946
Li 10 (loamy sand)	0.88	5.9	-	-	26.54	3016	0.876
La Gironda (silty clay loam)	3.84	7.5	-	-	71.59	1864	0.951
Geometric mean (if not pH dependent)*					38.99	3105	-
Arithmetic mean (if not pH dependent)					52.58	3534	0.905
pH dependence			No				

[a)] Measured in calcium chloride solution
* Only relevant after implementation of the published EFSA guidance.

Metabolite RP 36221							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
LUFA 2.2 (loamy sand)	1.53	5.5	-	-	124	8109	0.854
LUFA 2.3 (sandy loam)	0.99	6.7	-	-	73.8	7452	0.862
Bruch West (sandy loam)	1.63	7.3	-	-	101	6213	0.853
Li 10 (loamy sand)	0.95	6.2	-	-	65.3	6873	0.897
Fiorentino Poggio (loam)	1.00	7.4	-	-	69.6	6958	0.806
Geometric mean (if not pH dependent)*					84.1	7093	
Arithmetic mean (if not pH dependent)					86.7	7121	0.854
pH dependence			No				

[a)] Measured in calcium chloride solution
* Only relevant after implementation of the published EFSA guidance.

Metabolite RP 25040							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
LUFA 2.2 (loamy sand)	1.53	5.5	-	-	1.807	118	0.904
Li 10 (loamy sand)	0.95	6.2	-	-	1.200	126	0.897
LUFA 2.3 (sandy loam)	0.99	6.7	-	-	2.048	207	0.869
Bruch West (sandy loam)	1.63	7.3	-	-	1.941	119	0.892
Fiorentino Poggio (loam)	1.00	7.4	-	-	2.331	233	0.885
Geometric mean (if not pH dependent)*					1.822	154	-
Arithmetic mean (if not pH dependent)					1.865	161	0.889
pH dependence			No				

[a)] Measured in calcium chloride solution
* Only relevant after implementation of the published EFSA guidance.

Metabolite LS720942							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
LUFA 2.2 (loamy sand)	1.53	5.5	-	-	7.27	475	0.852
LUFA 2.3 (sandy loam)	0.99	6.7	-	-	4.15	419	0.801
Bruch West (sandy loam)	1.63	7.3	-	-	5.90	362	0.836
Li 10 (loamy sand)	0.95	6.2	-	-	3.72	392	0.831
Fiorentino Poggio (loam)	1.00	7.4	-	-	4.18	418	0.809
Geometric mean (if not pH dependent)*					4.88	412	
Arithmetic mean (if not pH dependent)					5.04	413	0.826
pH dependence			No				

[a)] Measured in calcium chloride solution
* Only relevant after implementation of the published EFSA guidance.

Metabolite RP 32596							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Madera (sandy loam)	0.34	7.3			2.029	593	0.7075
Clayton (loamy sand)	1.19	6.1			7.446	626	0.6404
Columbia (silt loam)	2.60	6.8			9.906	380	0.6767
Leland (clay)	1.10	7.1			10.221	932	0.7796
Clayton (sand, sediment)	0.61	6.1			4.934	788	0.6578
Geometric mean (if not pH dependent)*					5.964	635	-
Arithmetic mean (if not pH dependent)					6.907	664	0.692
pH dependence			No				

[a)] Medium not stated
* Only relevant after implementation of the published EFSA guidance.

Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching	Elution (mm): 500 mm Time period (d): 24 to 30 hours
	Leachate: 0.3-1.9% radioactivity in leachate Radioactivity mostly retained in top 10 cm for 3 soils (15 cm in 1 soil)

Mobility in soil column leaching transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching	Ageing time: 30 days Elution (mm): 508 mm Time period (d): 8-10 days
	Leachate: 0.03-0.51 % radioactivity in leachate in 3 soils, 52.2% in the sand soil (6.3% iprodione, 27.1% RP 35606, 13.1% RP 30228, 2% RP 25040, 3.2% RP 32596) Radioactivity mostly retained in top 12 cm (2 soils) and top 18 cm (2 soils)

Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)

Lysimeter/ field leaching studies	No data, not required.

Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1

Hydrolytic degradation of the active substance and metabolites > 10 %	pH 5: 131-146 d at 25 °C (1st order linear regression[10]) RP 35606: max. 11.4 % AR (30 d) RP 30228: max. 13.9 % AR (32 d)
	pH 6: 25 d at 25 °C (1st order linear regression[10]) RP 35606: max. 6.9 % AR (4 d) RP 30228: max. 51.9 % AR (32 d)
	pH 7: 3-6.4 d at 25 °C (1st order linear regression[10]) RP 35606: max. 35 % AR (2 d) RP 30228: max. 94.3 % AR (32 d)

Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)

Photolytic degradation of active substance and metabolites above 10 %	Direct photolysis not expected to be a significant process in natural aquatic systems. No metabolite > 5% AR.
Quantum yield of direct phototransformation in water at Σ > 290 nm	No data, not required.

'Ready biodegradability' (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.1)

Readily biodegradable (yes/no)	No

[10] The use of 1st order linear regression is not in line with current kinetic evaluation methodology. It is accepted in this case since hydrolytic degradation rates are not used in the risk assessment.

Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

Parent										
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed a)	t. °C b)	DT_{50} / DT_{90} whole sys. (suspended sediment test)		St. (χ^2)	DT_{50} / DT_{90} Water (pelagic test)		St. (χ^2)	Method of calculation
				At study temp	Normalised to *x* °C c)		At study temp	Normalised to x °C c)		
Fresh, 10 µg/L	8.2	6.8	20	-	-	-	0.27/ 15.7	-	2.7	FOMC α=0.4182, β=0.0640
Fresh, 100 µg/L	8.2	6.8	20	-	-	-	0.23/ 14.4	-	6.7	FOMC α=0.4084, β=0.0514

a) Measured in water
b) Temperature of incubation=temperature that the environmental media was collected or std temperature of 20°C
c) Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

Metabolite RP 35606	**Max in total system 30 % after 0.25 days**									
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed a)	t. °C b)	DT_{50} / DT_{90} whole sys. (suspended sediment test)		St. (χ^2)	DT_{50} / DT_{90} Water (pelagic test)		St. (χ^2)	Method of calculation
				At study temp	Normalised to x °C c)		At study temp	Normalised to x °C c)		
Fresh, 10 µg/L	8.2	6.8	20	-	-	-	0.24/ 0.8	-	31.8	SFO
Fresh, 100 µg/L	8.2	6.8	20	-	-	-	0.57/ 1.9	-	25.8	SFO

a) Measured in water
b) Temperature of incubation=temperature that the environmental media was collected or std temperature of 20°C
c) Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

Metabolite RP 30228	**Max in total system 65 % after 14 days**									
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed a)	t. °C b)	DT_{50} / DT_{90} whole sys. (suspended sediment test)		St. (χ^2)	DT_{50} / DT_{90} Water (pelagic test)		St. (χ^2)	Method of calculation
				At study temp	Normalised to x °C c)		At study temp	Normalised to x °C c)		
Fresh, 10 µg/L	8.2	6.8	20	-	-	-	1.2/ 3.9	-	7.5	SFO
Fresh, 100 µg/L	8.2	6.8	20	-	-	-	3.6/ 12.0	-	6.8	SFO

a) Measured in water
b) Temperature of incubation=temperature that the environmental media was collected or std temperature of 20°C
c) Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

Mineralisation and non extractable residues (for parent dosed experiments)					
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed	Mineralisation *x* % after *n* d. (end of the study).	Non-extractable residues. max *x* % after *n* d (suspended sediment test)	Non-extractable residues. max *x* % after *n* d (end of the study) (suspended sediment test)
Fresh, 10 µg/L	8.2	6.8	0.42 % after 46 days	-	-
Fresh, 100 µg/L	8.2	6.8	0.62 % after 46 days	-	-

Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

Parent + RP 35606	**Distribution (iprodione + RP35606: max in water 76.5% after 0 d. Max. sed 20.0 % after 7 d; Iprodione: max in water 7.5% after 1 d. Max. sed 20.0 % after 7 d RP 35606: max in water 73.3% after 0 d. Max. sed 4.0 % after 6 h)**								
Water / sediment system	pH water phase a)	pH sed b)	t. °C	Whole system					
				Persistence endpoints			Modelling endpoints		
				DT_{50} / DT_{90} whole sys.	St. (χ^2)	Method of calculation	DT_{50} / DT_{90} whole sys.	St. (χ^2)	Method of calculation
Mill Stream pond	7.9/7.4	7.2	20	2.1/75.6	11.9	FOMC α = 0.4844, β = 0.6576	22.8 d)	11.9	FOMC
Iron Hatch	7.9/7.6	7.0	20	4.8/44.7	13.1	FOMC α = 0.9688, β = 4.5772	5.9	15.7	SFO
Geometric mean at 20°C c)				-			11.6		

a) pH in water phase measured at time 0 / at 100 days
b) Measured in water
c) Normalised using a Q10 of 2.58; geomean based on SFO (or pseudo-SFO values)
d) Calculated from DT_{90_FOMC}/3.32

Parent + RP 35606									
Water / sediment system	pH water phase a)	pH sed b)	t. °C	Persistence endpoints					
				Water			Sediment		
				$DissT_{50}$ / $DissT_{90}$ Water (d)	St. (χ^2)	Method of calculation	$DissT_{50}$ / $DissT_{90}$ Sed (d)	St. (χ^2)	Method of calculation
Mill Stream pond	7.9/7.4	7.2	20	1.1/23.7	17.2	FOMC α = 0.6005, β = 0.5244	13.6/91.3	18.5	HS k1= 0.0926, k2= 0.0207, tb = 5.74
Iron Hatch	7.9/7.6	7.0	20	2.8/14.1	10.3	DFOP k1= 3.4×10^4, k2= 0.1427, g= 0.26	No reliable value	-	-

a) pH in water phase measured at time 0 / at 100 days
b) Measured in water

Metabolite RP 30228	**Distribution (e.g. max in water 10.3% after 1 d. Max. sed 79.2 % after 100 d). Max in total system 79.2 % after 100 days. kinetic formation fraction: from parent (iprodione + RP 35606)**									
Water / sediment system	pH water phase a)	pH sed b)	t. °C	DT_{50} /DT_{90} whole sys. d)	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
Mill Stream pond	7.9/7.4	7.2	20	>1000 (ffm: 0.89)	7.1	7.5/25.1	9.5	-	-	SFO
Iron Hatch	7.9/7.6	7.0	20	No reliable value	-	13.3/44.2	18.0	-	-	SFO
Geometric mean at 20°C c)				1000						

a) pH in water phase measured at time 0 / at 100 days
b) Measured in water
c) Normalised using a Q10 of 2.58
d) Persistence and modelling endpoints

Mineralisation and non extractable residues (from parent dosed experiments)					
Water / sediment system	pH water phase	pH sed	Mineralisation x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
Mill Stream pond	7.9/7.4	7.2	0.63% after 100 days	15.2% after 30 days	10.1% after 100 days
Iron Hatch	7.9/7.6	7.0	0.83% after 100 days	13.4% after 30 days	9.0% after 100 days

Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

Direct photolysis in air	Not studied - no data requested
Photochemical oxidative degradation in air	DT_{50} of 0.585 days derived by the Atkinson model (AOP v1.92). OH (12 h) concentration assumed = 1.5x10^6 cm^{-3}
Volatilisation	from plant surfaces (BBA guideline): negligible after 24 hours
	from soil surfaces (BBA guideline): <0.1 % after 24 hours
Metabolites	No data, not required.

Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure	The following residue definition is provisional because of the lack of information on the route of degradation of iprodione radiolabelled in the hydantoin position. Soil: Iprodione, RP 35606, RP 30228, RP 36221, RP 25040, RP 32596, LS 720942, RP 30181 (assumed to be formed from hydantoin moiety) Surface water: Iprodione, RP 35606, RP 30228, RP 36221, RP 25040, RP 32596, LS 720942, RP 30181 (assumed to be formed from hydantoin moiety) Sediment: Iprodione, RP 30228, RP 36221, RP 25040, RP 32596, LS 720942, RP 30181(assumed to be formed from hydantoin moiety) Ground water: Iprodione, RP 35606, RP 30228, RP 36221, RP 25040, RP 32596, LS 720942, RP 30181(assumed to be formed from hydantoin moiety) Air: Iprodione

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

	See section 5, Ecotoxicology

Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5

Soil (indicate location and type of study)	No data provided
Surface water (indicate location and type of study)	No data provided
Ground water (indicate location and type of study)	Public systematic GW monitoring of iprodione France: 21 detections > 0.1 µg/L between 1992-2013 (over a total of 74301 analyses) Czech Republic: no detection > 0.1 µg/L between 2009-2012 (over a total of 156 analyses) Denmark: no detection > 0.1 µg/L in 1995, 1996 and 2011 (over a total of 29 analyses) Italy: 3 detections > 0.1 µg/L between 2007-2010 (over a total of 4873 analyses) The Netherlands: no detection > 0.1 µg/L in 2003, 2007 and 2012 (over a total of 455 analyses)
Air (indicate location and type of study)	No data provided

PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

Parent Method of calculation	DT_{50} (d): 89.4 days Kinetics: DFOP (kinetic parameters used in PECsoil calculations: k_1 = 0.2425, k_2 = 0.0063, g = 0.121) Field or Lab: non normalised worst-case from laboratory studies
Application data	Crop: carrots Depth of soil layer: 5 cm (20 cm for plateau) Soil bulk density: 1.5 g/cm^3 % plant interception: 25/25/60/60 Number of applications: 4 Interval (d): 10 Application rate(s): 750 g a.s./ha
	Crop: lettuce Depth of soil layer: 5 cm (20 cm for plateau) Soil bulk density: 1.5 g/cm^3 % plant interception: 25/25/40 Number of applications: 3 Interval (d): 14 Application rate(s): 750 g a.s./ha

$PEC_{(s)}$ (mg/kg)	Carrots, 4 x 750 g/ha		Lettuce, 3 x 750 g/ha	
	Actual	Time weighted average	Actual	Time weighted average
Initial	1.862	-	1.759	-
Long term 21d	-	1.708	-	1.592
Plateau concentration	0.061 after 4 yr	-	0.056 after 4 yr	-
PECaccu	1.923	-	1.815	-

Metabolite RP 25040 Method of calculation	Molecular weight relative to the parent: 245.1/330.2 DT_{50} (d): 22.5 days Kinetics: SFO Field or Lab: non normalised worst case from laboratory studies.
Application data	Application rate assumed: 76.8 g/ha (assumed RP 25040 is formed at a maximum of 13.8 % of the applied dose and molar ratio)

$PEC_{(s)}$ (mg/kg)	Carrots, 4 x 750 g/ha		Lettuce, 3 x 750 g/ha	
	Actual	Time weighted average	Actual	Time weighted average
Initial	0.143	-	0.144	-
Plateau concentration	Not relevant	-	Not relevant	-

Metabolite RP 35606 Method of calculation	Molecular weight relative to the parent: 348.2/330.2 DT_{50} (d): 33.1 days Kinetics: SFO Field or Lab: non normalised worst case from laboratory studies.
Application data	Application rate assumed: 201.7 g/ha (assumed RP 35606 is formed at a maximum of 25.5 % of the applied dose and molar ratio)

$PEC_{(s)}$ (mg/kg)	Carrots, 4 x 750 g/ha		Lettuce, 3 x 750 g/ha	
	Actual	Time weighted average	Actual	Time weighted average
Initial	0.435	-	0.424	-
Plateau concentration	Not relevant	-	Not relevant	-

Metabolite RP 30228 Method of calculation	Molecular weight relative to the parent: 330.2/330.2 DT_{50} (d): 83.8 days

	Kinetics: SFO Field or Lab: non normalised worst case from laboratory studies.
Application data	Application rate assumed: 221.3 g/ha (assumed RP 30228 is formed at a maximum of 29.5 % of the applied dose and molar ratio)

$PEC_{(s)}$ (mg/kg)	Carrots, 4 x 750 g/ha		Lettuce, 3 x 750 g/ha	
	Actual	**Time weighted average**	**Actual**	**Time weighted average**
Initial	0.587	-	0.550	-
Plateau concentration	Not relevant	-	Not relevant	-

Metabolite RP 36221 Method of calculation	Molecular weight relative to the parent: 290.1/330.2 DT_{50} (d): 1000 days Kinetics: SFO Field or Lab: non normalised worst case from laboratory studies.
Application data	Application rate assumed: 83.7 g/ha (assumed RP 36221 is formed at a maximum of 12.7 % of the applied dose and molar ratio)

$PEC_{(s)}$ (mg/kg)	Carrots, 4 x 750 g/ha		Lettuce, 3 x 750 g/ha	
	Actual	**Time weighted average**	**Actual**	**Time weighted average**
Initial	0.254	-	0.232	-
Plateau concentration	0.225 after 24 yr	-	0.205 after 24 yr	-
PECaccu	0.478		0.437	

Metabolite RP 32596 Method of calculation	Molecular weight relative to the parent: 162.0/330.2 DT_{50} (d): 39.6 days Kinetics: SFO Field or Lab: non normalised worst case from laboratory studies.
Application data	Application rate assumed: 46.4 g/ha (assumed RP 32596 is formed at a maximum of 12.6 % of the applied dose and molar ratio)

$PEC_{(s)}$ (mg/kg)	Carrots, 4 x 750 g/ha		Lettuce, 3 x 750 g/ha	
	Actual	**Time weighted average**	**Actual**	**Time weighted average**
Initial	0.106	-	0.102	-
Plateau concentration	Not relevant	-	Not relevant	-

Metabolite RP 30181 Method of calculation	Molecular weight relative to the parent: 142.2/330.2 DT_{50} (d): 8.9 days Kinetics: SFO Field or Lab: non normalised worst case from laboratory studies.
Application data	Application rate assumed: 40.7 g/ha (assumed RP 30181 is formed at a maximum of 12.6 % of the applied dose and molar ratio – same occurrence as for RP 32596)

$PEC_{(s)}$ (mg/kg)	**Carrots, 4 x 750 g/ha**		**Lettuce, 3 x 750 g/ha**	
	Actual	**Time weighted average**	**Actual**	**Time weighted average**
Initial	0.044	-	0.051	-
Plateau concentration	Not relevant	-	Not relevant	-

Metabolite LS720942 Method of calculation	Molecular weight relative to the parent: 205.0/330.2 DT_{50} (d): 11.1 days Kinetics: SFO Field or Lab: non normalised worst case from laboratory studies.
Application data	Application rate assumed: 64.3 g/ha (assumed LS 720942 is formed at a maximum of 13.8 % of the applied dose and molar ratio)

$PEC_{(s)}$ (mg/kg)	**Carrots, 4 x 750 g/ha**		**Lettuce, 3 x 750 g/ha**	
	Actual	**Time weighted average**	**Actual**	**Time weighted average**
Initial	0.081	-	0.089	-
Plateau concentration	Not relevant	-	Not relevant	-

PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – Modelling using FOCUS models, with appropriate FOCUSgw scenarios, according to FOCUS guidance. Models used: FOCUS PELMO 5.5.3 & FOCUS PEARL 4.4.4
	Iprodione: Molecular weight: 330.2 g/mol Water solubility (mg/L): 12.2 at 20°C Vapour pressure: 5×10^{-7} Pa at 25°C Geometric mean $DT_{50\ field}$ 5 d (normalisation to 20 °C, pF2 with Q10 of 2.58 and Walker equation coefficient 0.7) for soils with $pH_{CaCl2} \geq 5.9$. Worst-case $DT_{50\ lab}$ 94.1 d (normalisation to 20 °C, pF2 with Q10 of 2.58 and Walker equation coefficient 0.7) for soils with $pH_{CaCl2} < 5.9$. K_{OC}: 399 mL/g (arithmetic mean) $^1/_n$= 0.885 (arithmetic mean) Crop uptake factor: 0.4 when $DT_{50\ lab}$ is used (calculated based on Briggs equation), 0 when $DT_{50\ field}$ is used
	RP 25040: Molecular weight: 245.1 g/mol Water solubility (mg/L): 100 at 20°C Vapour pressure: 1×10^{-9} Pa at 20°C $DT_{50\ lab}$: minimum and maximum values of 0.6 d and 19.2 d are tested due to pH-dependence (normalisation to 20 °C, pF2 with Q10 of 2.58 and Walker equation coefficient 0.7). Formation fraction: 0.185 from iprodione (max. value) K_{OC}: 160.6 mL/g (arithmetic mean) $^1/_n$= 0.890 (arithmetic mean) Crop uptake factor: 0
	RP 35606: Molecular weight: 348.2 g/mol Water solubility (mg/L): 100 at 20°C Vapour pressure: 1×10^{-9} Pa at 20°C Geometric mean $DT_{50\ lab}$ 6.1 d (normalisation to 20 °C, pF2 with Q10 of 2.58 and Walker equation coefficient 0.7) Formation fraction: 0.698 from iprodione (ar. mean) K_{OC}: lowest and highest values of 15.4 and 49.6 mL/g are tested (since only 2 values are available) $^1/_n$= 0.781 (value associated with lowest Koc) and 1.063 (value associated with highest Koc)

	Crop uptake factor: 0
	RP 30228: Molecular weight: 330.2 g/mol Water solubility (mg/L): 100 at 20°C Vapour pressure: $1x10^{-9}$ Pa at 20°C Geometric mean $DT_{50\ lab}$ 35.5 d (normalisation to 20 °C, pF2 with Q10 of 2.58 and Walker equation coefficient 0.7) Formation fraction: 0.411 from RP 35606 (ar. mean) K_{OC}: 3534 mL/g (arithmetic mean) $^{1}/_{n}$= 0.905 (arithmetic mean) Crop uptake factor: 0
	RP 36221: Molecular weight: 290.1 g/mol Water solubility (mg/L): 100 at 20°C Vapour pressure: $1x10^{-9}$ Pa at 20°C Geometric mean $DT_{50\ lab}$ 600.8 d (normalisation to 20 °C, pF2 with Q10 of 2.58 and Walker equation coefficient 0.7) Formation fraction: 0.096 from RP 35606 (ar. mean) K_{OC}: 7121 mL/g (arithmetic mean) $^{1}/_{n}$= 0.854 (arithmetic mean) Crop uptake factor: 0
	RP 32596: Molecular weight: 162 g/mol Water solubility (mg/L): 100 at 20°C Vapour pressure: $1x10^{-9}$ Pa at 20°C Geometric mean $DT_{50\ lab}$ 30.7 d (normalisation to 20 °C, pF2 with Q10 of 2.58 and Walker equation coefficient 0.7) Formation fraction: 1 from RP 25040, 1 from RP 30228, 1 from RP 36221 K_{OC}: 664 mL/g (arithmetic mean) $^{1}/_{n}$= 0.692 (arithmetic mean) Crop uptake factor: 0
	RP 30181*: Molecular weight: 142.16 g/mol Water solubility (mg/L): 100 at 20°C Vapour pressure: $1x10^{-9}$ Pa at 20°C $DT_{50\ lab}$ 8.9 d (non-GLP preliminary study) Formation fraction: 1 from RP 30228, 1 from RP 36221 K_{OC}: 7.2 mL/g (QSAR) (preliminar, not accepted as fully reliable end point. Data gap conditional to results of soil metabolism study with hydantoin

	labelled moiety was identified during the peer review) $^{1}/_{n}$= 1 (default value) Crop uptake factor: 0 *PECgw calculations to be considered as indicative only because of the data gap for hydantoin label
	Separate additional simulations were performed for photoproducts
	LS720942: pseudo-application, modelled as parent substance, with application rate corrected for molar ratio (0.621) and maximum occurrence of 13.8%. Molecular weight: 205.0 g/mol Water solubility (mg/L): 100 at 20°C Vapour pressure: 1x10^{-9} Pa at ~~25~~ 20°C Geometric mean $DT_{50\ lab}$ 5.8 d (normalisation to 20 °C, pF2 with Q10 of 2.58 and Walker equation coefficient 0.7) K_{OC}: 413.2 mL/g (arithmetic mean) $^{1}/_{n}$= 0.826 (arithmetic mean) Crop uptake factor: 0
	RP 25040: pseudo-application, modelled as parent substance, with application rate corrected for molar ratio (0.742) and maximum occurrence of 13.8% Same input parameters as presented above for RP 25040.
	RP 32596: Formation fraction: 1 from RP 25040 Other input parameters are the same as presented above for RP 32596
Application rate	Crop: Carrots Gross application rate: 750 g/ha[11]. No. of applications: 4 Interval: 10 days Crop growth stage: BBCH 13-49 Canopy interception %: 25/25/60/60 Application rate net of interception: 562.5/562.5/300/300 g/ha[12]. Time of application (absolute or relative application dates): 1st application 7 days after emergence
	Crop: Lettuce (FOCUS crop: cabbage) Gross application rate: 750 g/ha[11].

