



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

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### Chemical Review Committee

#### Tenth meeting

Rome, 22–24 October 2014

Item 4 (a) (ii) of the provisional agenda\*

#### Technical work: consideration of draft decision guidance

documents: fenthion (ultra low volume (ULV)

formulations at or above 640 g active ingredient/L)

### Draft decision guidance document for fenthion (ultra low volume (ULV) formulations at or above 640 g active ingredient/L)

#### Note by the Secretariat

## I. Introduction

1. At its ninth meeting, the Chemical Review Committee reviewed a proposal submitted by Chad for a severely hazardous pesticide formulation, fenthion 640 ULV (concentration of 640 g/L fenthion), along with additional information collected by the Secretariat in accordance with part 2 of Annex IV to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, and concluded that the criteria set out in Annex IV to the Convention had been met.

2. In its decision CRC-9/4, the Committee recommended that the Conference of the Parties list fenthion (ultra low volume (ULV) formulations at or above 640 g active ingredient/L) in Annex III to the Convention as a severely hazardous pesticide formulation. As part of that decision, the Committee adopted a rationale for its conclusion and agreed to establish an intersessional drafting group to produce a draft decision guidance document.<sup>1</sup> A detailed workplan for the development of the decision guidance document was prepared by the Committee in line with the process adopted by the Conference of the Parties in decision RC-2/2 and amended by decision RC-6/3. The recommendation, rationale and workplan were annexed to the report of the Committee on the work of its ninth meeting (UNEP/FAO/RC/CRC.9/11, annexes I and III).

3. The material available to the intersessional drafting group included a summary of the outcome of the ninth meeting of the Committee, a copy of a working paper on the preparation of internal proposals and decision guidance documents for severely hazardous pesticide formulations, the proposal submitted by Chad and the additional information collected by the Secretariat, which were available to the Committee at its ninth meeting.

\* UNEP/FAO/RC/CRC.10/1.

<sup>1</sup> The members of the drafting group were Ms. Anja Bartels (Austria), Ms. Parvoleta Luleva (Bulgaria), Mr. Victor N'Goka (Congo), Mr. Droh Lanciné Goné (Côte d'Ivoire), Ms. Jacqueline Arroyo (Ecuador), Ms. Mirijam Seng (Germany), Mr. Ram Niwas Jindal (India), Mr. Mehdi Ghaemian (Islamic Republic of Iran), Mr. Michael Ramsay (Jamaica), Mr. Peter Opiyo (Kenya), Ms. Amal Al-Rashdan (Kuwait), Mr. Gaussono Kanouté (Mali), Mr. Sidi Ould Alouimine (Mauritania), Mr. Arturo Gavilan (Mexico), Ms. Leonarda van Leeuwen (Netherlands), Ms. Magdalena Frydrych (Poland), Mr. Jung-Kwan Seo (Republic of Korea), Mr. Jürgen Helbig (Spain), Mr. Azhari Omer Abdelbagi (Sudan) and Ms. Sarah Maillefer (Switzerland).

4. In accordance with the agreed workplan, the co-chairs of the intersessional drafting group (Ms. Anja Bartels (Austria) and Ms. Parvoleta Luleva (Bulgaria)), in consultation with the Secretariat, prepared an internal proposal based on the proposal by Chad and the additional information collected by the Secretariat. That internal proposal was circulated to the members of the drafting group for comments on 13 December 2013. It was amended in the light of the comments received and was circulated, on 20 February 2014, to all Committee members and to the observers who had attended the ninth meeting. Responses were received from Committee members and observers and taken into consideration in the revision of the draft decision guidance document.

5. The outcomes of the work of the intersessional drafting group, including a compilation of the comments received and the draft decision guidance document, were circulated to the members of the group on 29 April 2014.

6. The text of the draft decision guidance document, as submitted by the drafting group, is set out in the annex to the present note. It has not been formally edited. A tabular summary of the comments received, including information on how they were dealt with, is set out in the annex to document UNEP/FAO/RC/CRC.10/INF/5.

## **II. Proposed action**

7. The Committee may wish to finalize the draft decision guidance document and to forward it, together with its recommendation to list fenthion (ultra low volume (ULV) formulations at or above 640 g active ingredient/L), in Annex III to the Convention as a severely hazardous pesticide formulation, for consideration by the Conference of the Parties at its seventh meeting.

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**Annex****Rotterdam Convention**

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

**Draft**  
**Decision Guidance Document**

**Fenthion (Ultra Low Volume formulations (ULV)  
at or above 640 g active ingredient/L)**



**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 for the Rotterdam Convention include severely hazardous pesticide formulations. For the Rotterdam Convention, severely hazardous pesticide formulations are those that have been proposed by a developing country or country with economy in transition that is experiencing problems with such formulations under the conditions of use in its territory. Inclusion of a severely hazardous pesticide formulation in the Convention is based on a proposal submitted by a developing country or country with economy in transition as well as additional information collected by the Secretariat in line with parts 1 and 2 of Annex IV of the Convention. For each chemical included in the Rotterdam Convention, 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 [chemical name] in Annex III of the Convention and adopted the decision guidance document with the effect that this group of chemicals 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 of 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 and severely hazardous pesticide formulations for possible inclusion in Annex III of the Convention. The decision guidance document for a severely hazardous pesticide formulation reflects the information provided in a proposal submitted by a developing country or country with economy in transition as well as additional information collected by the Secretariat in line with parts 1 and 2 of Annex IV to the Convention. It is not intended as the only source of information on a chemical nor it is updated or revised following its approval by the Conference of the Parties.

There may be additional Parties that have experienced problems with this chemical or taken regulatory actions to ban or severely restrict the chemical and others that have not experienced problems nor 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](http://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.

