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Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

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Technical work: consideration of draft decision guidance documents: chlorpyrifos

Draft decision guidance document for chlorpyrifos

Note by the Secretariat

I. Introduction

1. At its nineteenth meeting, the Chemical Review Committee reviewed notifications of final regulatory action for chlorpyrifos submitted by the European Union, Malaysia and Sri Lanka, together with the supporting documentation referred to therein, and concluded that the notifications met all the criteria of Annex II to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade.

2. In decision CRC-19/3, the Committee adopted a rationale for its conclusion related to the notifications from the European Union, Malaysia and Sri Lanka, and recommended, in accordance with paragraph 6 of Article 5 of the Convention, that the Conference of the Parties list chlorpyrifos in Annex III to the Convention as a pesticide. By paragraph 4 of that decision, the Committee decided, in accordance with paragraph 1 of Article 7 of the Convention, to prepare a draft decision guidance document for chlorpyrifos.

3. Pursuant to decision CRC-19/3 and the workplan for the preparation of draft decision guidance documents adopted by the Committee (UNEP/FAO/RC/CRC.19/14, annex III), the intersessional drafting group established at the nineteenth meeting has prepared a draft decision guidance document for chlorpyrifos, which is set out in the annex to the present note, without formal editing. A compilation of comments relating to the draft decision guidance document received from Committee members and observers, including information on how those comments were addressed, is set out in document UNEP/FAO/RC/CRC.20/INF/4.

II. Proposed action

4. The Committee may wish to finalize the draft decision guidance document and to forward it, together with its recommendation to list chlorpyrifos in Annex III to the Convention as a pesticide, for consideration by the Conference of the Parties at its twelfth meeting.

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

Annex

Draft Decision Guidance Document

Chlorpyrifos

Rotterdam Convention

Operation of the prior informed consent procedure
for banned or severely restricted chemicals

**Secretariat of the Rotterdam Convention
on the Prior Informed Consent Procedure for
Certain Hazardous Chemicals and Pesticides in
International Trade**

Introduction

The objective of the Rotterdam Convention is to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties. The Secretariat of the Convention is provided jointly by the United Nations Environment Programme (UNEP) and the Food and Agriculture Organization of the United Nations (FAO).

Candidate chemicals[1] for inclusion in the prior informed consent (PIC) procedure under the Rotterdam Convention include those that have been banned or severely restricted by national regulatory actions in two or more Parties[2] in two different regions. Inclusion of a chemical in the PIC procedure is based on regulatory actions taken by Parties that have addressed the risks associated with the chemical by banning or severely restricting it. Other ways might be available to control or reduce such risks. Inclusion does not, however, imply that all Parties to the Convention have banned or severely restricted the chemical. For each chemical included in Annex III of the Rotterdam Convention and subject to the PIC procedure, Parties are requested to make an informed decision whether they consent or not to the future import of the chemical.

At its […] meeting, held in […] on […], the Conference of the Parties agreed to list chlorpyrifos in Annex III of the Convention and adopted the decision-guidance document with the effect that this chemical became subject to the PIC procedure.

The present decision-guidance document was communicated to designated national authorities on […], in accordance with Articles 7 and 10 of the Rotterdam Convention.

Purpose of the decision guidance document

For each chemical included in Annex III to the Rotterdam Convention, a decision-guidance document has been approved by the Conference of the Parties. Decision-guidance documents are sent to all Parties with a request that they make a decision regarding future import of the chemical.

Decision-guidance documents are prepared by the Chemical Review Committee. The Committee is a group of government-designated experts established in line with Article 18 of the Convention, which evaluates candidate chemicals for possible inclusion in Annex III of the Convention. Decision-guidance documents reflect the information provided by two or more Parties in support of their national regulatory actions to ban or severely restrict the chemical. They are not intended as the only source of information on a chemical nor are they updated or revised following their adoption by the Conference of the Parties.

There may be additional Parties that have taken regulatory actions to ban or severely restrict the chemical and others that have not banned or severely restricted it. Risk evaluations or information on alternative risk mitigation measures submitted by such Parties may be found on the Rotterdam Convention website (www.pic.int).

Under Article 14 of the Convention, Parties can exchange scientific, technical, economic and legal information concerning the chemicals under the scope of the Convention including toxicological, ecotoxicological and safety information. This information may be provided directly to other Parties or through the Secretariat. Information provided to the Secretariat will be posted on the Rotterdam Convention website.

Information on the chemical may also be available from other sources.

[1] According to the Convention, the term “chemical” means a substance, whether by itself or in a mixture or preparation and whether manufactured or obtained from nature, but does not include any living organism. It consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial.

[2] According to the Convention, the term “Party” means a State or regional economic integration organization that has consented to be bound by the Convention and for which the Convention is in force.

Disclaimer

The use of trade names in the present document is primarily intended to facilitate the correct identification of the chemical. It is not intended to imply any approval or disapproval of any particular company. As it is not possible to include all trade names presently in use, only a number of commonly used and published trade names have been included in the document.

While the information provided is believed to be accurate according to data available at the time of preparation of the present decision-guidance document, FAO and UNEP disclaim any responsibility for omissions or any consequences that may arise there from. Neither FAO nor UNEP shall be liable for any injury, loss, damage or prejudice of any kind that may be suffered as a result of importing or prohibiting the import of this chemical.

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of FAO or UNEP concerning the legal status of any country, territory, city or area or of its authorities or concerning the delimitation of its frontiers or boundaries.

STANDARD CORE SET OF ABBREVIATIONS

<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to
°C	degree Celsius (centigrade)
°F	degree Fahrenheit
µg	microgram
AAC	Acceptable Air Concentration
AChE	acetylcholinesterase
ADI	acceptable daily intake
ADR	transport of dangerous goods by road
ACGIH	the American Conference of Governmental Industrial Hygienists, charitable scientific organization
ARfD	acute reference dose
ATSDR	Agency for Toxic Substances and Disease Registry
BEI	Biological Exposure Indices
bw	body weight
CAC	Codex Alimentarius Commission
CalEPA	California Environmental Protection Agency
CAS	Chemical Abstracts Service
CCPR	Codex Committee on Pesticides Residues
CXLs	Codex maximum residue levels of pesticide residues in or on food and feed
cm	centimetre
DNT	Developmental neurotoxicity
DT_{50}	dissipation time 50%
EC_{50}	median effective concentration
EFSA	European Food Safety Authority
ER_{50}	medium effective rate
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
g	gram
h	hour
ha	hectare
HSDB	Hazardous Substances Data Bank of the U.S. National Library of Medicine's Toxicology Data Network
ILO	International Labour Organization
IMDG	International Maritime Dangerous Goods
IPCS	International Programme on Chemical Safety
IUPAC	International Union of Pure and Applied Chemistry

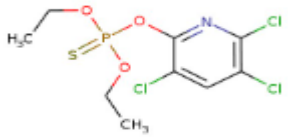
STANDARD CORE SET OF ABBREVIATIONS

JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)
kg	kilogram
Koc	soil organic carbon-water partition coefficient.
Kow	octanol–water partition coefficient
kPa	kilopascal
L	litre
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
LOAEL	lowest-observed-adverse-effect level
LOEL	lowest-observed-effect level
mg	milligram
ml	millilitre
mm Hg	millimeter mercury
MRL	maximum residue limit
ng	nanogram
NIOSH	US National Institute for Occupational Safety and Health
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration
Pow	octanol-water partition coefficient, also referred to as Kow
PPDB	Pesticides Properties DataBase
ppm	parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/L are used).
RBC	Red blood cells
RfD	reference dose (for chronic oral exposure; comparable to ADI)
RID	regulation concerning the international carriage of dangerous goods by rail
STEL	Short time exposure limit
TEAP	Technology and Economic Assessment Panel
TLV	Threshold Limit Values
TWA	time-weighed average
UNEP	United Nations Environment Programme
UV	ultraviolet
WHO	World Health Organization
wt	weight

Decision guidance document for a banned or severely restricted chemical

Chlorpyrifos **Published:**

1. Identification and uses (see annex 1 for further details)

Common name	Chlorpyrifos
Chemical name and other names or synonyms	IUPAC: O,O-diethyl-O-3,5,6-trichloro-2-pyridyl phosphorothioate CAS: O,O-diethyl-O-(3,5,6-trichloro-2-pyridinyl) phosphorothioate, *O*,*O*-diethyl *O*-3,5,6-trichloropyridin-2-yl phosphorothioate Synonym: Chlorpyrifos-ethyl
Molecular formula	$C_9H_{11}Cl_3NO_3PS$
Chemical structure	
CAS-No.(s)	2921-88-2
Harmonized System Customs Code	2933.39 (other compounds containing an unfused pyridine ring)
Other numbers	EC numbers: EINECS 220-864-4; EEC 015-084-00-4
Category	Pesticide
Regulated category	Pesticide
Use(s) in regulated category	In Malaysia, chlorpyrifos was registered as a plant protection product to control pests in various types of crops and for use in public health to control urban pests, such as cockroaches, termites, mosquitoes, ants, flies and bugs. The registration of chlorpyrifos pesticides for use in agriculture is cancelled but chlorpyrifos may still be used in public health to control urban pests, such as cockroaches, termites, mosquitoes, ants, flies and bugs. Therefore, the final regulatory action is notified as a severe restriction. In Sri Lanka, chlorpyrifos was used for agricultural pest control in rice and vegetables[3]. In the European Union chlorpyrifos was used as an acaricide and insecticide.
Trade names	Trade names listed by Malaysia: Chemitox 75, G-505, Starfos 505, Lorsban 40EC, Nurelle-D505EC, Dursban 75+, Eclipse 505, Pest-ban 100, Fighter 505, Tricel 21.2EC, Tricel 38.7EC, ZA 505; Trade names listed by Sri Lanka: more than 21 trade products, e.g. Pyrinex, Vitashield, Pyrimac, Pyriban, Lidorban, Unifos 400, Cyren 40, Mackfos; Trade names listed by the European Union: Pyrinex 250 CS, Pyrinex, EF-1551EC, RIMI 101 RB, Chlorpyrifos-ethyl 5G GR, SAP250 CS, Dursban, OMS 0971, Lorsban, Brodan, Killmaster, Suscon, Coroban, Terial, Danusban, Durmet, Eradex. *This is an indicative list of trade names. It is not intended to be exhaustive.*
Formulation types	The main formulation types mentioned in the notifications are Emulsifiable concentrate (EC), Capsule suspension (CS), Bait ready for use (RB) and Granule (GR).
Uses in other categories	There is no reported use as an industrial chemical.
Basic manufacturers	Cheminova Agro A/S (Denmark), M/S United Phosphorus Limited, BASF Finlay (Pvt.) Ltd., Dow Agrosciences (USA), Excel Industries Ltd. (India), Ficom Organics (India), Fugian Fuzhou General Fine Chemical (China), Luxembourg Industries (Pamol) Ltd. (Israel), Adama Makhteshim Ltd. (Israel), Pazchem Ltd. (Israel), UPL Ltd. “Uniphos House” (India), Mitsu Industries Ltd. (India). *This is an indicative list of current and former manufacturers. It is not intended to be exhaustive*.