[11] For pseudo-application of LS720642: application rate of 64.3 g/ha (corresponding to 750 g a.s./ha corrected for molar ratio of 0.621 and maximum occurrence of 13.8%) / For pseudo-application of RP 25040: application rate of 76.8 g/ha (corresponding to 750 g a.s./ha corrected for molar ratio of 0.742 and maximum occurrence of 13.8%)

[12] For pseudo-application of LS720642: 48.2/48.2/25.7/25.7 g/ha / For pseudo-application of RP 25040: 57.6/57.6/30.7/30.7 g/ha

	No. of applications: 3 Interval: 14 days Crop growth stage: BBCH 10-49 Canopy interception %: 25/25/40 Application rate net of interception: 562.5/562.5/450 g/ha[13]. Time of application (absolute or relative application dates): 1st application 7 days after emergence

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

Use on carrots – 4 x 750 g/ha – soils with pH_{CaCl2} < 5.9 ($DT_{50\ iprodione}$ = 94.1 days)

Scenario	PECgw (µg/L) – PELMO 5.5.3								
	Iprodione	RP 35606	RP 30228	RP 36221	RP 30181	RP 25040		RP 32596	
						$DT_{50\ RP\ 25040}$= 0.6 d	$DT_{50\ RP\ 25040}$= 19.2 d	$DT_{50\ RP\ 25040}$= 0.6 d	$DT_{50\ RP\ 25040}$= 19.2 d
PECgw calculated with lowest Kfoc value of RP 35606 (15.4 mL/g) and 1/n = 0.781									
Chateaudun 1st	0.007	0.009	0.001	<0.001	**0.929**	<0.001	0.001	<0.001	<0.001
Chateaudun 2nd	0.008	0.015	0.001	0.001	**1.035**	<0.001	0.001	<0.001	<0.001
Hamburg 1st	**0.114**	**0.632**	**0.108**	0.031	**4.938**	<0.001	0.010	0.016	0.016
Hamburg 2nd	**0.154**	**1.083**	**0.187**	0.053	**5.535**	<0.001	0.013	0.026	0.027
Jokioinen	0.001	**0.179**	0.008	0.002	**6.525**	<0.001	<0.001	0.002	0.002
Kremsmunster 1st	0.087	**0.131**	0.007	0.003	**2.085**	<0.001	0.007	0.002	0.002
Kremsmunster 2nd	**0.109**	**0.182**	0.011	0.004	**2.225**	<0.001	0.009	0.002	0.003
Porto 1st	0.074	**0.645**	0.008	0.004	**2.292**	<0.001	0.007	0.002	0.002
Porto 2nd	**0.141**	**1.405**	0.015	0.008	**3.099**	<0.001	0.013	0.003	0.003
Thiva 1st	<0.001	0.012	<0.001	0.001	**0.635**	<0.001	<0.001	<0.001	<0.001
Thiva 2nd	0.001	0.028	0.001	0.001	**0.828**	<0.001	<0.001	<0.001	<0.001
PECgw calculated with highest Kfoc value of RP 35606 (49.6 mL/g) and 1/n = 1.063									
Chateaudun 1st	0.007	**0.129**	0.002	0.001	**0.940**	<0.001	0.001	0.001	0.001
Chateaudun 2nd	0.008	**0.153**	0.003	0.002	**1.039**	<0.001	0.001	0.001	0.001
Hamburg 1st	**0.114**	**1.298**	**0.175**	0.048	**4.883**	<0.001	0.010	0.026	0.027
Hamburg 2nd	**0.154**	**1.643**	**0.229**	0.063	**5.432**	<0.001	0.013	0.033	0.034
Jokioinen	0.001	**0.771**	0.010	0.004	**6.438**	<0.001	<0.001	0.002	0.002
Kremsmunster 1st	0.087	**0.400**	0.011	0.004	**2.090**	<0.001	0.007	0.002	0.003
Kremsmunster 2nd	**0.109**	**0.464**	0.014	0.005	**2.211**	<0.001	0.009	0.003	0.003
Porto 1st	0.074	**1.430**	0.010	0.006	**2.291**	<0.001	0.007	0.002	0.002
Porto 2nd	**0.141**	**2.245**	0.017	0.009	**3.076**	<0.001	0.013	0.003	0.003
Thiva 1st	<0.001	**0.148**	0.001	0.001	**0.643**	<0.001	<0.001	<0.001	<0.001
Thiva 2nd	0.001	**0.197**	0.002	0.002	**0.832**	<0.001	<0.001	<0.001	<0.001

[13] For pseudo-application of LS720642: 48.2/48.2/38.6 g/ha / For pseudo-application of RP 25040: 57.6/57.6/46.1 g/ha

Scenario	PECgw (µg/L) – PEARL 4.4.4									
	Iprodione	RP 35606	RP 30228	RP 36221	RP 30181[b]		RP 25040		RP 32596	
					DT_{50} RP 25040= 0.6 d	DT_{50} RP 25040= 19.2 d	DT_{50} RP 25040= 0.6 d	DT_{50} RP 25040= 19.2 d	DT_{50} RP 25040= 0.6 d	DT_{50} RP 25040= 19.2 d
PECgw calculated with lowest Kfoc value of RP 35606 (15.4 mL/g) and 1/n = 0.781										
Chateaudun 1st	0.027	0.026[a]	0.001	<0.001	**1.217**	**1.223**	<0.001	0.002	<0.001	<0.001
Chateaudun 2nd	0.034	0.040	0.002	<0.001	**1.340**	**1.346**	<0.001	0.003	<0.001	<0.001
Hamburg 1st	**0.232**	**0.523**[a]	**0.111**	0.029	**4.809**	**4.819**	<0.001	0.019	0.010	0.012
Hamburg 2nd	**0.301**	**0.797**	**0.179**[a]	0.048	**5.228**	**5.238**	<0.001	0.025	0.017	0.019
Jokioinen	<0.001	0.061	0.006	<0.001	**5.580**	**5.588**	<0.001	<0.001	<0.001	<0.001
Kremsmunster 1st	**0.128**	**0.112**[a]	0.006	0.002	**1.902**	**1.909**	<0.001	0.010	<0.001	<0.001
Kremsmunster 2nd	**0.154**	**0.147**[a]	0.009	0.003	**2.045**	**2.051**	<0.001	0.012	0.001	0.001
Porto 1st	0.034	**0.214**	0.003	0.001	**1.648**	**1.651**	<0.001	0.003	<0.001	<0.001
Porto 2nd	0.076	**0.586**[a]	0.008	0.004	**2.253**	**2.257**	<0.001	0.008	<0.001	<0.001
Thiva 1st	0.001	0.004	<0.001	<0.001	**0.483**	**0.486**	<0.001	<0.001	<0.001	<0.001
Thiva 2nd	0.002	0.010[a]	0.001	<0.001	**0.596**	**0.600**	<0.001	<0.001	<0.001	<0.001
PECgw calculated with highest Kfoc value of RP 35606 (49.6 mL/g) and 1/n = 1.063										
Chateaudun 1st	0.027	**0.177**	0.004	0.001	**1.226**	**1.231**	<0.001	0.002	<0.001	<0.001
Chateaudun 2nd	0.034	**0.206**[a]	0.005	0.002	**1.341**	**1.346**	<0.001	0.003	<0.001	<0.001
Hamburg 1st	**0.232**	**1.041**[a]	**0.185**	0.049	**4.736**	**4.742**	<0.001	0.019	0.016	0.017
Hamburg 2nd	**0.301**	**1.244**[a]	**0.233**[a]	0.062	**5.086**	**5.093**	<0.001	0.025	0.021	0.023
Jokioinen	<0.001	**0.415**[a]	0.010	0.002	**5.507**	**5.515**	<0.001	<0.001	<0.001	<0.001
Kremsmunster 1st	**0.128**	**0.387**[a]	0.009	0.003	**1.908**	**1.914**	<0.001	0.010	0.001	0.001
Kremsmunster 2nd	**0.154**	**0.451**[a]	0.012	0.004	**2.032**	**2.037**	<0.001	0.012	0.002	0.002
Porto 1st	0.034	**0.700**[a]	0.005	0.003	**1.663**	**1.666**	<0.001	0.003	<0.001	<0.001
Porto 2nd	0.076	**1.196**[a]	0.010	0.005	**2.242**	**2.246**	<0.001	0.008	0.001	0.001
Thiva 1st	0.001	0.083[a]	0.003	0.002	**0.490**	**0.492**	<0.001	<0.001	<0.001	<0.001
Thiva 2nd	0.002	**0.105**[a]	0.004	0.002	**0.599**	**0.603**	<0.001	<0.001	<0.001	<0.001

[a] Although RP 35606 and RP 30228 are not formed from RP 25040, depending on the DT50 used for RP 25040 (0.6 or 19.2 d), PECgw for some scenarios are very slightly different for these metabolites (max. difference does not exceed 0.003 µg/L). Only the worst-case value is reported.

[b] Although RP 30181 is not formed from RP 25040, depending on the DT50 used for RP 25040 (0.6 or 19.2 d), PECgw are different.

Use on carrots – 4 x 750 g/ha – soils with pH_{CaCl2} ≥ 5.9 ($DT_{50\ iprodione}$ = 5 days)

Scenario	PECgw (µg/L) – PELMO 5.5.3						
	Iprodione	RP 35606	RP 30228	RP 36221	RP 30181	RP 25040[a]	RP 32596[a]
PECgw calculated with lowest Kfoc value of RP 35606 (15.4 mL/g) and 1/n = 0.781							
Chateaudun 1st	<0.001	<0.001	<0.001	<0.001	**0.662**	<0.001	<0.001
Chateaudun 2nd	<0.001	0.001	<0.001	<0.001	**0.990**	<0.001	<0.001
Hamburg 1st	<0.001	<0.001	<0.001	<0.001	**3.300**	<0.001	<0.001
Hamburg 2nd	<0.001	**0.192**	0.017	0.005	**5.824**	<0.001	0.003
Jokioinen	<0.001	0.001	<0.001	<0.001	**6.392**	<0.001	<0.001
Kremsmunster 1st	<0.001	0.010	0.001	<0.001	**1.546**	<0.001	<0.001
Kremsmunster 2nd	<0.001	0.039	0.002	0.001	**2.241**	<0.001	<0.001
Porto 1st	<0.001	<0.001	<0.001	<0.001	**1.175**	<0.001	<0.001
Porto 2nd	<0.001	0.039	0.001	<0.001	**2.914**	<0.001	<0.001
Thiva 1st	<0.001	<0.001	<0.001	<0.001	**0.251**	<0.001	<0.001
Thiva 2nd	<0.001	<0.001	<0.001	<0.001	**0.545**	<0.001	<0.001
PECgw calculated with highest Kfoc value of RP 35606 (49.6 mL/g) and 1/n = 1.063							
Chateaudun 1st	<0.001	0.004	<0.001	<0.001	**0.530**	<0.001	<0.001
Chateaudun 2nd	<0.001	0.027	<0.001	<0.001	**0.917**	<0.001	<0.001
Hamburg 1st	<0.001	0.015	0.002	0.001	**3.109**	<0.001	<0.001
Hamburg 2nd	<0.001	**0.379**	0.043	0.013	**5.589**	<0.001	0.006
Jokioinen	<0.001	**0.163**	0.001	0.001	**6.279**	<0.001	<0.001
Kremsmunster 1st	<0.001	0.023	0.001	<0.001	**1.439**	<0.001	<0.001
Kremsmunster 2nd	<0.001	**0.138**	0.003	0.001	**2.115**	<0.001	0.001
Porto 1st	<0.001	0.011	<0.001	<0.001	**1.089**	<0.001	<0.001
Porto 2nd	<0.001	**0.102**	0.001	<0.001	**2.845**	<0.001	<0.001
Thiva 1st	<0.001	<0.001	<0.001	<0.001	**0.227**	<0.001	<0.001
Thiva 2nd	<0.001	0.002	<0.001	<0.001	**0.521**	<0.001	<0.001

[a] Whichever DT50 is used for RP 25040 (0.6 or 19.2 days), PECgw for RP 25040 and RP 32596 are exactly the same.

Scenario	PECgw (µg/L) – PEARL 4.4.4							
	Iprodione	RP 35606	RP 30228	RP 36221	RP 30181[c]		RP 25040[d]	RP 32596[d]
					$DT_{50\ RP\ 25040}$= 0.6 d	$DT_{50\ RP\ 25040}$= 19.2 d		
PECgw calculated with lowest Kfoc value of RP 35606 (15.4 mL/g) and 1/n = 0.781								
Chateaudun 1st	<0.001	<0.001	<0.001	<0.001	**0.876**	**0.882**	<0.001	<0.001
Chateaudun 2nd	<0.001	<0.001	<0.001	<0.001	**1.209**	**1.218**	<0.001	<0.001
Hamburg 1st	<0.001	0.001	<0.001	<0.001	**3.143**	**3.155**	<0.001	<0.001
Hamburg 2nd	<0.001	**0.135**	0.020	0.005	**4.947**	**4.964**	<0.001	0.001
Jokioinen	<0.001	<0.001	<0.001	<0.001	**5.490**	**5.501**	<0.001	<0.001
Kremsmunster 1st	<0.001	0.016	<0.001	<0.001	**1.304**	**1.307**	<0.001	<0.001
Kremsmunster 2nd	<0.001	0.019	0.001	<0.001	**1.977**	**1.986**	<0.001	<0.001
Porto 1st	<0.001	<0.001	<0.001	<0.001	**0.693**	**0.695**	<0.001	<0.001
Porto 2nd	<0.001	0.029	<0.001	<0.001	**2.100**	**2.108**	<0.001	<0.001
Thiva 1st	<0.001	<0.001	<0.001	<0.001	**0.174**	**0.175**	<0.001	<0.001
Thiva 2nd	<0.001	<0.001	<0.001	<0.001	**0.416**	**0.419**	<0.001	<0.001
PECgw calculated with highest Kfoc value of RP 35606 (49.6 mL/g) and 1/n = 1.063								
Chateaudun 1st	<0.001	0.006	<0.001	<0.001	**0.663**	**0.665**	<0.001	<0.001
Chateaudun 2nd	<0.001	0.023	<0.001	<0.001	**1.076**	**1.082**	<0.001	<0.001
Hamburg 1st	<0.001	0.017[a]	0.003	<0.001	**2.889**	**2.893**	<0.001	<0.001
Hamburg 2nd	<0.001	**0.296**[b]	0.046	0.012	**4.684**	**4.696**	<0.001	0.003
Jokioinen	<0.001	0.100	0.001	<0.001	**5.382**	**5.401**	<0.001	<0.001
Kremsmunster 1st	<0.001	0.018	<0.001	<0.001	**1.170**	**1.173**	<0.001	<0.001
Kremsmunster 2nd	<0.001	0.077	0.002	<0.001	**1.834**	**1.841**	<0.001	<0.001
Porto 1st	<0.001	0.002	<0.001	<0.001	**0.624**	**0.624**	<0.001	<0.001
Porto 2nd	<0.001	**0.103**[a]	<0.001	<0.001	**2.014**	**2.021**	<0.001	<0.001
Thiva 1st	<0.001	<0.001	<0.001	<0.001	**0.160**	**0.161**	<0.001	<0.001
Thiva 2nd	<0.001	0.002	<0.001	<0.001	**0.381**	**0.383**	<0.001	<0.001

[a] Although RP 35606 and RP 30228 are not formed from RP 25040, depending on the DT50 used for RP 25040 (0.6 or 19.2 d), PECgw for some scenarios are very slightly different for these metabolites (max. difference does not exceed 0.002 µg/L). Only the worst-case value is reported.
[b] For this scenario, a higher difference in PECgw values is observed depending on the DT50 used for RP 25040. PECgw value is 0.285 µg/L with $DT_{50\_RP25040}$ of 19.2 days and 0.296 µg/L with $DT_{50\_RP25040}$ of 0.6 day.
[c] Although RP 30181 is not formed from RP 25040, depending on the DT50 used for RP 25040 (0.6 or 19.2 d), PECgw are different.
[d] Whichever DT50 is used for RP 25040 (0.6 or 19.2 days), PECgw for RP 25040 and RP 32596 are exactly the same.

Use on lettuce – 3 x 750 g/ha – soils with pHCaCl2 < 5.9 (DT$_{50\ iprodione}$ = 94.1 days)

Scenario	PECgw (µg/L) – PELMO 5.5.3								
						RP 25040		RP 32596	
	Iprodione	RP 35606	RP 30228	RP 36221	RP 30181	$DT_{50\ RP\ 25040}$= 0.6 d	$DT_{50\ RP\ 25040}$= 19.2 d	$DT_{50\ RP\ 25040}$= 0.6 d	$DT_{50\ RP\ 25040}$= 19.2 d
PECgw calculated with lowest Kfoc value of RP 35606 (15.4 mL/g) and 1/n = 0.781									
Chateaudun 1st	0.005	0.014	0.001	<0.001	**0.930**	<0.001	0.001	<0.001	<0.001
Chateaudun 2nd	0.008	0.027	0.001	0.001	**1.011**	<0.001	0.001	<0.001	<0.001
Hamburg 1st	0.100	**0.621**	**0.102**	0.030	**4.728**	<0.001	0.009	0.015	0.016
Hamburg 2nd	**0.138**	**1.051**	**0.177**	0.052	**5.041**	<0.001	0.012	0.026	0.026
Jokioinen	0.001	**0.105**	0.006	0.002	**6.303**	<0.001	<0.001	0.001	0.001
Kremsmunster 1st	0.067	**0.118**	0.006	0.002	**2.029**	<0.001	0.006	0.002	0.002
Kremsmunster 2nd	0.089	**0.173**	0.010	0.004	**2.072**	<0.001	0.007	0.002	0.002
Porto 1st	0.092	**0.567**	0.008	0.004	**2.051**	<0.001	0.008	0.002	0.002
Porto 2nd	**0.166**	**1.317**	0.015	0.009	**2.804**	<0.001	0.015	0.003	0.003
Sevilla 1st	<0.001	0.003	<0.001	<0.001	**0.554**	<0.001	<0.001	<0.001	<0.001
Sevilla 2nd	<0.001	0.009	<0.001	<0.001	**0.734**	<0.001	<0.001	<0.001	<0.001
Thiva	0.001	**0.164**	0.002	0.003	**1.062**	<0.001	<0.001	0.001	0.001
PECgw calculated with highest Kfoc value of RP 35606 (49.6 mL/g) and 1/n = 1.063									
Chateaudun 1st	0.005	**0.141**	0.003	0.001	**0.947**	<0.001	0.001	0.001	0.001
Chateaudun 2nd	0.008	**0.175**	0.003	0.002	**1.018**	<0.001	0.001	0.001	0.001
Hamburg 1st	0.100	**1.268**	**0.167**	0.048	**4.671**	<0.001	0.009	0.023	0.024
Hamburg 2nd	**0.138**	**1.597**	**0.222**	0.063	**4.931**	<0.001	0.012	0.030	0.030
Jokioinen	0.001	**0.690**	0.009	0.003	**6.240**	<0.001	<0.001	0.002	0.002
Kremsmunster 1st	0.067	**0.386**	0.011	0.004	**2.038**	<0.001	0.006	0.002	0.002
Kremsmunster 2nd	0.089	**0.456**	0.013	0.005	**2.065**	<0.001	0.007	0.003	0.003
Porto 1st	0.092	**1.308**	0.009	0.006	**2.059**	<0.001	0.008	0.002	0.002
Porto 2nd	**0.166**	**2.153**	0.017	0.010	**2.779**	<0.001	0.015	0.004	0.004
Sevilla 1st	<0.001	**0.125**	0.001	<0.001	**0.559**	<0.001	<0.001	<0.001	<0.001
Sevilla 2nd	<0.001	**0.170**	0.001	0.001	**0.736**	<0.001	<0.001	<0.001	<0.001
Thiva	0.001	**0.424**	0.004	0.004	**1.057**	<0.001	<0.001	0.001	0.001

Scenario	PECgw (µg/L) – PEARL 4.4.4									
	Iprodione	RP 35606	RP 30228	RP 36221	RP 30181[b]		RP 25040		RP 32596	
					$DT_{50\ RP\ 25040}$= 0.6 d	$DT_{50\ RP\ 25040}$= 19.2 d	$DT_{50\ RP\ 25040}$= 0.6 d	$DT_{50\ RP\ 25040}$= 19.2 d	$DT_{50\ RP\ 25040}$= 0.6 d	$DT_{50\ RP\ 25040}$= 19.2 d
PECgw calculated with lowest Kfoc value of RP 35606 (15.4 mL/g) and 1/n = 0.781										
Chateaudun 1st	0.014	0.018	<0.001	<0.001	**1.116**	**1.122**	<0.001	0.001	<0.001	<0.001
Chateaudun 2nd	0.020	0.036	0.002	<0.001	**1.234**	**1.240**	<0.001	0.002	<0.001	<0.001
Hamburg 1st	**0.209**	**0.511[a]**	**0.108**	0.029	**4.622**	**4.632**	<0.001	0.017	0.009	0.011
Hamburg 2nd	**0.280**	**0.770[a]**	**0.164**	0.048	**4.847**	**4.855**	<0.001	0.023	0.017	0.018
Jokioinen	<0.001	0.053[a]	0.004	<0.001	**5.411**	**5.421**	<0.001	<0.001	<0.001	<0.001
Kremsmunster 1st	0.098	**0.101[a]**	0.005	0.002	**1.660**	**1.668**	<0.001	0.008	<0.001	<0.001
Kremsmunster 2nd	**0.128**	**0.146**	0.008	0.003	**1.706**	**1.713**	0.001	0.010	0.001	0.001
Porto 1st	0.039	**0.219**	0.003	0.002	**1.591**	**1.593**	<0.001	0.004	<0.001	<0.001
Porto 2nd	0.087	**0.602[a]**	0.008	0.004	**2.167**	**2.171**	<0.001	0.008	<0.001	<0.001
Sevilla 1st	<0.001	0.005	<0.001	<0.001	**0.525**	**0.528**	<0.001	<0.001	<0.001	<0.001
Sevilla 2nd	<0.001	0.013	<0.001	<0.001	**0.708**	**0.713**	<0.001	<0.001	<0.001	<0.001
Thiva	0.003	0.070[a]	0.002	0.002	**0.724**	**0.729**	<0.001	<0.001	<0.001	<0.001
PECgw calculated with highest Kfoc value of RP 35606 (49.6 mL/g) and 1/n = 1.063										
Chateaudun 1st	0.014	**0.157[a]**	0.003	0.001	**1.133**	**1.138**	<0.001	0.001	<0.001	<0.001
Chateaudun 2nd	0.020	**0.195**	0.004	0.002	**1.233**	**1.238**	<0.001	0.002	<0.001	<0.001
Hamburg 1st	**0.209**	**1.042[a]**	**0.176**	0.049	**4.538**	**4.548**	<0.001	0.017	0.015	0.016
Hamburg 2nd	**0.280**	**1.241[a]**	**0.215**	0.062	**4.716**	**4.724**	<0.001	0.023	0.020	0.021
Jokioinen	<0.001	**0.427[a]**	0.010	0.002	**5.357**	**5.366**	<0.001	<0.001	0.001	0.001
Kremsmunster 1st	0.098	**0.304**	0.009	0.003	**1.670**	**1.677**	<0.001	0.008	0.001	0.001
Kremsmunster 2nd	**0.128**	**0.354**	0.011	0.004	**1.703**	**1.709**	<0.001	0.010	0.001	0.002
Porto 1st	0.039	**0.685[a]**	0.005	0.003	**1.608**	**1.611**	<0.001	0.004	<0.001	<0.001
Porto 2nd	0.087	**1.200**	0.010	0.006	**2.166**	**2.170**	<0.001	0.008	0.001	0.001
Sevilla 1st	<0.001	**0.105**	0.002	<0.001	**0.538**	**0.541**	<0.001	<0.001	<0.001	<0.001
Sevilla 2nd	<0.001	**0.138**	0.003	0.001	**0.719**	**0.723**	<0.001	<0.001	<0.001	<0.001
Thiva	0.003	**0.234[a]**	0.003	0.003	**0.721**	**0.726**	<0.001	<0.001	<0.001	<0.001

[a] Although RP 35606 and RP 30228 are not formed from RP 25040, depending on the DT50 used for RP 25040 (0.6 or 19.2 d), PECgw for some scenarios are very slightly different for these metabolites (max. difference does not exceed 0.003 µg/L). Only the worst-case value is reported.
[b] Although RP 30181 is not formed from RP 25040, depending on the DT50 used for RP 25040 (0.6 or 19.2 d), PECgw are different.

Use on lettuce – 3 x 750 g/ha – soils with pHCaCl2 ≥ 5.9 (DT$_{50\ iprodione}$ = 5 days)

Scenario	PECgw (µg/L) – PELMO 5.5.3						
	Iprodione	RP 35606	RP 30228	RP 36221	RP 30181	RP 25040[a]	RP 32596[a]
PECgw calculated with lowest Kfoc value of RP 35606 (15.4 mL/g) and 1/n = 0.781							
Chateaudun 1st	<0.001	<0.001	<0.001	<0.001	**0.696**	<0.001	<0.001
Chateaudun 2nd	<0.001	0.006	<0.001	<0.001	**1.069**	<0.001	<0.001
Hamburg 1st	<0.001	0.002	0.002	0.001	**3.544**	<0.001	0.001
Hamburg 2nd	<0.001	**0.533**	0.081	0.023	**5.660**	<0.001	0.011
Jokioinen	<0.001	<0.001	<0.001	<0.001	**5.634**	<0.001	<0.001
Kremsmunster 1st	<0.001	0.002	<0.001	<0.001	**1.581**	<0.001	<0.001
Kremsmunster 2nd	<0.001	**0.120**	0.005	0.002	**2.107**	<0.001	0.001
Porto 1st	<0.001	<0.001	<0.001	<0.001	**1.016**	<0.001	<0.001
Porto 2nd	<0.001	**0.113**	0.002	0.001	**2.876**	<0.001	<0.001
Sevilla 1st	<0.001	<0.001	<0.001	<0.001	**0.247**	<0.001	<0.001
Sevilla 2nd	<0.001	<0.001	<0.001	<0.001	**0.346**	<0.001	<0.001
Thiva	<0.001	0.037	0.001	0.001	**1.694**	<0.001	<0.001
PECgw calculated with highest Kfoc value of RP 35606 (49.6 mL/g) and 1/n = 1.063							
Chateaudun 1st	<0.001	0.004	<0.001	<0.001	**0.602**	<0.001	<0.001
Chateaudun 2nd	<0.001	0.073	0.001	0.001	**1.010**	<0.001	<0.001
Hamburg 1st	<0.001	0.028	0.003	0.001	**3.361**	<0.001	0.001
Hamburg 2nd	<0.001	**0.704**	0.094	0.027	**5.403**	<0.001	0.014
Jokioinen	<0.001	**0.104**	0.001	<0.001	**5.523**	<0.001	<0.001
Kremsmunster 1st	<0.001	0.017	<0.001	<0.001	**1.464**	<0.001	<0.001
Kremsmunster 2nd	<0.001	**0.245**	0.006	0.003	**2.007**	<0.001	0.001
Porto 1st	<0.001	0.010	<0.001	<0.001	**0.926**	<0.001	<0.001
Porto 2nd	<0.001	**0.198**	0.002	0.001	**2.817**	<0.001	<0.001
Sevilla 1st	<0.001	<0.001	<0.001	<0.001	**0.210**	<0.001	<0.001
Sevilla 2nd	<0.001	<0.001	<0.001	<0.001	**0.334**	<0.001	<0.001
Thiva	<0.001	**0.198**	0.002	0.001	**1.665**	<0.001	<0.001

[a] Whichever DT50 is used for RP 25040 (0.6 or 19.2 days), PECgw for RP 25040 and RP 32596 are exactly the same.