## 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   |
| µg               | microgram  |
| add.             | Addendum   |
| approx.          | approximately  |
| ARfD             | Acute Reference Dose   |
| a.i.             | active ingredient  |
| ADI              | Acceptable Daily Intake  |
| AOEL             | Acceptable Operator Exposure Level   |
| APVMA            | Australian Pesticides and Veterinary Medicines Authority   |
| bw               | body weight  |
| °C               | degree Celsius (centigrade)  |
| CAS              | Chemical Abstracts Service   |
| cm               | centimetre   |
| CRC              | Chemical Review Committee  |
| d                | day  |
| DPVC             | Directorate of Plant Protection and Conditioning   |
| DT <sub>50</sub> | Degradation time, 50 %   |
| EC               | Emulsifiable Concentrate   |
| E.C.             | European Community   |
| EC <sub>50</sub> | Effect Concentration, 50%  |
| ED <sub>50</sub> | Effect Dose, 50%   |
| EHC              | Environmental Health Criteria  |
| EPA              | Environmental Protection Agency  |
| EU               | European Union   |
| FAO              | Food and Agriculture Organization of the United Nations  |
| g                | gram   |
| h                | hour   |
| ha               | hectare  |
| IARC             | International Agency for Research on Cancer  |
| IPCS             | International Programme on Chemical Safety   |
| IPM              | Integrated Pest Management   |
| ISO              | International Organization for Standardization   |
| IUPAC            | International Union of Pure and Applied Chemistry  |
| 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) |
| k                | Kilo- (x 1000)   |

| <b>STANDARD CORE SET OF ABBREVIATIONS</b> |   |
|---|---|
| kg  | kilogram  |
| K <sub>oc</sub>                           | organic carbon-water partition coefficient  |
| L   | litre   |
| LC <sub>50</sub>                          | Lethal Concentration, 50%   |
| LD <sub>50</sub>                          | Lethal Dose, 50%  |
| LOAEL                                     | Lowest Observed Adverse Effect Level  |
| LOEL                                      | Lowest Observed Effect Level  |
| Log P <sub>ow</sub>                       | log octanol/water partition coefficient   |
| m   | meter   |
| mg  | milligram   |
| mL  | millilitre  |
| MRL                                       | Maximum Residue Limit   |
| 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  |
| P <sub>ow</sub>                           | octanol-water partition coefficient   |
| PPE                                       | Personal Protective Equipment   |
| 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). |
| RC  | Rotterdam Convention  |
| RfD                                       | Reference Dose for chronic oral exposure (comparable to ADI)  |
| UNEP                                      | United Nations Environment Programme  |
| USA                                       | United States of America  |
| USEPA                                     | United States Environmental Protection Agency   |
| UV  | ultraviolet   |
| WHO                                       | World Health Organization   |
| w/w                                       | weight/weight (percent)   |
| wt.                                       | weight  |

## Decision guidance document for a severely hazardous pesticide formulation causing human health problems

**FENTHION (ULTRA LOW VOLUME FORMULATIONS (ULV) AT OR ABOVE 640 G ACTIVE INGREDIENT/L)**

**Published:**

### 1. Identification and uses (see Annex 1 for further details)

**Name or trade name of the hazardous pesticide formulation** Fenthion 640 ULV

**Name of the active ingredient or ingredients in the formulation** Fenthion

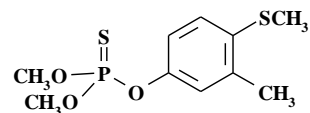
**Relative amount of each active ingredient in the formulation** 640 g fenthion/L

**Type of formulation** Ultra Low Volume (ULV)

**Name(s) of the producer(s), if available** Arysta Life Science

**Molecular formula** C<sub>10</sub>H<sub>15</sub>O<sub>3</sub>PS<sub>2</sub>

**Chemical structure**



**CAS-No.(s)** 55-38-9

### 2. Reasons for inclusion in the PIC procedure

Ultra Low Volume formulations (ULV) containing fenthion at or above 640 g/L are listed in Annex III to the Rotterdam Convention in the category of severely hazardous pesticide formulations, and, accordingly subject to the PIC procedure.

These pesticide formulations were found to cause human health problems to the applicators under conditions of use in Chad, consistent with the provisions of Article 6 and Annex IV to the Convention.

The rationale developed by the Chemical Review Committee at its ninth session (2013) in support of their recommendation to include such formulations in the PIC procedure can be found in Annex I to this document.

### 3. Description of common and recognized pattern of use of the formulation in the reporting country

#### 3.1 Permitted uses of the formulation

The formulation Fenthion 640 ULV is registered in Chad; the permitted uses are for avian control (spraying on bird roosts) at 1.8 to 3 L/ha. Use is exclusively permitted to be carried out by the Directorate of Plant Protection and Conditioning (DPVC). More information on the actual amounts used in Chad can be found in Annex I point 5.

#### 3.2 Restrictions in handling or use

In Chad, the use of Fenthion 640 ULV as avicide is exclusively permitted to be carried out by the DPVC. The application is severely restricted to technicians specialized in bird control (Plant Protection Service team equipped with rotary sprayer, aerial application by specialized companies).

The label includes some precautionary statements on use (requirement for personal protective equipment), illustrated by pictograms. The personal protective equipment required for operators for handling and application comprises gloves, shoes, long-sleeved protective clothing and a mask.

### 3.3 Availability/applicability of protective clothing

The person harmed in the incident that is reported in detail did wear full protective equipment in accordance with prevailing provisions.

### 3.4 Actual uses

The formulation is registered; the permitted uses are for avian control. Use is only permitted to be carried out by the DPVC.

Fenthion 640 ULV was used as an avicide against granivorous birds (*Quelea quelea*) to reduce damage to grain crops. The product was used with a motorized backpack sprayer at a dose of 1.8 to 3 L/ha in 2009, 2011 and 2012.

After a first intervention in 2009 by governmental order, which consisted of seven teams, the Ministry of Agriculture and Irrigation through the DPVC organised in 2011 and 2012 missions composed of four teams, three of which were charged with survey and control and the fourth was charged with supplies and monitoring.

## 4. Description of the incident(s), including adverse effects and way in which the formulation was used

### 4.1 Description of the incident(s)

In the course of the 2011 avian control mission a technician, approximately 60 years old and with a long history of hypertension (the technician had hypertension but did not signal it to the DPVC when departing on the control campaign), was intoxicated during the treatment of a nest situated 200 km from N'Djaména (Bokoro) on 17 June 2011.