[3] According to the notification of final regulatory action submitted by Sri Lanka, before the final regulatory action, the residential indoor use of chlorpyrifos for termite controls was prohibited.

2. Reasons for inclusion in the PIC procedure

Chlorpyrifos is included in the PIC procedure as a pesticide. It has been listed on the basis of the final regulatory action to severely restrict its use notified by Malaysia as well as on the basis of the final regulatory actions to ban its use notified by Sri Lanka and the European Union. Contact details of the designated national authorities of these three Parties are set out in annex 3 to the decision guidance document.

No final regulatory actions relating to industrial chemical uses have been notified.

2.1 Final regulatory action (see Annex 2 for further details)

Malaysia

The regulatory action is notified as a severe restriction. Based on the Circular Letter from the Pesticides Board dated 28 April 2021 informing the industry on the Pesticides Board's decision dated 9 April 2021, the registration of chlorpyrifos pesticides for use in agriculture is cancelled. The regulatory action has entered into force on 1 May 2023.

The ban of use of all types of chlorpyrifos formulations in the agriculture in Malaysia as of 1 May 2023 was decided due to the risks of adverse effects to human health, ecology and the environment through agricultural use of chlorpyrifos, as well as food safety risks due to the maximum residue limits (MRL) by violations of chlorpyrifos residues in agricultural commodities.

Chlorpyrifos is restricted to use by specialist public health services including for urban pests such as cockroaches, termites, mosquitoes, ants, flies, and bugs.

Reason: Human Health

Sri Lanka

The regulatory action is notified as a ban. Sri Lanka by this action prohibited all applications of chlorpyrifos pesticides as well as its formulation, trade and import. The ban was introduced by the decision of the Pesticide Technical & Advisory Committee of Sri Lanka dated 5 April 2013. As a result of the decision, the registration of all products and formulations containing the active ingredient chlorpyrifos was cancelled. The ban entered into force on 28 December 2016. Effective from that date, the use of chlorpyrifos as a pesticide for agriculture and structural termite controls was prohibited in Sri Lanka. Effective from the same date, the production, trade and import of chlorpyrifos had been prohibited. Dealers and shops were given a grace period to finish off the old stock of chlorpyrifos products by 28 December 2018.

Already in 2004, the Pesticide Technical & Advisory Committee of Sri Lanka had decided to prohibit the residential indoor use of chlorpyrifos for termite controls, while other uses had remained allowed.

Reason: Human Health and Environment

European Union

The regulatory action is notified as a ban. As of 16 January 2020, it is prohibited to place on the market or use plant production products containing chlorpyrifos by Commission Implementing Regulation (EU) 2020/18 of 10 January 2020 concerning the non- renewal of the approval of the active substance chlorpyrifos, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of the plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Official Journal of the European Union L 7, 13.1.2020, p. 14). EU Member States had to withdraw all authorisations for plant protection products containing chlorpyrifos as an active substance by 16 February 2020 at the latest. Disposal, storage, placing on the market and use of existing stocks of plant protection products containing chlorpyrifos is prohibited as of 16 April 2020.

Reason: Human Health

2.2 Risk evaluation (see Annex 1 for further details)

Malaysia

The final regulatory action was based on a risk evaluation to protect human health. The Pesticides Board reviewed and scrutinized many research information documents and publications related to chlorpyrifos from within and outside the country.

The risk evaluation was based on national and international risk evaluations. Evidence from the Department of Agriculture's Pesticides Monitoring Program reports that chlorpyrifos residues consistently exceeded national maximum residue limits (MRLs) in recommended crops, risking long term exposure of consumers to chlorpyrifos residues. In addition, according to data generated by the National Poison Centre Malaysia over a 10-year period (2006-2015), 40 % of reported cases of insecticide poisoning involved pesticides from the organophosphate group, with chlorpyrifos being the most commonly reported pesticide. The data from 2016-2019 recorded that 24% of insecticide poisoning cases (1374 cases) involved chlorpyrifos.

A study by Hod et al. (2011) showed the relationship between chlorpyrifos blood level and exposure symptoms among paddy farmers in Selangor indicating that exposure levels under conditions of use were leading to harmful effects.

The evaluation was also based on the pesticide risk assessment of the active substance chlorpyrifos by EFSA (2011), the Human health risk assessment (2020) and Ecological risk assessment (2021) of chlorpyrifos by the United States.

According to the supporting documentation, Malaysia used findings from the international risks assessments and compared these with local conditions of use of chlorpyrifos in plant protection products. Studies conducted by EFSA and the Department of Pesticide Regulation in California have shown that chlorpyrifos has the potential to cause genotoxic effects and developmental toxicity in humans, and compared these with local conditions of use of chlorpyrifos in plant protection products. Malaysia anticipated that the risks to human health under Malaysian conditions are much higher than in the European Union and California. Malaysia stated that the hot and humid conditions in the tropics can make wearing proper protective clothing sometimes impossible, and if the proper protective equipment is available, the cost might be an issue for poor farmers.

Summarizing the above, the final regulatory action was based on a risk evaluation, which included a health hazard evaluation of chlorpyrifos and the prevailing conditions of the use of pesticides in Malaysia (application doses, methods, protective measures, agricultural practices).

Sri Lanka

Sri Lanka's risk evaluation was also based on national and international risk evaluations, including the human health assessment on chlorpyrifos conducted by USA EPA in 2000. This study had been used as a basis for Sri Lanka's 2004 decision to ban the use of chlorpyrifos for indoor termite control. The ban on all use of chlorpyrifos formulations was based on a risk and hazards evaluation related to human health (excessive occupational exposure of farmers and poisoning cases among the farming communities) and to the environment (risks to indigenous fish communities).

The study by Aponso *et al.* (2002) on exposure and risk assessment for farmers occupationally exposed to chlorpyrifos in Sri Lanka showed that farmers using chlorpyrifos on cucurbits (grows on trellises = canopies) can be exposed to unnecessarily high levels of chlorpyrifos via dermal exposure. It was interpreted by the Sri Lanka to indicate the high occupational risk of chlorpyrifos to the farmers under use conditions in Sri Lanka.

The study by Aponso et al. (2003) on "Analysis of water for pesticides in two major agricultural areas of the dry zone" concluded that farmers take minimal precautions when handling pesticides and 70% of the farmers did not apply the recommended dosage. It also reported that unwarranted practices such as washing spray equipment in streams and disposal of empty containers close to water bodies would have a high potential to contaminate internal water bodies such as water wells and small tanks. Furthermore, it concluded that there are strong indications of acute pesticide poisoning potential among the farmers (UNEP/FAO/RC/CRC.19/INF/14, p. 320).

The results of the study by Sumith et al. (2012) on potential impact of agricultural pesticides on widely distributed fishes (*Teleostei*, family: *Cyprinidae*) in agricultural areas in Sri Lanka showed that chlorpyrifos, diazinon and carbosulfan had the greatest number of agricultural applications and identified as dominant pollutants. The study revealed dynamic impact of agricultural pollutants (including chlorpyrifos) on indigenous fish communities and their existence. Stringent pesticide management options and good agricultural practices are recommended to protect fish in agricultural catchments in Sri Lanka (UNEP/FAO/RC/CRC.19/INF/14, p. 336).

Summarizing the above, the final regulatory action was based on an evaluation of risks to human health and to the environment, taking into account the prevailing conditions of the use of pesticides, especially chlorpyrifos, in Sri Lanka (application doses, methods, protective measures, agricultural practices).

European Union

The overall conclusion of the European Union risk assessment of chlorpyrifos in relation to impacts on human health, based on the information available and the proposed conditions of use, was that the EU approval criteria for active ingredients in plant protection products were not satisfied.

The supporting documentation (UNEP/FAO/RC/CRC.19/INF/15/Rev.2) contains the main results of the risk assessment. As a first step, the risk evaluation of the active substance chlorpyrifos was done by a rapporteur Member State, taking into account proposed uses and exposure conditions that prevail in the EU. The rapporteur Member State then submitted its renewal assessment report (RAR) to the European Food Safety Authority (EFSA). After the commenting period for Member States, the applicants and the public, in April 2019, the EFSA convened an expert discussion related to chlorpyrifos impacts to mammalian toxicology and human health. On 31 July 2019, EFSA issued a statement on the outcome of the risk assessment for human health for chlorpyrifos. Concerns were raised with regard to chromosome aberration and DNA damage (oxidative stress and topoisomerase II inhibition), resulting in an unclear genotoxic potential. Consequently, the experts determined that it was not possible to establish health-based reference values for chlorpyrifos or to conduct relevant consumer and non-dietary risk assessments. Therefore, the experts also determined that it cannot be excluded that there is a probability of adverse effects to human health at any level of exposure.

The renewal report, which summarizes the results of the evaluation process, concluded that from the assessments made on the basis of the available information (RAR, comments thereon, EFSA statement, applicant comments on the EFSA statement and draft renewal report), no plant protection product containing the active substance chlorpyrifos is expected to satisfy the requirements laid down in article 29(1) of Regulation (EC) No. 1107/2009 and the uniform principles laid down in Regulation (EU) No. 546/2011.

Because the European Union approval criteria related to the effects of chlorpyrifos on human health were not satisfied, the results of other risk assessment components, such as the initial environmental risk assessment, could not alter this conclusion. This is the reason why only concerns for human health are listed as reasons for the final regulatory action.

Summarizing the above, the final regulatory action was based on a risk evaluation which identified concerns for human health under the foreseen conditions of use of chlorpyrifos as an active ingredient in pesticides in the European Union.

3. Protective measures that have been applied concerning the chemical

3.1 Regulatory measures to reduce exposure

Malaysia

The regulatory action is notified as a severe restriction. The registration of chlorpyrifos pesticides for use in agriculture is cancelled as of 1 May 2023. Chlorpyrifos is restricted to use in public health including the control of urban pests such as cockroaches, termites, mosquitoes, ants, flies, and bugs.