Scenario	PECgw (µg/L) – PEARL 4.4.4							
	Iprodione	RP 35606	RP 30228	RP 36221	RP 30181[b] DT_{50} RP 25040 = 0.6 d	RP 30181[b] DT_{50} RP 25040 = 19.2 d	RP 25040[c]	RP 32596[c]
PECgw calculated with lowest Kfoc value of RP 35606 (15.4 mL/g) and 1/n = 0.781								
Chateaudun 1st	<0.001	<0.001	<0.001	<0.001	**0.769**	**0.774**	<0.001	<0.001
Chateaudun 2nd	<0.001	0.006	<0.001	<0.001	**1.226**	**1.235**	<0.001	<0.001
Hamburg 1st	<0.001	0.009	0.003	0.002	**3.502**	**3.514**	<0.001	<0.001
Hamburg 2nd	<0.001	**0.450**[a]	0.091[a]	0.024	**5.011**	**5.031**	<0.001	0.007
Jokioinen	<0.001	<0.001	<0.001	<0.001	**4.885**	**4.894**	<0.001	<0.001
Kremsmunster 1st	<0.001	0.002	<0.001	<0.001	**1.264**	**1.272**	<0.001	<0.001
Kremsmunster 2nd	<0.001	0.082	0.003	0.001	**1.588**	**1.598**	<0.001	<0.001
Porto 1st	<0.001	<0.001	<0.001	<0.001	**0.682**	**0.683**	<0.001	<0.001
Porto 2nd	<0.001	0.080	<0.001	<0.001	**2.212**	**2.222**	<0.001	<0.001
Sevilla 1st	<0.001	<0.001	<0.001	<0.001	**0.204**	**0.206**	<0.001	<0.001
Sevilla 2nd	<0.001	<0.001	<0.001	<0.001	**0.393**	**0.396**	<0.001	<0.001
Thiva	<0.001	0.015[a]	<0.001	<0.001	**1.241**	**1.251**	<0.001	<0.001
PECgw calculated with highest Kfoc value of RP 35606 (49.6 mL/g) and 1/n = 1.063								
Chateaudun 1st	<0.001	0.004	<0.001	<0.001	**0.652**	**0.656**	<0.001	<0.001
Chateaudun 2nd	<0.001	0.063[a]	0.001	<0.001	**1.132**	**1.139**	<0.001	<0.001
Hamburg 1st	<0.001	0.036	0.006	0.001	**3.213**	**3.218**	<0.001	<0.001
Hamburg 2nd	<0.001	**0.436**[a]	0.097	0.026	**4.656**	**4.669**	<0.001	0.007
Jokioinen	<0.001	0.071	<0.001	<0.001	**4.794**	**4.802**	<0.001	<0.001
Kremsmunster 1st	<0.001	0.014	<0.001	<0.001	**1.141**	**1.147**	<0.001	<0.001
Kremsmunster 2nd	<0.001	**0.164**[a]	0.004	0.001	**1.493**	**1.501**	<0.001	<0.001
Porto 1st	<0.001	0.001	<0.001	<0.001	**0.623**	**0.624**	<0.001	<0.001
Porto 2nd	<0.001	**0.171**	<0.001	<0.001	**2.119**	**2.128**	<0.001	<0.001
Sevilla 1st	<0.001	<0.001	<0.001	<0.001	**0.176**	**0.177**	<0.001	<0.001
Sevilla 2nd	<0.001	<0.001	<0.001	<0.001	**0.379**	**0.382**	<0.001	<0.001
Thiva	<0.001	**0.109**	0.001	<0.001	**1.182**	**1.191**	<0.001	<0.001

[a] Although RP 35606 and RP 30228 are not formed from RP 25040, depending on the DT50 used for RP 25040 (0.6 or 19.2 d), PECgw for some scenarios are very slightly different for these metabolites (max. difference does not exceed 0.003 µg/L). Only the worst-case value is reported.
[b] Although RP 30181 is not formed from RP 25040, depending on the DT50 used for RP 25040 (0.6 or 19.2 d), PECgw are different.
[c] Whichever DT50 is used for RP 25040 (0.6 or 19.2 days), PECgw for RP 25040 and RP 32596 are exactly the same.

Separated simulations for photoproducts – Uses on carrots and lettuce

Scenario	**PECgw (µg/L)**		
	LS 720942	**RP 25040**	**RP 32596**
	PEARL/PELMO	PEARL/PELMO	PEARL/PELMO
Chateaudun	< 0.001	< 0.001	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001
Kremsmunster	< 0.001	< 0.001	< 0.001
Porto	< 0.001	< 0.001	< 0.001
Sevilla*	< 0.001	< 0.001	< 0.001
Thiva	< 0.001	< 0.001	< 0.001

* Only relevant for lettuce

PEC surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5 / 9.3.1)

Please note that PECsw values have not been updated with updated Kfoc values. As a consequence it cannot be excluded that PECsw values presented below are underestimated.

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: Step 1-2 v.2.1 Molecular weight (g/mol): 330.2 K_{OC} (mL/g): 927.1 (arithmetic mean) (correct value is 399 mL/g) DT_{50} soil (d): 5 d for soils with $pH_{CaCl2} \geq 5.9$ (normalised geometric mean from field) and 94.1 d for soils with $pH_{CaCl2} < 5.9$ (normalised worst-case from laboratory). DT_{50} water/sediment system (d): 11.6 (geomean from sediment water studies) DT_{50} water (d): 11.6 (geomean from sediment water studies) DT_{50} sediment (d): 1000 (FOCUS default)
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: SWASH 3.1 (PRZM 1.5.6, MACRO 4.4.2, TOXSWA 3.3.1), SWAN 3.0.0 Water solubility (mg/L): 12.2 (20°C) Vapour pressure: $5x10^{-7}$ Pa at 25°C Koc (mL/g): 927.1 (arithmetic mean) (correct value is 399 mL/g) 1/n: 0.884 (geometric mean) (the correct value is the arithmetic mean of 0.885) Q10=2.58, Walker equation coefficient 0.7 Crop uptake factor: 0.5
Application rate	Crop and growth stage: root vegetables (BBCH 13-49) Number of applications: 4 Interval (d): 10 Application rate(s): 750 g a.s./ha Crop interception and season (Step 2): minimal crop cover in March-May and full canopy in October-February Application windows (Step 3): Early: 1st application 7 days after emergence[14] Late: last application 27 days before harvest
	Crop and growth stage: leafy vegetables (BBCH 10-49) Number of applications: 3 Interval (d): 14

[14] Please note that some application windows for early and late applications are in fact very similar for some scenarios in particular when multiple applications are considered since the crop cycles are quite short. In some case, the the "late" application occurs before the "early" application.

Application rate(s): 750 g a.s./ha Crop interception and season (Step 2): minimal crop cover in March-May and full canopy in October-February Application windows (Step 3): Early: 1st application 7 days after emergence Late: last application 27 days before harvest

Reminder: PECsw Steps 1 to 4 are provisional (incorrect Kfoc was used)

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Roots vegetables*	0 h	474.791	-	4150	-
	21 d	-	262.168	-	-
Leafy vegetables*	0 h	356.093	-	3110	-
	21 d	-	196.626	-	-

* Calculations are reported for multiple applications only (worst-case compared to single application) / Iprodione soil DT50 has no impact on PECsw values at Step 1

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Soils with pH_{CaCl2} < 5.9 (iprodione DT50 = 94.1 days)					
Roots vegetables Southern EU March-May*	0 h	122.688	-	1130	-
	21 d	-	90.342	-	-
Leafy vegetables Southern EU March-May*	0 h	93.213	-	857	-
	21 d	-	68.584	-	-
Soils with pH_{CaCl2} ≥ 5.9 (iprodione DT50 = 5 days)					
Roots vegetables Southern EU March-May*	0 h	31.238	-	281	-
	21 d	-	22.528	-	-
Leafy vegetables Southern EU March-May*	0 h	27.202	-	245	-
	21 d	-	19.633	-	-

* Worst-case compared to Northern Europe / Calculations are reported for multiple applications only (worst-case compared to single application)

For Step 4: D = Drift mitigation by no-spray buffer zones [m]
R = Runoff mitigation by vegetated filter strips [m]

PECsw,max of iprodione following single application to root vegetables (early) - iprodione soil DT50 = 94.1 days

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	4.750 Drift	0.682 Drift	0.682 Drift	0.355 Drift	0.355 Drift
D6	ditch	4.762 Drift	1.447 Drainage	1.447 Drainage	1.447 Drainage	1.447 Drainage
R1	pond	0.625 Runoff	0.585 Runoff	0.274 Runoff	0.564 Runoff	0.148 Runoff
R1	stream	6.085 Runoff	6.085 Runoff	2.752 Runoff	6.085 Runoff	1.437 Runoff
R2	stream	4.137 Drift	1.957 Runoff	0.886 Runoff	1.957 Runoff	0.464 Runoff
R2, 2nd	stream	4.210 Drift	1.225 Runoff	0.816 Drift	1.225 Runoff	0.424 Drift
R3	stream	6.414 Runoff	6.414 Runoff	2.905 Runoff	6.414 Runoff	1.519 Runoff
R4	stream	10.480 Runoff	10.480 Runoff	4.756 Runoff	10.480 Runoff	2.489 Runoff

PECsw,max of iprodione following multiple applications to root vegetables (early) - iprodione soil DT50 = 94.1 days

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	3.199 Drift	0.452 Drift	0.452 Drift	0.234 Drift	0.234 Drift
D6	ditch	5.430 Drainage	5.430 Drainage	5.430 Drainage	5.430 Drainage	5.430 Drainage
R1	pond	1.366 Runoff	1.317 Runoff	0.578 Runoff	1.290 Runoff	0.302 Runoff
R1	stream	15.402 Runoff	15.402 Runoff	7.000 Runoff	15.402 Runoff	3.665 Runoff
R2	stream	6.353 Runoff	6.353 Runoff	2.892 Runoff	6.353 Runoff	1.515 Runoff
R2, 2nd	stream	4.520 Runoff	4.520 Runoff	2.054 Runoff	4.520 Runoff	1.076 Runoff
R3	stream	15.213 Runoff	15.213 Runoff	6.948 Runoff	15.213 Runoff	3.647 Runoff
R4	stream	21.078 Runoff	21.078 Runoff	9.582 Runoff	21.078 Runoff	5.018 Runoff

PECsw,max of iprodione following single application to root vegetables (late) - iprodione soil DT50 = 94.1 days

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	4.749 Drift	0.682 Drift	0.682 Drift	0.355 Drift	0.355 Drift
D6	ditch	4.702 Drift	0.866 Drainage	0.866 Drainage	0.866 Drainage	0.866 Drainage
R1	pond	1.081 Runoff	1.050 Runoff	0.458 Runoff	1.033 Runoff	0.239 Runoff
R1	stream	4.716 Runoff	4.716 Runoff	2.149 Runoff	4.716 Runoff	1.127 Runoff
R2	stream	4.145 Drift	1.145 Runoff	0.803 Drift	1.145 Runoff	0.417 Drift
R2, 2nd	stream	4.210 Drift	0.816 Drift	0.816 Drift	0.649 Runoff	0.424 Drift
R3	stream	4.823 Runoff	4.823 Runoff	2.203 Runoff	4.823 Runoff	1.156 Runoff
R4	stream	8.169 Runoff	8.169 Runoff	3.712 Runoff	8.169 Runoff	1.944 Runoff

PECsw,max of iprodione following multiple applications to root vegetables (late) - iprodione soil DT50 = 94.1 days

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	3.198 Drift	0.452 Drift	0.452 Drift	0.234 Drift	0.234 Drift
D6	ditch	6.229 Drainage	6.229 Drainage	6.229 Drainage	6.229 Drainage	6.229 Drainage
R1	pond	1.388 Runoff	1.360 Runoff	0.575 Runoff	1.344 Runoff	0.295 Runoff
R1	stream	13.997 Runoff	13.997 Runoff	6.357 Runoff	13.997 Runoff	3.326 Runoff
R2	stream	6.294 Runoff	6.294 Runoff	2.842 Runoff	6.294 Runoff	1.485 Runoff
R2, 2nd	stream	5.008 Runoff	5.008 Runoff	2.276 Runoff	5.008 Runoff	1.192 Runoff
R3	stream	16.605 Runoff	16.605 Runoff	7.584 Runoff	16.605 Runoff	3.977 Runoff
R4	stream	24.394 Runoff	24.394 Runoff	11.053 Runoff	24.394 Runoff	5.783 Runoff

PECsw,max of iprodione following single application to leafy vegetables (early) - iprodione soil DT50 = 94.1 days

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	4.750 Drift	0.682 Drift	0.682 Drift	0.355 Drift	0.355 Drift
D3, 2nd	ditch	4.749 Drift	0.682 Drift	0.682 Drift	0.355 Drift	0.355 Drift
D4	pond	0.651 Drainage	0.651 Drainage	0.651 Drainage	0.651 Drainage	0.651 Drainage
D4	stream	3.802 Drift	1.412 Drainage	1.412 Drainage	1.412 Drainage	1.412 Drainage
D6	ditch	4.906 Drainage	4.906 Drainage	4.906 Drainage	4.906 Drainage	4.906 Drainage
R1	pond	0.502 Runoff	0.501 Runoff	0.209 Runoff	0.500 Runoff	0.106 Runoff
R1, 2nd	pond	0.678 Runoff	0.676 Runoff	0.284 Runoff	0.676 Runoff	0.144 Runoff
R1	stream	4.715 Runoff	4.715 Runoff	2.138 Runoff	4.715 Runoff	1.119 Runoff
R1, 2nd	stream	3.691 Runoff	3.691 Runoff	1.678 Runoff	3.691 Runoff	0.879 Runoff
R2	stream	4.138 Drift	1.970 Runoff	0.891 Runoff	1.970 Runoff	0.467 Runoff
R2, 2nd	stream	4.210 Drift	1.181 Runoff	0.816 Drift	1.181 Runoff	0.424 Drift
R3	stream	6.558 Runoff	6.558 Runoff	2.970 Runoff	6.558 Runoff	1.553 Runoff
R3, 2nd	stream	6.195 Runoff	6.195 Runoff	2.829 Runoff	6.195 Runoff	1.484 Runoff
R4	stream	5.689 Runoff	5.689 Runoff	2.588 Runoff	5.689 Runoff	1.356 Runoff
R4, 2nd	stream	10.428 Runoff	10.428 Runoff	4.735 Runoff	10.428 Runoff	2.481 Runoff

PECsw,max of iprodione following multiple applications to leafy vegetables (early) - iprodione soil DT50 = 94.1 days

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	3.463 Drift	0.480 Drift	0.480 Drift	0.247 Drift	0.247 Drift
D3, 2nd	ditch	3.464 Drift	0.480 Drift	0.480 Drift	0.247 Drift	0.247 Drift
D4	pond	2.233 Drainage	2.232 Drainage	2.232 Drainage	2.231 Drainage	2.231 Drainage
D4	stream	4.528 Drainage	4.528 Drainage	4.528 Drainage	4.528 Drainage	4.528 Drainage
D6	ditch	12.867 Drainage	12.867 Drainage	12.867 Drainage	12.867 Drainage	12.867 Drainage
R1	pond	2.078 Runoff	2.074 Runoff	0.861 Runoff	2.071 Runoff	0.437 Runoff
R1, 2nd	pond	2.219 Runoff	2.214 Runoff	0.929 Runoff	2.210 Runoff	0.473 Runoff
R1	stream	11.074 Runoff	11.074 Runoff	5.022 Runoff	11.074 Runoff	2.628 Runoff
R1, 2nd	stream	8.339 Runoff	8.339 Runoff	3.793 Runoff	8.339 Runoff	1.986 Runoff
R2	stream	3.928 Runoff	3.928 Runoff	1.749 Runoff	3.928 Runoff	0.908 Runoff
R2, 2nd	stream	3.053 Drift	2.840 Runoff	1.294 Runoff	2.840 Runoff	0.679 Runoff
R3	stream	16.085 Runoff	16.085 Runoff	7.348 Runoff	16.085 Runoff	3.856 Runoff
R3, 2nd	stream	11.819 Runoff	11.819 Runoff	5.398 Runoff	11.819 Runoff	2.832 Runoff
R4	stream	21.359 Runoff	21.359 Runoff	9.715 Runoff	21.359 Runoff	5.090 Runoff
R4, 2nd	stream	13.083 Runoff	13.083 Runoff	5.952 Runoff	13.083 Runoff	3.117 Runoff

PECsw,max of iprodione following single application to leafy vegetables (late) - iprodione soil DT50 = 94.1 days

Scenario	Water body	PEC$_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	4.745 Drift	0.682 Drift	0.682 Drift	0.354 Drift	0.354 Drift
D3, 2nd	ditch	4.731 Drift	0.680 Drift	0.680 Drift	0.353 Drift	0.353 Drift
D4	pond	0.171 Drainage	0.168 Drainage	0.168 Drainage	0.167 Drainage	0.167 Drainage
D4	stream	3.573 Drift	0.698 Drift	0.698 Drift	0.398 Drainage	0.398 Drainage
D6	ditch	4.702 Drift	3.798 Drainage	3.798 Drainage	3.798 Drainage	3.798 Drainage
R1	pond	0.867 Runoff	0.843 Runoff	0.367 Runoff	0.829 Runoff	0.191 Runoff
R1, 2nd	pond	0.853 Runoff	0.849 Runoff	0.358 Runoff	0.846 Runoff	0.183 Runoff
R1	stream	3.888 Runoff	3.888 Runoff	1.766 Runoff	3.888 Runoff	0.925 Runoff
R1, 2nd	stream	3.141 Drift	2.960 Runoff	1.346 Runoff	2.960 Runoff	0.705 Runoff
R2	stream	4.210 Drift	0.982 Runoff	0.816 Drift	0.982 Runoff	0.424 Drift
R2, 2nd	stream	4.162 Drift	1.911 Runoff	0.870 Runoff	1.911 Runoff	0.456 Runoff
R3	stream	4.425 Drift	3.381 Runoff	1.529 Runoff	3.381 Runoff	0.799 Runoff
R3, 2nd	stream	5.100 Runoff	5.100 Runoff	2.328 Runoff	5.100 Runoff	1.221 Runoff
R4	stream	7.081 Runoff	7.081 Runoff	3.221 Runoff	7.081 Runoff	1.688 Runoff
R4, 2nd	stream	6.546 Runoff	6.546 Runoff	2.979 Runoff	6.546 Runoff	1.561 Runoff

PECsw,max of iprodione following multiple applications to leafy vegetables (late) - iprodione soil DT50 = 94.1 days

Scenario	Water body	PEC$_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	3.464 Drift	0.480 Drift	0.480 Drift	0.247 Drift	0.247 Drift
D3, 2nd	ditch	3.463 Drift	0.480 Drift	0.480 Drift	0.247 Drift	0.247 Drift
D4	pond	1.242 Drainage	1.237 Drainage	1.237 Drainage	1.234 Drainage	1.234 Drainage
D4	stream	2.836 Drift	2.702 Drainage	2.702 Drainage	2.702 Drainage	2.702 Drainage
D6	ditch	11.168 Drainage	11.168 Drainage	11.168 Drainage	11.168 Drainage	11.168 Drainage
R1	pond	2.605 Runoff	2.598 Runoff	1.079 Runoff	2.594 Runoff	0.547 Runoff
R1, 2nd	pond	2.082 Runoff	2.079 Runoff	0.871 Runoff	2.077 Runoff	0.443 Runoff
R1	stream	12.070 Runoff	12.070 Runoff	5.486 Runoff	12.070 Runoff	2.873 Runoff
R1, 2nd	stream	13.110 Runoff	13.110 Runoff	5.963 Runoff	13.110 Runoff	3.124 Runoff
R2	stream	3.859 Runoff	3.859 Runoff	1.758 Runoff	3.859 Runoff	0.921 Runoff
R2, 2nd	stream	3.638 Runoff	3.638 Runoff	1.650 Runoff	3.638 Runoff	0.864 Runoff
R3	stream	11.079 Runoff	11.079 Runoff	5.061 Runoff	11.079 Runoff	2.656 Runoff
R3, 2nd	stream	8.560 Runoff	8.560 Runoff	3.910 Runoff	8.560 Runoff	2.051 Runoff
R4	stream	16.600 Runoff	16.600 Runoff	7.522 Runoff	16.600 Runoff	3.935 Runoff
R4, 2nd	stream	12.821 Runoff	12.821 Runoff	5.844 Runoff	12.821 Runoff	3.064 Runoff

PECsw,max of iprodione following single application to root vegetables (early) - iprodione soil DT50 = 5 days

Scenario	Water body	PEC$_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	4.750 Drift	0.682 Drift	0.682 Drift	0.355 Drift	0.355 Drift
D6	ditch	4.740 Drift	0.681 Drift	0.681 Drift	0.354 Drift	0.354 Drift
R1	pond	0.450 Runoff	0.411 Runoff	0.204 Runoff	0.390 Runoff	0.113 Runoff
R1	stream	4.316 Runoff	4.316 Runoff	1.951 Runoff	4.316 Runoff	1.020 Runoff
R2	stream	4.137 Drift	0.941 Runoff	0.801 Drift	0.941 Runoff	0.416 Drift
R2, 2nd	stream	4.210 Drift	0.816 Drift	0.816 Drift	0.424 Drift	0.424 Drift
R3	stream	4.397 Drift	3.825 Runoff	1.733 Runoff	3.825 Runoff	0.906 Runoff
R4	stream	8.665 Runoff	8.665 Runoff	3.932 Runoff	8.665 Runoff	2.057 Runoff

PECsw,max of iprodione following multiple applications to root vegetables (early) - iprodione soil DT50 = 5 days

Scenario	Water body	PEC$_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	3.199 Drift	0.452 Drift	0.452 Drift	0.234 Drift	0.234 Drift
D6	ditch	3.193 Drift	0.451 Drift	0.451 Drift	0.233 Drift	0.233 Drift
R1	pond	0.540 Drift	0.472 Drift	0.257 Drift	0.435 Drift	0.147 Drift
R1	stream	4.316 Runoff	4.316 Runoff	1.951 Runoff	4.316 Runoff	1.020 Runoff
R2	stream	2.903 Runoff	2.903 Runoff	1.311 Runoff	2.903 Runoff	0.685 Runoff
R2, 2nd	stream	2.826 Drift	0.540 Drift	0.540 Drift	0.305 Runoff	0.279 Drift
R3	stream	5.597 Runoff	5.597 Runoff	2.557 Runoff	5.597 Runoff	1.342 Runoff
R4	stream	13.103 Runoff	13.103 Runoff	5.953 Runoff	13.103 Runoff	3.119 Runoff

PECsw,max of iprodione following single application to root vegetables (late) - iprodione soil DT50 = 5 days

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	4.749 Drift	0.682 Drift	0.682 Drift	0.355 Drift	0.355 Drift
D6	ditch	4.667 Drift	0.670 Drift	0.670 Drift	0.348 Drift	0.348 Drift
R1	pond	0.677 Runoff	0.646 Runoff	0.294 Runoff	0.629 Runoff	0.157 Runoff
R1	stream	3.124 Drift	2.778 Runoff	1.266 Runoff	2.778 Runoff	0.664 Runoff
R2	stream	4.145 Drift	0.803 Drift	0.803 Drift	0.683 Runoff	0.417 Drift
R2, 2nd	stream	4.210 Drift	0.816 Drift	0.816 Drift	0.424 Drift	0.424 Drift
R3	stream	4.397 Drift	1.291 Runoff	0.852 Drift	1.291 Runoff	0.443 Drift
R4	stream	7.005 Runoff	7.005 Runoff	3.184 Runoff	7.005 Runoff	1.666 Runoff

PECsw,max of iprodione following multiple applications to root vegetables (late) - iprodione soil DT50 = 5 days

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	3.198 Drift	0.452 Drift	0.452 Drift	0.234 Drift	0.234 Drift
D6	ditch	3.194 Drift	0.451 Drift	0.451 Drift	0.233 Drift	0.233 Drift
R1	pond	0.486 Drift	0.404 Drift	0.242 Drift	0.366 Runoff	0.143 Drift
R1	stream	4.185 Runoff	4.185 Runoff	1.891 Runoff	4.185 Runoff	0.988 Runoff
R2	stream	3.722 Drift	2.712 Runoff	1.223 Runoff	2.712 Runoff	0.639 Runoff
R2, 2nd	stream	2.826 Drift	0.540 Drift	0.540 Drift	0.279 Drift	0.279 Drift
R3	stream	4.979 Runoff	4.979 Runoff	2.221 Runoff	4.979 Runoff	1.155 Runoff
R4	stream	14.755 Runoff	14.755 Runoff	6.685 Runoff	14.755 Runoff	3.498 Runoff

PECsw,max of iprodione following single application to leafy vegetables (early) - iprodione soil DT50 = 5 days

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	4.750 Drift	0.682 Drift	0.682 Drift	0.355 Drift	0.355 Drift
D3, 2nd	ditch	4.749 Drift	0.682 Drift	0.682 Drift	0.355 Drift	0.355 Drift
D4	pond	0.164 Drift	0.102 Drift	0.102 Drift	0.068 Drift	0.068 Drift
D4	stream	3.785 Drift	0.733 Drift	0.733 Drift	0.381 Drift	0.381 Drift
D6	ditch	4.659 Drift	0.669 Drift	0.669 Drift	0.348 Drift	0.348 Drift
R1	pond	0.164 Drift	0.108 Runoff	0.102 Drift	0.098 Runoff	0.068 Drift
R1, 2nd	pond	0.164 Drift	0.102 Drift	0.102 Drift	0.068 Drift	0.068 Drift
R1	stream	3.130 Drift	1.373 Runoff	0.623 Runoff	1.373 Runoff	0.326 Runoff
R1, 2nd	stream	3.141 Drift	0.608 Drift	0.608 Drift	0.550 Runoff	0.316 Drift
R2	stream	4.138 Drift	0.939 Runoff	0.802 Drift	0.939 Runoff	0.416 Drift
R2, 2nd	stream	4.210 Drift	0.816 Drift	0.816 Drift	0.424 Drift	0.424 Drift
R3	stream	4.397 Drift	3.852 Runoff	1.745 Runoff	3.852 Runoff	0.912 Runoff
R3, 2nd	stream	4.413 Drift	0.855 Drift	0.855 Drift	0.768 Runoff	0.444 Drift
R4	stream	3.126 Drift	1.254 Runoff	0.606 Drift	1.254 Runoff	0.315 Drift
R4, 2nd	stream	4.799 Runoff	4.799 Runoff	2.180 Runoff	4.799 Runoff	1.141 Runoff