The technician took part in both filling and application. He was wearing protective clothing during the whole operation: the protective kit comprised of a hat, glasses, mask, cotton overall, gloves and boots covered by trousers. It is reported that he could read and understand the label.

The effects were observed 1 hour after application. The intoxicated person presented the following symptoms: vomiting, abundant salivation and titubation.

He was immediately brought to Bokoro hospital, then moved to the emergency department of N'Djaména hospital where he received further care. On the advice of the doctor, he was discharged the same day for home care. Unfortunately, despite the care at home, he relapsed on the fourth day and passed away.

A second case of lethal intoxication of an operator following handling/land treatment with Fenthion 640 ULV in Chad was mentioned as having occurred in 2009. In addition, another operator had gone into a coma for one week under the same circumstances. However, these cases were reported by Chad as supplementary information but not included in the pesticide incident report form of the proposal.

### 4.2 Description of the adverse effects

See point 4.1 above. For further information see incident report form in Annex II.

### 4.3 Relationship of the adverse effects observed to recognized acute toxicological effects of the active ingredient(s)

Fenthion has been classified by WHO as class II chemical (moderately hazardous).

Fenthion is a cholinesterase inhibitor, acting by contact, inhalation or ingestion.

Acute toxicity: Fenthion affects the central nervous, cardiovascular, and respiratory systems, and may irritate eyes and mucous membranes. As with all organophosphates, fenthion is readily absorbed through the skin.

The organophosphate insecticides are cholinesterase inhibitors. They are highly toxic by all routes of exposure. When inhaled, the first effects usually occur in the respiratory system and may include bloody or runny nose, coughing, chest discomfort, difficult or short breath, and wheezing due to constriction or excess fluid in the bronchial tubes. Skin contact with organophosphates may cause localized sweating and involuntary muscle contractions. Eye contact will cause pain, bleeding, tears, pupil constriction, and blurred vision. Following exposure by any route, systemic effects may begin within a few minutes or be delayed for up to 12 hours. These may include pallor, nausea, vomiting, diarrhea, abdominal cramps, headache, dizziness, eye pain, blurred vision, constriction or dilation of the eye pupils, tears, salivation, sweating and confusion. Severe poisoning will affect the central nervous system, producing lack of coordination, slurred speech, loss of reflexes, weakness, fatigue, involuntary muscle contractions, twitching, tremors of the tongue or eyelids and eventually paralysis of the body extremities and the respiratory muscles.

Some organophosphates may cause delayed symptoms beginning 1 to 4 weeks after an acute exposure which may or may not have produced immediate symptoms. In such cases, numbness, tingling, weakness and cramping may appear in the lower limbs and progress to incoordination and paralysis. Improvement may occur over months or years, but some residual impairment will remain.



Acute poisoning of fenthion results in miosis (pinpoint pupils), headache, nausea/vomiting, dizziness, muscle weakness, drowsiness, lethargy, agitation or anxiety. If the poisoning is moderate or severe, it results in chest tightness, breathing difficulty, hypertension, abdominal pain, diarrhea, heavy salivation, profuse sweating, or fasciculation. In an extremely severe case, such as a suicide attempt, the victim may get coma, respiratory arrest, seizures, loss of reflexes and flaccid paralysis.

Several cases of intentional or accidental human poisonings via ingestion and/or dermal exposure are known.

(Source: Extension Toxicology Network 1993, <http://extoxnet.orst.edu/pips/fenthion.htm>)

The effects observed in the victim are representative for acute exposure to fenthion: vomiting, salivation, nervous system effects (titubation). Another intoxicated person is reported to have gone into coma.

#### **4.4 Extent of incident (e.g. number of people affected for human health incidents)**

During the control missions in 2009, 2011 and 2012 three incidents were reported in Chad. One incident of a lethal intoxication from 2011 is reported in detail. A second case of lethal intoxication of an operator following handling/land treatment with Fenthion 640 ULV is mentioned as having occurred in 2009. In addition, another operator had gone into a coma for one week under the same circumstances.

#### **5. Any regulatory, administrative or other measure taken, or intended to be taken, by the proposing Party in response to such incidents**

No measure was or is intended to be taken. The use is already severely restricted to bird control that is only permitted to be carried out by the Directorate of Plant Protection and Conditioning (DPVC), after making people aware of the danger that the product constitutes for human beings, livestock and the environment. The product will be used pending the development of alternatives such as traditional trapping nets.

#### **6. WHO hazard classification of the formulation**

The WHO hazard classification for the formulation is not known. The active substance fenthion is classified as follows:

| Route  | Species | LD <sub>50</sub> (mg/kg bw) | WHO toxicity class      |
|--------|---------|-----------------------------|-------------------------|
| Oral   | Rat     | approx. 250                 | II Moderately hazardous |
| Dermal | Rat     | 586                         | II Moderately hazardous |

#### **7. Alternative pest-control practices**

##### **General**

There are a number of alternative methods available, involving non-chemical strategies, including alternative technologies, depending on the national circumstances and local conditions of use. Countries should consider promoting, as appropriate, integrated pest management (IPM) as a means of reducing or eliminating the use of hazardous pesticides.

Advice may be available through National IPM focal points, the FAO, and agricultural research or development agencies. Additional information on alternatives of use for Fenthion 640 ULV may be found on the Rotterdam Convention website [www.pic.int](http://www.pic.int).

Information on alternative practices in French language can be found in document UNEP-FAO-RC-CRC.9-4-Add.2, p. 159-170 (<http://www.pic.int/TheConvention/ChemicalReviewCommittee/Meetingsanddocuments/CRC9/POPRC9Documents/tabid/3291/language/en-US/Default.aspx>)

##### **Chad**

The following alternative pest-control practices against granivorous birds are reported: capturing birds with Japanese trapping nets and locally produced nets; nest removal campaign; protection of crops with nets; guarding of crops and/or scaring of birds from crops.