Sri Lanka

The regulatory action is notified as a ban. All applications of chlorpyrifos pesticides as well as its formulation, trade and import are prohibited. The registration of all products and formulations containing the active ingredient chlorpyrifos was cancelled on 28 December 2016. The ban entered into force on 28 December 2016 but it was given a grace period for stock clearance at dealers/shops until 28 December 2018.

The European Union

The regulatory action is notified as a ban. Complete entry into force of all provisions of Commission Implementing Regulation (EU) 2020/18 of 10 January 2020 concerning the non- renewal of the approval of the active substance chlorpyrifos was on 16 January 2020. EU Member States had to withdraw authorisations for plant protection products containing chlorpyrifos as an active substance by 16 February 2020. The grace period for disposal, storage, placing on the market and use of existing stocks of plant protection products containing chlorpyrifos ended on 16 April 2020.

3.2 Other measures to reduce exposure

Malaysia

None reported.

Sri Lanka

None reported.

The European Union

None reported

3.3 Alternatives

Malaysia

The following information on chemical alternative options for certain major crops was made available:

Vegetables: cypermethrin, deltamethrin, permethrin, indoxacarb, *Bacillus thuringiensis* subsp. *kurstaki* (3A, 3B), fenvalerate, imidacloprid, lufenuron, emamectin benzoate, diafenthiuron + fenoxycarb, diflubenzuron, diazinon+ cypermethrin, teflubenzuron, abamectin, azadirachtin, chlorfluazuron, diafenthiuron, spinosad, thiocyclam hydrogen oxalate, alpha-cypermethrin, esfenvalerate, malathion, and diazinon.

Paddy: sulfoxaflor + fipronil, imidacloprid, pymetrozine, triflumezopyrim, cartap hydrochloride, malathion, fenobucarb, dinotefuran, carbaryl, fenitrothion + fenobucarb, etofenprox, buprofezin + cartap hydrochloride, buprofezin + esfenvalerate, buprofezin + tebufenozide, cartap hydrochloride + isoprocarb, and lambda-cyhalothrin, methoxyfenozide, and tebufenozide.

Oil palm: *Bacillus thuringiensis* subsp. *kur*staki, chlorantraniliprole, and fipronil

Sri Lanka

The following information on chemical alternatives were considered sufficient for all uses of chlorpyrifos:

Rice leaf-folder, Rice case worm – chlorfluazuron 5%, methoxyfenozide 24%, flubendiamide 24%, novaluron 10%, chromafenozide 5%.
Rice stem borer – thiocyclam 4%, Chlorantraniliprole 20%, thiamethoxam 20%.
Stem borer, legume pod borer – novaluron 10%, chlorfluazuron 5%, etofenprox 10%.
Root-eating ants – diazinon 5%.

Integrated Pest Management (IPM) concept and its practices have been practised as the government policy over the years.

The European Union

No information on alternatives was made available.

3.4 Socio-economic effects

Malaysia

It is anticipated that the withdrawal of chlorpyrifos usage in agriculture would not cause any adverse impacts in agriculture, as there are many cost-effective alternatives that are safer than chlorpyrifos.

Sri Lanka

According to the conclusion of a review by Manuweera et al (2008), there is no good evidence that a pesticide ban necessarily results in reduced output or increased costs for the farmer. Overall, the review identified no significant changes in food production during 1990s, and no changes in the rate of increase in production costs or yield that could be attributed to the pesticide restrictions.

The European Union

No assessment of socio-economic effects was reported.

4. Hazards and Risks to human health and the environment

4.1 Hazard Classification	
WHO / IPCS	Moderately hazardous (Class II) (WHO, 2019)
IARC	Not evaluated

European Union	Classification according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (CLP-Regulation) Acute Tox. 3 * H301 -Toxic if swallowed Aquatic Acute 1 H400 – Very toxic to aquatic life (M = 10000) Aquatic Chronic 1 H410 – Very toxic to aquatic life with long lasting effects * The manufacturers or importers must apply at least the minimum classification but must classify in a more severe hazard category in the event that further information is available which shows that the hazard(s) meet the criteria for the classification in the more severe category (see Annex VI, Section 1.2.1 of the CLP Regulation.)
US EPA	Chlorpyrifos is classified as Toxicity Category II via the dermal route and Toxicity Category IV for skin irritation potential. *Chlorpyrifos: Third Revised Human Health Risk Assessment for Registration Review:* https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0944

4.2 Exposure limits

Occupational Exposure Limits

ACGIH: 0.1 mg/m^3, as 8 hour TWA; (skin); A4 (not classifiable as a human carcinogen); BEI issued: Acetylcholinesterase activity in red blood cells = 70% of individual's baseline; Butylcholinesterase activity in serum or plasma = 60% of individual's baseline; Sample at end of shift (ICSC:0851 (April 2014))

NIOSH: 0.2mg/ m^3 over a 10 hr. work shift and 0.6 mg/m^3 not to be exceeded over a 15 minute work period

Excursion Limit Recommendation: Excursions in worker exposure levels may exceed 3 times the TLV-TWA for no more than a total of 30 minutes during a work day, and under no circumstances should they exceed 5 times the TLV-TWA, provided that the TLV-TWA is not exceeded.

(American Conference of Governmental Industrial Hygienists. Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices. ACGIH, Cincinnati, OH 2014, p. 112)

Australia: 0.2 mg/m3, 0.6 mg/m3 TWA (deletion proposed), skin (1999); https://www.apvma.gov.au/sites/default/files/publication/14751-chlorpyrifos-irr-ohs.pdf

United Kingdom: 0.2 mg/cu m, 10-min STEL 0.6 mg/cu m (1991).

HSDB: Minimum Risk Level, Acute Oral: 0.003 mg/kg/day (L134) Intermediate Oral: 0.003 mg/kg/day (L134) Chronic Oral: 0.001 mg/kg/day (L134)
(Toxin and Toxin Target Database (T3DB), Pubchem)

JMPR (2004)

Acceptable Daily Intake (ADI): 0-0.01 mg/kg bw per day
Acute Reference Dose (ARfD): 0.1 mg/kg bw per day

EFSA (2014)

ADI: 0.001 mg/kg bw per day
ARfD: 0.005 mg/kg bw per day
AOEL: 0.001 mg/kg bw per day

EFSA (2019)

EFSA could not derive reference values in 2019 since a genotoxic potential could not be excluded for chlorpyrifos.

European Union (2020)

The MRL was set to the limit of analytical detection (0.01 mg/kg) for all commodities. The residue definition differs for the following combinations pesticide-code number: Chlorpyrifos-methyl - code 500000: sum of chlorpyrifos-methyl and desmethyl chlorpyrifos-methyl
http://data.europa.eu/eli/reg/2020/1085/oj

Codex Alimentarius (FAO-WHO)

All CXLs for chlorpyriphos were revoked in 2022 by the CAC Meeting based on the CCPR Report in 2022: “The JMPR Secretariat informed that chlorpyrifos (17) and chlorpyrifos-methyl (90) were scheduled together for a periodic

evaluation by the 2024 JMPR in response to the concern form raised by EU but that the available toxicology dossier for chlorpyrifos was incomplete. As public health concern was expressed in the concern form and it was unlikely that data to complete risk assessment would be available, CCPR agreed to revoke all CXLs. It was further agreed to maintain chlorpyrifos on the periodic review schedule for the 2024 JMPR pending confirmation that a full data package would be available for review (53:36-37)*. The Observer from AGRO-CARE confirmed its commitment to provide the necessary data for the periodic review of chlorpyrifos (17) (53:219)*."
(*) paragraphs in CCPR report 53 of 2022

4.3 Packaging and labelling

The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:

Hazard Class and Packing Group:	UN Number 2783 UN Hazard Class: 6.1 UN Pack Group: III
International Maritime Dangerous Goods (IMDG) Code	 DANGER Toxic if swallowed, in contact with skin or if inhaled Causes damage to nervous system Causes damage to the nervous system through prolonged or repeated exposure Very toxic to aquatic life with long lasting effects
Transport Emergency Card	ICSC 0851 – Chlorpyrifos (https://www.inchem.org/documents/icsc/icsc/eics0851.htm)

4.4 First aid

NOTE: The following advice is based on information available from the World Health Organisation and the notifying countries and was correct at the time of publication. This advice is provided for information only and is not intended to supersede any national first aid protocols.

International Chemical Safety Cards (ICSCs):
https://www.ilo.org/dyn/icsc/showcard.display?p_lang=en&p_card_id=0851&p_version=2

STRICT HYGIENE! AVOID EXPOSURE OF ADOLESCENTS AND CHILDREN! IN ALL CASES CONSULT A DOCTOR! FIRST AID: USE PERSONAL PROTECTION.			
	SYMPTOMS	**PREVENTION**	**FIRST AID**
Inhalation	Pupillary constriction, muscle cramp, excessive salivation. Muscle twitching. Convulsions. Dizziness. Sweating. Wheezing. Laboured breathing. Unconsciousness.	Use local exhaust or breathing protection.	Fresh air, rest. Refer immediately for medical attention. See Notes.
Skin	MAY BE ABSORBED! See Inhalation.	Protective gloves. Protective clothing.	Remove contaminated clothes. Rinse and then wash skin with water and soap. Refer immediately for medical attention. See Notes.
Eyes	Redness. Pain. Pupillary constriction. Blurred vision.	Wear face shield or eye protection in combination with breathing protection if powder.	Rinse with plenty of water (remove contact lenses if easily possible). Refer for medical attention.
Ingestion	Excessive salivation. Nausea. Vomiting. Abdominal cramps.	Do not eat, drink, or smoke during work. Wash hands before eating.	Rinse mouth. Do NOT induce vomiting. Refer immediately for medical attention. See Notes.

	Diarrhoea. Further see Inhalation.		

Fire-Fighting Measures

	Acute Hazards	Prevention	Fire Fighting
Fire & Explosion	Combustible. Gives off irritating or toxic fumes (or gases) in a fire. Liquid formulations containing organic solvents may be flammable. Risk of fire and explosion if formulations contain flammable/explosive solvents.	NO open flames.	Use water spray, foam, powder, carbon dioxide. In case of fire: keep drums, etc., cool by spraying with water.