PECsw,max of iprodione following multiple applications to leafy vegetables (early) - iprodione soil DT50 = 5 days

Scenario	Water body	PEC$_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	3.463 Drift	0.480 Drift	0.480 Drift	0.247 Drift	0.247 Drift
D3, 2nd	ditch	3.464 Drift	0.480 Drift	0.480 Drift	0.247 Drift	0.247 Drift
D4	pond	0.188 Drift	0.115 Drift	0.115 Drift	0.076 Drift	0.076 Drift
D4	stream	2.745 Drift	0.516 Drift	0.516 Drift	0.265 Drift	0.265 Drift
D6	ditch	3.432 Drift	0.476 Drift	0.476 Drift	0.244 Drift	0.244 Drift
R1	pond	0.554 Drift	0.476 Drift	0.267 Drift	0.433 Drift	0.154 Drift
R1, 2nd	pond	0.356 Drift	0.280 Drift	0.185 Drift	0.239 Drift	0.112 Drift
R1	stream	5.844 Runoff	5.844 Runoff	2.650 Runoff	5.844 Runoff	1.387 Runoff
R1, 2nd	stream	2.674 Runoff	2.674 Runoff	1.216 Runoff	2.674 Runoff	0.637 Runoff
R2	stream	3.007 Drift	1.469 Runoff	0.664 Runoff	1.469 Runoff	0.347 Runoff
R2, 2nd	stream	3.053 Drift	0.642 Runoff	0.574 Drift	0.642 Runoff	0.295 Drift
R3	stream	5.509 Runoff	5.509 Runoff	2.517 Runoff	5.509 Runoff	1.321 Runoff
R3, 2nd	stream	3.213 Drift	2.460 Runoff	1.123 Runoff	2.460 Runoff	0.589 Runoff
R4	stream	11.939 Runoff	11.939 Runoff	5.430 Runoff	11.939 Runoff	2.845 Runoff
R4, 2nd	stream	4.904 Runoff	4.904 Runoff	2.204 Runoff	4.904 Runoff	1.149 Runoff

PECsw,max of iprodione following single application to leafy vegetables (late) - iprodione soil DT50 = 5 days

Scenario	Water body	PEC$_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	4.745	0.682	0.682	0.354	0.354
		Drift	Drift	Drift	Drift	Drift
D3, 2nd	ditch	4.731	0.680	0.680	0.353	0.353
		Drift	Drift	Drift	Drift	Drift
D4	pond	0.164	0.102	0.102	0.068	0.068
		Drift	Drift	Drift	Drift	Drift
D4	stream	3.565	0.691	0.691	0.359	0.359
		Drift	Drift	Drift	Drift	Drift
D6	ditch	4.689	0.674	0.674	0.350	0.350
		Drift	Drift	Drift	Drift	Drift
R1	pond	0.383	0.359	0.171	0.346	0.093
		Runoff	Runoff	Runoff	Runoff	Runoff
R1, 2nd	pond	0.164	0.111	0.102	0.108	0.068
		Drift	Runoff	Drift	Runoff	Drift
R1	stream	3.141	2.152	0.977	2.152	0.512
		Drift	Runoff	Runoff	Runoff	Runoff
R1, 2nd	stream	3.141	1.140	0.608	1.140	0.316
		Drift	Runoff	Drift	Runoff	Drift
R2	stream	4.210	0.816	0.816	0.424	0.424
		Drift	Drift	Drift	Drift	Drift
R2, 2nd	stream	4.162	1.387	0.806	1.387	0.419
		Drift	Runoff	Drift	Runoff	Drift
R3	stream	4.425	0.857	0.857	0.537	0.445
		Drift	Drift	Drift	Runoff	Drift
R3, 2nd	stream	4.410	2.276	1.039	2.276	0.545
		Drift	Runoff	Runoff	Runoff	Runoff
R4	stream	5.784	5.784	2.631	5.784	1.379
		Runoff	Runoff	Runoff	Runoff	Runoff
R4, 2nd	stream	4.492	4.492	2.044	4.492	1.071
		Runoff	Runoff	Runoff	Runoff	Runoff

PECsw,max of iprodione following multiple applications to leafy vegetables (late) - iprodione soil DT50 = 5 days

Scenario	Water body	PEC$_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	3.464 Drift	0.480 Drift	0.480 Drift	0.247 Drift	0.247 Drift
D3, 2nd	ditch	3.463 Drift	0.480 Drift	0.480 Drift	0.247 Drift	0.247 Drift
D4	pond	0.182 Drift	0.112 Drift	0.112 Drift	0.074 Drift	0.074 Drift
D4	stream	2.826 Drift	0.531 Drift	0.531 Drift	0.273 Drift	0.273 Drift
D6	ditch	3.461 Drift	0.653 Drainage	0.653 Drainage	0.653 Drainage	0.653 Drainage
R1	pond	0.448 Runoff	0.398 Runoff	0.208 Runoff	0.371 Runoff	0.117 Runoff
R1, 2nd	pond	0.274 Runoff	0.236 Runoff	0.131 Runoff	0.215 Runoff	0.077 Drift
R1	stream	4.174 Runoff	4.174 Runoff	1.898 Runoff	4.174 Runoff	0.994 Runoff
R1, 2nd	stream	2.811 Runoff	2.811 Runoff	1.278 Runoff	2.811 Runoff	0.670 Runoff
R2	stream	3.054 Drift	1.313 Runoff	0.585 Runoff	1.313 Runoff	0.304 Runoff
R2, 2nd	stream	3.053 Drift	1.441 Runoff	0.657 Runoff	1.441 Runoff	0.344 Runoff
R3	stream	5.018 Runoff	5.018 Runoff	2.292 Runoff	5.018 Runoff	1.203 Runoff
R3, 2nd	stream	3.212 Drift	2.918 Runoff	1.333 Runoff	2.918 Runoff	0.699 Runoff
R4	stream	11.199 Runoff	11.199 Runoff	5.094 Runoff	11.199 Runoff	2.669 Runoff
R4, 2nd	stream	5.215 Runoff	5.215 Runoff	2.377 Runoff	5.215 Runoff	1.246 Runoff

Metabolite RP 35606

Parameters used in FOCUSsw step 1 and 2

Molecular weight: 348.2 g/mol

Soil or water metabolite: both

Koc (mL/g): 32 (worst-case for PECsw) (correct value is 15.4 mL/g)

DT_{50} soil (d): 6.1 (normalised geomean from laboratory)

DT_{50} water/sediment system (d): 11.6 (geomean from sediment water studies)

DT_{50} water (d): 11.6 (geomean from sediment water studies)

DT_{50} sediment (d): 1000 (FOCUS default)

Maximum occurrence observed (% molar basis with respect to the parent)

Total Water and Sediment: 100%

Soil: 25.5%

Parameters used in FOCUSsw step 3 (if performed)	Water solubility (mg/L): 100 (default) Vapour pressure: 10^{-9} Pa at 20°C (default) Koc (mL/g): 32 (lowest value) (correct value is 15.4 mL/g) 1/n: 1.063 (correct value is 0.781) Additional simulations using highest Koc of 49.6 mL/g and 1/n of 1.063 should also be performed to see which combination is worst-case Q10=2.58, Walker equation coefficient 0.7 Crop uptake factor: 0 Metabolite kinetically generated in simulation : yes Formation fraction in soil (k_f/k_{dp}): 0.698 (molar basis) from iprodione Formation fraction in sediment water (k_f/k_{dp}): 1 from iprodione
Application rate	Same as parent iprodione

Reminder: PECsw Step 1 to 4 are provisional (incorrect Kfoc and 1/n were used)

FOCUS STEP 1 Scenario	**Day after overall maximum**	**PEC_{SW} (µg/L)** Roots vegetables*		Leafy vegetables*	
		Actual	**TWA**	**Actual**	**TWA**
	0h	286.991	-	215.243	-

* Calculations are reported for multiple applications only (worst-case compared to single application)

FOCUS STEP 2 Scenario	**Day after overall maximum**	**PEC_{SW} (µg/L)** Roots vegetables		Leafy vegetables	
		Actual	**TWA**	**Actual**	**TWA**
Southern EU March-May*	0 h	25.624	-	22.023	-

* Worst-case compared to Northern Europe / Calculations are reported for multiple applications only (worst-case compared to single application)

PECsw,max of RP35606 following single application to root vegetables (early) - iprodione soil DT50 = 94.1 days

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	5.034	0.742	0.742	0.396	0.396
		Drift	Drift	Drift	Drift	Drift
D6	ditch	5.114	0.858	0.858	0.858	0.858
		Drift	Drainage	Drainage	Drainage	Drainage
R1	pond	0.173	0.108	0.108	0.082	0.072
		Drift	Drift	Drift	Runoff	Drift
R1	stream	3.306	0.640	0.640	0.347	0.333
		Drift	Drift	Drift	Runoff	Drift
R2	stream	4.370	0.847	0.847	0.503	0.440
		Drift	Drift	Drift	Runoff	Drift
R2, 2nd	stream	4.447	0.861	0.861	0.582	0.448
		Drift	Drift	Drift	Runoff	Drift
R3	stream	4.644	0.900	0.900	0.523	0.468
		Drift	Drift	Drift	Runoff	Drift
R4	stream	3.266	0.633	0.633	0.329	0.329
		Drift	Drift	Drift	Drift	Drift

PECsw,max of RP35606 following multiple applications to root vegetables (early) - iprodione soil DT50 = 94.1 days

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	3.444	0.547	0.547	0.317	0.317
		Drift	Drift	Drift	Drift	Drift
D6	ditch	4.393	2.222	2.222	2.222	2.222
		Drift	Drainage	Drainage	Drainage	Drainage
R1	pond	0.282	0.226	0.157	0.194	0.102
		Runoff	Runoff	Drift	Runoff	Drift
R1	stream	2.224	1.941	0.882	1.941	0.462
		Drift	Runoff	Runoff	Runoff	Runoff
R2	stream	2.938	1.690	0.755	1.690	0.393
		Drift	Runoff	Runoff	Runoff	Runoff
R2, 2nd	stream	2.984	1.679	0.763	1.679	0.400
		Drift	Runoff	Runoff	Runoff	Runoff
R3	stream	3.137	1.311	0.599	1.311	0.314
		Drift	Runoff	Drift	Runoff	Runoff
R4	stream	2.210	1.416	0.644	1.416	0.337
		Drift	Runoff	Runoff	Runoff	Runoff

PECsw,max of RP35606 following single application to root vegetables (late) - iprodione soil DT50 = 94.1 days

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	5.029 Drift	0.736 Drift	0.736 Drift	0.390 Drift	0.390 Drift
D6	ditch	5.020 Drift	0.802 Drift	0.802 Drift	0.561 Drainage	0.561 Drainage
R1	pond	0.173 Drift	0.108 Drift	0.108 Drift	0.072 Drift	0.072 Drift
R1	stream	3.300 Drift	0.639 Drift	0.639 Drift	0.392 Runoff	0.332 Drift
R2	stream	4.378 Drift	0.848 Drift	0.848 Drift	0.464 Runoff	0.441 Drift
R2, 2nd	stream	4.447 Drift	0.861 Drift	0.861 Drift	0.448 Drift	0.448 Drift
R3	stream	4.644 Drift	0.900 Drift	0.900 Drift	0.586 Runoff	0.468 Drift
R4	stream	3.293 Drift	0.638 Drift	0.638 Drift	0.342 Runoff	0.332 Drift

PECsw,max of RP35606 following multiple applications to root vegetables (late) - iprodione soil DT50 = 94.1 days

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	3.434 Drift	0.538 Drift	0.538 Drift	0.308 Drift	0.308 Drift
D6	ditch	3.838 Drift	2.605 Drainage	2.605 Drainage	2.605 Drainage	2.605 Drainage
R1	pond	0.336 Drift	0.245 Drift	0.188 Drift	0.205 Runoff	0.118 Drift
R1	stream	2.250 Runoff	2.250 Runoff	1.022 Runoff	2.250 Runoff	0.535 Runoff
R2	stream	3.243 Drift	1.645 Runoff	0.735 Runoff	1.645 Runoff	0.382 Runoff
R2, 2nd	stream	2.984 Drift	1.980 Runoff	0.900 Runoff	1.980 Runoff	0.472 Runoff
R3	stream	3.139 Drift	2.049 Runoff	0.936 Runoff	2.049 Runoff	0.491 Runoff
R4	stream	2.226 Drift	0.839 Runoff	0.425 Drift	0.839 Runoff	0.220 Drift

PECsw,max of RP35606 following single application to leafy vegetables (early) - iprodione soil DT50 = 94.1 days

Scenario	Water body	PEC$_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	5.032 Drift	0.740 Drift	0.740 Drift	0.394 Drift	0.394 Drift
D3, 2nd	ditch	5.041 Drift	0.748 Drift	0.748 Drift	0.402 Drift	0.402 Drift
D4	pond	0.907 Drainage	0.907 Drainage	0.907 Drainage	0.907 Drainage	0.907 Drainage
D4	stream	4.120 Drift	1.184 Drainage	1.184 Drainage	1.184 Drainage	1.184 Drainage
D6	ditch	5.145 Drift	1.540 Drainage	1.540 Drainage	1.540 Drainage	1.540 Drainage
R1	pond	0.173 Drift	0.108 Drift	0.108 Drift	0.072 Drift	0.072 Drift
R1, 2nd	pond	0.173 Drift	0.108 Drift	0.108 Drift	0.072 Drift	0.072 Drift
R1	stream	3.306 Drift	0.641 Drift	0.641 Drift	0.443 Runoff	0.333 Drift
R1, 2nd	stream	3.317 Drift	0.643 Drift	0.643 Drift	0.496 Runoff	0.334 Drift
R2	stream	4.370 Drift	0.847 Drift	0.847 Drift	0.511 Runoff	0.440 Drift
R2, 2nd	stream	4.447 Drift	0.861 Drift	0.861 Drift	0.633 Runoff	0.448 Drift
R3	stream	4.645 Drift	0.900 Drift	0.900 Drift	0.534 Runoff	0.468 Drift
R3, 2nd	stream	4.661 Drift	1.152 Runoff	0.903 Drift	1.152 Runoff	0.469 Drift
R4	stream	3.302 Drift	0.640 Drift	0.640 Drift	0.333 Drift	0.333 Drift
R4, 2nd	stream	3.286 Drift	0.825 Runoff	0.637 Drift	0.825 Runoff	0.331 Drift

PECsw,max of RP35606 following multiple applications to leafy vegetables (early) - iprodione soil DT50 = 94.1 days

Scenario	Water body	PEC$_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	3.695 Drift	0.546 Drift	0.546 Drift	0.299 Drift	0.299 Drift
D3, 2nd	ditch	3.712 Drift	0.564 Drift	0.564 Drift	0.317 Drift	0.317 Drift
D4	pond	2.482 Drainage	2.482 Drainage	2.482 Drainage	2.482 Drainage	2.482 Drainage
D4	stream	3.244 Drainage	3.244 Drainage	3.244 Drainage	3.244 Drainage	3.244 Drainage
D6	ditch	4.156 Drift	4.069 Drainage	4.069 Drainage	4.069 Drainage	4.069 Drainage
R1	pond	0.284 Drift	0.273 Runoff	0.164 Drift	0.271 Runoff	0.105 Drift
R1, 2nd	pond	0.272 Drift	0.188 Drift	0.157 Drift	0.143 Drift	0.101 Drift
R1	stream	2.397 Drift	1.708 Runoff	0.776 Runoff	1.708 Runoff	0.407 Runoff
R1, 2nd	stream	2.406 Drift	0.871 Runoff	0.452 Drift	0.871 Runoff	0.232 Drift
R2	stream	3.174 Drift	1.234 Runoff	0.597 Drift	1.234 Runoff	0.306 Drift
R2, 2nd	stream	3.224 Drift	0.972 Runoff	0.606 Drift	0.972 Runoff	0.311 Drift
R3	stream	3.389 Drift	1.750 Runoff	0.764 Runoff	1.750 Runoff	0.394 Runoff
R3, 2nd	stream	3.391 Drift	1.935 Runoff	0.884 Runoff	1.935 Runoff	0.463 Runoff
R4	stream	2.401 Drift	1.002 Runoff	0.456 Runoff	1.002 Runoff	0.239 Runoff
R4, 2nd	stream	2.405 Drift	1.174 Runoff	0.534 Runoff	1.174 Runoff	0.280 Runoff

PECsw,max of RP35606 following single application to leafy vegetables (late) - iprodione soil DT50 = 94.1 days

Scenario	Water body	PEC$_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	5.022 Drift	0.730 Drift	0.730 Drift	0.384 Drift	0.384 Drift
D3, 2nd	ditch	5.005 Drift	0.730 Drift	0.730 Drift	0.385 Drift	0.385 Drift
D4	pond	0.432 Drainage	0.430 Drainage	0.430 Drainage	0.429 Drainage	0.429 Drainage
D4	stream	3.811 Drift	0.775 Drift	0.775 Drift	0.580 Drainage	0.580 Drainage
D6	ditch	5.022 Drift	1.063 Drainage	1.063 Drainage	1.063 Drainage	1.063 Drainage
R1	pond	0.173 Drift	0.108 Drift	0.108 Drift	0.083 Runoff	0.072 Drift
R1, 2nd	pond	0.173 Drift	0.108 Drift	0.108 Drift	0.072 Drift	0.072 Drift
R1	stream	3.317 Drift	0.643 Drift	0.643 Drift	0.339 Runoff	0.334 Drift
R1, 2nd	stream	3.317 Drift	0.643 Drift	0.643 Drift	0.357 Runoff	0.334 Drift
R2	stream	4.447 Drift	0.861 Drift	0.861 Drift	0.448 Drift	0.448 Drift
R2, 2nd	stream	4.396 Drift	0.852 Drift	0.852 Drift	0.443 Runoff	0.443 Drift
R3	stream	4.674 Drift	0.906 Drift	0.906 Drift	0.690 Runoff	0.471 Drift
R3, 2nd	stream	4.658 Drift	0.963 Runoff	0.902 Drift	0.963 Runoff	0.469 Drift
R4	stream	3.312 Drift	0.642 Drift	0.642 Drift	0.446 Runoff	0.333 Drift
R4, 2nd	stream	3.317 Drift	0.643 Drift	0.643 Drift	0.580 Runoff	0.334 Drift

PECsw,max of RP35606 following multiple applications to leafy vegetables (late) - iprodione soil DT50 = 94.1 days

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	3.693 Drift	0.544 Drift	0.544 Drift	0.297 Drift	0.297 Drift
D3, 2nd	ditch	3.712 Drift	0.564 Drift	0.564 Drift	0.317 Drift	0.317 Drift
D4	pond	1.842 Drainage	1.838 Drainage	1.838 Drainage	1.836 Drainage	1.836 Drainage
D4	stream	3.073 Drift	2.485 Drainage	2.485 Drainage	2.485 Drainage	2.485 Drainage
D6	ditch	3.926 Drift	3.168 Drainage	3.168 Drainage	3.168 Drainage	3.168 Drainage
R1	pond	0.361 Runoff	0.354 Runoff	0.154 Runoff	0.351 Runoff	0.091 Drift
R1, 2nd	pond	0.211 Drift	0.161 Runoff	0.130 Drift	0.137 Runoff	0.086 Drift
R1	stream	2.403 Drift	1.437 Runoff	0.654 Runoff	1.437 Runoff	0.342 Runoff
R1, 2nd	stream	2.405 Drift	1.419 Runoff	0.646 Runoff	1.419 Runoff	0.338 Runoff
R2	stream	3.224 Drift	1.410 Runoff	0.641 Runoff	1.410 Runoff	0.336 Runoff
R2, 2nd	stream	3.224 Drift	0.621 Runoff	0.606 Drift	0.621 Runoff	0.311 Drift
R3	stream	3.389 Drift	2.056 Runoff	0.897 Runoff	2.056 Runoff	0.463 Runoff
R3, 2nd	stream	3.391 Drift	1.497 Runoff	0.684 Runoff	1.497 Runoff	0.359 Runoff
R4	stream	2.401 Drift	0.836 Runoff	0.451 Drift	0.836 Runoff	0.232 Drift
R4, 2nd	stream	2.405 Drift	0.895 Runoff	0.452 Drift	0.895 Runoff	0.232 Drift

PECsw,max of RP35606 following single application to root vegetables (early) - iprodione soil DT50 = 5 days

Scenario	Water body	PEC$_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	5.013 Drift	0.721 Drift	0.721 Drift	0.375 Drift	0.375 Drift
D6	ditch	5.109 Drift	2.073 Drainage	2.073 Drainage	2.073 Drainage	2.073 Drainage
R1	pond	0.587 Runoff	0.541 Runoff	0.264 Runoff	0.515 Runoff	0.145 Runoff
R1	stream	5.234 Runoff	5.234 Runoff	2.368 Runoff	5.234 Runoff	1.237 Runoff
R2	stream	4.853 Runoff	4.853 Runoff	2.192 Runoff	4.853 Runoff	1.146 Runoff
R2, 2nd	stream	4.447 Drift	0.861 Drift	0.861 Drift	0.448 Drift	0.448 Drift
R3	stream	5.637 Runoff	5.637 Runoff	2.554 Runoff	5.637 Runoff	1.336 Runoff
R4	stream	4.024 Runoff	4.024 Runoff	1.826 Runoff	4.024 Runoff	0.956 Runoff

PECsw,max of RP35606 following multiple applications to root vegetables (early) - iprodione soil DT50 = 5 days

Scenario	Water body	PEC$_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	3.374 Drift	0.478 Drift	0.478 Drift	0.247 Drift	0.247 Drift
D6	ditch	9.650 Drainage	9.650 Drainage	9.650 Drainage	9.650 Drainage	9.650 Drainage
R1	pond	1.055 Runoff	0.998 Runoff	0.459 Runoff	0.967 Runoff	0.245 Runoff
R1	stream	12.123 Runoff	12.123 Runoff	5.511 Runoff	12.123 Runoff	2.886 Runoff
R2	stream	9.850 Runoff	9.850 Runoff	4.450 Runoff	9.850 Runoff	2.325 Runoff
R2, 2nd	stream	3.037 Runoff	3.037 Runoff	1.380 Runoff	3.037 Runoff	0.723 Runoff
R3	stream	9.704 Runoff	9.704 Runoff	4.433 Runoff	9.704 Runoff	2.327 Runoff
R4	stream	10.090 Runoff	10.090 Runoff	4.587 Runoff	10.090 Runoff	2.403 Runoff

PECsw,max of RP35606 following single application to root vegetables (late) - iprodione soil DT50 = 5 days

Scenario	Water body	PEC$_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	5.013 Drift	0.721 Drift	0.721 Drift	0.375 Drift	0.375 Drift
D6	ditch	4.990 Drift	4.397 Drainage	4.397 Drainage	4.397 Drainage	4.397 Drainage
R1	pond	0.478 Runoff	0.442 Runoff	0.217 Runoff	0.422 Runoff	0.120 Runoff
R1	stream	4.265 Runoff	4.265 Runoff	1.841 Runoff	4.265 Runoff	0.945 Runoff
R2	stream	4.378 Drift	3.573 Runoff	1.596 Runoff	3.573 Runoff	0.830 Runoff
R2, 2nd	stream	4.447 Drift	1.084 Runoff	0.861 Drift	1.084 Runoff	0.448 Drift
R3	stream	4.734 Runoff	4.734 Runoff	2.163 Runoff	4.734 Runoff	1.135 Runoff
R4	stream	4.658 Runoff	4.658 Runoff	2.116 Runoff	4.658 Runoff	1.109 Runoff

PECsw,max of RP35606 following multiple applications to root vegetables (late) - iprodione soil DT50 = 5 days

Scenario	Water body	PEC$_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	3.376 Drift	0.479 Drift	0.479 Drift	0.249 Drift	0.249 Drift
D6	ditch	11.343 Drainage	11.343 Drainage	11.343 Drainage	11.343 Drainage	11.343 Drainage
R1	pond	0.968 Drift	0.912 Runoff	0.442 Drift	0.883 Runoff	0.246 Drift
R1	stream	12.301 Runoff	12.301 Runoff	5.591 Runoff	12.301 Runoff	2.928 Runoff
R2	stream	10.387 Runoff	10.387 Runoff	4.692 Runoff	10.387 Runoff	2.452 Runoff
R2, 2nd	stream	2.984 Drift	1.192 Runoff	0.570 Drift	1.192 Runoff	0.295 Drift
R3	stream	14.007 Runoff	14.007 Runoff	6.399 Runoff	14.007 Runoff	3.356 Runoff
R4	stream	8.861 Runoff	8.861 Runoff	4.016 Runoff	8.861 Runoff	2.101 Runoff

PECsw,max of RP35606 following single application to leafy vegetables (early) - iprodione soil DT50 = 5 days