**Annexes**

- Annex I **Rationale for the recommendation by the Chemical Review Committee to include the severely hazardous formulation in the PIC procedure**
- Annex II **Information on reported incident from incident report**
- Annex III **Safety data sheet(s) on pesticide active ingredient(s)**
- Annex IV **Further information on the pesticide active ingredient**
- Annex V **References**

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| <b>Annex I Rationale for the recommendation by the Chemical Review Committee to include the severely hazardous formulation in the PIC procedure</b> |
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**Rationale for the conclusion by the Chemical Review Committee that the proposal submitted by Chad for listing fenthion 640 ULV in Annex III to the Rotterdam Convention as a severely hazardous pesticide formulation meets the criteria of part 3 of Annex IV to the Convention**

**1. Scope of the proposal**

The proposal submitted by Chad referred to the formulation Fenthion 640 ULV (concentration of 640 g/L fenthion). This is an Ultra Low Volume (ULV) formulation.

The proposal and supporting documentation were made available to the Chemical Review Committee for its consideration in documents UNEP/FAO/RC/CRC.9/4, Add. 1 and Add. 2.

Fenthion 640 ULV was used as an avicide against granivorous birds (*Quelea quelea*) in the context of bird control to reduce damage to grain crops. The product was used with a motorized backpack sprayer at a dose of 1.8 to 3 L/ha in 2009, 2011 and 2012.

The formulation is registered; the permitted uses are for avian control. Use is only permitted to be carried out by the Directorate of Plant Protection and Conditioning (DPVC).

After a first intervention in 2009 by governmental order, which consisted of seven teams, the Ministry of Agriculture and Irrigation through the Directorate of Plant Protection and Conditioning (DPVC) organised in 2011 and 2012 a mission composed of four teams, three of which were charged with survey and control and the fourth charged with supplies and monitoring.

One incident is reported in detail: In the course of the avian control mission a 60 year-old technician who had a long history of hypertension (the technician had hypertension but did not signal it to the DPVC when he departed on the control campaign) was intoxicated in a nest situated 200 km from N'Djaména (Bokoro) on the date of 17 June 2011. The technician took part in both activities, filling of the sprayer and application of the pesticide. He was wearing protective clothing during the whole operation: a protective kit comprising a hat, glasses, mask, a cotton overall, gloves and boots covered by trousers. The effects were observed one hour after application. The intoxicated person showed the following symptoms: vomiting, abundant salivation and titubation one hour after application. He was immediately brought to Bokoro hospital, then moved to the emergency department of N'Djaména hospital where he received further care. On the advice of the doctor, he was discharged the same day for home care. Unfortunately, despite the care at home, he relapsed on the fourth day and passed away.

In document UNEP/FAO/RC/CRC.9/4/Add.1 a second case of lethal intoxication of an operator following handling/land treatment with Fenthion 640 ULV is mentioned as occurring in 2009. In addition, one operator had gone into a coma for one week under the same circumstances. However, these cases were not included in the pesticide incident report form of the proposal.

The documentation required according to Part 1 of Annex IV to the Convention was submitted by Chad in its proposal and published in PIC Circular XXXVI, of December 2012.

The information collected by the Secretariat according to Part 2 of Annex IV to the Convention was submitted by Parties and observers and was made available to the Committee in document UNEP/FAO/RC/CRC.9/4/Add.2.

**2. Criterion Annex IV, part 3 (a)**

*In reviewing the proposals forwarded by the Secretariat pursuant to paragraph 5 of Article 6, the Chemical Review Committee shall take into account:*

*(a) The reliability of the evidence indicating that use of the formulation, in accordance with common or recognized practices within the proposing Party, resulted in the reported incidents;*

In Chad, Fenthion 640 ULV is reported to have been used in the field near grain crops and it was applied by means of motorized backpack sprayers against bird roosts at rates of 1.8 to 3 L/ha. The label gives, among others, indication of high toxicity by inhalation and prolonged ingestion.

The use of Fenthion 640 ULV was by governmental order of the Ministry of Agriculture and Irrigation through the Directorate of Plant Protection and Conditioning (DPVC), who had organised bird control teams in 2009, 2011 and 2012.

An incident of a lethal intoxication of a 60 year old technician was reported who had been involved in mixing and loading and had sprayed the product onto bird nests during the night by the use of a backpack sprayer. He was wearing protective clothing during the whole operation: a protective kit comprising a hat, glasses, mask, a cotton overall, gloves and boots covered by trousers.

Although uncertainty was identified as regards the causal link between the death of the operator and the use of Fenthion 640 ULV taking into account his precondition of hypertension, however, the symptoms can be clearly linked to intoxication after the use. Further it has been indicated that the adverse effects from organophosphates poisoning generally can be acute, intermediate and delayed.

The Committee concluded that evidence indicating that the use of Fenthion 640 ULV, in accordance with common and recognized practices within Chad, resulted in the reported incident was reliable.

The Committee concluded that this criterion was met.

**3. Criterion Annex IV, part 3 (b)**

*The relevance of such incidents to other States with similar climate, conditions and patterns of use of the formulation;*

Documentation was available to the Committee (UNEP/FAO/RC/CRC.9/4/Add.2) indicating that the above listed conditions for Chad are similar to the conditions prevailing in other African States. It is reported from Gambia that in the 1980s the product was used for bird control (UNEP/FAO/RC/CRC.9/4/Add.2). The product is used for control of granivorous birds in Niger and also in Mauritania (for more than 20 years) (UNEP/FAO/RC/CRC.9/4/Add.2). In a Master's thesis from Mauritania, cases of poisoning caused by avicide treatments of fenthion are reported (UNEP/FAO/RC/CRC.9/4/Add.2).

Different formulations of fenthion are in use as an insecticide in several countries (e.g. Australia, Madagascar, Morocco and New Zealand).

A case of poisoning with a different fenthion formulation is reported from Norway in the context of a suicide attempt (UNEP/FAO/RC/CRC.9/4/Add.2). Poisoning incidents from use of fenthion in mosquito control are reported by FAO (UNEP/FAO/RC/CRC.9/4/Add.2).

Taking into account the information available, the Committee concluded that the criterion was met.