Spillage disposal:
Evacuate danger area! Consult an expert! Personal protection: chemical protection suit including self-contained breathing apparatus. Do NOT let this chemical enter the environment. Do NOT wash away into sewer. Sweep spilled substance into covered containers. If appropriate, moisten first to prevent dusting. Carefully collect remainder. Then store and dispose of according to local regulations.

Storage:
Store only in original container. Keep in a well-ventilated room. Separated from food and feedstuffs. Provision to contain effluent from fire extinguishing. Store in an area without drain or sewer access.

Routes of exposure
The substance can be absorbed into the body by inhalation, through the skin and by ingestion

Effects of short-term exposure
The substance may cause effects on the nervous system by a cholinesterase inhibiting effect. Exposure far above the OEL could cause death. The effects may be delayed. Medical observation is indicated.

Inhalation risk
A harmful concentration of airborne particles can be reached quickly on spraying or when dispersed, especially if powdered.

Effects of long-term or repeated exposure
Cholinesterase inhibition. Cumulative effects are possible. See Acute Hazards/Symptoms.

Environment
The substance is very toxic to aquatic organisms. This substance may be hazardous to the environment. Special attention should be given to birds and bees. Bioaccumulation of this chemical may occur along the food chain, for example in fish and algae. The substance may cause long-term effects in the aquatic environment. This substance does enter the environment under normal use. Great care, however, should be taken to avoid any additional release, for example through inappropriate disposal.

Notes
Do NOT take working clothes home.
Do NOT use in the vicinity of a fire or a hot surface, or during welding.
Depending on the degree of exposure, periodic medical examination is suggested.
Specific treatment is necessary in case of poisoning with this substance; the appropriate means with instructions must be available.
Following the disappearance of symptoms from a short-term exposure, delayed effects could become manifest (after several days or weeks).
If the substance is formulated with solvent(s) also consult the card(s) (ICSC) of the solvent(s).
Carrier solvents used in commercial formulations may change physical and toxicological properties.

4.5 Waste management

Regulatory actions to ban a chemical should not result in creation of a stockpile requiring waste disposal. For guidance on how to avoid creating stockpiles of obsolete pesticides, the following guidelines are available: *FAO Guidelines on Prevention of Accumulation of Obsolete Pesticide Stocks* (FAO, 1995), *The Pesticide Storage and Stock Control Manual*; (FAO, 1996a) and *Guidelines for the management of small quantities of unwanted and obsolete pesticides* (FAO, 1999).

In all cases waste should be disposed of in accordance with the provisions of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (1996), any guidelines thereunder, and any other relevant regional agreements.

It should be noted that the disposal/destruction methods recommended in the literature are often not available in, or suitable for, all countries, e.g., high temperature incinerators may not be available. Consideration should be given to the use of alternative destruction technologies. Further information on possible approaches may be found in Technical Guidelines for the Disposal of Bulk Quantities of Obsolete Pesticides in Developing Countries (FAO, 1996b).

The most recent FAO tools and resources on pesticide related waste management are available from the Pesticide Related Waste Management section of the International Code of Conduct on Pesticide Management website https://www.fao.org/pest-and-pesticide-management/pesticide-risk-reduction/code-conduct/waste-management/en/

5. References

Regulatory actions

Malaysia

Circular letter from the Pesticides Board, dated April 28, 2021 (UNEP/FAO/RC/CRC.19/INF/13)
Minutes from the 88th Pesticides Board Meeting, dated April 9, 2021. (UNEP/FAO/RC/CRC.19/INF/13)

Sri Lanka

Ban of registration by the Government Extraordinary Gazette No. 1999/33 dated 28/12/2016 under the Control of Pesticides Act No.33 of 1980. (UNEP/FAO/RC/CRC.19/INF/14)

European Union

Commission Implementing Regulation (EU) 2020/18 of 10 January 2020 concerning the non-renewal of the approval of the active substance chlorpyrifos, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Official Journal of the European Union L 7, 13.1.2020, p. 14) http://data.europa.eu/eli/reg_impl/2020/18/oj

Supporting Documentation

***Malaysia* UNEP/FAO/RC/CRC.19/INF/13**

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Annexes to the decision guidance document

Annex 1 **Further information on chlorpyrifos**

Annex 2 **Details on final regulatory actions reported**

Annex 3 **Addresses of designated national authorities**

Annex 1 to the decision guidance document - Further information on chlorpyrifos

The information presented in this Annex reflects the conclusions of the notifying parties: Malaysia, Sri Lanka and the European Union. The notification from Malaysia was published in PIC Circular LVII of June 2023, the notification from Sri Lanka in PIC Circular XLIX of June 2019 and the notification from the European Union in PIC Circular Circular LVI of December 2022.

Where possible, information on hazards provided by the notifying parties has been presented together, while the evaluation of the risks, specific to the conditions prevailing in the notifying Parties are presented separately. This information has been taken from the documents referenced in the notifications in support of the final regulatory actions to ban chlorpyrifos (Sri Lanka, European Union) or severe restriction (Malaysia).

Furthermore, information from the FAO/WHO JMPR 1999 monograph of the toxicological evaluation of chlorpyrifos, as well as other sources such as PubChem, has been taken into account.

Note: The Persistent Organic Pollutants Review Committee (POPRC) adopted the risk profile for chlorpyrifos at its 19th meeting. Chlorpyrifos was concluded to meet all the criteria warranting global action.

1. Physico-Chemical properties

1.1 Identity	ISO: Chlopyrifos
	IUPAC: O,O-diethyl O-3,5,6-trichloro-2-pyridyl phosphorothioate
	CAS: O,O-diethyl O-(3,5,6-trichloro-2-pyridinyl) phosphorothioate
1.2 Molecular Formula	$C_9H_{11}Cl_3NO_3PS$
1.3 Molecular Weight	350.6 g/mol
1.4 Colour and Texture	Colourless-to-white or pale yellow crystals with characteristic odour: “mild mercaptan”
1.5 Melting Point	41-42 °C (purity 97-99%)
	41.5-44 °C (106-108 °F)
1.6 Boiling Point	Decomposes before boiling; at 170-180 °C
	156-157 °C at 0.1 mm Hg
1.7 Flash Point	82 °F (closed up)
	> 200 °F
1.8 Decomposition temperature	320 °F at 760 mm Hg
	170 – 180 °C
1.9 Vapour pressure	99.8 % purity:
	3.35×10^{-3} Pa (2.51×10^{-5} mm Hg) at 25 °C
	1.43 x 10-3 Pa (1.07×10^{-5} mm Hg) at 20 °C
1.10 Density (g/cm3)	1.4 g/cm³
1.11 Henry’s law constant	0.478 Pa m³ mol^{-1} at 20 °C
1.12 Solubility	**In water**:
	3.9 mg/L at 19.5 °C /OECD 105 method

	1.05 mg/L at 20 °C in unbuffered solution
	1.2 mg/L at 25 °C
	In organic solvents: at 20 °C, 99.9 % purity
	Hexane 774 g/L;
	Acetone, Ethyl acetate, Dichloromethane, Toluene > 4000 g/L
	Methanol 209 g/L
	Isooctane 79% wt/wt
1.13 Partition coefficient	log_{10}Pow = 4.7 – 5.21 at 20 °C (99.8% purity)
1.14 Dissociation constant	Not determinable by titration, spectrophotometric or conductometric methods, due to very low water solubility
1.15 UV/VIS absorption	In neutral medium (CH_3OH/H_2O):

λmax (nm)	ε (L x mol^{-1} x cm^{-1})
203	21,174
230	10,359
290	5,620

In acidic medium (CH_3OH/HCl):

λmax (nm)	ε (L x mol^{-1} x cm^{-1})
203	22,223
230	10,347
290	5,907

In alkaline medium (CH_3OH/NaOH):

λmax (nm)	ε (L x mol^{-1} x cm^{-1})
242	9,413
290	1,633
323	6,701

1.16 Flammability	Not flammable (98.4% purity)
1.17 Explosive properties	Not explosive (98.1% purity)
1.18 Oxidising properties	Non-oxidising (97.6% purity)

2. Toxicological Properties

2.1 General

2.1.1 Mode of Action

The main effect following short- to long-term repeated oral administration of chlorpyrifos is the inhibition of acetylcholinesterase (AChE) activity, which, at high-dose levels, was leading to endogenous cholinergic overstimulation resulting in typical cholinergic symptoms. Erythrocyte (RBC) AChE inhibition was the critical effect in all studies. Epidemiological studies suggest that chlorpyrifos might be acting on the developing nervous system through unknown mechanisms. (EFSA, 2019)

2.1.2 Symptoms of Poisoning

Acute exposure can cause symptoms such as headache, dizziness, nausea, vomiting, abdominal cramps, diarrhea, and in severe cases, convulsions, respiratory depression, and coma. (Malaysian notification)

Further acute symptoms include blurred vision, watering of the eyes (called lacrimation), excessive salivation, runny nose, confusion, muscle weakness or tremors and sudden changes in heart rate. (ATSDR, 1997)

Evidence of polyneuropathy from acute poisonings. (EFSA, 2019)

Inhalation

Symptoms following inhalation are pupillary constriction, muscle cramp, excessive salivation, muscle twitching, convulsions, dizziness, sweating, wheezing, laboured breathing, unconsciousness. (International Chemical Safety Cards (ICSCs), 0851. April, 2014)

Dermal

May be absorbed (ICSCs. 0851, April 2014)

Eyes

Redness, pain, pupillary constriction, blurred vision (ICSCs. 0851, April 2014)

Ingestion

Excessive salivation, nausea, vomiting, abdominal cramps, diarrhea (ICSCs. 0851, April 2014)

2.1.3 Absorption, distribution, excretion and metabolism in mammals

In rats, chlorpyrifos is extensively absorbed after oral administration, it is widely distributed, moderately to extensively metabolised by oxidation and hydrolysis and eliminated mostly through urine within 48 h. In the acute toxicity studies, chlorpyrifos showed high, moderate and low acute toxicity when administered by the oral, dermal and inhalation routes. (EFSA, 2019)

2.2 Toxicological studies

2.2.1 Acute toxicity

LD_{50}: 66 mg/kg bw (Oral, Rat)

$LD_{50:}$ 1250 mg/kg bw (Dermal, Rat)

LC_{50}: 0.1 mg/L (Inhalation, Rat)

Source: FAO Pesticide Registration Toolkit, Pesticides Property Database, Chlorpyrifos (Ref: OMS 971)

Lewis, K.A., Tzilivakis, J., Warner, D. and Green, A. (2016) An international database for pesticide risk assessments and management. Human and Ecological Risk Assessment: An International Journal, 22(4), 1050-1064. DOI: 10.1080/10807039.2015.1133242

In the acute toxicity studies, chlorpyrifos showed high, moderate and low acute toxicity when administered by the oral, dermal and inhalation routes, respectively. The substance did not elicit a potential for skin or eye irritation, skin sensitisation or phototoxicity. (EFSA, 2019)

One impurity (sulfotep) has been considered as toxicologically relevant by the European Commission. Its relevance is likely based upon the fact that it has a lower oral LD_{50} value than chlorpyrifos; but no toxicological concern is identified for this impurity up to its specified limit in the technical specifications of 3 g/kg. (EFSA, 2019)

Chlorpyrifos is classified by US EPA as a moderate oral toxicant (Category II). The acute oral LD_{50} is 32 mg/kg for hens and 82 to 504 mg/kg for rats,

mice, and guinea pigs. The oral LD_{50} for chlorpyrifos-oxon is > 100 mg/kg in male rats and 300 mg/kg in female rats. The dermal LD_{50} in rats is 202 mg/kg/d. The 4-hour inhalation LC50 in rats is > 2 mg/L. Chlorpyrifos is a Category IV skin and eye irritant, causing slight conjunctival and dermal irritation. Human deaths are reported due to accidental exposure or intentional ingestion. Chlorpyrifos doses > 300 mg/kg in humans have resulted in unconsciousness, convulsions, cyanosis, and uncontrolled urination.