Scenario	Water body	PEC$_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	5.013 Drift	0.721 Drift	0.721 Drift	0.375 Drift	0.375 Drift
D3, 2nd	ditch	5.024 Drift	0.731 Drift	0.731 Drift	0.385 Drift	0.385 Drift
D4	pond	0.178 Drift	0.113 Drift	0.113 Drift	0.077 Drift	0.077 Drift
D4	stream	4.005 Drift	0.782 Drift	0.782 Drift	0.410 Drift	0.410 Drift
D6	ditch	5.017 Drainage	5.017 Drainage	5.017 Drainage	5.017 Drainage	5.017 Drainage
R1	pond	0.220 Runoff	0.198 Runoff	0.108 Drift	0.187 Runoff	0.072 Drift
R1, 2nd	pond	0.206 Runoff	0.188 Runoff	0.108 Drift	0.178 Runoff	0.072 Drift
R1	stream	3.306 Drift	3.076 Runoff	1.395 Runoff	3.076 Runoff	0.730 Runoff
R1, 2nd	stream	3.317 Drift	2.513 Runoff	1.143 Runoff	2.513 Runoff	0.599 Runoff
R2	stream	4.867 Runoff	4.867 Runoff	2.199 Runoff	4.867 Runoff	1.149 Runoff
R2, 2nd	stream	4.447 Drift	0.861 Drift	0.861 Drift	0.448 Drift	0.448 Drift
R3	stream	5.659 Runoff	5.659 Runoff	2.564 Runoff	5.659 Runoff	1.341 Runoff
R3, 2nd	stream	6.137 Runoff	6.137 Runoff	2.803 Runoff	6.137 Runoff	1.471 Runoff
R4	stream	3.302 Drift	2.015 Runoff	0.917 Runoff	2.015 Runoff	0.480 Runoff
R4, 2nd	stream	10.209 Runoff	10.209 Runoff	4.637 Runoff	10.209 Runoff	2.429 Runoff

PECsw,max of RP35606 following multiple applications to leafy vegetables (early) - iprodione soil DT50 = 5 days

Scenario	Water body	PEC$_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	3.657 Drift	0.508 Drift	0.508 Drift	0.261 Drift	0.261 Drift
D3, 2nd	ditch	3.704 Drift	0.556 Drift	0.556 Drift	0.309 Drift	0.309 Drift
D4	pond	0.271 Drift	0.190 Drift	0.190 Drift	0.147 Drift	0.147 Drift
D4	stream	2.918 Drift	0.648 Drift	0.648 Drift	0.401 Drift	0.401 Drift
D6	ditch	5.022 Drainage	5.022 Drainage	5.022 Drainage	5.022 Drainage	5.022 Drainage
R1	pond	0.736 Runoff	0.703 Runoff	0.345 Drift	0.685 Runoff	0.196 Drift
R1, 2nd	pond	0.634 Drift	0.550 Drift	0.302 Drift	0.505 Drift	0.174 Drift
R1	stream	7.485 Runoff	7.485 Runoff	3.395 Runoff	7.485 Runoff	1.777 Runoff
R1, 2nd	stream	6.822 Runoff	6.822 Runoff	3.103 Runoff	6.822 Runoff	1.626 Runoff
R2	stream	6.472 Runoff	6.472 Runoff	2.922 Runoff	6.472 Runoff	1.528 Runoff
R2, 2nd	stream	3.224 Drift	2.342 Runoff	1.051 Runoff	2.342 Runoff	0.548 Runoff
R3	stream	11.044 Runoff	11.044 Runoff	5.046 Runoff	11.044 Runoff	2.648 Runoff
R3, 2nd	stream	9.351 Runoff	9.351 Runoff	4.269 Runoff	9.351 Runoff	2.241 Runoff
R4	stream	8.984 Runoff	8.984 Runoff	4.088 Runoff	8.984 Runoff	2.141 Runoff
R4, 2nd	stream	10.209 Runoff	10.209 Runoff	4.637 Runoff	10.209 Runoff	2.429 Runoff

PECsw,max of RP35606 following single application to leafy vegetables (late) - iprodione soil DT50 = 5 days

Scenario	Water body	PEC$_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	5.012 Drift	0.721 Drift	0.721 Drift	0.375 Drift	0.375 Drift
D3, 2nd	ditch	5.014 Drift	0.738 Drift	0.738 Drift	0.393 Drift	0.393 Drift
D4	pond	0.257 Drainage	0.255 Drainage	0.255 Drainage	0.254 Drainage	0.254 Drainage
D4	stream	3.778 Drift	0.741 Drift	0.741 Drift	0.391 Drift	0.391 Drift
D6	ditch	9.123 Drainage	9.123 Drainage	9.123 Drainage	9.123 Drainage	9.123 Drainage
R1	pond	0.583 Runoff	0.554 Runoff	0.255 Runoff	0.538 Runoff	0.137 Runoff
R1, 2nd	pond	0.191 Runoff	0.181 Runoff	0.108 Drift	0.175 Runoff	0.072 Drift
R1	stream	3.892 Runoff	3.892 Runoff	1.768 Runoff	3.892 Runoff	0.926 Runoff
R1, 2nd	stream	3.317 Drift	3.011 Runoff	1.263 Runoff	3.011 Runoff	0.642 Runoff
R2	stream	4.447 Drift	2.245 Runoff	1.023 Runoff	2.245 Runoff	0.536 Runoff
R2, 2nd	stream	4.396 Drift	3.981 Runoff	1.808 Runoff	3.981 Runoff	0.947 Runoff
R3	stream	4.674 Drift	4.188 Runoff	1.828 Runoff	4.188 Runoff	0.942 Runoff
R3, 2nd	stream	7.272 Runoff	7.272 Runoff	3.320 Runoff	7.272 Runoff	1.742 Runoff
R4	stream	4.833 Runoff	4.833 Runoff	2.190 Runoff	4.833 Runoff	1.146 Runoff
R4, 2nd	stream	4.770 Runoff	4.770 Runoff	2.175 Runoff	4.770 Runoff	1.140 Runoff

PECsw,max of RP35606 following multiple applications to leafy vegetables (late) - iprodione soil DT50 = 5 days

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}] and main entry route				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	3.657 Drift	0.508 Drift	0.508 Drift	0.261 Drift	0.261 Drift
D3, 2nd	ditch	3.704 Drift	0.555 Drift	0.555 Drift	0.309 Drift	0.309 Drift
D4	pond	1.029 Drainage	1.024 Drainage	1.024 Drainage	1.022 Drainage	1.022 Drainage
D4	stream	3.093 Drift	1.461 Drainage	1.461 Drainage	1.461 Drainage	1.461 Drainage
D6	ditch	14.676 Drainage	14.676 Drainage	14.676 Drainage	14.676 Drainage	14.676 Drainage
R1	pond	0.858 Runoff	0.799 Runoff	0.379 Runoff	0.768 Runoff	0.205 Runoff
R1, 2nd	pond	0.585 Runoff	0.540 Runoff	0.260 Runoff	0.516 Runoff	0.142 Runoff
R1	stream	9.544 Runoff	9.544 Runoff	4.339 Runoff	9.544 Runoff	2.272 Runoff
R1, 2nd	stream	7.469 Runoff	7.469 Runoff	3.397 Runoff	7.469 Runoff	1.780 Runoff
R2	stream	5.902 Runoff	5.902 Runoff	2.629 Runoff	5.902 Runoff	1.365 Runoff
R2, 2nd	stream	3.799 Runoff	3.799 Runoff	1.724 Runoff	3.799 Runoff	0.903 Runoff
R3	stream	9.273 Runoff	9.273 Runoff	4.237 Runoff	9.273 Runoff	2.224 Runoff
R3, 2nd	stream	10.392 Runoff	10.392 Runoff	4.745 Runoff	10.392 Runoff	2.490 Runoff
R4	stream	8.582 Runoff	8.582 Runoff	3.905 Runoff	8.582 Runoff	2.045 Runoff
R4, 2nd	stream	7.976 Runoff	7.976 Runoff	3.629 Runoff	7.976 Runoff	1.901 Runoff

Since the risk assessment for aquatic organisms is based on the sum of PECsw for iprodione and RP 35606 for soils with pH CaCl2 ≥ 5.9 (iprodione soil DT50 of 5 days), the corresponding values are reported below.

Sum of PECsw,max of iprodione and RP 35606 following single application to root vegetables (early application) – iprodione soil DT50 = 5 days

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}]				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	9.763	1.403	1.403	0.730	0.730
D6	ditch	9.849	2.754	2.754	2.427	2.427
R1	pond	1.037	0.952	0.468	0.905	0.258
R1	stream	9.550	9.550	4.319	9.550	2.257
R2	stream	8.990	5.794	2.993	5.794	1.562
R2, 2nd	stream	8.657	1.677	1.677	0.872	0.872
R3	stream	10.034	9.462	4.287	9.462	2.242
R4	stream	12.689	12.689	5.758	12.689	3.013

Sum of PECsw,max of iprodione and RP 35606 following multiple applications to root vegetables (early application) – iprodione soil DT50 = 5 days

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}]				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	6.573	0.930	0.930	0.481	0.481
D6	ditch	12.843	10.101	10.101	9.883	9.883
R1	pond	1.595	1.470	0.716	1.402	0.392
R1	stream	16.439	16.439	7.462	16.439	3.906
R2	stream	12.753	12.753	5.761	12.753	3.010
R2, 2nd	stream	5.863	3.577	1.920	3.342	1.002
R3	stream	15.301	15.301	6.990	15.301	3.669
R4	stream	23.193	23.193	10.540	23.193	5.522

Sum of PECsw,max of iprodione and RP 35606 following single application to root vegetables (late application) – iprodione soil DT50 = 5 days

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}]				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	9.762	1.403	1.403	0.730	0.730
D6	ditch	9.657	5.067	5.067	4.745	4.745
R1	pond	1.155	1.088	0.511	1.051	0.277
R1	stream	7.389	7.043	3.107	7.043	1.609
R2	stream	8.523	4.376	2.399	4.256	1.247
R2, 2nd	stream	8.657	1.900	1.677	1.508	0.872
R3	stream	9.131	6.025	3.015	6.025	1.578
R4	stream	11.663	11.663	5.300	11.663	2.775

Sum of PECsw,max of iprodione and RP 35606 following multiple applications to root vegetables (late application) – iprodione soil DT50 = 5 days

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}]				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	6.574	0.931	0.931	0.483	0.483
D6	ditch	14.537	11.794	11.794	11.576	11.576
R1	pond	1.454	1.316	0.684	1.249	0.389
R1	stream	16.486	16.486	7.482	16.486	3.916
R2	stream	14.109	13.099	5.915	13.099	3.091
R2, 2nd	stream	5.810	1.732	1.110	1.471	0.574
R3	stream	18.986	18.986	8.620	18.986	4.511
R4	stream	23.616	23.616	10.701	23.616	5.599

Sum of PECsw,max of iprodione and RP 35606 following single application to leafy vegetables (early application) – iprodione soil DT50 = 5 days

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}]				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	9.763	1.403	1.403	0.730	0.730
D3, 2nd	ditch	9.773	1.413	1.413	0.740	0.740
D4	pond	0.342	0.215	0.215	0.145	0.145
D4	stream	7.790	1.515	1.515	0.791	0.791
D6	ditch	9.676	5.686	5.686	5.365	5.365
R1	pond	0.384	0.306	0.210	0.285	0.140
R1, 2nd	pond	0.370	0.290	0.210	0.246	0.140
R1	stream	6.436	4.449	2.018	4.449	1.056
R1, 2nd	stream	6.458	3.121	1.751	3.063	0.915
R2	stream	9.005	5.806	3.001	5.806	1.565
R2, 2nd	stream	8.657	1.677	1.677	0.872	0.872
R3	stream	10.056	9.511	4.309	9.511	2.253
R3, 2nd	stream	10.550	6.992	3.658	6.905	1.915
R4	stream	6.428	3.269	1.523	3.269	0.795
R4, 2nd	stream	15.008	15.008	6.817	15.008	3.570

Sum of PECsw,max of iprodione and RP 35606 following multiple applications to leafy vegetables (early application) – iprodione soil DT50 = 5 days

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}]				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	7.120	0.988	0.988	0.508	0.508
D3, 2nd	ditch	7.168	1.036	1.036	0.556	0.556
D4	pond	0.459	0.305	0.305	0.223	0.223
D4	stream	5.663	1.164	1.164	0.666	0.666
D6	ditch	8.454	5.498	5.498	5.266	5.266
R1	pond	1.290	1.179	0.612	1.118	0.350
R1, 2nd	pond	0.990	0.830	0.487	0.744	0.286
R1	stream	13.329	13.329	6.045	13.329	3.164
R1, 2nd	stream	9.496	9.496	4.319	9.496	2.263
R2	stream	9.479	7.941	3.586	7.941	1.875
R2, 2nd	stream	6.277	2.984	1.625	2.984	0.843
R3	stream	16.553	16.553	7.563	16.553	3.969
R3, 2nd	stream	12.564	11.811	5.392	11.811	2.830
R4	stream	20.923	20.923	9.518	20.923	4.986
R4, 2nd	stream	15.113	15.113	6.841	15.113	3.578

Sum of PECsw,max of iprodione and RP 35606 following single application to leafy vegetables (late application) – iprodione soil DT50 = 5 days

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}]				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	9.757	1.403	1.403	0.729	0.729
D3, 2nd	ditch	9.745	1.418	1.418	0.746	0.746
D4	pond	0.421	0.357	0.357	0.322	0.322
D4	stream	7.343	1.432	1.432	0.750	0.750
D6	ditch	13.812	9.797	9.797	9.473	9.473
R1	pond	0.966	0.913	0.426	0.884	0.230
R1, 2nd	pond	0.355	0.292	0.210	0.283	0.140
R1	stream	7.033	6.044	2.745	6.044	1.438
R1, 2nd	stream	6.458	4.151	1.871	4.151	0.958
R2	stream	8.657	3.061	1.839	2.669	0.960
R2, 2nd	stream	8.558	5.368	2.614	5.368	1.366
R3	stream	9.099	5.045	2.685	4.725	1.387
R3, 2nd	stream	11.682	9.548	4.359	9.548	2.287
R4	stream	10.617	10.617	4.821	10.617	2.525
R4, 2nd	stream	9.262	9.262	4.219	9.262	2.211

Sum of PECsw,max of iprodione and RP 35606 following multiple applications to leafy vegetables (late application) – iprodione soil DT50 = 5 days

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}]				
		Step 3	Step 4			
		Edge of field	10mD	10mD+R	20mD	20mD+R
D3	ditch	7.121	0.988	0.988	0.508	0.508
D3, 2nd	ditch	7.167	1.035	1.035	0.556	0.556
D4	pond	1.211	1.136	1.136	1.096	1.096
D4	stream	5.919	1.992	1.992	1.734	1.734
D6	ditch	18.137	15.329	15.329	15.329	15.329
R1	pond	1.306	1.197	0.587	1.139	0.322
R1, 2nd	pond	0.859	0.776	0.391	0.731	0.219
R1	stream	13.718	13.718	6.237	13.718	3.266
R1, 2nd	stream	10.280	10.280	4.675	10.280	2.450
R2	stream	8.956	7.215	3.214	7.215	1.669
R2, 2nd	stream	6.852	5.240	2.381	5.240	1.247
R3	stream	14.291	14.291	6.529	14.291	3.427
R3, 2nd	stream	13.604	13.310	6.078	13.310	3.189
R4	stream	19.781	19.781	8.999	19.781	4.714
R4, 2nd	stream	13.191	13.191	6.006	13.191	3.147

Metabolite RP 30228 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 330.2 g/mol Soil or water metabolite: both Koc (mL/g): 3534 (arithmetic mean) DT_{50} soil (d): 35.5 (normalised geomean from laboratory) DT_{50} water/sediment system (d): 1000 (FOCUS default) DT_{50} water (d): 1000 (FOCUS default) DT_{50} sediment (d): 1000 (FOCUS default) Maximum occurrence observed (% molar basis with respect to the parent) Total Water and Sediment: 79% Soil: 31% (the correct value is 29.5%)
Parameters used in FOCUSsw step 3 (if performed)	Water solubility (mg/L): 100 (default) Vapour pressure: 10^{-9} Pa at 20°C (default) Koc (mL/g): 3534 (arithmetic mean) 1/n: 0.905 (arithmetic mean) Q10=2.58, Walker equation coefficient 0.7 Crop uptake factor: 0 Metabolite kinetically generated in simulation : yes Formation fraction in soil (k_f/k_{dp}): 0.411 (molar basis) from RP 35606 Formation fraction in sediment water (k_f/k_{dp}): 0.79 from RP 35606
Application rate	Same as parent iprodione

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Roots vegetables*	0 h	76.068	-	2050	-
Leafy vegetables*	0 h	57.051	-	1540	-

* Calculations are reported for multiple applications only (worst-case compared to single application)

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)			
		Roots vegetables*		Roots vegetables*	
		Actual	TWA	Actual	TWA
Southern EU March-May*	0 h	15.026	-	11.685	-

* Worst-case compared to Northern Europe / Calculations are reported for multiple applications only (worst-case compared to single application)

Reminder: PECsw Step 3 are provisional (incorrect Kfoc and 1/n were used for precursors)

PECsw,max of RP 30228 following single and multiple applications to root vegetables (early and late) - iprodione soil DT50 = 94.1 days

Scenario	Water body	Step 3 $PEC_{sw,max}$ [µg L^{-1}] and main entry route			
		Early application		Late application	
		Single application	Multiple applications	Single application	Multiple applications
		Edge of field	Edge of field	Edge of field	Edge of field
R1	pond	0.002 Runoff	0.015 Runoff	0.006 Runoff	0.019 Runoff
R1	stream	0.008 Runoff	0.051 Runoff	0.012 Runoff	0.067 Runoff
R2	stream	0.010 Runoff	0.040 Runoff	0.009 Runoff	0.039 Runoff
R2, 2nd	stream	0.021 Runoff	0.055 Runoff	0.004 Runoff	0.082 Runoff
R3	stream	0.012 Runoff	0.058 Runoff	0.015 Runoff	0.100 Runoff
R4	stream	0.004 Runoff	0.026 Runoff	0.006 Runoff	0.017 Runoff
D3	ditch	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage
D6	ditch	0.039 Drainage	0.132 Drainage	0.020 Drainage	0.158 Drainage

PECsw,max of RP 30228 following single and multiple applications to leafy vegetables (early and late) - iprodione soil DT50 = 94.1 days

Scenario	Water body	Step 3 $PEC_{sw,max}$ [µg L^{-1}] and main entry route			
		Early application		Late application	
		Single application	Multiple applications	Single application	Multiple applications
		Edge of field	Edge of field	Edge of field	Edge of field
R1	pond	0.006 Runoff	0.023 Runoff	0.003 Runoff	0.026 Runoff
R1, 2nd	pond	0.005 Runoff	0.011 Runoff	0.003 Runoff	0.017 Runoff
R1	stream	0.010 Runoff	0.040 Runoff	0.006 Runoff	0.043 Runoff
R1, 2nd	stream	0.009 Runoff	0.018 Runoff	0.003 Runoff	0.032 Runoff
R2	stream	0.010 Runoff	0.029 Runoff	0.009 Runoff	0.034 Runoff
R2, 2nd	stream	0.021 Runoff	0.026 Runoff	0.004 Runoff	0.009 Runoff
R3	stream	0.012 Runoff	0.042 Runoff	0.015 Runoff	0.048 Runoff
R3, 2nd	stream	0.034 Runoff	0.088 Runoff	0.027 Runoff	0.073 Runoff
R4	stream	0.006 Runoff	0.018 Runoff	0.004 Runoff	0.012 Runoff
R4, 2nd	stream	0.021 Runoff	0.043 Runoff	0.031 Runoff	0.072 Runoff

D3	ditch	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage
D3, 2nd	ditch	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage
D4	pond	0.011 Drainage	0.034 Drainage	0.004 Drainage	0.019 Drainage
D4	stream	0.018 Drainage	0.055 Drainage	0.005 Drainage	0.029 Drainage
D6	ditch	0.045 Drainage	0.106 Drainage	0.017 Drainage	0.065 Drainage

PECsw,max of RP 30228 following single and multiple applications to root vegetables (early and late) - iprodione soil DT50 = 5 days

Scenario	Water body	Step 3 $PEC_{sw,max}$ [µg L^{-1}] and main entry route			
		Early application		Late application	
		Single application	Multiple applications	Single application	Multiple applications
		Edge of field	Edge of field	Edge of field	Edge of field
R1	pond	0.005 Runoff	0.030 Runoff	0.011 Runoff	0.040 Runoff
R1	stream	0.027 Runoff	0.213 Runoff	0.034 Runoff	0.282 Runoff
R2	stream	0.023 Runoff	0.088 Runoff	0.021 Runoff	0.078 Runoff
R2, 2nd	stream	0.041 Runoff	0.138 Runoff	0.022 Runoff	0.161 Runoff
R3	stream	0.056 Runoff	0.279 Runoff	0.072 Runoff	0.345 Runoff
R4	stream	0.031 Runoff	0.246 Runoff	0.048 Runoff	0.128 Runoff
D3	ditch	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage
D6	ditch	0.003 Drainage	0.012 Drainage	0.004 Drainage	0.016 Drainage

PECsw,max of RP 30228 following single and multiple applications to leafy vegetables (early and late) - iprodione soil DT50 = 5 days

Scenario	Water body	Step 3 $PEC_{sw,max}$ [µg L^{-1}] and main entry route			
		Early application		Late application	
		Single application	Multiple applications	Single application	Multiple applications
		Edge of field	Edge of field	Edge of field	Edge of field
R1	pond	0.011 Runoff	0.056 Runoff	0.015 Runoff	0.071 Runoff
R1, 2nd	pond	0.033 Runoff	0.082 Runoff	0.020 Runoff	0.106 Runoff
R1	stream	0.041 Runoff	0.187 Runoff	0.042 Runoff	0.159 Runoff
R1, 2nd	stream	0.080 Runoff	0.155 Runoff	0.034 Runoff	0.252 Runoff
R2	stream	0.024 Runoff	0.055 Runoff	0.020 Runoff	0.078 Runoff
R2, 2nd	stream	0.042 Runoff	0.067 Runoff	0.020 Runoff	0.028 Runoff
R3	stream	0.055 Runoff	0.219 Runoff	0.061 Runoff	0.247 Runoff
R3, 2nd	stream	0.226 Runoff	0.283 Runoff	0.135 Runoff	0.209 Runoff
R4	stream	0.048 Runoff	0.188 Runoff	0.055 Runoff	0.147 Runoff
R4, 2nd	stream	0.174 Runoff	0.271 Runoff	0.115 Runoff	0.258 Runoff
D3	ditch	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage
D3, 2nd	ditch	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage
D4	pond	0.004 Drainage	0.010 Drainage	0.002 Drainage	0.016 Drainage
D4	stream	0.006 Drainage	0.020 Drainage	0.003 Drainage	0.021 Drainage
D6	ditch	0.028 Drainage	0.096 Drainage	0.036 Drainage	0.116 Drainage

Metabolite RP 36221 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 290.1 g/mol Soil or water metabolite: soil Koc (mL/g): 19862 (arithmetic mean) (correct value is 7121 mL/g) DT_{50} soil (d): 1000 (worst-case from laboratory) (correct value is 600.8 d, geometric mean) DT_{50} water/sediment system (d): 1000 (FOCUS default) DT_{50} water (d): 1000 (FOCUS default) DT_{50} sediment (d): 1000 (FOCUS default) Maximum occurrence observed (% molar basis with respect to the parent) Total Water and Sediment: 0.001% Soil: 12.7%
Parameters used in FOCUSsw step 3 (if performed)	Water solubility (mg/L): 100 (default) Vapour pressure: 10^{-9} Pa at 20°C (default) Koc (mL/g): 19862 (arithmetic mean) (correct value is 7121 mL/g) 1/n: 0.854 Q10=2.58, Walker equation coefficient 0.7 Crop uptake factor: 0 Metabolite kinetically generated in simulation : no
Application rate	Same as parent iprodione Pseudo-application in Step 3 considering granular application, with application rate corrected for molar ratio, maximum occurrence of 12.7% and crop interception (25/25/60/60% for root vegetables, 25/25/40% for leafy vegetables)

Reminder: PECsw Step 1 to 4 are provisional (incorrect Kfoc was used)

FOCUS STEP 1 Scenario	**Day after overall maximum**	**PEC_{SW} (µg/L)**			
		Roots vegetables*		Leafy vegetables*	
		Actual	**TWA**	**Actual**	**TWA**
	0h	4.060	-	3.045	-

* Calculations are reported for multiple applications only (worst-case compared to single application)

FOCUS STEP 2 Scenario	**Day after overall maximum**	**PEC_{SW} (µg/L)**			
		Roots vegetables		Leafy vegetables	
		Actual	**TWA**	**Actual**	**TWA**
Southern EU March-May*	0 h	1.202	-	0.902	-

* Worst-case compared to Northern Europe / Calculations are reported for multiple applications only (worst-case compared to single application)

PECsw,max of RP 36221 following single and multiple applications to root vegetables (early application)

Scenario	Water body	PEC$_{sw,max}$ [µg L^{-1}] and main entry route					
		Single application			Multiple applications		
		Step 3	Step 4		Step 3	Step 4	
		Edge-of-Field	10mD+R	20mD+R	Edge-of-Field	10mD+R	20mD+R
D3	ditch	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage
D6	ditch	0.003 Drainage	0.003 Drainage	0.003 Drainage	0.014 Drainage	0.014 Drainage	0.014 Drainage
R1	pond	0.022 Runoff	0.009 Runoff	0.004 Runoff	0.080 Runoff	0.032 Runoff	0.016 Runoff
R1	stream	0.062 Runoff	0.028 Runoff	0.015 Runoff	0.221 Runoff	0.100 Runoff	0.052 Runoff
R2	stream	0.008 Runoff	0.004 Runoff	0.002 Runoff	0.030 Runoff	0.013 Runoff	0.007 Runoff
R2, 2nd	stream	0.018 Runoff	0.008 Runoff	0.004 Runoff	0.065 Runoff	0.029 Runoff	0.015 Runoff
R3	stream	0.043 Runoff	0.019 Runoff	0.010 Runoff	0.154 Runoff	0.070 Runoff	0.037 Runoff
R4	stream	0.088 Runoff	0.040 Runoff	0.021 Runoff	0.297 Runoff	0.134 Runoff	0.070 Runoff

PECsw,max of RP 36221 following single and multiple applications to root vegetables (late application)