**4. Criterion Annex IV, part 3 (c)**

*The existence of handling or applicator restrictions involving technology or techniques that may not be reasonably or widely applied in States lacking the necessary infrastructure;*

In Chad, the application of Fenthion 640 ULV is restricted to technicians specialized in bird control (Plant Protection Service team equipped with motorized backpack sprayer or aerial application by specialized companies).

General handling or applicator restrictions for the use of products containing fenthion have been provided by several Parties, namely from the EU, Australia, Norway. For example personal protective equipment (PPE) is required.

Taking into account the information available, the Committee concluded that the criterion was met.

**5. Criterion Annex IV, part 3 (d)**

*The significance of reported effects in relation to the quantity of the formulation used;*

In Chad, Fenthion 640 ULV is reported to have been used in the field near grain crops and it was applied in 2009, 2011 and 2012 by means of motorized backpack sprayer against bird roosts. The following quantities were used in 2009: 112 liters to treat 45 dormitories (59 ha) in ten days for one hour per day and by six land teams at a dose of 1.8 L/ha; in 2011: 105.5 liters for 16 dormitories (54.7 ha) in 30 days for one hour per day and by six land teams at a dose of 1.9 L/ha; in 2012: 275 liters to treat 25 dormitories (53 ha) in 30 days for one hour per day and by 3 land teams at a dose of 3 L/ha.

In 2011, the mission lasted forty-five (45) days for the teams in charge of survey and control; and fifteen (15) days for the team in charge of supply and monitoring, from 6 June to 21 July 2011.

Taking into account the information available, the Committee concluded that this criterion was met.

**6. Criterion Annex IV, part 3 (e)**

*That intentional misuse is not in itself an adequate reason to list a formulation in Annex III.*

Intentional misuse was not reported as a reason for the proposal.

Taking into account the information available, the Committee concluded that this criterion was met.

The Committee concluded at its ninth session that the proposal from Chad to list Fenthion 640 ULV (640 g/L fenthion) in Annex III to the Convention as a severely hazardous pesticide formulation met the documentation requirements of Annex IV part 1 and the criteria set out in Annex IV part 3 of the Convention, considering the information collected by the Secretariat according to Part 2 of Annex IV.

The Committee therefore recommends that Fenthion 640 ULV (640 g/L fenthion, CAS number 55-38-9) be included in Annex III of the Rotterdam Convention as a severely hazardous pesticides formulation.

**Annex II Information on reported incident from incident report****Country Name: Chad**

Address of Designated National Authority

**Chad**  
**Pesticides**

Mr. Moussa Abderaman Abdoulaye

Directeur Adjoint / Chargé de la gestion des pesticides  
 Direction de Protection des Végétaux et du Conditionnement  
 (DPVC)  
 Ministère de l'Agriculture et de l'Irrigation  
 B.P. 1551  
 N'Djamena  
 Chad

**Phone:** +235 66 32 52 52**Fax:** +235 99 32 52 52**Email:** charafa2009@gmail.com**PART B - PESTICIDE INCIDENT REPORT FORM****I. Product identity: What formulation was used when the incident took place****1. Name of the formulation: FENTHION**.....**2. Type of formulation (check one of the following):**
 *Emulsifiable Conc. (EC)*     *Wettable Powder (WP)*     *Dustable powder (DP)*
 *Water Soluble Powder (SP)*     *Ultra Low Volume (ULV)*     *Tablet (TB)*
 *Granular (GR)*     *other, please specify: .....*
**3. Trade name and name of producer, if available: Fenthion 640 ULV produced in Senegal by "Arysta life science"**  
.....**4. Name of the active ingredient(s) in the formulation: Fenthion**  
.....**5. Relative amount of each active ingredient in the formulation (% concentration, g/l, etc.): 640 g/litre**  
.....**6. Attach copy of the label(s), if available.****II. Description of the incident: How the formulation was used.****7. Date of incident: the night of 17 June 2011****8. Location of incident: village/city: GOGOI (Bokoro)**
 province/state/region: **Hadjer-Lamis** .....

 country: **Chad** .....

**9. Person exposed (identity should be checked and recorded before submission of the form)**Sex:  male  female  age: **60 years (approximately)**If age unknown:  child (<14 yrs)  adolescent (14-19 yrs)  adult (>19 yrs)**10. Main activity at time of exposure (check one or more of the following):** application in field  mixing/loading  veterinary therapy household application  vector control application  human therapy re-entry to treated field  other, please specify: **spraying bird nests at night****11. Was protective clothing used during application?**  no  yes

If no, please explain why:.....

If yes, briefly describe (check one or more of the following):

 gloves  overalls  eye glasses  respirator face mask  boots/shoes  long-sleeve shirt  long pants other, please specify:.....**12. Information on how product was being used:**(a) Location of exposure/incident (*field, garden, greenhouse, house, etc.*):**Granivorous birds roosts** .....

(b) List the animals/crop(s)/stored products treated if relevant:

**Quelea quelea or red-billed quelea**.....(c) Application method: (*How product was used e.g. hand, bucket & brush, soil injection, spray(backpack, tractor mounted,etc), drip irrigation, aerial (helicopter, plane etc.)*):**Motorized backpack sprayer**.....(d) Dose applied/concentration (*or amount of pesticide applied*):**2 litres/ha**.....

(e) Duration of the exposure period:

 hours  ½ day  day  other (specify):**13. If more than one pesticide formulation was used at the same time, please respond to points i) to iv) below for each formulation. (see also Part I Product Identity)**i) Was the pesticide in its original container?  no  yesii) Was the label available?  no  yesIf yes, was exposed individual able to read and understand label?  no  yesiii) Does the label include the reported use?  no  yes

If no, describe how the use reported above differs from that recommended on the label

*(use a separate page if necessary):* .....iv) Is the reported incident typical of how the formulation is generally used?  no  yes**14. Climatic conditions under which the incident occurred (eg. temperature, relative humidity):**

Beginning of the rainy season .....