The main target of chlorpyrifos toxicity after short-term excessive oral exposure (not those expected from typical ambient, real-world exposure) is the nervous system of adult and developing organisms. Cholinergic syndromes resulting from the overstimulation of the muscarinic and nicotinic ACh receptors include hypersalivation, respiratory distress, miosis, muscular twitches, tremors, ataxia, diarrhea, and vomiting. Other effects include hematological and liver enzyme changes, chromodactyorrhea, tachycardia, renal effects, hypothermia, and body weight decreases. No delayed neuropathy was observed in hens. (CalEPA, 2018)

2.2.2 Short term toxicity

The main effect following short- to long-term repeated oral administration of chlorpyrifos was the inhibition of AChE activity, which, at high-dose levels, was leading to endogenous cholinergic overstimulation resulting in typical cholinergic symptoms. Erythrocyte (RBC) AChE inhibition was the critical effect in all studies. The relevant NOAEL was 0.1 mg/kg body weight per day for both short-term and long-term exposure based on a significant decrease of RBC AChE activity at 1 mg /kg bw per day in a 90-day and 2-year rat study supported by a 2-year study in dogs. (EFSA, 2019)

Target organ / critical effect	Rat: Nervous system/RBC AChE inhibition Mouse: RBC and brain AChE inhibition Dog: RBC AChE inhibition
Relevant oral NOAEL	90-day, rat: 0.1 mg/kg bw per day 90-day, mouse: 1 mg/kg bw per day 90-day & 2-year, dog: 0.1 mg/kg bw per day
Relevant dermal NOAEL	21-day, rat: > 5 mg/kg bw per day
Relevant inhalation NOAEL	14-day, rat: > 0.296 x 10–3 mg/L air (nose-only)

2.2.3 Genotoxicity (including mutagenicity)

Malaysia

Mutation studies in bacteria and mammalian cells were negative, as were cytogenetics assays. An acceptable unscheduled DNA synthesis (UDS) assay was negative. Two studies designed to evaluate DNA damage were reportedly positive, but could not be fully evaluated by DPR because the underlying data were not available. The positive findings of the DNA damage tests thus cannot be dismissed at this time. (CalEPA, 2018)

European Union

Concerns were identified as regards the genotoxic potential of chlorpyrifos, which cannot be ruled out based on the information available - positive findings were found in an *in vitro* chromosome aberration study and two *in vitro* unscheduled DNA synthesis assays; *in vivo* positive findings were found in open literature on chromosome aberration and on DNA damage caused through oxidative stress or by topoisomerase II inhibition which is considered a molecular initiating event for infant leukaemia. Consequently,

health-based reference values cannot be established for chlorpyrifos and dietary and non-dietary risk assessments cannot be conducted.

2.2.4 Long term toxicity and carcinogenicity

European Union

No evidence for a carcinogenicity potential was found upon chlorpyrifos administration in rats or mice.

Long-term effects (target organ/critical effect)	Nervous system/RBC AChE inhibition (rat, mouse) Decrease in bw gain (rat)
Relevant long-term NOAEL	0.1 mg/kg bw per day (2-year, rat) 0.9 mg/kg bw per day (18-month, mouse)
Carcinogenicity (target organ, tumor type)	No carcinogenic potential
Relevant NOAEL for carcinogenicity	10 mg/kg bw per day (highest dose tested in 2-year, rat studies) 47.1 mg/kg bw per day (highest dose tested in 18-month, mouse study)

2.2.5 Effects on reproduction

European Union

In a two-generation reproductive toxicity study in rats, chlorpyrifos did not affect the reproductive performance up to the highest dose tested, while RBC AChE inhibition was the critical effect related to parental toxicity.

Reproduction target/critical effect	Parental toxicity: RBC AChE inhibition Reproductive toxicity: no adverse effects Offspring's toxicity: Decreased pup growth and viability
Relevant parental NOAEL	0.1 mg/kg bw per day
Relevant reproductive NOAEL	5 mg/kg bw per day (highest dose tested)
NOAEL	1 mg/kg bw per day

The experts agreed that chlorpyrifos is not an endocrine disruptor in humans. The overall dose–response pattern for cholinergic overstimulation indicates that chlorpyrifos is a potent AChE inhibitor, and this is practically limiting the possibility of exploring additional target organs/systems.

2.2.6 Neurotoxicity / delayed neurotoxicity / special studies where available

Malaysia

A number of systemic effects were identified as being associated with exposure to chlorpyrifos including respiratory, cardiovascular gastrointestinal, hepatic, endocrine, renal dermal, ocular and body weight. (ATSDR, 1997)

New findings from published animal studies indicated that the developing nervous system is sensitive to low doses of chlorpyrifos that are not expected to inhibit brain or RBC AChE activities. Based on the five studies CalEPA established a collective LOEL of 0.1 mg/kg/day for neurodevelopmental effects including in cognition, motor control, and behavior in rats and mice.

A NOEL of 0.01 mg/kg/day was established by Silva et al., (2017) based on increased anxiety and motor activity in rat pups. The exposure duration in the 5 published studies varied from 1 to 35 days. Therefore, the NOEL of 0.01 mg/kg/day could be applicable to acute and repeated exposures to chlorpyrifos in infants, children, and females of childbearing age. (CalEPA, 2018)

European Union

Overall, separate lines of evidence indicate that chlorpyrifos may affect a variety of neuronal targets and processes that are not directly related to AChE. Therefore, this would represent an additional concern to be taken into consideration for the risk assessment.

Taking into consideration the DNT study outcome (reduction in cerebellum height – that could not be explained by the maternal AChE inhibition), the epidemiological evidence showing an association between chlorpyrifos exposure during development and neurodevelopmental outcomes, and the overall analysis of the published literature (in vivo, in vitro and human data), the experts suggested that the classification of chlorpyrifos as toxic for the reproduction, REPRO 1B, H360D 'May damage the unborn child' in accordance with the criteria set out in Regulation (EC) No 1272/2008 would be appropriate. (EFSA, 2019)

2.2.7 Summary of mammalian toxicity and overall evaluation

Malaysia

In addition to its impact on human health, chlorpyrifos has been shown to cause neurotoxic symptoms in animals, including hypoactivity, lacrimation, salivation, foot splay, ataxia, and tremors. The lethal dose (LD_{50}) for mammals (oral) ranges from 80 to 250 mg/kg/d, while the dermal LD_{50} for male rats is 202 mg/ kg. The inhalational lethal dose is calculated to be 78 and 94 mg/kg for female mice and rats, respectively. However, rats have shown tolerance to prolonged and significant AChE inhibition after subcutaneous injection.

In terms of genotoxicity, chlorpyrifos has been shown to induce micronuclei in erythroblasts and cause cytogenetic effects in human lymphoid cells. It has also produced significant increases in sister chromatid exchanges (SCEs), X chromosome loss, and sex-linked recessive lethality in *Drosophila melanogaster*.

European Union

The genotoxicity potential remains unclarified (positive findings from an in vitro chromosome aberration study and two in vitro unscheduled DNA synthesis assays; in vivo positive findings from open literature on chromosome aberration and on DNA damage caused through oxidative stress or by topoisomerase II inhibition which was considered a molecular initiating event (MIE) for infant leukaemia).

The effects recorded in the DNT study (decrease in cerebellum height corrected by brain weight already at the lowest dose tested, which is a relevant endpoint for hazard characterisation) indicate a concern.

The epidemiological evidence supports the developmental neurological outcomes in children for chlorpyrifos.

3. Human exposure / Risk evaluation

3.1 Food

Malaysia

Department of Agriculture Malaysia has revealed that food crops, including those intended for export, have consistently exceeded the national maximum limits for chlorpyrifos residues. This presents a potential risk to both workers and consumers who may be exposed to the pesticide. From the dietary risk assessment, it is clear that the use of chlorpyrifos in agriculture possesses risk

to the consumers from the exposure to chlorpyrifos residue exceeding legal limits over a long-term exposure.

3.2 Air

None reported

3.3 Water

Sri Lanka

The risk evaluation raised concerns regarding a possible risk to groundwater due to potential contamination by the parent substance and a number of relevant metabolites (e.g. TCP).

3.4 Occupational exposure

Malaysia

Agricultural workers in Malaysia who have been exposed to chlorpyrifos have reported symptoms such as headaches, dizziness, and skin irritation. A study conducted in Sabak Bernam, Malaysia found that 7% of paddy farmers had chlorpyrifos in their blood, with a mean concentration of 7.29 nanograms per milliliter blood.

Sri Lanka

The study by Aponso et al. (2002) showed that farmers using chlorpyrifos on cucurbits on trellises can be exposed to unnecessary residue levels as measured by major metabolite, 3,5,6-trichloro-2-pyridinol (TCP): results indicated that dermal exposure under normal use ranged from 4.8- 19.6 microgram/cm^2 on exposed skin; the elimination half-life of the urinary TCP metabolite was 31.2 hr; the calculated hazard quotient of cholinesterase inhibition ranged from 0.8-2.7, and margin of safety ranged from 3.6-14.3 for the farmer. This indicates the high occupational risk of chlorpyrifos to the farmer under use conditions.