Scenario	Water body	PEC$_{sw,max}$ [µg L^{-1}] and main entry route					
		Single application			Multiple applications		
		Step 3	Step 4		Step 3	Step 4	
		Edge-of-Field	10mD+R	20mD+R	Edge-of-Field	10mD+R	20mD+R
D3	ditch	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage
D6	ditch	0.003 Drainage	0.003 Drainage	0.003 Drainage	0.014 Drainage	0.014 Drainage	0.014 Drainage
R1	pond	0.020 Runoff	0.008 Runoff	0.004 Runoff	0.082 Runoff	0.033 Runoff	0.016 Runoff
R1	stream	0.039 Runoff	0.018 Runoff	0.009 Runoff	0.220 Runoff	0.099 Runoff	0.052 Runoff
R2	stream	0.008 Runoff	0.004 Runoff	0.002 Runoff	0.030 Runoff	0.013 Runoff	0.007 Runoff
R2, 2nd	stream	0.018 Runoff	0.008 Runoff	0.004 Runoff	0.064 Runoff	0.029 Runoff	0.015 Runoff
R3	stream	0.043 Runoff	0.020 Runoff	0.010 Runoff	0.167 Runoff	0.076 Runoff	0.039 Runoff
R4	stream	0.088 Runoff	0.040 Runoff	0.021 Runoff	0.262 Runoff	0.119 Runoff	0.062 Runoff

PECsw,max of RP 36221 following single and multiple applications to leafy vegetables (early application)

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}] and main entry route					
		Single application			Multiple applications		
		Step 3	Step 4		Step 3	Step 4	
		Edge-of-Field	10mD+R	20mD+R	Edge-of-Field	10mD+R	20mD+R
D3	ditch	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage
D3, 2nd	ditch	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage
D4	pond	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage
D4	stream	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	0.004 Drainage	0.004 Drainage	0.004 Drainage
D6	ditch	0.003 Drainage	0.003 Drainage	0.003 Drainage	0.016 Drainage	0.016 Drainage	0.016 Drainage
R1	pond	0.034 Runoff	0.014 Runoff	0.007 Runoff	0.109 Runoff	0.045 Runoff	0.022 Runoff
R1, 2nd	pond	0.022 Runoff	0.009 Runoff	0.005 Runoff	0.074 Runoff	0.031 Runoff	0.015 Runoff
R1	stream	0.061 Runoff	0.028 Runoff	0.014 Runoff	0.195 Runoff	0.088 Runoff	0.046 Runoff
R1, 2nd	stream	0.038 Runoff	0.017 Runoff	0.009 Runoff	0.125 Runoff	0.057 Runoff	0.030 Runoff
R2	stream	0.008 Runoff	0.004 Runoff	0.002 Runoff	0.027 Runoff	0.012 Runoff	0.006 Runoff
R2, 2nd	stream	0.017 Runoff	0.008 Runoff	0.004 Runoff	0.059 Runoff	0.027 Runoff	0.014 Runoff
R3	stream	0.042 Runoff	0.019 Runoff	0.010 Runoff	0.138 Runoff	0.063 Runoff	0.033 Runoff
R3, 2nd	stream	0.012 Runoff	0.006 Runoff	0.003 Runoff	0.040 Runoff	0.018 Runoff	0.010 Runoff
R4	stream	0.075 Runoff	0.034 Runoff	0.018 Runoff	0.233 Runoff	0.105 Runoff	0.055 Runoff
R4, 2nd	stream	0.075 Runoff	0.034 Runoff	0.018 Runoff	0.221 Runoff	0.100 Runoff	0.052 Runoff

PECsw,max of RP 36221 following single and multiple applications to leafy vegetables (late application)

Scenario	Water body	$PEC_{sw,max}$ [µg L^{-1}] and main entry route					
		Single application			Multiple applications		
		Step 3	Step 4		Step 3	Step 4	
		Edge-of-Field	10mD+R	20mD+R	Edge-of-Field	10mD+R	20mD+R
D3	ditch	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage
D3, 2nd	ditch	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage
D4	pond	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage
D4	stream	<0.001 Drainage	<0.001 Drainage	<0.001 Drainage	0.004 Drainage	0.004 Drainage	0.004 Drainage
D6	ditch	0.003 Drainage	0.003 Drainage	0.003 Drainage	0.016 Drainage	0.016 Drainage	0.016 Drainage
R1	pond	0.021 Runoff	0.009 Runoff	0.004 Runoff	0.110 Runoff	0.045 Runoff	0.023 Runoff
R1, 2nd	pond	0.022 Runoff	0.009 Runoff	0.005 Runoff	0.074 Runoff	0.030 Runoff	0.015 Runoff
R1	stream	0.038 Runoff	0.017 Runoff	0.009 Runoff	0.197 Runoff	0.089 Runoff	0.046 Runoff
R1, 2nd	stream	0.038 Runoff	0.017 Runoff	0.009 Runoff	0.125 Runoff	0.057 Runoff	0.030 Runoff
R2	stream	0.008 Runoff	0.004 Runoff	0.002 Runoff	0.027 Runoff	0.012 Runoff	0.006 Runoff
R2, 2nd	stream	0.008 Runoff	0.004 Runoff	0.002 Runoff	0.058 Runoff	0.026 Runoff	0.014 Runoff
R3	stream	0.041 Runoff	0.018 Runoff	0.010 Runoff	0.132 Runoff	0.060 Runoff	0.031 Runoff
R3, 2nd	stream	0.012 Runoff	0.006 Runoff	0.003 Runoff	0.039 Runoff	0.018 Runoff	0.009 Runoff
R4	stream	0.076 Runoff	0.034 Runoff	0.018 Runoff	0.226 Runoff	0.102 Runoff	0.053 Runoff
R4, 2nd	stream	0.075 Runoff	0.034 Runoff	0.018 Runoff	0.223 Runoff	0.101 Runoff	0.053 Runoff

RP25040 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 245.1 g/mol Soil or water metabolite: soil Koc (mL/g): 353 (arithmetic mean) (correct value is 161 mL/g) DT_{50} soil (d): 3.6 (normalised geomean from laboratory) (correct value is 19.2 days – worst-case due to pH-dependence) DT_{50} water/sediment system (d): 1000 (FOCUS default) DT_{50} water (d): 1000 (FOCUS default) DT_{50} sediment (d): 1000 (FOCUS default) Maximum occurrence observed (% molar basis with respect to the parent) Total Water and Sediment: 0.001% Soil: 13.8%
Parameters used in FOCUSsw step 3 (if performed)	Not performed
Application rate	Same as parent iprodione

Reminder: PECsw Step 1 to 2 are provisional (incorrect Kfoc was used)

FOCUS STEP 1 Scenario	**Day after overall maximum**	**PEC_{SW} (µg/L)**			
		Roots vegetables*		Leafy vegetables*	
		Actual	**TWA**	**Actual**	**TWA**
	0h	69.652	-	52.239	-

* Calculations are reported for multiple applications only (worst-case compared to single application)

FOCUS STEP 2 Scenario	**Day after overall maximum**	**PEC_{SW} (µg/L)**			
		Roots vegetables		Leafy vegetables	
		Actual	**TWA**	**Actual**	**TWA**
Southern EU March-May*	0 h	2.830	-	2.593	-

* Worst-case compared to Northern Europe / Calculations are reported for multiple applications only (worst-case compared to single application)

Metabolite RP 32596 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 162.02 g/mol Soil or water metabolite: soil Koc (mL/g): 664 (arithmetic mean) DT_{50} soil (d): 28.2 (normalised geomean from laboratory) (correct value is 30.7 days) DT_{50} water/sediment system (d): 1000 (FOCUS default) DT_{50} water (d): 1000 (FOCUS default) DT_{50} sediment (d): 1000 (FOCUS default) Maximum occurrence observed (% molar basis with respect to the parent) Total Water and Sediment: 0.001% Soil: 12.3% (the correct value is 12.6%)
Parameters used in FOCUSsw step 3 (if performed)	Not performed
Application rate	Same as parent iprodione

FOCUS STEP 1 Scenario	**Day after overall maximum**	**PEC_{SW} (µg/L)**			
		Roots vegetables*		Leafy vegetables*	
		Actual	**TWA**	**Actual**	**TWA**
	0h	32.012	-	24.009	-

* Calculations are reported for multiple applications only (worst-case compared to single application)

FOCUS STEP 2 Scenario	**Day after overall maximum**	**PEC_{SW} (µg/L)**			
		Roots vegetables		Leafy vegetables	
		Actual	**TWA**	**Actual**	**TWA**
Southern EU March-May*	0 h	6.250	-	4.812	-

* Worst-case compared to Northern Europe / Calculations are reported for multiple applications only (worst-case compared to single application)

Metabolite LS720942 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 205 g/mol Soil or water metabolite: soil Koc (mL/g): 1385 (arithmetic mean) (correct value is 413 mL/g) DT_{50} soil (d): 5.8 (normalised geomean from laboratory) DT_{50} water/sediment system (d): 1000 (FOCUS default) DT_{50} water (d): 1000 (FOCUS default) DT_{50} sediment (d): 1000 (FOCUS default) Maximum occurrence observed (% molar basis with respect to the parent) Total Water and Sediment: 0.001% Soil: 13.8%
Parameters used in FOCUSsw step 3 (if performed)	Not performed
Application rate	Same as parent iprodione

Reminder: PECsw Step 1 to 2 are provisional (incorrect Kfoc was used)

FOCUS STEP 1 Scenario	**Day after overall maximum**	**PEC_{SW} (µg/L)**			
		Roots vegetables*		Leafy vegetables*	
		Actual	**TWA**	**Actual**	**TWA**
	0h	30.097	-	22.573	-

* Calculations are reported for multiple applications only (worst-case compared to single application)

FOCUS STEP 2 Scenario	**Day after overall maximum**	**PEC_{SW} (µg/L)**			
		Roots vegetables		Leafy vegetables	
		Actual	**TWA**	**Actual**	**TWA**
Southern EU March-May*	0 h	1.990		1.712	-

* Worst-case compared to Northern Europe / Calculations are reported for multiple applications only (worst-case compared to single application)

Metabolite RP 30181 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 142.16 g/mol Soil or water metabolite: soil Koc (mL/g): 7.2 (QSAR) (preliminar, not accepted as fully reliable end point. Data gap conditional to results of soil metabolism study with hydantoin labelled moiety was identified during the peer review) DT_{50} soil (d): 8.9 (from no GLP preliminary study) DT_{50} water/sediment system (d): 1000 (FOCUS default) DT_{50} water (d): 1000 (FOCUS default) DT_{50} sediment (d): 1000 (FOCUS default) Maximum occurrence observed (% molar basis with respect to the parent) Total Water and Sediment: 0.001% Soil: 12.3% (the correct value is 12.6%)
Parameters used in FOCUSsw step 3 (if performed)	Not performed
Application rate	Same as parent iprodione

FOCUS STEP 1 Scenario	**Day after overall maximum**	**PEC_{SW} (µg/L)**			
		Roots vegetables*		Leafy vegetables*	
		Actual	**TWA**	**Actual**	**TWA**
	0h	52.451	-	39.339	-

* Calculations are reported for multiple applications only (worst-case compared to single application)

FOCUS STEP 2 Scenario	**Day after overall maximum**	**PEC_{SW} (µg/L)**			
		Roots vegetables		Leafy vegetables	
		Actual	**TWA**	**Actual**	**TWA**
Southern EU March-May*	0 h	5.088	-	4.175	-

* Worst-case compared to Northern Europe / Calculations are reported for multiple applications only (worst-case compared to single application)

Greenhouse uses

Parameters used	Parent: Molecular weight (g/mol): 330.2 DT_{50} water (d): 11.6 (geomean from sediment water studies)
	RP 35606: Molecular weight (g/mol): 348.2 DT_{50} water (d): 11.6 (geomean from sediment water studies) Maximum occurrence in water: 100%
	RP 30228: Molecular weight (g/mol): 330.2 DT_{50} water (d): 1000 (FOCUS default) Maximum occurrence in water: 10.6%
Application rate	Crop and growth stage: leafy vegetables (BBCH 10-49) Number of applications: 3 Interval (d): 14 Application rate(s): 750 g a.s./ha (corrected for molar ratio and maximum occurrence in water for metabolites) Emission from greenhouse : 0.1% application rate

Crop	Day after overall maximum	PEC_{SW} (µg/L)		
		Iprodione	RP 35606	RP 30228
Leafy vegetables*	0h	0.405	0.428	0.079

* Calculations are reported for multiple applications only (worst-case compared to single application)

Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

Method of calculation	No data, not required
PEC Maximum concentration	No data, not required

Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

Method of calculation	
PEC Maximum concentration	

Section 5 Ecotoxicology

Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

Species	Test substance	Time scale	End point	Toxicity (mg/kg bw per day)
Birds				
Colinus virginianus	Iprodione	Acute	LD_{50}	> 2000*
Colinus virginianus	Iprodione	Short-term	LD_{50}	> 3988.4
Anas platyrhynchos	Iprodione	Short-term	LD_{50}	> 1301
Colinus virginianus	Iprodione	Long-term	NOEL	**22.3**
Anas platyrhynchos	Iprodione	Long-term	NOEL	26
Mammals				
Rat	Iprodione	Acute	LD_{50}	**> 2000**
Rat	BAS 610 06 F	Acute	LD_{50}	> 2000
Rat	Iprodione	Long-term [*for screening step*]	NOAEL [developmental study]	20
Rabbit	Iprodione	Long-term [*for screening step*]	NOAEL [developmental study]	**< 20**
Rat	Iprodione	Long-term [*for first tier risk assessment*]	LOAEL [2-generation study]	**26.9**
Endocrine disrupting properties (Annex Part A, points 8.1.5): - No available data for birds. - For mammals see Section 2.				
Additional higher tier studies (Annex Part A, points 10.1.1.2): - Long-term field study on voles - Identification of focal species (birds/mammals), PT, PD. - Residue decline in plants: Southern and Northern Europe: DT_{50} grasses = 3.56 days; DT_{50} non-grass herbs = 3.56 days. - Residue decline in arthropods: Southern and Northern Europe: DT_{50} foliage dwelling arthropods = 2.22 days, DT50 ground dwelling arthropods = 3.19 days. Northern Europe: RUD ground dwelling arthropods = 1.69. - Deposition factor.				
Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3)				

Values in bold are used for TER calculation

* the extrapolated value of **3776** mg a.s./kg b.w. is used in the risk assessment

Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)

Lettuce at 750 g a.s./ha [3 applications]

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small omnivorous bird	Acute	154.83	24.4	10
All	Small omnivorous bird	Long-term	38.64	**0.6**	5
Tier 1 (Birds)					
BBCH 10-19	Small insectivorous bird	Long-term	6.74	**3.3**	5
BBCH 10-19	Medium herbivorous/granivorous bird	Long-term	22.06	**1.0**	5
BBCH 10-49	Small granivorous bird	Long-term	7.51	**3.0**	5
BBCH 10-49	Small omnivorous bird	Long-term	6.50	**3.4**	5
BBCH ≥ 20	Small insectivorous bird	Long-term	5.78	**3.9**	5
Higher tier Southern Europe (birds)					
BBCH 10-19 BBCH ≥ 20	Yellow wagtail	Long-term	2.51 (residues, PT)	8.88	5
BBCH 10-49	Crested lark	Long-term	3.73 (residues, PT, PD, DF)	5.98	5
BBCH 10-49	Serin	Long-term	3.67 (residues, PT, PD, DF)	6.08	5
BBCH 10-19	Feral pigeon	Long-term	8.43 (residues)	**2.65**	5
Higher tier Northern Europe (birds)					
BBCH 10-49	Skylark	Long-term	4.18 (residues, PT, PD, DF)	5.33	5
BBCH 10-19 BBCH ≥ 20	Yellow wagtail	Long-term	2.34 (residues, PT)	9.52	5
BBCH 10-19	Wood pigeon	Long-term	1.63 (residues)	13.69	5
BBCH 10-49	Serin	Long-term	6.94 (DF)	**3.21**	5
Screening Step (Mammals)*					
All	Small granivorous mammal	Acute	132.99	> 15	10

*The long-term risk assessment for mammals could not be conducted due tot he lack of a reliable endpoint

Risk from bioaccumulation and food chain behaviour				
Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm-eating birds	Long-term	2.45	9.1	5
Fish-eating birds	Long-term	0.672	33.17	5
Higher tier: Not required.				

Risk from consumption of contaminated water					
Scenarios	**Indicator or focal species**	**Time scale**	**PEC_{dw}xDWR**	**TER**	**Trigger**
Leaf scenario	Birds	acute	345	10.9	5
Puddle scenario, Screening step					
Application rate (g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed.					

Carrot at 750 g a.s./ha [4 applications]

Growth stage	**Indicator or focal species**	**Time scale**	**DDD (mg/kg bw per day)**	**TER**	**Trigger**
Screening Step (Birds)					
All	Small omnivorous bird	Acute	178.65	21.1	10
All	Small omnivorous bird	Long-term	48.94	**0.5**	5
Tier 1 (Birds)					
BBCH 10-19	Small insectivorous bird	Long-term	8.53	**2.6**	5
BBCH 10-39	Small granivorous bird	Long-term	8.61	**2.6**	5
BBCH 10-39	Small omnivorous bird	Long-term	8.23	**2.7**	5
BBCH ≥ 20	Small insectivorous bird	Long-term	7.33	**3.0**	5
BBCH ≥ 40	Small granivorous bird	Long-term	2.57	8.7	5
BBCH ≥ 40	Small omnivorous bird	Long-term	2.50	8.9	5
Higher tier Southern Europe (birds)					
BBCH 10-19 BBCH ≥ 20	Yellow wagtail	Long-term	3.02 (residues, PT)	7.38	5
BBCH 10-39	Crested Lark	Long-term	4.38 (residues, PT, PD, DF)	5.09	5
BBCH 10-39	Serin	Long-term	4.825 (residues, PT, PD, DF)	**4.62**	5
Higher tier Northern Europe (birds)					
BBCH 10-19 BBCH ≥ 20	Yellow wagtail	Long-term	2.822 (residues)	7.90	5
BBCH 10-39	Skylark	Long-term	5.156 (residues, PT, PD, DF)	**4.33**	5
BBCH 10-39	Serin	Long-term	9.04 (DF)	**2.47**	5
Screening Step (Mammals)*					
All	Small herbivorous mammal	Acute	133.2	> 15	10
Higher tier –					

*The long-term risk assessment for mammals could not be conducted due tot he lack of a reliable endpoint

Risk from bioaccumulation and food chain behaviour[*indicate when not relevant* i.e *if Log kow≤3]*

Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm-eating birds	Long-term	2.45	9.1	5
Fish-eating birds	Long-term	0.672	33.17	5
Higher tier: Not required.				

Risk from consumption of contaminated water

Scenarios	**Indicator or focal species**	**Time scale**	**PEC_{dw}xDWR**	**TER**	**Trigger**
Leaf scenario	Birds	acute	345	10.9	5

Puddle scenario, Screening step

Application rate (g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed

* Weight of evidence approach: the field study on voles, under worst case conditions, demonstrates no adverse effect on the population dynamics, health constitution and reproductive performance after application of iprodione in grassland.

Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)*

* This section does not yet reflect the new EFSA Guidance Document on aquatic organisms which has been noted in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014.

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Laboratory tests				
Fish				
Oncorhynchus mykiss	Iprodione	Acute 96 hr (flow-through)	Mortality, LC_{50}	4.1 mg a.s./L $_{(mm)}$
Lepomis macrochirus	Iprodione	Acute 96 hr (flow-through)	Mortality, LC_{50}	3.7 mg a.s./L$_{(mm)}$
Ictalurus punctatus	Iprodione	Acute 96 hr (flow-through)	Mortality, LC_{50}	**3.1 mg a.s./L$_{(mm)}$**
Cyprinodon variegatus	Iprodione	Acute 96 hr (flow-through)	Mortality, LC_{50}	7.7 mg a.s./L$_{(mm)}$
Oncorhynchus mykiss	RP 30228	Acute 96 hr (flow-through)	Mortality, LC_{50}	> 0.39 mg met./L$_{(mm)}$
Lepomis macrochirus	RP 30228	Acute 96 hr (flow-through)	Mortality, LC_{50}	**0.550 mg met./L$_{(mm)}$**[2]
Danio rerio	RP 32596	Chronic (semi-static)	ELS, 28d-LC50	**1.3 mg met./L$_{(nom)}$**
Oncorhynchus mykiss	BAS 610 06 F	Acute 96 hr (flow-through)	Mortality, LC_{50}	35 mg prep./L (26.25 mg a.s./L $_{(mm)}$)
Pimephales promelas	Iprodione	Chronic (flow-through)	ELS, 34 d NOEC	0.26 mg a.s./L $_{(mm)}$
Pimephales promelas	Iprodione	Chronic (flow-through)	Partial LC, 56 d NOEC	**0.0731 mg a.s./L$_{(m.m.)}$**
Pimephales promelas	Iprodione	Chronic (flow-through)	Short-term reproduction assay, 23 d NOEC	0.0085 mg a.s./L$_{(twa)}$
Xenopus laevis	Iprodione	Chronic (flow-through)	AMA, 21 d NOEC	0.61 mg a.s./L $_{(mm)}$
Aquatic invertebrates				
Daphnia magna	Iprodione	48 h (static)	Mortality, EC_{50}	**0.660 mg a.s./L$_{(nom)}$**
Americamysis bahia	Iprodione	48 h (flow-through)	Mortality, EC_{50}	> 0.97 mg a.s./L $_{(mm)}$
Procambarus simulans	Iprodione	7 d (flow-through)	Mortality, EC_{50}	> 4.1 mg a.s./L $_{(mm)}$
Crassostrea virginica	Iprodione	96 h (flow-through)	Mortality, EC_{50}	2.3 mg a.s./L $_{(mm)}$
Daphnia magna	RP 30228	48 h (static)	Mortality, EC_{50}	**>0.500 mg met./L $_{(nom)}$**
Daphnia magna	RP 36221	48 h (static)	Mortality, EC_{50}	**0.364 mg met./L $_{(mm)}$**
Daphnia magna	RP 25040	48 h (static)	Mortality, EC_{50}	**56.28 mg met./L $_{(mm)}$**
Daphnia magna	RP 32596	48 h (static)	Mortality, EC_{50}	**1.26 mg met./L $_{(nom)}$**
Daphnia magna	BAS 610 06 F	48 h (semi-static)	Mortality, EC_{50}	0.4 mg prep./L (0.3 mg a.s./L $_{(mm)}$)
Daphnia magna	Iprodione	21 d (flow-through)	Reproduction NOEC	0.170 mg a.s./L $_{(mm)}$
Ceriodaphnia dubia	Iprodione	8 d (flow-through)	Reproduction NOEC	0.122 mg a.s./L $_{(mm)}$
Americamysis bahia	Iprodione	28 d (flow-through)	Reproduction NOEC	**0.0075 mg a.s./L $_{(mm)}$**
Sediment-dwelling organisms				
Chironomus riparius (spiked water study)	RP 30228	28 d (static)	NOEC	**0.057 mg met./L $_{(mm)}$**
Chironomus riparius (spiked sediment study)	RP 30228	28 d (static)	NOEC	**95.3 mg met./kg dry sediment $_{(ini\ m)}$**
Algae				
Pseudokirchneriella	Iprodione	72 h (static)	Growth rate: E_rC_{50}	**> 1.5 mg a.s./L $_{(mm)}$** *

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
supcapitata (Selenastrum capricornutum)			Biomass: E_bC_{50}	> 1.5 mg a.s./L $_{(mm)}$
Scenedesmus subspicatus	RP 30228	72 h (static)	Growth rate: E_rC_{50} Biomass: E_bC_{50} NOEC	**> 0.352 mg met./L $_{(mm)}$** > 0.352 mg met./L $_{(mm)}$ 0.128 mg met./L $_{(mm)}$
Pseudokirchneriella supcapitata	RP 36221	72 h (static)	Growth rate: E_rC_{50} Yield: E_yC_{50} NOEC	**0.567 mg met./L $_{(mm)}$** 0.154 mg met./L $_{(mm)}$ 0.038 mg met./L $_{(mm)}$
Pseudokirchneriella supcapitata	RP 25040	72 h (static)	Growth rate: E_rC_{50} Yield: E_yC_{50} NOEC	**86.9 mg met./L $_{(mm)}$** 14.66 mg met./L $_{(mm)}$ 1.90 mg met./L $_{(mm)}$
Pseudokirchneriella supcapitata	RP 32596	72 h (static)	Growth rate: E_rC_{50} Yield: E_yC_{50} NOEC	**7.76 mg met./L $_{(mm)}$** 2.08 mg met./L $_{(mm)}$ 0.28 mg met./L $_{(mm)}$
Scenedesmus subspicatus	BAS 610 06 F	72 h (static)	Growth rate: E_rC_{50} Biomass: E_bC_{50} NOEC	> 9.1 < 20 mg prep./L > 9.1 < 20 mg prep./L (> 6.8 < 15 mg a.s./L$_{(nom)}$) 9.1 mg prep./L (6.8 mg a.s./L$_{(nom)}$)
Higher plant				
Lemna gibba	Iprodione	7 d (static)	Fronds number, E_rC_{50} Dry weight, E_bC_{50} NOEC	**> 12.64 mg a.s./L$_{(twa)}$** **> 12.64 mg a.s./L$_{(twa)}$** 12.64 mg a.s./L$_{(twa)}$
Further testing on aquatic organisms: -				
Potential endocrine disrupting properties (Annex Part A, point 8.2.3) - Dose-dependency effect on vitellogenin concentration in males. - Dose-substance-related effect on increased incidence of interstitial cell hyperplasia in males.				

Values in bold are used for TER calculation

[1] ($_{nom}$) nominal concentration; ($_{mm}$) mean measured concentration; ($_{twa}$) time-weighted average concentration; ($_{ini\ m}$) initial measured concentration; prep.: preparation; a.s.: active substance

[2] No clear endpoint could be determined in the acute study with *O. mykiss* (*i.e.,* mortality < 50% at the highest tested concentration); thus, the (greater) endpoint (LC_{50} = 0.550 mg/L) of the acute study with *L. macrochirus* is considered as relevant endpoint for the acute risk assessment for fish.

*the study was not evaluated according to the most recent validity criteria.