15. Were other individuals affected in the same incident?  no  yes

16. Include any other details that may be useful in describing the incident and the way in which the formulation was used, in particular how the use reported here reflects common or recognized use patterns for this formulation (*additional pages may be attached*).

### III. Description of adverse effects:

17. Individual's reaction (check one or more of the following):

- dizziness     headache     blurred vision     excessive sweating  
 hand tremor     convulsion     staggering     narrow pupils/miosis  
 excessive salivation     nausea/vomiting     death

other, please specify: . death occurred 200 km from the place of treatment (N'Djamena).....

18. Route of exposure (*check main route or more than one if applicable*)

- mouth     skin     eyes     inhalation  
 other, please specify:

19. How soon after last use of the formulation were the adverse effects observed:

1 hour .....

### IV. Management:

20. Treatment given:             No     Yes     Unknown

Hospitalization:             No     Yes     Unknown

21. Include any other details/information regarding treatment including medical intervention/first aid/hospitalization/local practices, etc. (*additional pages may be attached*):

.....

### V. Reporting/communication:

22. Date of data collection/consultation: 27 November 2011 .....

23. Name and address of investigator/data collector: DJEKADOM RIABE SAMUEL  
Head, Department of Surveillance, Intervention and Logistic DPVC - N'Djamena (CHAD)

24. Category of investigator/data collector:

- medical     paramedical     non-medical

If non-medical, then specify type of person (*applicator, formulator, vendor, extension worker, manager, etc.*): supervisor .....

25. Contact if further information is needed:    Tel: .....

Fax: .....    E.mail:

26. Has this incident been reported elsewhere?     No     Yes

If yes, where: .....

Send the completed incident report form to the Designated National Authority.  
(Name and address of the DNA)



**Annex III Safety data sheet(s) on pesticide active ingredient(s)**

Note: No safety data sheet on the product Fenthion 640 ULV was found.



WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTE

FOOD AND AGRICULTURE  
ORGANIZATION

ORGANISATION POUR L'ALIMENTATION  
ET L'AGRICULTURE

VBC/DS/77.23

ORIGINAL: ENGLISH

**DATA SHEETS ON PESTICIDES No. 23**

December 1976

**FENTHION**

It must be noted that the issue of a Data Sheet for a particular pesticide does not imply endorsement of the pesticide by WHO or FAO for any particular use, or exclude its use for other purposes not stated. While the information provided is believed to be accurate according to data available at the time when the sheet was compiled, neither WHO nor FAO are responsible for any errors or omissions, or any consequences therefrom.

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**Part 1 - General Information****CLASSIFICATION:**

Primary use: Insecticide

Secondary use: Avicide, Acaricide

Chemical group: Organophosphorus compound

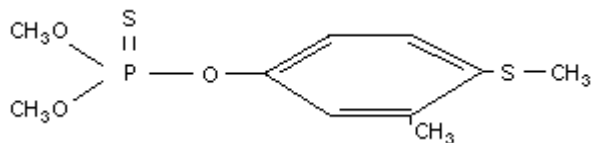
Data sheet No. 23

Date issued: December 1976

## 1.1 COMMON NAME: FENTHION (ISO)

### 1.1.1 Identity:

dimethyl 3-methyl-4-methylthiophenyl phosphorothionate.



### 1.1.2

| <u>Synonyms</u> | <u>Local synonyms</u> |
|-----------------|-----------------------|
|-----------------|-----------------------|

Baytex  
Lebaycid  
Queletox  
Tignvon  
OMS-2

## 1.2 SYNOPSIS

An organophosphorus insecticide of moderate mammalian toxicity which may be absorbed through the skin, from the gastrointestinal tract and by inhalation. It is active upon metabolism into the more toxic oxygen analogue. Symptoms after acute poisoning tend to be prolonged.

## 1.3 SELECTED PROPERTIES

### 1.3.1 Physical characteristics

When pure, colourless, almost odourless liquid of boiling point 87°C at 0.01 mm Hg. The technical material is 95-98% pure, a brown oily liquid with a weak garlic odour.

### 1.3.2 Solubility

Water at 20°C, 54-56 ppm, readily soluble in most organic materials and glyceride oils.

### 1.3.3 Stability

It is stable up to 160°C and is resistant to light and alkaline hydrolysis.

### 1.3.4 Vapour pressure (volatility)

4 x 10<sup>-5</sup> mm Hg at 20°C. It has a low vapour pressure but is slightly volatile

## 1.4 AGRICULTURE, HORTICULTURE AND FORESTRY

### 1.4.1 Common formulations

Fogging concentrates between 40% and 60%; wettable powders 25% to 40%; emulsifiable concentrates 50%; dusts 3%; ultra low volume application 1000 g per litre.

#### 1.4.2 Pests mainly controlled

Used as a contact and stomach insecticide and is highly persistent. Effective against fruit flies, leaf hoppers, cereal bugs, weaver birds, animal parasites, mites, aphids, codling moth.

#### 1.4.3 Use pattern

Used preharvest on sugar cane, rice, field corn, beets, pome and stone fruit, citrus fruits, pistachio, cotton at rates up to 2 kg/ha. Active matter - also on olives, coffee, cocoa, vegetables, vines and corn at rates up to 1 kg/ha.

#### 1.4.4 Unintended effects

Not phytotoxic if used at the recommended dose rates. Applications are not likely to give rise to contamination of food.

### 1.5 PUBLIC HEALTH PROGRAMMES

Mainly as larvicide in mosquito control. Not recommended for residual indoor application due to rather high mammalian toxicity.

### 1.6 HOUSEHOLD USE

Not recommended for indoor use.

## Part 2 - Toxicology and risks

### 2.1 TOXICOLOGY-MAMMALS

#### 2.1.1 Absorption route

Absorbed by the intact skin as well as by inhalation and from the gastro-intestinal tract.

#### 2.1.2 Mode of action

Cholinesterase inhibition after conversion into the more toxic oxygen analogue in the body.

#### 2.1.3 Excretion

In rats 86% of an oral dose is eliminated in seven days (urine 45% and faeces 40%). Metabolites include the sulfone and sulfoxide of both the parent compound and its oxygen analogue.