3.5 Medical data contributing to regulatory decision

Malaysia

According to data gathered by the National Poison Centre Malaysia over a 10-year period (2006-2015), 40 % of reported cases of insecticide poisoning involved pesticides from the organophosphate group, with chlorpyrifos being the most commonly reported pesticide. The data from 2016-2019 recorded that 24% of insecticide poisoning cases (N=1374) involved chlorpyrifos.

In a study, the presence of chlorpyrifos and the pesticide exposure symptoms of paddy farmers in Sabak Bernam, Malaysia, were investigated. The study involved 100 respondents and showed that 7% of the farmers had chlorpyrifos in their blood, with a mean of 7.29 nanogram per milliliter blood (SO 5.84 nanogram per milliliter). The study revealed that 75% of the farmers had experienced at least one pesticide exposure symptom, indicating that many of them were at risk of suffering from the harmful effects of pesticides, including chlorpyrifos (Hod et al., 2011).

Sri Lanka

The study by Aponso et al. (2003) on analysis of water for pesticides showed that the farming community in the study area was reported to have clinical symptoms of exposure by 83%, related to acute toxicity, but 21% of the group had confirmed effects related to pesticide exposure. The main symptoms found were dysuria, myalgia & headache.

European Union

No neurotoxic effects in manufacturing plant personnel reported. Evidence of polyneuropathy from acute poisonings. Epidemiological studies (taken together toxicity literature studies) suggest that the CPF might be acting on the developing nervous system through unknown mechanisms.

3.6 Public exposure

See section 3.5 Medical data

3.7 Summary – overall risk evaluation

Malaysia

Malaysia used both findings from the EU and California to assess the situation locally and determine if the risk is lower, similar, or higher under Malaysian conditions. It is anticipated that the risk to human health under Malaysian conditions is much higher than in the EU and California. The hot and humid conditions in the tropics can make wearing personal protective equipment (PPE) sometimes impossible, and if the PPE is available, the cost might be an issue for poor farmers.

Sri Lanka

The major reasons for regulatory concerns over chlorpyrifos include;

• The risk of certain impurities with hazardous profiles (some of which are potentially genotoxic) result from the use of chlorpyrifos, which leads to concerns about the exposure of consumers and the possible risk of environmental contamination.

• Impurities, of which at least one is extremely hazardous (sulfotep), have been implicated in the active substance as sold on the market (technical material) at levels raising concerns (as evidenced by original manufacturers).

• Residue intake by sensitive groups such as children might exceed the acceptable daily intake and that consumption of a number of crops might pose an acute risk to children and adults.

• The risk evaluation raised concerns regarding a possible risk to groundwater due to potential contamination by the parent substance and a number of relevant metabolites (e.g. TCP).

• Non-compliance with recommended measures for the safe use of chlorpyrifos by users.

• The low rate of utilization of protective equipment by growers/applicators.

European Union

Overall, no reference values could in any case be set because of the unclear genotoxicity potential of chlorpyrifos; moreover, significant uncertainties were linked to the neurodevelopmental toxicity study, where effects were observed at the lowest dose tested in rats (decrease in cerebellum height corrected by brain weight). These concerns were supported by the available epidemiological evidence related to developmental neurological outcomes in children. In the absence of toxicological reference values, a risk assessment for consumers, operators, workers, bystanders and residents cannot be conducted. This issue represents a critical area of concern for chlorpyrifos.

In addition, the recorded toxicological effects meet the criteria for classification as toxic for reproduction category 1B (regarding developmental toxicity).

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

4 Environmental fate and effects

4.1 Fate

4.1.1 Soil

PubChem

If released to soil, chlorpyrifos is expected to have low to no mobility based upon a measured Koc range of 995 to 31,000. Volatilization from moist soil surfaces may be an important fate process based upon a Henry's Law constant of 3.55X10-5 atm-cu m/mole. The volatilization half-life of chlorpyrifos from 3 moist soils was in the range of 45-163 hours using an airstream of 1 km/hr passed over the soil and a volatilization half-life of 3 days was observed from moist soil surfaces in a laboratory study. A 0.64% volatilization after 3.2 days indicates that chlorpyrifos volatilizes slowly

from soil. In several tests lasting 7-11 days, chlorpyrifos applied to turf lost a mean amount of 8.25% to volatilization. Photodegradation on soil surfaces exposed to sunlight has been observed to occur. Results of laboratory studies using non-sterile versus sterilized soils have shown that biodegradation is an important fate process. Field dissipation half-lives can range from 4-139 days. Half-lives can typically range from 33-56 days for soil incorporated applications and 7-15 days for surface applications. The primary route of degradation is transformation to 3,5,6-trichloropyridin-2-ol, which is subsequently degraded to organochlorine compounds and carbon dioxide.

4.1.2 Water

PubChem

If released into water, chlorpyrifos is expected to adsorb to suspended solids and sediment based upon the Koc. Volatilization from water surfaces is expected to be an important fate process based upon this compound's Henry's Law constant. Estimated volatilization half-lives for a model river and model lake are 2.2 and 21.5 days, respectively. However, volatilization from water surfaces is expected to be attenuated by adsorption to suspended solids and sediment in the water column. The estimated volatilization half-life from a model pond is 2 years if adsorption is considered. Measured BCF values of 58 to 2880 suggest bioconcentration in aquatic organisms is moderate to very high. Direct photo-transformation of chlorpyrifos was observed in buffer solutions and river waters, under both natural and artificial lighting conditions with approximate 50% conversion after 30-40 days. The hydrolysis half-lives at 25 °C in aqueous buffers at pH 5, pH 7 and pH 9 were 72, 72 and 16 days respectively. Biodegradation is expected to be an important fate process. Chlorpyrifos degraded about 40% faster in active (natural) water as compared to the same water which had been sterilized with formalin. The reported half-life in active water was 24.5 days. The aerobic half-life in nursery recycling pond water was 30 and 52 days at 22 and 10 °C, respectively; the anaerobic half-life was 52 days at 22 °C.

4.1.3 Air

PubChem

If released to air, a vapor pressure of 2.02X10-5 mm Hg at 25 °C indicates chlorpyrifos will exist in both the vapor and particulate phases in the atmosphere. Vapor-phase chlorpyrifos will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 5 hours. Particulate-phase chlorpyrifos will be removed from the atmosphere by wet or dry deposition. Chlorpyrifos absorbs light greater than 295 nm and photolysis has been observed in air. The summer photolysis half-life is estimated as 4.2 days with the winter photolysis half-life estimated as 9.7 days.

4.1.4 Bioconcentration

Sri Lanka

Chlorpyrifos accumulates in the tissues of aquatic organisms. Studies involving continuous exposure of fish during the embryonic through fry stages have shown BCF values of 58 to 5100.

Note: The Persistent Organic Pollutants Review Committee (POPRC) adopted the risk profile for chlorpyrifos at its 19th meeting. Chlorpyrifos was concluded to meet all the criteria warranting global action.

POPRC Risk profile for chlorpyrifos

Chlorpyrifos shows moderate bioaccumulation in aquatic and air-breathing organisms. In combination with high toxicity, even moderate bioaccumulation can lead to body concentrations that elicit adverse effects.

Note: The Persistent Organic Pollutants Review Committee (POPRC) adopted the risk profile for chlorpyrifos at its 19th meeting. Chlorpyrifos was concluded to meet all the criteria warranting global action.

4.1.5 Persistence

POPRC Risk profile for chlorpyrifos

Environmental degradation half-lives of chlorpyrifos range from a few days to over 200 days, depending on ecosystem type, soil or sediment characteristics, and other environmental factors, including temperature (Gebremariam et al. 2012). Monitoring data from the Arctic demonstrate that chlorpyrifos can be transported over long distances to remote regions. Similar to most organic chemicals, the degradation of chlorpyrifos is temperature dependent, so it is expected to persist in these regions for a considerable length of time. Frequent findings of chlorpyrifos in all media in the Arctic support this, as well as measurements of total chlorpyrifos (including chlorpyrifos oxon) in dated sediment cores from three west coast parks in the USA (Washington and California), three Alaska parks north of the 60th parallel, and two parks in the Rocky Mountains of the USA (Colorado and Montana) (Landers et al. 2008). In conclusion, chlorpyrifos can be considered persistent in some environments.

Note: The Persistent Organic Pollutants Review Committee (POPRC) adopted the risk profile for chlorpyrifos at its 19th meeting. Chlorpyrifos was concluded to meet all the criteria warranting global action.

4.2 Effects on non-target organisms
4.2.1 Terrestrial vertebrates

Sri Lanka
Chlorpyrifos is moderately to very highly toxic to birds. Its oral LD_{50} in pheasants is 8.41 mg/k g, 112 mg /kg in mallard ducks, 21.0 mg/kg in house sparrows, and 32 mg/kg in chickens. The LD_{50} for a granular product (15G) in bobwhite quail is 108 mg/kg. Two one-generation reproductive studies resulted in NOELs of 125 ppm (the highest dose tested) for bobwhite quail and 25 pm for mallard ducks. At 125 ppm, mallards laid significantly fewer eggs.

European Union
Birds
Bobwhite quail (*Colinus virginianus*) Acute LD_{50}: 39.24 mg a.s./kg bw
Japanese quail (*Coturnix coturnix*) Acute LD_{50}: 13.3 mg a.s./kg bw
Note: The EFSA Draft Renewal Assessment Report (2017) on chlorpyrifos contains toxicity data for a number of other bird (and mammal) species**.**

4.2.2 Aquatic species

Sri Lanka
Chlorpyrifos is very highly toxic to freshwater fish, aquatic invertebrates and estuarine and marine organisms. Cholinesterase inhibition was observed in acute toxicity tests of fish exposed to very low concentrations of this insecticide. Chlorpyrifos toxicity to fish may be related to water temperature. Its 96- hour LC_{50} varied in rainbow trout from 7.1 micrograms per liter (µg/l) to 51 µg/l at three different temperatures. The 24- hour LC_{50} for chlorpyrifos in goldfish is 180 µg/l, and less than 1,000 µg/l in mosquito fish. The 96- hour LC_{50} for chlorpyrifos in mature rainbow trout is 9 µg/ l, 98 µg/l in lake trout, 806 µg/l in goldfish, 10 µg/l in bluegill, and 331.7 µg/l in fathead minnow.