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	Active substance	Metabolite1	Metabolite2	Metabolite3
$logP_{O/W}$	3			
Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content)	46.8 (whole fish)*			
Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content)				
Annex VI Trigger for the bioconcentration factor				
Clearance time (days) (CT_{50})				
(CT_{90})				
Level and nature of residues (%) in organisms after the 14 day depuration phase				
Higher tier study: -				

* based on total ^{14}C or on specific compounds

Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

Lettuce at 750 g a.s./ha [3 applications]

FOCUSsw step 1-3 - TERs for Iprodione (acidic soil) – Lettuce at 750 g a.s./ha [3 applications]

Scenario	**PEC global max (µg L)**	**Fish acute**	**Fish chronic**	**Aquatic invertebrates**	**Aquatic invertebrates prolonged**	**Algae**	**Higher plant**	**Sed. dweller prolonged**	**Microcosm / Mesocosm**
		Ictalurus punctatus	*Pimephales promelas*	*Daphnia magna*	*Americamysis bahia*	*Pseudokirchneriella subcapitata*	*Lemna gibba*	-	
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}	NOEC	NOEC
		3100 µg/L	73.1 µg/L	660 µg/L	7.5 µg/L	> 1500 µg/L	> 12640 µg/L	-	-
FOCUS Step 1									
	356.09	**8.70**	**0.20**	**1.85**	**0.02**	> **4.21**	> 35		
FOCUS Step 2									
	93.21	**33**	**0.8**	**7.1**	**0.08**	> 16			
FOCUS Step 3									
D3 / ditch	4.75	653	15.4	139	**1.6**				
D4 / pond	2.33	1388	31.4	296	**3.4**				
D4 / stream	4.53	685	16.1	146	**1.7**				
D6 / ditch	12.87	241	**5.7**	**51**	**0.6**				
R1 / pond	2.60	1190	28.1	253	**2.9**				
R1 / stream	13.11	236	**5.6**	**50**	**0.6**				
R2 / stream	4.21	736	17.4	157	**1.8**				
R3 / stream	16.08	193	**4.5**	**41**	**0.5**				
R4 / stream	21.36	145	**3.4**	**31**	**0.4**				
Trigger		100	10	100	10	10	10	10	

Values in bold fail the trigger

$FOCUS_{sw}$ step 4 - TERs for Iprodione (acidic soil) – Lettuce at 750 g a.s./ha [3 applications]

Organisms : *Pimephales promelas*					
Toxicity endpoint:73.1 µg/L					
Mitigation options	**[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**	**[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)**	**PECsw (µg/L)**	**TER**	**Trigger**
FOCUS Step 4					
D6 / ditch	20	-	12.87	**6.0**	10
R1 / stream	10	10	5.96	12	10
R3 / stream	10	10	3.86	10	10
R4 / stream	20	20	5.09	14	10
Organisms : *Daphnia magna*					
Toxicity endpoint: 660 µg/L					
Mitigation options	**[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**	**[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)**	**PECsw (µg/L)**	**TER**	**Trigger**
FOCUS Step 4					
D6 / ditch	20	-	12.87	**51**	100
R1 / stream	10	10	5.96	111	100
R3 / stream	20	20	3.86	171	100
R4 / stream	20	20	5.09	130	100
Organisms : *Americamysis bahia*					
Toxicity endpoint: 7.5 µg/L					
Mitigation options	**[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**	**[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)**	**PECsw (µg/L)**	**TER**	**Trigger**
FOCUS Step 4					
D3 / ditch	10	-	0.68	**11**	10
D4 / pond	20	-	2.23	**3.4**	10
D4 / stream	20	-	4.53	**1.7**	10
D6 / ditch	20	-	12.87	**0.6**	10
R1 / pond	20	20	0.55	14	10
R1 / stream	20	20	3.12	**2.4**	10
R2 / stream	20	20	0.921	**8.1**	10
R3 / stream	20	20	3.856	**1.9**	10
R4 / stream	20	20	5.090	**1.5**	10

Values in bold fail the trigger

FOCUS$_{sw}$ step 1-3 - TERs for Iprodione + RP 35606 (alkaline soil) – Lettuce at 750 g a.s./ha [3 applications]

Scenario	PEC global max* (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged	Microcosm / Mesocosm
		Ictalurus punctatus	*Pimephales promelas*	*Daphnia magna*	*Americamysis bahia*	*Pseudokirchneriella subcapitata*	*Lemna gibba*		
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}	NOEC	NOEC
		3100 µg/L	73.1 µg/L	660 µg/L	7.5 µg/L	> 1500 µg/L	> 12640 µg/L	-	-
FOCUS Step 1									
	571.34	**5.42**	**0.13**	**1.15**	**0.01**	**> 2.62**	> 22		
FOCUS Step 2									
	49.22	**63**	**1.5**	**13.4**	**0.15**	> 30			
FOCUS Step 3									
D3 / ditch	9.77	317	**7.5**	**68**	**0.8**				
D4 / pond	1.21	2560	60.4	545	**6.2**				
D4 / stream	7.79	398	**9.4**	**85**	**1.0**				
D6 / ditch	18.14	171	**4.0**	**36**	**0.4**				
R1 / pond	1.31	2374	56.0	505	**5.7**				
R1 / stream	13.72	226	**5.3**	**48**	**0.5**				
R2 / stream	9.48	327	**7.7**	**70**	**0.8**				
R3 / stream	16.55	187	**4.4**	**40**	**0.5**				
R4 / stream	20.92	148	**3.5**	**32**	**0.4**				
Trigger		100	10	100	10	10	10	10	

Values in bold fail the trigger

* PEC values obtained by adding the PEC values of iprodione and the metabolite RP 35606 in alkaline soils.

FOCUS$_{sw}$ step 4 - TERs for Iprodione + RP 35606 (alkaline soil) – Lettuce at 750 g a.s./ha [3 applications]

Organisms : *Pimephales promelas*					
Toxicity endpoint: 73.1 µg/L					
Mitigation options	**[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**	**[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)**	**PECsw (µg/L)**	**TER**	**Trigger**
FOCUS Step 4					
D3 / ditch	10	-	1.42	51.6	10
D4 / stream	10	-	1.99	36.7	10
D6 / ditch	20	-	15.33	**4.8**	10
R1 / stream	10	10	6.24	11.7	10
R2 / stream	10	10	3.59	20	10
R3 / stream	20	20	3.97	18	10
R4 / stream	20	20	4.99	14.7	10
Organisms : *Daphnia magna*					
Toxicity endpoint: 660 µg/L					
Mitigation options	**[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**	**[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)**	**PECsw (µg/L)**	**TER**	**Trigger**
FOCUS Step 4					
D3 / ditch	10	-	1.42	465	100
D4 / stream	10	-	1.99	331	100
D6 / ditch	20	-	15.33	**43**	100
R1 / stream	10	10	6.24	106	100
R2 / stream	10	10	3.59	184	100
R3 / stream	20	20	3.97	166	100
R4 / stream	20	20	4.99	132	100

Organisms : *Americamysis bahia*					
Toxicity endpoint: 7.5 µg/L					
Mitigation options	**[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**	**[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)**	**PECsw (µg/L)**	**TER**	**Trigger**
FOCUS Step 4					
D3 / ditch	20	-	0.75	10	10
D4 / pond	20	-	1.1	**6.8**	10
D4 / stream	20	-	1.73	**4.3**	10
D6 / ditch	20	-	15.33	**0.5**	10
R1 / pond	10	10	0.61	12	10
R1 / stream	20	20	3.27	**2.3**	10
R2 / stream	20	20	1.87	**4.0**	10
R3 / stream	20	20	3.97	**1.9**	10
R4 / stream	20	20	4.99	**1.5**	10

Values in bold fail the trigger

* PEC values obtained by adding the PEC values of iprodione and the metabolite RP 35606 in alkaline soils.

FOCUS$_{sw}$ step 1-3 - TERs for RP 35606 – Lettuce at 750 g a.s./ha [3 applications]

Scenario	PEC global max*(µg L)	Fish acute	Fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant
		Ictalurus punctatus	*Pimephales promelas*	*Daphnia magna*	*Americamysis bahia*	*Pseudokirchneriella subcapitata*	*Lemna gibba*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}
		310 µg/L*	7.31 µg/L*	66 µg/L*	0.75 µg/L*	> 150 µg/L*	> 1264 µg/L*
FOCUS Step 1							
	215.2	**1.44**	**0.03**	**0.31**	**0.003**	**0.70**	**5.87**
FOCUS Step 2							
	22	**14.08**	**0.33**	**3.00**	**0.03**	**6.81**	57.39
FOCUS Step 3							
D3 / ditch	5.02	**61.70**	**1.46**	**13.14**	**0.15**	29.86	
D4 / pond	1.1	301.26	**7.10**	**64.14**	**0.73**	145.77	
D4 / stream	4.0	**77.40**	**1.83**	**16.48**	**0.19**	37.45	
D6 / ditch	14.68	**21.12**	**0.50**	**4.50**	**0.05**	10.22	
R1 / pond	0.86	361.31	**8.52**	**76.92**	**0.87**	174.83	
R1 / stream	9.54	**32.48**	**0.77**	**6.92**	**0.08**	15.72	
R2 / stream	6.47	**47.90**	**1.13**	**10.20**	**0.12**	23.18	
R3 / stream	11.04	**28.07**	**0.66**	**5.98**	**0.07**	13.58	
R4 / stream	10.21	**30.37**	**0.72**	**6.46**	**0.07**	14.69	
Trigger		100	10	100	10	10	10

Values in bold fail the trigger * The metabolite is assumed 10 times more toxic than the active substance

FOCUS$_{sw}$ step 4 - TERs for RP 35606 – Lettuce at 750 g a.s./ha [3 applications]

Organisms : *Americamysis bahia*					
Toxicity endpoint: 0.75 µg/L*					
Mitigation options	**[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**	**[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)**	**PECsw (µg/L)**	**TER**	**Trigger**
FOCUS Step 4					
D3 / ditch	20	20	0.39	**1.91**	10
D4 / pond	20	20	1.02	**0.73**	10
D4 / stream	20	20	1.46	**0.51**	10
D6 / ditch	20	20	14.68	**0.05**	10
R1 / pond	20	20	0.20	**3.66**	10
R1 / stream	20	20	2.27	**0.33**	10
R2 / stream	20	20	1.52	**0.49**	10
R3 / stream	20	20	2.65	**0.28**	10
R4 / stream	20	20	2.43	**0.31**	10

***** The metabolite is assumed 10 times more toxic than the active substance

FOCUS$_{sw}$ step 1-3 - TERs for RP 30228 – Lettuce at 750 g a.s./ha [3 applications]

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged	Sed. dweller prolonged
		Lepomis macrochirus	*Pimephales promelas*	*Daphnia magna*	*Americamysis bahia*	*Scenedesmus subspicatus*	*Lemna gibba*	*Chironomus riparius*	*Chironomus riparius*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}	NOEC	NOEC
		550 µg/L	7.31 µg/L*	> 500 µg/L	0.75 µg/L*	> 352 µg/L	> 1264* µg/L	57 µg/L	95300 µg/kg dry sediment
FOCUS Step 1sw	57.05	**9.64**	**0.13**	**> 8.76**	**0.013**	**> 6.17**	> 22.15	**1**	
FOCUS Step 1sed	1540								62
FOCUS Step 2									
	11.63	**47**	**0.6**	**> 43**	**0.1**	>30		**4.9**	
FOCUS Step 3									
D3 / ditch	< 0.001	> 550000	>7310	> 50000	> 750.0			> 57000	
D4 / pond	0.034	16176	215	> 14706	22.1			1676	
D4 / stream	0.055	10000	133	> 9091	13.6			1036	
D6 / ditch	0.116	4741	63	> 4310	**6.5**			491	
R1 / pond	0.106	5189	69	> 4717	**7.1**			538	
R1 / stream	0.252	2183	29	> 1984	**3.0**			226	
R2 / stream	0.078	7051	93.7	> 6410	**9.6**			731	
R3 / stream	0.283	1943	25.8	> 1767	**2.7**			201	
R4 / stream	0.271	2030	27	> 1845	**2.8**			210	
Trigger		100	10	100	10	10	10	10	10

Values in bold fail the trigger
* The metabolite is assumed 10 times more toxic than the active substance.

FOCUS$_{sw}$ step 1-2 - TERs for RP 32596 – Lettuce at 750 g a.s./ha [3 applications]

Scenario	PEC global max (µg L)	Fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant
		Danio rerio	*Danio rerio*	*Daphnia magna*	*Americamysis bahia*	*Pseudokirchneriella subcapitata*	*Lemna gibba*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}
		1300 µg/L	320	1260 µg/L	0.75 µg/L*	7760µg/L	> 1264* µg/L
FOCUS Step 1							
	24.01	54.1	13.3	**52.5**	**0.03**	323	> 52.6
FOCUS Step 2							
	4.81	270.2		262	**0.2**		
Trigger		100	10	100	10	10	10

Values in bold fail the trigger
***** The metabolite is assumed 10 times more toxic than the active substance.

FOCUS$_{sw}$ step 1-3 - TERs for RP 36221– Lettuce at 750 g a.s./ha [3 applications]

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant
		Ictalurus punctatus	*Pimephales promelas*	*Daphnia magna*	*Americamysis bahia*	*Pseudokirchneriella subcapitata*	*Lemna gibba*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}
		310 µg/L*	7.31 µg/L*	364 µg/L	0.75 µg/L*	567 µg/L	> 1264 µg/L*
FOCUS Step 1							
	3.04	426.9	**2.4**	120	**0.2**	186	> 415.1
FOCUS Step 2	0.902						
			8.1		**0.8**		
FOCUS Step 3							
D3 / ditch	<0.0001		>73100		>7500.0		
D6 / ditch	0.016		457		46.9		
R1 / pond	0.11		66		**6.8**		
R1 / stream	0.197		37		**3.8**		
R2 / stream	0.059		124		12.7		
R3 / stream	0.138		53		**5.4**		
R4 / stream	0.233		31		**3.2**		
D4 / pond	<0.0001		>73100		>7500.0		
D4 / stream	0.004		1827		187.5		
Trigger			10	100	10	10	10

Values in bold fail the trigger
***** The metabolite is assumed 10 times more toxic than the active substance.

FOCUS$_{sw}$ step 4 - TERs for RP 36221– Lettuce at 750 g a.s./ha [3 applications]

Organisms : *Americamysis bahia* **Toxicity endpoint:** 0.75 µg/L*					
Mitigation options	**[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**	**[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)**	**PECsw (µg/L)**	**TER**	**Trigger**
FOCUS Step 4					
R1 / pond	10	10	0.045	16.7	10
R1 / stream	20	20	0.046	16.3	10
R3 / stream	10	10	0.063	11.9	10
R4 / stream	20	20	0.055	13.6	10

Values in bold fail the trigger
***** The metabolite is assumed 10 times more toxic than the active substance.

FOCUS$_{sw}$ step 1-2 - TERs for RP 25040 – Lettuce at 750 g a.s./ha [3 applications]

Scenario	**PEC global max (µg L)**	**fish acute**	**fish chronic**	**Aquatic invertebrates**	**Aquatic invertebrates prolonged**	**Algae**	**Higher plant**
		Ictalurus punctatus	*Pimephales promelas*	*Daphnia magna*	*Americamysis bahia*	*Pseudokirchneriella subcapitata*	*Lemna gibba*
		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	EC_{50}
		310 µg/L*	7.31 µg/L*	56280 µg/L	0.75 µg/L*	86900 µg/L	> 1264 µg/L*
FOCUS Step 1							
	52.24	**5.9**	**0.1**	1077	**0.014**	**1663**	>24.2
FOCUS Step 2							
	2.59	119.6	**2.8**		**0.3**		
Trigger		100	10	100	10	10	10

Values in bold fail the trigger
***** The metabolite is assumed 10 times more toxic than the active substance.

$FOCUS_{sw}$ step 1-2 - TERs for LS720942 – Lettuce at 750 g a.s./ha [3 applications]

Scenario	PEC global max (µg L)	Fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant
		Ictalurus punctatus	*Pimephales promelas*	*Daphnia magna*	*Americamysis bahia*	*Pseudokirchneriella subcapitata*	*Lemna gibba*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}
		310 µg/L*	7.31 µg/L*	66 µg/L*	0.75 µg/L*	>150 µg/L*	> 1264 µg/L*
FOCUS Step 1							
	22.57	**13.7**	**0.3**	**2.92**	**0.03**	> **6.6**	>56.0
FOCUS Step 2							
	1.71	181	**4.3**	**38.6**	**0.4**	> 87.6	
Trigger		100	10	100	10	10	10

Values in bold fail the trigger
*The metabolite is assumed 10 times more toxic than the active substance.

$FOCUS_{sw}$ step 1-2 - TERs for RP 30181 – Lettuce at 750 g a.s./ha [3 applications]

Scenario	PEC global max (µg L)	Fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant
		Ictalurus punctatus	*Pimephales promelas*	*Daphnia magna*	*Americamysis bahia*	*Pseudokirchneriella subcapitata*	*Lemna gibba*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}
		310 µg/L*	7.31 µg/L*	66 µg/L*	0.75 µg/L*	> 150 µg/L*	> 1264 µg/L*
FOCUS Step 1							
	39.34	**7.88**	**0.2**	**1.68**	**0.02**	> **3.8**	32.1
FOCUS Step 2							
	4.17	**74.3**	**1.8**	**15.8**	**0.2**	> 35.9	
Trigger		100	10	100	10	10	10

Values in bold fail the trigger
*The metabolite is assumed 10 times more toxic than the active substance.

Lettuce at 750 g a.s./ha [3 applications] – Indoor use

TERs for Iprodione + RP 35606 – Lettuce at 750 g a.s./ha [3 applications] – Indoor use

	PEC global max* (µg L)	Fish acute	Fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant
		Ictalurus punctatus	*Pimephales promelas*	*Daphnia magna*	*Americamysis bahia*	*Pseudokirchneriella subcapitata*	*Lemna gibba*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}
		3100 µg/L	~~90~~73.1 µg/L	660 µg/L	7.5 µg/L	> 1500 µg/L	> 12640 µg/L
	0.833**	3721.5	87.8	792.3	**9.0**	>1800	>15174
Trigger		100	10	100	10	10	10

* $PEC_{sw, max}$ value calculated considering an overall emission of 0.1 % of the application rate. ** PEC value obtained by adding the PEC values of iprodione and the metabolite RP 35606.
Values in bold fail the trigger

TERs for RP 30228 – Lettuce at 750 g a.s./ha [3 applications] – Indoor use

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged	Sed. dweller prolonged
		Lepomis macrochirus	*Pimephales promelas*	*Daphnia magna*	*Americamysis bahia*	*Scenedesmus subspicatus*	*Lemna gibba*	*Chironomus riparius*	*Chironomus riparius*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}	NOEC	NOEC
		550 µg/L	7.31 µg/L*	> 500 µg/L	0.75 µg/L*	> 352 µg/L	> 1264* µg/L	57 µg/L	95300 µg/kg dry sediment
	0.079	6962	92.5	>6329	**9**	>4456	>16000	721	--
Trigger		100	10	100	10	10	10	10	10

* $PEC_{sw, max}$ value calculated considering an overall emission of 0.1 % of the application rate.
Values in bold fail the trigger

Carrot at 750 g a.s./ha [4 applications]

FOCUS$_{sw}$ step 1-3 - TERs for Iprodione (acidic soil) – Carrot at 750 g a.s./ha [4 applications]

Scenario	**PEC global max (µg L)**	**Fish acute**	**Fish chronic**	**Aquatic invertebrates**	**Aquatic invertebrates prolonged**	**Algae**	**Higher plant**	**Sed. dweller prolonged**	**Microcosm / Mesocosm**
		Ictalurus punctatus	*Pimephales promelas*	*Daphnia magna*	*Americamysis bahia*	*Pseudokirchneriella subcapitata*	*Lemna gibba*	-	
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}	NOEC	NOEC
		3100 µg/L	73.1 µg/L	660 µg/L	7.5 µg/L	> 1500 µg/L	> 12640 µg/L	-	-
FOCUS Step 1									
	474.79	**6.53**	**0.15**	**1.39**	**0.01**	**> 3.16**	> 27		
FOCUS Step 2									
	122.69	**25**	**0.6**	**5.4**	**0.06**	> 12			
FOCUS Step 3									
D3 / ditch	4.75	653	15.4	139	**1.6**				
D6 / ditch	6.23	498	11.7	106	**1.2**				
R1 / pond	1.39	2233	52.7	476	**5.4**				
R1 / stream	15.40	201	**4.7**	**43**	**0.5**				
R2 / stream	6.35	488	11.5	104	**1.2**				
R3 / stream	16.60	187	**4.4**	**40**	**0.5**				
R4 / stream	24.39	127	**3**	**27**	**0.3**				
Trigger		100	10	100	10	10	10	10	

Values in bold fail the trigger

FOCUS$_{sw}$ step 4 - TERs for Iprodione (acidic soil) – Carrot at 750 g a.s./ha [4 applications]

Organisms : *Pimephales promelas*					
Toxicity endpoint: 73.1 µg/L					
Mitigation options	**[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**	**[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)**	**PECsw (µg/L)**	**TER**	**Trigger**
FOCUS Step 4					
R1 / stream	10	10	7.0	10.4	10
R3 / stream	20	20	3.98	18.4	10
R4 / stream	20	20	5.78	12.6	10
Organisms : *Daphnia magna*					
Toxicity endpoint: 660 µg/L					
Mitigation options	**[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**	**[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)**	**PECsw (µg/L)**	**TER**	**Trigger**
FOCUS Step 4					
R1 / stream	20	20	3.66	180	100
R3 / stream	20	20	3.98	166	100
R4 / stream	20	20	5.78	114	100
Organisms : *Americamysis bahia*					
Toxicity endpoint: 7.5 µg/L					
Mitigation options	**[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**	**[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)**	**PECsw (µg/L)**	**TER**	**Trigger**
FOCUS Step 4					
D3 / ditch	10	-	0.68	11	10
D6 / ditch	20	-	6.23	**1.2**	10
R1 / pond	10	10	0.58	13	10
R1 / stream	20	20	3.66	**2.0**	10
R2 / stream	20	20	1.51	**5.0**	10
R3 / stream	20	20	3.98	**1.9**	10
R4 / stream	20	20	5.78	**1.3**	10

Values in bold fail the trigger

FOCUS$_{sw}$ step 1-3 - TERs for Iprodione + RP 35606 (alkaline soil) – Carrot at 750 g a.s./ha [4 applications]

Scenario	PEC global max* (µg L)	Fish acute	Fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged	Microcosm / Mesocosm
		Ictalurus punctatus	*Pimephales promelas*	*Daphnia magna*	*Americamysis bahia*	*Pseudokirchneriella subcapitata*	*Lemna gibba*		
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}	NOEC	NOEC
		3100 µg/L	73.1 µg/L	660 µg/L	7.5 µg/L	> 1500 µg/L	> 12640 µg/L	-	-
FOCUS Step 1									
	761.78	**4.07**	**0.09**	**0.87**	**0.01**	**> 1.97**	> 17		
FOCUS Step 2									
	56.86	**55**	**1.3**	**12**	**0.13**	> 26			
FOCUS Step 3									
D3 / ditch	9.76	318	**7.5**	**68**	**0.8**				
D6 / ditch	14.54	213	**5**	**45**	**0.5**				
R1 / pond	1.59	1944	45.8	414	**4.7**				
R1 / stream	16.49	188	**4.4**	**40**	**0.5**				
R2 / stream	14.11	220	**5.2**	**47**	**0.5**				
R3 / stream	18.99	163	**3.9**	**35**	**0.4**				
R4 / stream	23.62	131	**3.1**	**28**	**0.3**				
Trigger		100	10	100	10	10	10	10	

Values in bold fail the trigger
* PEC values obtained by adding the PEC values of iprodione and the metabolite RP 35606 in alkaline soils.

$FOCUS_{sw}$ step 4 - TERs for Iprodione + RP 35606 (alkaline soil) – Carrot at 750 g a.s./ha [4 applications]

Organisms : *Pimephales promelas*					
Toxicity endpoint: 73.1 µg/L					
Mitigation options	**[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**	**[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)**	**PECsw (µg/L)**	**TER**	**Trigger**
FOCUS Step 4					
D3 / ditch	10	-	1.40	52.1	10
D6 / ditch	20	-	11.58	**6.3**	10
R1 / stream	20	20	3.92	18.7	10
R2 / stream	10	10	5.91	12.4	10
R3 / stream	10	10	8.62	8.5	10
R4 / stream	20	20	5.60	13.1	10
Organisms : *Daphnia magna*					
Toxicity endpoint: 660 µg/L					
Mitigation options	**[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**	**[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)**	**PECsw (µg/L)**	**TER**	**Trigger**
FOCUS Step 4					
D3 / ditch	10	-	1.403	470	100
D6 / ditch	20	-	11.576	**57**	100
R1 / stream	20	20	3.916	169	100
R2 / stream	10	10	5.915	112	100
R3 / stream	20	20	4.511	146	100
R4 / stream	20	20	5.599	118	100

Organisms : *Americamysis bahia*					
Toxicity endpoint: 7.5 µg/L					
Mitigation options	**[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**	**[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)**	**PECsw (µg/L)**	**TER**	**Trigger**
FOCUS Step 4					
D3 / ditch	20	-	0.73	10	10
D6 / ditch	20	-	11.58	**0.6**	10
R1 / pond	10	10	0.72	10	10
R1 / stream	20	20	3.92	**1.9**	10
R2 / stream	20	20	3.09	**2.4**	10
R3 / stream	20	20	4.51	**1.7**	10
R4 / stream	20	20	5.60	**1.3**	10

Values in bold fail the trigger
* PEC values obtained by adding the PEC values of iprodione and the metabolite RP 35606 in alkaline soils.