#### 2.1.4 Toxicity, single dose

|                               |               |                                 |           |
|-------------------------------|---------------|---------------------------------|-----------|
| Oral LD <sub>50</sub> rat (M) | 215 mg/kg     | Dermal LD <sub>50</sub> rat (M) | 330 mg/kg |
|                               | (F) 245 mg/kg | rat (F)                         | 330 mg/kg |

Dermal LD<sub>50</sub> rabbit (M) 150 mg/kg

#### Most susceptible species

Calf - oral LD<sub>50</sub> approximately 40 mg/kg

#### 2.1.5 Toxicity, repeated doses

##### Oral

Rats of both sexes were given repeated oral doses of 10, 25, 50 and 100 mg/kg for five days. No deaths were observed at 10 and 25 mg/kg. One out of four animals died at 50 mg/kg and all died at 100 mg/kg. Fasciculations were observed after a single dose of 25 mg/kg.

Daily oral doses of 25 mg/kg for 75 days, six days a week to 30 rats killed 12 animals. Daily administration of 30 mg/kg five days a week for 13 weeks to male rats gave a 30% mortality and 80-90% reduction of cholinesterase activity. Cholinesterase recovery was slow, up to 40 days.

##### Inhalation

Female rats tolerated a daily one-hour inhalation exposure to fenthion of 0.163 mg/l for 30 days with inhibition of cholinesterase but no deaths. At 0.415 mg/l, all animals died within 10 days.

##### Dermal

Dermal administration of fenthion at 14.5 and 25 mg/kg for 60 days to rats resulted in 40% mortality in the higher dosed group. Blood cholinesterase activity was reduced to 20% of normal in the lower group. The five-day repeated dermal LD<sub>50</sub> has been given as 73 mg/kg/day to rats (total dose 365 mg/kg).

##### Cumulation of compound

Fenthion is not cumulative to any marked degree. However, cholinesterase recovery is slow after inhibition by this compound.

##### Cumulation of effect

Repeated exposure may produce cumulative effect on cholinesterase.

#### 2.1.6 Dietary studies

##### Short-term

Male and female rats were fed fenthion at dietary levels of 0.25, 0.50, 2.5 and 5.0 mg/kg for three months. Reduction of erythrocyte cholinesterase activity was observed at all dose levels. At the lowest level, 0.25 mg/kg, the inhibition, approximately 10-20%, was not progressive with time. Mortalities were observed in the females at 5.0 mg/kg, the animals died manifesting muscarinic and nicotinic effects. Histological examination revealed reduced spermatogenesis in the testis and atrophic prostate glands at the highest feeding levels (2.5 and 5.0 mg/kg).

##### Long-term

Six groups of 25 males and 25 female rats were fed for one year on diets of 2, 3, 5, 25 and 100 ppm fenthion. Survival of male rats at 25 ppm was slightly decreased and cholinesterase activity was reduced at the 5 ppm level and above with only those animals at 2 and 3 ppm showing no adverse enzyme effects. Haemosiderosis was evident in the spleen of the rats at the 100 ppm level.

### 2.1.7 Supplementary studies of toxicity

#### Carcinogenicity

No information available.

#### Teratogenicity

A three generation study in rats at 3.15 and 75 ppm involving two litters per generation produced no adverse effects on rat reproduction. Only slight growth depression was observed at the highest dietary level.

#### Neurotoxicity

No neurological disruption in hens was observed when fenthion was administered orally as a single dose of 25 mg/kg and at up to 100 ppm in the diet for 30 days.

### 2.1.8 Modifications of toxicity

Fenthion potentiates the acute intraperitoneal toxicity of malathion dioxathion and coumaphos in rats. The greatest - almost threefold - potentiation was with coumaphos. Reduction of cholinesterase activity was also potentiated by a combination of fenthion and coumaphos when fed to dogs.

## 2.2 TOXICOLOGY-MAN

### 2.2.1 Absorption

Ingestion has proved to be the important cause of severe poisoning with this compound. It may also be absorbed through the skin and by inhalation of dust particles.

### 2.2.2 Dangerous doses

Single: not known.

Repeated: not known.

### 2.2.3 Observations on occupationally exposed workers

Fenthion has been widely used in many parts of the world for control of household pests and mosquitos. Twenty-seven out of 28 workers who sprayed fenthion as residual indoor application for 15 days in a malaria control operational trial without taking adequate precautions, demonstrated various degrees of poisoning. These included headache, vertigo, blurred vision, muscle and abdominal pains, cramps, diarrhoea and prolonged vomiting. Very severe reduction of whole blood cholinesterase activity was observed, and it was still reduced a month after the end of spraying. However, in a second smaller spraying operation when precautions were more stringent, only one out of 12 men showed mild symptoms.

In mosquito larviciding operations, dermal exposure was found to average 3.6 mg/h with both power and hand sprayers and 12.3 mg/h using a granular formulation dispersed by hand. Some workers showed some plasma cholinesterase depression but in no case was erythrocyte cholinesterase depressed.

### 2.2.4 Observations on exposure of the General population

No information available.

#### 2.2.5 Observations of volunteers

No information available.

#### 2.2.6 Reported mishaps

Apart from the incident when applied in a trial as a residual indoor insecticide, most incidents have been from ingestion of quantities of fenthion. In these separate incidents there has been recovery although the patients were suffering from severe poisoning (one was comatose and cyanosed at presentation). However, extensive treatment with pralidoxime, atropine, artificial respiration, and in one case endotracheal intubation, were necessary. In these cases the acute effects were prolonged; in one case, recovery took 30 days.

### 2.3 TOXICITY TO NON-MAMMALIAN SPECIES

#### 2.3.1 Fish

Information being obtained.

#### 2.3.2 Birds

Harmful.

#### 2.3.3 Other species

Information being obtained.

### Part 3 - For regulatory authorities

#### RECOMMENDATIONS ON REGULATION OF COMPOUND

### 3.1 RECOMMENDED RESTRICTIONS ON AVAILABILITY

(For definition of categories, [see introduction](#).)