European Union
Fish
Onchorhynchus mykiss: LC_{50} (96 h flow through): 8.0 µg a.s./L.

Aquatic invertebrates
Daphnia magna: LC_{50} (48 h flow through): 0.1 µg a.s./L

Algae
Scenedesmus subcapitata: EbC_{50} (96 h): 480 µg/L
Note: The EFSA Draft Renewal Assessment Report (2017) on chlorpyrifos contains ecotoxicity data for a number of other aquatic species.

4.2.3 Honeybees and other arthropods

Malaysia
Chlorpyrifos is highly toxic to bees and other pollinators. Even at low doses chlorpyrifos can impair the cognitive functions of bees, affecting their ability to navigate and forage. The acute oral LD_{50} values for honeybees range from 0.1 to 1.5 µg/bee.

European Union

Apis mellifera (bee)
Acute Oral toxicity (LD_{50}): 0.15 µg a.i./bee
Acute Contact toxicity (LD_{50}): 0.068 µg a.i./bee
Bee brood development NOED larvae: 0.018 µg a.s./larva
Note: The EFSA Draft Renewal Assessment Report (2017) on chlorpyrifos also contains data for semi-field tests with bees (cage and tunnel test).

4.2.4 Earthworms
Malaysia
Chlorpyrifos can be toxic to earthworms which play an important role in soil health and nutrient cycling. The acute toxicity of chlorpyrifos to earthworms varies depending on the species and the soil type. The LC_{50}-values range from 0.06 to 40 mg/kg soil.

European Union
Eisenia foetida: chronic 56-days NOEC reproduction: 0.075 mg chlorpyrifos/kg soil.
Note: The EFSA Draft Renewal Assessment Report (2017) on chlorpyrifos also contains data for other soil organisms, e.g. springtail.

4.2.5 Soil microorganisms
No data available.

4.2.6 Terrestrial plants
European Union
Tests carried out with various crops all show ER_{50} values >2400 g a.s./ha.

5 Environmental Exposure/Risk Evaluation
5.1 Terrestrial vertebrates
No data available.

5.2 Aquatic species
Sri Lanka
See section 5.6.

5.3 Honey bees
No data available.

5.4 Earthworms
No data available.

5.5 Soil microorganisms
No data available.

5.6 Summary – overall risk evaluation
Sri Lanka
The results of study by Sumith et al. (2012) on potential impact of agricultural pesticides on widely distributed fishes (Teleostei, family: *Cypriniade*) in agricultural areas in Sri Lanka showed that chlorpyrifos, diazon and carbosulfan had the greatest number of agricultural applications and identified as dominant pollutants. The study revealed dynamic impact of agricultural pollutants (including chorpyrifos) on indigenous fish communities and their existence. Stringent pesticide management options and good agricultural practices are recommended to protect fish in agricultural catchments in Sri Lanka.

Annex 2 to the decision guidance document – Details on final regulatory actions reported

Malaysia

1	**Effective date(s) of entry into force of actions**	1 May 2023
	Reference to the regulatory document	1. Circular from the Pesticides Board, dated April 28, 2021 2. Minutes from the 88th Pesticides Board Meeting, dated April 9, 2021
2	**Succinct details of the final regulatory action(s)**	The notified regulatory action relates to chlorpyrifos (CAS No. 2921-88-2) in the pesticide category. The regulatory action is notified as a severe restriction. The Pesticides Board of Malaysia decided on 28 April 2021 to cancel the registration of all products containing chlorpyrifos for agricultural use. The ban entered into force on 1 May 2023. Chlorpyrifos is no longer authorized as a plant protection product in agriculture. However, the registration of chlorpyrifos products continues for use in public health and urban pest control.

3 Reasons for action

The ban of use of all types of chlorpyrifos formulations in agriculture was decided due to the risks of adverse effects to human health, ecology and the environment through agricultural use of chlorpyrifos, as well as food safety risks due to the maximum residue limits (MRL) violations of chlorpyrifos residues in agricultural commodities.

4 Basis for inclusion into Annex III

The final regulatory action was based on a risk evaluation taking into account the prevailing conditions in Malaysia.

4.1 Risk evaluation

The final regulatory action was based on a risk evaluation, which included a health hazard evaluation of chlorpyrifos and the prevailing conditions of the use of pesticides in Malaysia (application doses, methods, protective measures, agricultural practices).

According to the supporting documentation, Malaysia used findings from the international risks assessments and compared these with local conditions of use of chlorpyrifos in plant protection products. Malaysia anticipated that the risks to human health under Malaysian conditions are much higher than in the European Union and California. Malaysia stated the hot and humid conditions in the tropics can make wearing proper protective clothing sometimes impossible, and if the proper protective equipment is available, the cost might be an issue for poor farmers.

The notification states that the final regulatory action was based on a risk evaluation to protect human health. The scope of the review considered the assessment of risks for humans and socioeconomic impacts. The Pesticides Board reviewed and scrutinized many research information documents and publications related to chlorpyrifos from within and outside Malaysia. The following topics were covered by the chlorpyrifos pesticide review:

(a) Physico-chemical, toxicological and ecotoxicological information;
(b) Assessment of chlorpyrifos poisoning cases in Malaysia;
(c) Evaluation of the studies conducted by other regulatory bodies such as the European Food Safety Authority (EFSA), the Department of Pesticide Regulation in California; United States Environmental Protection Agency;
(d) Evaluation of the study of the exposure of chlorpyrifos among paddy farmers in Malaysia;
(e) Evaluation of alternative pesticides to chlorpyrifos;
(f) Impact assessment on the agriculture sector.

In the supporting documentation, the national and international risk evaluations are presented, including the study conducted by Rozita Hod et al. (2011) on the relationship between the chlorpyrifos blood level among paddy farmers in Selangor and exposure symptoms, the assessment of carbofuran and chlorpyrifos by the National Poison Centre Malaysia, the conclusion on the peer review of the pesticide risk assessment of the active substance chlorpyrifos by EFSA (2011), the human health risk assessment (2020) and ecological risk assessment (2021) of chlorpyrifos by United States Environmental Protection Agency, the justification of cancellation of chlorpyrifos registrations in California by the California Department of Pesticide Regulation (2020).

In a study conducted by Rozita Hod et al (2011) the presence of chlorpyrifos and the pesticides exposure symptoms of paddy farmers in Sabak Bernam, Malaysia were investigated. The study involved 100 respondents and showed that 7% of the respondents had chlorpyrifos in their blood, with a mean value of 7.29 nanogram per millilitre blood (sd 5.84 nanogram per milliliter). The percentage of farmers who experienced at least one pesticide exposure symptoms was 75 percent. The farmers had low scores on safe practice of pesticide use even though they have high marks on knowledge and attitude.

An assessment of carbofuran and chlorpyrifos by the National Poison Centre of Malaysia concludes that based on 10 years of data (2006-2015), 40% of reported cases of insecticide poisoning involved pesticides from the organophosphate group, with chlorpyrifos having the highest number of cases. Data on poisoning cases received by the National Poison Centre from 2016 to 2019 showed that chlorpyrifos accounted for 24% of all reported cases of insecticide poisoning (N=1374), chlorpyrifos contributed more to intentional poisoning cases than unintentional cases. Acute poisoning caused by chlorpyrifos can have severe effects and can lead to long-term neurological disorders. Scientific evidence shows that exposure to chlorpyrifos in pregnant women and children can cause neurotoxic effects that can affect children's growth and development.

		EFSA's initial statement dated 31 July 2019 and its updated statement dated 11 November 2019 confirmed EFSA's conclusions on the peer review of the pesticide risk assessment of the active substance chlorpyrifos. In Commission Implementing Regulation (EU) 2020/17 of 10 January 2020 concerning the non-renewal of the approval of the active substance chlorpyrifos-methyl concerns were identified concerning developmental neurotoxicity (DNT) for which epidemiological evidence exists, showing an association between exposure to chlorpyrifos and/or chlorpyrifos-methyl during development and adverse neurodevelopmental outcomes in children. It was concluded that the concerns raised for chlorpyrifos with regard to chromosome aberration and DNA damage (oxidative stress and topoisomerase II inhibition) may apply to chlorpyrifos-methyl, resulting in an unclear genotoxicity potential, developmental neurotoxicity (DNT) effects observed at the lowest dose tested in the DNT study with chlorpyrifos, decrease in cerebellum height corrected by brain weight, indicating a health concern, as well as concluded that the epidemiological evidence supports the developmental neurological outcomes in children for both chlorpyrifos and chlorpyrifos-methyl. The California Department of Pesticide Regulation (DPR) evaluated the strengths and uncertainties associated with the use of the available database for deriving critical endpoints for chlorpyrifos. Following the recommendation of the Scientific Review Panel (SRP), DPR thoroughly evaluated developmental neurotoxicity as the critical endpoint for the chlorpyrifos risk assessment. Based on the evaluation of the toxicity database and exposure analyses, this assessment supports the finding that chlorpyrifos meets the criteria to be listed as a toxic air contaminant pursuant to the law of California.
4.2	**Criteria used**	Risks to human health
	Relevance to other States and Region	Malaysia exports a number of agriculture produces to neighbouring countries. With the withdrawal of chlorpyrifos from use in agriculture in Malaysia, the risk of consumers' exposure to chlorpyrifos in crops exported to these countries will be reduced .
5	**Alternatives**	See section 3.3.
6	**Waste management**	None reported
7	**Other**	None reported