FOCUS$_{sw}$ step 1-3 - TERs for RP 35606– Carrot at 750 g a.s./ha [4 applications]

Scenario	**PEC global max* (µg L)**	**Fish acute**	**Fish chronic**	**Aquatic invertebrates**	**Aquatic invertebrates prolonged**	**Algae**	**Higher plant**
		Ictalurus punctatus	*Pimephales promelas*	*Daphnia magna*	*Americamysis bahia*	*Pseudokirchneriella subcapitata*	*Lemna gibba*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}
		310 µg/L*	7.31 µg/L*	66 µg/L*	0.75 µg/L*	> 150 µg/L*	> 1264 µg/L*
FOCUS Step 1							
	286.99	**1.1**	**0.03**	**0.2**	**0.003**	**0.5**	**4.4**
FOCUS Step 2							
	25.62	**12.1**	**0.3**	**2.6**	**0.03**	**5.9**	49.3
FOCUS Step 3							
D3 / ditch	9.76	**61.6**	**1.5**	**13.1**	**0.15**	**29.8**	
D6 / ditch	14.54	**27.3**	**0.6**	**5.8**	**0.07**	**13.2**	
R1 / pond	1.59	293.8	**6.9**	**62.6**	**0.71**	142.2	
R1 / stream	16.49	**25.2**	**0.6**	**5.4**	**0.06**	**12.2**	
R2 / stream	14.11	**29.8**	**0.7**	**6.4**	**0.07**	**14.4**	
R3 / stream	18.99	**31.9**	**0.8**	**6.8**	**0.08**	**15.5**	
R4 / stream	23.62	**30.7**	**0.7**	**6.5**	**0.07**	**14.9**	
Trigger		**100**	**10**	**100**	**10**	**10**	10

Values in bold fail the trigger
* The metabolite is assumed 10 times more toxic than the active substance

FOCUS$_{sw}$ step 4 - TERs for RP 35606 – Carrot at 750 g a.s./ha [4 applications]

Organisms : *Americamysis bahia*					
Toxicity endpoint: 0.75 µg/L*					
Mitigation options	**[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**	**[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)**	**PECsw (µg/L)**	**TER**	**Trigger**
FOCUS Step 4					
D3 / ditch	20	20	0.396	**1.9**	10
D6 / ditch	20	20	11.34	**0.1**	10
R1 / pond	20	20	0.25	**3.0**	10
R1 / stream	20	20	2.93	**0.3**	10
R2 / stream	20	20	2.45	**0.3**	10
R3 / stream	20	20	3.36	**0.2**	10
R4 / stream	20	20	2.40	**0.3**	10

*** The metabolite is assumed 10 times more toxic than the active substance**

FOCUS$_{sw}$ step 1-3 - TERs for RP 30228 – Carrot at 750 g a.s./ha [4 applications]

Scenario	PEC global max (µg L)	Fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged	Sed. dweller prolonged
		Lepomis macrochirus	*Pimephales promelas*	*Daphnia magna*	*Americamysis bahia*	*Scenedesmus subspicatus*	*Lemna gibba*	*Chironomus riparius*	*Chironomus riparius*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}	NOEC	NOEC
		550 µg/L	7.31 µg/L*	> 500 µg/L	0.75 µg/L*	> 352 µg/L	> 1264* µg/L	57 µg/L	95300 µg/kg dry sediment
FOCUS Step 1sw	76.07	**7.23**	**0.1**	**> 6.57**	**0.01**	**> 4.63**	> 16.62	**0.75**	
FOCUS Step 1sed	2050								46
FOCUS Step 2									
	15.026	**37**	**0.5**	**> 33**	**0.05**	> 23.4		**3.79**	
FOCUS Step 3									
D3 / ditch	< 0.001	> 550000	>7310.0	> 500000	> 750			> 57000	
D6 / ditch	0.158	3481	46.3	> 3165	**5**			361	
R1 / pond	0.040	13750	182.8	> 12500	19			1425	
R1 / stream	0.282	1950	25.9	> 1773	**3**			202	
R2 / stream	0.161	3416	45.4	> 3106	**5**			354	
R3 / stream	0.345	1594	21.2	> 1449	**2**			165	
R4 / stream	0.246	2236	29.7	> 2033	**3**			231	
Trigger		100	10	100	10	10	10	10	10

Values in bold fail the trigger
***** The metabolite is assumed 10 times more toxic than the active substance.

FOCUS$_{sw}$ step 1-2 - TERs for RP 32596 – Carrot at 750 g a.s./ha [4 applications]

Scenario	PEC global max (µg L)	Fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant
		Danio rerio	*Danio rerio*	*Daphnia magna*	*Americamysis bahia*	*Pseudokirchneriella subcapitata*	*Lemna gibba*
		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	EC_{50}
		1300 µg/L	320	1260 µg/L	0.75 µg/L*	7760 µg/L	> 1264* µg/L
FOCUS Step 1							
	32.01	**40.6**	10	**39.4**	**0.02**	242	>39.5
FOCUS Step 2							
	6.25	208		202	**0.1**		
Trigger		100	10	100	10	10	10

Values in bold fail the trigger
***** The metabolite is assumed 10 times more toxic than the active substance.

FOCUS$_{sw}$ step 1-3 - TERs for RP 36221– Carrot at 750 g a.s./ha [4 applications]

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant
		Ictalurus punctatus	*Pimephales promelas*	*Daphnia magna*	*Americamysis bahia*	*Pseudokirchneriella subcapitata*	*Lemna gibba*
		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	EC_{50}
		310 µg/L*	7.31 µg/L*	364 µg/L	0.75 µg/L*	4567 µg/L	> 1264 µg/L*
FOCUS Step 1							
	4.06	**76.4**	**1.8**	**89.7**	**0.2**	139	311
FOCUS Step 2							
	1.20	257.9	**6.1**	303	**0.6**		
FOCUS Step 3							
D3 / ditch	<0.0001		73100		7500		
D6 / ditch	0.014		522.1		53.6		
R1 / pond	0.082		89.1		**9.1**		
R1 / stream	0.221		33.1		**3.4**		
R2 / stream	0.065		112.5		11.5		
R3 / stream	0.167		43.8		**4.5**		
R4 / stream	0.297		24.6		**2.5**		
Trigger		100	10	100	10	10	10

Values in bold fail the trigger
***** The metabolite is assumed 10 times more toxic than the active substance.

FOCUS$_{sw}$ step 4 - TERs for RP 36221– Carrot at 750 g a.s./ha [4 applications]

Organisms : *Americamysis bahia* **Toxicity endpoint:** 0.75 µg/L*					
Mitigation options	**[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**	**[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)**	**PECsw (µg/L)**	**TER**	**Trigger**
FOCUS Step 4					
R1 / pond	10	10	0.033	22.7	10
R1 / stream	20	20	0.052	14.4	10
R3 / stream	20	20	0.039	19.2	10
R4 / stream	20	20	0.07	10.7	10

Values in bold fail the trigger
* The metabolite is assumed 10 times more toxic than the active substance

FOCUS$_{sw}$ step 1-2 - TERs for RP 25040 – Carrot at 750 g a.s./ha [4 applications]

Scenario	**PEC global max (µg L)**	**fish acute**	**fish chronic**	**Aquatic invertebrates**	**Aquatic invertebrates prolonged**	**Algae**	**Higher plant**
		Ictalurus punctatus	*Pimephales promelas*	*Daphnia magna*	*Americamysis bahia*	*Pseudokirchneriella subcapitata*	*Lemna gibba*
		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	EC_{50}
		310 µg/L*	7.31 µg/L*	56280 µg/L	0.75 µg/L	86900 µg/L	> 1264 µg/L*
FOCUS Step 1							
	69.65	**4.5**	**0.1**	808	**0.01**	210	>18.1
FOCUS Step 2							
	2.83	109.5	**2.6**		**0.3**		
Trigger		100	10	100	10	10	10

Values in bold fail the trigger
* The metabolite is assumed 10 times more toxic than the active substance.

FOCUS$_{sw}$ step 1-2 - TERs for LS720942 – Carrot at 750 g a.s./ha [4 applications]

Scenario	PEC global max (µg L)	Fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant
		Ictalurus punctatus	*Pimephales promelas*	*Daphnia magna*	*Americamysis bahia*	*Pseudokirchneriella subcapitata*	*Lemna gibba*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}
		310 µg/L*	7.31 µg/L*	66 µg/L*	0.75 µg/L*	> 150 µg/L*	> 1264 µg/L*
FOCUS Step 1							
	30.097	10.3	**0.2**	**2.19**	**0.02**	> **5.0**	>42
FOCUS Step 2							
	1.990	**163**	**4.7**	**33.2**	**0.4**	> 75.4	
Trigger		100	10	100	10	10	10

Values in bold fail the trigger
***** The metabolite is assumed 10 times more toxic than the active substance.

FOCUS$_{sw}$ step 1-2 - TERs for RP 30181 – Carrot at 750 g a.s./ha [4 applications]

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant
		Ictalurus punctatus	*Pimephales promelas*	*Daphnia magna*	*Americamysis bahia*	*Pseudokirchneriella subcapitata*	*Lemna gibba*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}
		310 µg/L*	9 µg/L*	66 µg/L*	0.75 µg/L*	> 150 µg/L*	> 1264 µg/L*
FOCUS Step 1							
	52.451	**5.91**	**0.1**	**1.26**	**0.01**	> **2.9**	>24.1
FOCUS Step 2							
	5.088	**60.9**	**1.4**	**13.0**	**0.1**	>29.5	
Trigger		100	10	100	10	10	10

Values in bold fail the trigger

* The metabolite is assumed 10 times more toxic than the active substa

Effects on bees (Regulation (EU) N° 283/2013. Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)*

Species	Test substance	Time scale/type of endpoint	End point	toxicity
Apis mellifera	Iprodione	Acute	Oral toxicity (48 h LD_{50})	> 100 µg a.s./bee
Apis mellifera	BAS 610 06 F	Acute	Oral toxicity (48 h LD_{50})	> 147.9 µg prep./bee (> 110.9 µg a.s./bee)
Apis mellifera	BAS 610 10 F (equivalent to BAS 610 06 F)	Acute	Oral toxicity (48 h LD_{50})	> 250.9 µg prep./bee (> 107.6 µg a.s./bee)
Apis mellifera	Iprodione	Acute	Contact toxicity (48 h LD_{50})	> 100 µg a.s./bee
Apis mellifera	BAS 610 06 F	Acute	Contact toxicity (48 h LD_{50})	> 133.3 µg prep./bee (> 100 µg a.s./bee)
Apis mellifera	BAS 610 10 F (equivalent to BAS 610 06 F)	Acute	Contact toxicity (48 h LD_{50})	> 233.2 µg prep./bee (> 100 µg a.s./bee)
Apis mellifera	BAS 610 06 F	Chronic	LDD_{50}	16.6 µg a.s./bee/day
Apis mellifera	BAS 610 06 F	Acute toxicity to honeybee larvae (single exposure)	NOEL	12.5 µg a.s./larva
Osmia lignaria *Apis mellifera*	Iprodione	Acute toxicity to solitary bees	Oral toxicity (72 h LD_{50})	> 125 µg a.s./bee
Osmia lignaria *Apis mellifera*	Iprodione	Acute toxicity to solitary bees	Contact toxicity (72 h LD_{50})	> 125 µg a.s./bee

Potential for accumulative toxicity: *no*

Semi-field test (Cage and tunnel test)

Semi-field test to assess potential effects of BAS 610 10 F on mortality, foraging activity and honey bee brood development (Barth M., 2011a):

BAS 610 10 F was applied at a rate of 1125 g a.s./ha under tunnel conditions to flowering *Phacelia tanacetifolia* during active foraging conditions. No lethal or sublethal effects on honeybee mortality, foraging conditions, behaviour, colony strength and colony development were observed. However, for the termination rates in the test item, two replicates are higher than in control (even if not significant according to the study report). Even if these values are not statistically different from the control, it is not known if these higher termination rates are treatment related or not.

Field tests

Field test to assess potential effects of BAS 610 10 F on colony and brood development (Barth M., 2014a):

BAS 610 10 F was applied at a rate of 1125 g a.s./ha under field conditions to flowering *Phacelia tanacetifolia* during active foraging conditions. Following the application no unacceptable effects on mortality, foraging activity, behaviour, colony development, colony strength, and colony weight were observed. However, regarding the brood development, a higher termination rate was observed at the end of the study (even if not significant according to the study report). These observed effects on the termination rate were caused only by one replicate (2). Even if no statistical difference was observed from the control, it is not known if the higher termination rates are treatment related or not.

Field test to assess potential effects of BAS 610 10 F on colony and brood development (Barth M., 2015a):

BAS 610 10 F was applied at a rate of 1125 g a.s./ha under field conditions to flowering *Phacelia tanacetifolia* during active foraging conditions. Following the application no unacceptable effects on mortality, foraging activity, behaviour, colony development, brood development, colony strength, and colony weight were observed. After the overwintering, no differences were observed between the treatment groups and the control in both trials regarding the colony strength, colony weight and general brood development.

Risk assessment for bees from contact and oral dietary exposure

Species	Test substance	Scenario	Risk quotient	HQ/ETR	Trigger
Screening level assessment					
Apis mellifera	iprodione	Not relevant	$ETR_{acute\ adult\ oral}$	<0.06	0.2
	iprodione	Not relevant	$HQ_{contact}$	<7.5	42
	BAS 610 10 F	Not relevant	$ETR_{acute\ adult\ oral}$	<0.05	0.2
	BAS 610 10 F	Not relevant	$HQ_{contact}$	<7.5	42
	BAS 610 10 F	Not relevant	$ETR_{chronic\ adult}$	**0.343**	0.03
	BAS 610 10 F	Not relevant	ETR_{larvae}	**0.26**[1]	0.2
Osmia lignaria	iprodione	Not relevant	$ETR_{acute\ adult\ oral}$	0.03	0.04
	iprodione	Not relevant	$HQ_{contact}$	6	8
1st tier oral assessment: root vegetables, 750 g a.i./ha, BBCH 13-49					
Apis mellifera	BAS 610 10 F	weeds, BBCH 10 - 39	$ETR_{chronic\ adult}$	**0.09**	0.03
		weeds, BBCH 40 - 69	$ETR_{chronic\ adult}$	0.03	0.03
		field margin, BBCH 10 – 39; BBCH 10 - 69	$ETR_{chronic\ adult}$	0.0009	0.03
		adjacent crop, BBCH 10 - 39; BBCH 10 - 69	$ETR_{chronic\ adult}$	0.0006	0.03
		next crop, BBCH 10 - 39; BBCH 10 - 69	$ETR_{chronic\ adult}$	0.02	0.03
		weeds, BBCH 10 - 39	ETR_{larvae}	0.11[1]	0.2
		weeds, BBCH 40 - 69	ETR_{larvae}	0.03[1]	0.2
		field margin, BBCH 10 - 39; BBCH 10 - 69	ETR_{larvae}	0.001[1]	0.2
		adjacent crop, BBCH 10 - 39; BBCH 10 - 69	ETR_{larvae}	0.0007[1]	0.2
		next crop, BBCH 10 - 39; BBCH 10 - 69	ETR_{larvae}	0.02[1]	0.2
1st tier oral assessment: lettuce, 750 g a.i./ha, BBCH 10-49[2]					
	BAS 610 10 F	weeds, BBCH 10 - 49	$ETR_{chronic\ adult}$	**0.09**	0.03
		field margin, BBCH 10 - 49	$ETR_{chronic\ adult}$	0.0009	0.03
		adjacent crop, BBCH 10 - 49	$ETR_{chronic\ adult}$	0.0006	0.03
		next crop, BBCH 10 - 49	$ETR_{chronic\ adult}$	0.02	0.03
		weeds, BBCH 10 - 49	ETR_{larvae}	0.11[1]	0.2
		field margin, BBCH 10 - 49	ETR_{larvae}	0.001[1]	0.2
		adjacent crop, BBCH 10 - 49	ETR_{larvae}	0.0007[1]	0.2
		next crop, BBCH 10 - 49	ETR_{larvae}	0.02[1]	0.2

[1]Illustrative risk assessment based on a surrogate (single exposure) endpoint
[2]The risk assessment is not triggered for the uses in permanent greenhouses.
[3] The risk assessment is only triggered in those cases when the crop is allowed to flower (i.e. for seeds production).

Risk assessment for honeybees from consumption of contaminated water (root vegetables, lettuce)

Species	Test substance	Risk quotient	ETR	Trigger
Screening level risk assessment from exposure to residues in guttation fluid (water solubility: 9 mg a.s./L)				
Apis mellifera	a.s.	$ETR_{acute\ adult\ oral}$	<0.001	0.2
	BAS 610 10 F	$ETR_{acute\ adult\ oral}$	<0.0009	0.2
	BAS 610 10 F	$ETR_{chronic\ adult\ oral}$	0.003	0.03
	BAS 610 10 F	ETR_{larvae}	0.06[1]	0.2
Risk assessment from exposure to residues in surface water (worst case PECsw of 474.791 µg/L – root vegetables, FOCUS step 1)				
Apis mellifera	a.s.	$ETR_{acute\ adult\ oral}$	<5.4E-05	0.2
	BAS 610 10 F	$ETR_{acute\ adult\ oral}$	<4.9E-05	0.2
	BAS 610 10 F	$ETR_{chronic\ adult\ oral}$	0.0003	0.03
	BAS 610 10 F	ETR_{larvae}	0.004[1]	0.2

[1]Illustrative risk assessment based on a surrogate endpoint (single exposure).

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	BAS 610 06 F	Mortality, LR_{50}	> 6750 g/ha 44.5 % effect at 6750 g/ha
		Reproduction, ER_{50}	Not determined.
Aphidius rhopalosiphi	BAS 610 06 F	Mortality, LR_{50}	> 6750 g/ha 19 % effect at 6750 g/ha
		Reproduction, ER_{50}	Not determined.

First tier risk assessment for lettuce and carrot at 750 g a.s./ha [4 applications] (worst-case scenario)

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
BAS 610 06 F	*Typhlodromus pyri*	> 6750	< 0.4	< 0.007	2
BAS 610 06 F	*Aphidius rhopalosiphi*	> 6750	< 0.4	< 0.007	2

[1]indicate distance assumed to calculate the drift rate

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./ OM[1]	Time scale	End point	Toxicity
Earthworms					
Eisenia foetida	Iprodione	Mixed with soil/ 10 % OM	Chronic	Mortality, reproduction	NOEC = 1000 mg a.s./kg d.w.soil (NOECcorr = 500 mg a.s./kg d.w.soil)
Eisenia foetida	BAS 610 06 F	Mixed with soil/ 5% OM	Chronic	Mortality, reproduction	EC_{10} = 114 mg a.s./kg d.w.soil (EC_{10}corr = 57 mg a.s./kg d.w.soil)
Eisenia foetida	RP 30228	Mixed with soil/ 10 % OM	Chronic	Mortality, reproduction	NOEC = 1000 mg met./kg d.w.soil (NOECcorr = 500 mg met./kg d.w.soil)
Eisenia foetida	RP 32596	Mixed with soil/ 10 % OM	Chronic	Mortality, reproduction	NOEC = 100 mg met./kg d.w.soil (NOECcorr = 50 mg met./kg d.w.soil)
Eisenia foetida	RP 36221	Mixed with soil/ 5% OM	Chronic	Mortality, reproduction	NOEC = 43.4 mg met./kg d.w.soil (NOECcorr = 21.7 mg met/kg d.w.soil)
Eisenia foetida	RP 25040	Mixed with soil/ 10 % OM	Chronic	Mortality, reproduction	NOEC = 100 mg met./kg d.w.soil
Other soil macroorganisms					
Folsomia candida	BAS 610 06 F	Mixed with soil/ 5% OM	Chronic	Mortality, reproduction	NOEC = 750 mg a.s./kg d.w.soil (NOECcorr = 375 mg a.s./kg d.w.soil)
Hypoaspis aculeifer	BAS 610 06 F	Mixed with soil/ 5% OM	Chronic	Mortality, reproduction	NOEC = 188 mg a.s./kg d.w.soil (NOECcorr = 94 mg met/kg d.w.soil)

[1]To 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)
-

Nitrogen transformation	Iprodione	< 25 % effect at day 28	8 mg a.s./kg d.w.soil (equivalent to 6.0 kg a.s./ha)
Nitrogen transformation	BAS 610 06 F	< 25 % effect at day 28	20.33 mg prod./kg d.w.soil (equivalent to 15.24 kg prod./ha)
Nitrogen transformation	RP 30228	< 25 % effect at day 28	8 mg met./kg d.w.soil (equivalent to 6.0 kg met./ha)
Nitrogen transformation	RP 32596	< 25 % effect at day 28	8 mg met.kg d.w.soil (equivalent to 6.0 kg met./ha)
Nitrogen transformation	RP 36221	< 25 % effect at day 42	10 mg met./kg d.w.soil (equivalent to 7.5 kg met./ha)
Nitrogen transformation	RP 25040	< 25 % effect at day 28	10 mg met./kg d.w.soil (equivalent to 7.5 kg met./ha)

Toxicity/exposure ratios for soil organisms

Lettuce and carrot at 750 g a.s./ha [4 applications] (worst-case scenario)

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
Eisenia fetida	Iprodione	Chronic	1.923*	260	5
Eisenia fetida	BAS 610 06 F	Chronic	1.923*	29.6	5
Eisenia fetida	RP 30228	Chronic	0.587	852	5
Eisenia fetida	RP 32596	Chronic	0.106	472	5
Eisenia fetida	RP 36221	Chronic	0.478*	45.4	5
Eisenia fetida	RP 25040	Chronic	0.144	694	5
Eisenia fetida	RP 35 606**	Chronic	0.435	115	5
Eisenia fetida	LS720942**	Chronic	0.089	562	5
Other soil macroorganisms					
Folsomia candida	Iprodione (BAS 610 06 F)	Chronic	1.923*	195	5
Folsomia candida	RP 30228**	Chronic	0.587	64	5
Folsomia candida	RP 32596**	Chronic	0.106	354	5
Folsomia candida	RP 36221**	Chronic	0.478*	78	5
Folsomia candida	RP 25040**	Chronic	0.144	260	5
Folsomia candida	RP 35 606**	Chronic	0.435	86	5
Folsomia candida	LS720942**	Chronic	0.089	421	5
Hypoaspis aculeifer	Iprodione (BAS 610 06 F)	Chronic	1.923*	49	5
Hypoaspis aculeifer	RP 30228**	Chronic	0.587	16	5
Hypoaspis aculeifer	RP 32596**	Chronic	0.106	89	5
Hypoaspis aculeifer	RP 36221**	Chronic	0.478*	20	5
Hypoaspis aculeifer	RP 25040**	Chronic	0.144	65	5
Hypoaspis aculeifer	RP 35 606**	Chronic	0.435	22	5
Hypoaspis aculeifer	LS720942**	Chronic	0.089	106	5

* $PEC_{soil\ accumulation}$
** The metabolite is assumed 10 times more toxic than the active substance.

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

Data on metabolites RP 30228, RP 32596, RP 36221, RP 25040, RP 35606, LS720942 and RP 30181 indicate that all metabolites seem to have no herbicidal activity.

Laboratory dose response tests

Species	Test substance	ER_{50} (g/ha) vegetative vigour*	ER_{50} (g/ha) emergence*
oilseed rape, lettuce, tomato, green cabbage, soya bean, carrot, onion, rye grass, oats, corn	BAS 610 06 F	> 2500	--
potato	BAS 610 06 F	> 750	
oilseed rape, lettuce, tomato, green cabbage, soya bean, carrot, onion, rye grass, oats, corn	BAS 610 06 F	> 2500	> 2500
Extended laboratory studies : - Semi-field and field test: -			

*dose is expressed in units of preparation

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	EC_{50} > 1000 mg a.s./L
Pseudomonas sp	EC_{50} > 10.4 mg a.s./L

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. : -
Available monitoring data concerning effect of the PPP. : -

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds[1]

Compartment	
soil	Iprodione
water	Iprodione, RP 35 606
sediment	Iprodione
groundwater	Iprodione, RP 35 606, RP 30181

[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	Iprodione
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][15]:	-
Peer review proposal[16] for harmonised classification according to Regulation (EC) No 1272/2008:	Aquatic acute 1, H400: Very toxic to aquatic life (Acute M = 100) Aquatic chronic 1, H410: Very toxic to aquatic life with long lasting effects (Chronic M = 100)

[15] 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.

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

Abbreviations

$1/n$	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AAOEL	acute acceptable operator exposure level
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AUC	area under the blood concentration/time curve
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony-forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
Cmax	concentration achieved at peak blood level
DAA	days after application
DAT	days after treatment
DDD	daily dietary dose
DM	dry matter
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemicals Agency
EEC	European Economic Community

EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
ETR	exposure toxicity ratio
ETR_{acute}	exposure toxicity ratio for acute exposure
ETR_{larvae}	exposure toxicity ratio for chronic exposure
ETR_{larvae}	exposure toxicity ratio for larvae
ETR_{HPG}	exposure toxicity ratio for effects on honeybee hypopharygeal glands
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	Time-weighted average factor
FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector
FIR	food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as International Group of National Associations of Manufacturers of Agrochemical Products; GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathione
Hb	haemoglobin
Hct	haematocrit
HPLC	high-pressure liquid chromatography or high-performance liquid chromatography
HPLC-MS	high-pressure liquid chromatography–mass spectrometry
HPG	hypopharygeal glands
HQ	hazard quotient
$HQ_{contact}$	hazard quotient for contact exposure
HR	hazard rate
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
iv	intravenous

JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
K_{Foc}	Freundlich organic carbon adsorption coefficient
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography–mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDD_{50}	lethal dietary dose; median
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mm	millimetre (also used for mean measured concentrations)
mN	milli-newton
MRL	maximum residue level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water-holding capacity
NESTI	national estimated short-term intake
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NPD	nitrogen–phosphorus detector
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration

PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in groundwater
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure–activity relationship
r^2	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SMILES	simplified molecular-input line-entry system
SPG	specific protection goal
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
Tmax	time until peak blood levels achieved
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid-stimulating hormone (thyrotropin)
TWA	time-weighted average
UDS	unscheduled DNA synthesis

UF	uncertainty factor
UV	ultraviolet
W/S	water/sediment
w/v	weight per unit volume
w/w	weight per unit weight
WBC	white blood cell
WG	water-dispersible granule
WHO	World Health Organization