Sri Lanka

1	**Effective date(s) of entry into force of actions**	28 December 2016
	Reference to the regulatory document	Ban of registration by the Government Extraordinary Gazette No. 1999/33 dated 28.12.2016 under the Control of Pesticides Act No.33 of 1980.
2	**Succinct details of the final regulatory action(s)**	The notified regulatory action relates to chlorpyrifos (CAS No. 2921-88-2) in the pesticide category. The regulatory action is notified as a ban. Sri Lanka by this action prohibited all applications of chlorpyrifos pesticides as well as its production, trade and import. The ban was introduced by the decision of the Pesticide Technical & Advisory Committee of Sri Lanka dated 5 April 2013. As a result of the decision, the registration of all products and formulations containing the active ingredient chlorpyrifos was cancelled on 28 December, 2016. The ban entered into force on 28 December 2016 and date for stock clearance at dealers/shops was set by 28 December 2018.
3	**Reasons for action**	The ban of all uses of chlorpyrifos formulations was decided due to the risks for human health (excessive occupational exposure of farmers and poisoning cases among the farming communities) and to the environment (risks to indigenous fish communities).
4	**Basis for inclusion into Annex III**	The final regulatory action was based on a risk evaluation taking into account the prevailing conditions in Sri Lanka.
4.1	**Risk evaluation**	The final regulatory action was based on an evaluation of risks to human health and to the environment, taking into account the prevailing conditions of the use of pesticides, especially chlorpyrifos, in Sri Lanka (application doses, methods, protective measures, agricultural practices). The notification states that the final regulatory action was based on a risk evaluation to protect human health. The scope of the review considered the assessment of risks for humans and socio-economic impacts. The Pesticide Technical & Advisory Committee of Sri Lanka scrutinized many research information documents and publications related to chlorpyrifos from within and outside Sri Lanka. The following topics were covered by the chlorpyrifos pesticide review: (a) Physico-chemical, toxicological and ecotoxicological information; (b) Human health assessment conducted by USA Environmental Protection Agency (EPA); (c) Evaluation of studies collected by Annals of the Sri Lanka Department of Agriculture; (d) Study on use of chlorpyrifos pesticides related to the environment; (e) Evaluation of alternative pesticides to chlorpyrifos; (f) Impact assessment on the agriculture sector. In the supporting documentation, the national and international risk evaluations are presented, including the human health assessment on chlorpyrifos conducted by US EPA in 2000 on exposure to chlorpyrifos by children in the USA due to increasing susceptibility of children occurring at high doses in the developmental neurotoxicity. This study had been used as a basis for Sri Lanka's 2004 decision to ban the use of chlorpyrifos for indoor termite control. The study by Aponso et al. (2002) on exposure and risk assessment for farmers occupationally exposed to chlorpyrifos in Sri Lanka showed that farmers using chlorpyrifos on cucurbits (grows on trellises = canopies) can be exposed to unnecessarily high levels of chlorpyrifos via dermal exposure. It was revealed that wearing long pants during spraying did not necessarily reduce the exposure. More than 30% of the farmers in the study used more than the officially recommended dose of chlorpyrifos to achieve a better pest control. Many of the knapsack spray tanks were old and about 30% were leaking. Many of the workers did not use a head cover despite the fact that the cucurbit crops grow and are sprayed on over-head canopies. Most farmers did not use gloves when mixing concentrated pesticides. All except three

		farmers showed a Hazard Quotient higher than 1, which indicates a risk to the applicator. The Margin of Safety values were greater than 1 in all cases. It is clear that the amount of compound applied is the deciding factor. However, the use of sound equipment and long-sleeved shirt can reduce exposure by 6-10%. The farmers received an occupational dose higher than RfD of chlorpyrifos, but it was below the NOEL. Although the study concluded that under conditions of this worst-case scenario, farmers experienced a minimal risk despite taking limited precautions, this might be due to the fact that in this study only small areas were sprayed. The study was interpreted by the Sri Lanka to indicate the high occupational risk of chlorpyrifos to the farmers under use conditions in Sri Lanka. The study by Aponso et al. (2003) on "Analysis of water for pesticides in two major agricultural areas of the dry zone" showed that in Polonnaruwa and Dambulla areas of Sri Lanka the farming community reported to have clinical symptoms of exposure by 83% related to acute toxicity, but 21% had confirmed effects related to pesticide exposure. It was stated that pesticides usage statistics in Sri Lanka indicate that about 60% of total insecticides were organophosphorus pesticides – major organophosphorus pesticides used in agriculture are chlorpyrifos 40% emulsifiable concentrate. The study concluded that farmers take minimal precautions when handling pesticides and 70% did not apply the recommended dosage. It also reports that unwarranted practices such as washing spray equipment in streams and disposal of empty containers close to water bodies would have a high potential to contaminate internal water bodies such as water wells and small tanks. Furthermore, it concluded that there were strong indications of acute pesticide poisoning potential among the farmers. The results of the study by Sumith et al. (2012) on potential impact of agricultural pesticides on widely distributed fishes (*Teleostei*, family: *Cyprinidae*) in agricultural areas in Sri Lanka showed that chlorpyrifos, diazinon and carbosulfan had the greatest number of agricultural applications and identified as dominant pollutants. The study revealed dynamic impact of agricultural pollutants (including chlorpyrifos) on indigenous fish communities and their existence. Stringent pesticide management options and good agricultural practices are recommended to protect fish in agricultural catchments in Sri Lanka. According to the supporting documentation, the list of chemical alternatives was considered sufficient for all uses of chlorpyrifos. Integrated pest management has been practised as the government policy over the years in Sri Lanka.
4.2	**Criteria used**	Risks to human health and the environment.
	Relevance to other States and Region	Similar human health and environmental risk associated with the use of chlorpyrifos are anticipated in other states and regions, in particular under similar cultural and agro-climatic conditions of developing countries.
5	**Alternatives**	See section 3.3.
6	**Waste management**	None reported
7	**Other**	The notification refers to the study of Eddleston et al. (2005) on self-poisonings with organophosphorus pesticides, including chlorpyrifos, in Sri Lanka, as an additional basis for the final regulatory action, other than a hazard or risk evaluation.

European Union

1	**Effective date(s) of entry into force of actions**	Complete entry into force was on 16 January 2020.
	Reference to the regulatory document	Commission Implementing Regulation (EU) 2020/18 of 10 January 2020 concerning the non-renewal of the approval of the active substance chlorpyrifos, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Official Journal of the European Union L 7, 13.1.2020, p. 14) http//data.europa.eu/eli/reg impl/2020/18/oj
2	**Succinct details of the final regulatory action(s)**	The notified regulatory action relates to chlorpyrifos (CAS No. 2921-88-2) in the pesticide category. It is prohibited to place on the market or use plant protection products containing chlorpyrifos because chlorpyrifos is not approved as an active substance under Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market. EU Member States had to withdraw all authorisations for plant protection products containing chlorpyrifos as active substance by 16 February 2020 at the latest. Disposal, storage, placing on the market and use of existing stocks of plant protection products containing chlorpyrifos is prohibited as of 16 April 2020.
3	**Reasons for action**	The ban on chlorpyrifos was based on the evaluation of the hazards and risk to human health: • It cannot be excluded that chlorpyrifos has a genotoxic potential. • Consequently, it is not possible to establish health-based reference values for chlorpyrifos and to conduct the relevant consumer and non-dietary risk assessments. • Furthermore, developmental neurotoxicity (DNT) effects were observed in rats and epidemiological evidence exists showing an association between exposure to chlorpyrifos and/or chlorpyrifos-methyl during development and adverse neurodevelopmental outcomes in children. • It is appropriate to classify chlorpyrifos as toxic for reproduction, category 1B.
4	**Basis for inclusion into Annex III**	The final regulatory action was based on a risk evaluation taking into account the prevailing conditions in the European Union.
4.1	**Risk evaluation**	The final regulatory action was based on a risk evaluation, which identified concerns for human health under the foreseen conditions of use of chlorpyrifos as an active ingredient in plant protection products in the European Union. It was based on the information available and the proposed conditions of use and concluded that the EU approval criteria for active ingredients and plant protection products are not satisfied for chlorpyrifos. As a first step, the risk evaluation of the active substance chlorpyrifos was done by a Rapporteur Member State, taking into account proposed uses and exposure conditions that prevail in the EU. The Rapporteur Member State then submitted its Renewal Assessment Report (RAR) to the European Food Safety Authority (EFSA). After the commenting period for Member States, the applicants and the public, in April 2019, the EFSA convened an expert discussion related to chlorpyrifos impacts to mammalian toxicology and human health. On 31 July 2019, EFSA issued a statement on the outcome of the risk assessment for human health for chlorpyrifos. Concerns were raised with regard to chromosome aberration and DNA damage (oxidative stress and topoisomerase II inhibition), resulting in an unclear genotoxic potential. Consequently, the experts determined that it was not possible to establish health-based reference values for chlorpyrifos and to conduct relevant consumer and non-dietary risk assessments. Therefore, the experts also determined that it cannot be excluded that there is a probability of adverse effects to human health at any level of exposure.

		The renewal report, which summarizes the results of the evaluation process, concludes that from the assessments made on the basis of the available information (RAR, comments thereon, EFSA statement, applicant comments on the EFSA statement and draft renewal report), no plant protection product containing the active substance chlorpyrifos is expected to satisfy the requirements laid down in Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011. Because the European Union approval criteria related to the effects of chlorpyrifos on human health were not satisfied, the results of other risk assessment components, such as the initial environmental risk assessment, could not alter this conclusion. This is the reason why only concerns for human health are listed as reasons for the final regulatory action.
4.2	**Criteria used**	Risks to human health
	Relevance to other States and Region	Similar human health problems are likely to be encountered in other regions where the chlorpyrifos is used, particularly in developing countries.
5	**Alternatives**	See section 3.3.
6	**Waste management**	None reported
7	**Other**	None reported

Annex 3 to the decision guidance document – Addresses of designated national authorities

Malaysia	
(From PIC website: 21 November 2023) Role: DNA P** Name: Mr. Mat Iesak Bin Ngathinee Job title: Director Department: Pesticides and Fertilisers Control Division / Department of Agriculture Institution: Ministry of Agriculture and Agro-based Industry Postal Address: 6th Floor, Wisma Tani, Jalan Sultan Salahuddin 50632 Kuala Lumpur Malaysia	Phone: +603 2030 1504 Fax: +603 2691 7551 Email: iesak@doa.gov.my

Sri Lanka	
(From PIC website: 21 November 2023) Role: DNA P** Name: Mr. Sumith Jayakody Arachchige Job title: Registrar of Pesticides Department: Office of the Registrar of Pesticides Institution: Ministry of Agriculture Postal Address: 1056, Getambe P.O. Box 49 20400 Peradeniya Sri Lanka	Phone: +94 81 2388 076 Fax: +94 81 2388 076 Email: mail2me.sumith@yahoo.com

The European Union	
(From PIC website: 21 November 2023) Role: DNA CP* Name: Mr. Juergen Helbig Job title: International Chemicals Policy Coordinator Department: DG Environment, Unit ENV.B2 - Safe and Sustainable Chemicals Institution: European Commission Postal Address: 1049 Brussels Belgium	Phone: +32 2 298 8521 Fax: +32 2 298 8874 Email: juergen.helbig@ec.europa.eu

***CP** Pesticides and industrial chemicals

****P** Pesticides