Liquid formulations above 10%, category 3. All others, category 4.  
Solid formulations above 10%, category 4. All others, category 5.

### 3.2 TRANSPORTATION AND STORAGE

#### All formulations

United Nations Classification 6.1.

Should be transported or stored in clearly labelled rigid and leakproof containers, under lock and key, secure from access by unauthorized persons and children. No food or drink should be transported or stored in the same compartment.

### 3.3 HANDLING

#### Formulations in categories 3 and 4

Full protective clothing should be used by those handling the compound. Adequate facilities should be available at all times during handling and should be close to the site of handling. Eating, drinking and smoking should be prohibited during handling and before washing after handling.

Formulations in category 5

No facilities other than those needed for handling of any chemical may be required.

**3.4 DISPOSAL AND/OR DECONTAMINATION OF CONTAINER**

Containers must either be burned or crushed and buried below topsoil. Care must be taken to avoid subsequent contamination of water sources. Decontamination of containers in order to use them for other purposes should not be permitted.

**3.5 SELECTION, TRAINING AND MEDICAL SUPERVISION OF WORKERS**Formulations in categories 3 and 4

Pre-employment medical examination of workers necessary. Workers suffering from active hepatic or renal disease should be excluded from contact. Pre-employment and periodic plasma and erythrocyte

cholinesterase determinations for workers desirable. Special account should be taken of the workers' mental ability to comprehend and follow instructions. Training of workers in techniques to avoid contact essential.

Formulations in category 5

No special cholinesterase monitoring of workers necessary. Warning of workers to minimize contact essential.

**3.6 ADDITIONAL REGULATIONS RECOMMENDED IF DISTRIBUTED BY AIRCRAFT**All formulations

Pilots and loaders should have special training in application methods and recognition of early symptoms of poisoning and must wear a suitable respirator. Use of flagmen not recommended. Flagmen, if used, should wear overalls and be located away from the dropping zone.

**3.7 LABELLING**Formulations in categories 3 and 4Minimum cautionary statement

Fenthion is an organophosphorus compound which inhibits cholinesterase. It is poisonous if swallowed. It may be absorbed through the skin or inhaled as dusts or mists. Avoid skin contact; wear protective gloves, clean protective clothing and a respirator when handling the material. Wash thoroughly with soap and water after using. Keep the material out of reach of children, and well away from foodstuffs, animal feed and their containers. If poisoning occurs, call a physician. Atropine and pralidoxime are the specific antidotes and artificial respiration may be needed.

Formulations in category 5Minimum cautionary statement

This formulation contains fenthion, a toxic substance which is poisonous if swallowed. Keep the material out of reach of children and well away from foodstuffs, animal feed and their containers.

### 3.8 RESIDUES IN FOOD

Maximum residue limits for fenthion have been recommended by the Joint FAO/WHO Meeting on Pesticide Residues.

## Part 4 - Prevention of poisoning in man and emergency aid

### 4.1 PRECAUTIONS IN USE

#### 4.1.1 General

Fenthion is an organophosphorus pesticide of moderate toxicity which penetrates the intact skin and is also absorbed by inhalation of dusts and from the gastrointestinal tract. Most formulations should be handled by trained personnel wearing protective clothing.

#### 4.1.2 Manufacture and formulation

##### T.L.V.

No information.

Closed system and forced ventilation may be required to reduce as much as possible the exposure of workers to the chemical. Formulation should not be attempted without advice from the manufacturer.

#### 4.1.3 Mixers and applicators

When opening the container and when mixing, protective impermeable boots, clean overalls, gloves and respirator should be worn. Mixing, if not mechanical, should always be carried out with a paddle of appropriate length. When spraying tall crops or during aerial application, a face mask should be worn as well as an impermeable hood, clothing, boots and gloves. The applicator should avoid working in spray mist and avoid contact with the mouth.

Particular care is needed when equipment is being washed after use. All protective clothing should be washed immediately after use, including the insides of gloves. Splashes must be washed immediately from the skin or eyes with large quantities of water. Before eating, drinking or smoking, hands and other exposed skin should be washed.

#### 4.1.4 Other associated workers (including flagmen in aerial operations)

Persons exposed to fenthion and associated with its application should wear protective clothing and observe the precautions described above in 4.1.3 under "mixers and applicators".

#### 4.1.5 Other populations likely to be affected

With good agricultural practice subject to 4.2 below, other populations should not be exposed to hazardous amounts of fenthion.

### 4.2 ENTRY OF PERSONS INTO TREATED AREAS

Unprotected persons should be kept out of treated areas for at least one day. (Does not apply when used as a larvicide.)



### 4.3 SAFE DISPOSAL OF CONTAINERS AND SPILLAGES

Residues in containers should be emptied in a dilute form into a deep pit taking care to avoid contamination of ground waters. Decontamination of containers in order to use them for other purposes should not be permitted. Spillage should be removed by washing with 5% sodium hydroxide solution and then rinsing with large quantities of water.

### 4.4 EMERGENCY AID

#### 4.4.1 Early symptoms of poisoning

Early symptoms of poisoning are headache, vertigo, blurring of vision, tightness in the chest, joint and muscle pains, abdominal cramps, diarrhoea and repeated vomiting. Other symptoms that may occur include insomnia, loss of appetite, weakness, slurred speech, constriction of the pupils and generalized anxiety.

#### 4.4.2 Treatment before person is seen by a physician if these symptoms appear following exposure

The person should stop work immediately, remove contaminated clothing and wash the affected skin with soap and water, if available, and flush the area with large quantities of water. If swallowed, vomiting should be induced if the person is conscious. In the event of collapse, artificial respiration should be given, bearing in mind that if mouth to mouth respiration is used, vomit may contain toxic amounts of fenthion.

## Part 5 - For medical and laboratory personnel

### 5.1 MEDICAL DIAGNOSIS AND TREATMENT OF CASES OF POISONING

#### 5.1.1 General information

An organophosphorus pesticide of moderate toxicity which is absorbed through the intact skin as well as by inhalation and from the gastrointestinal tract. It is converted *in vivo* to its oxygen analogue which is an active cholinesterase inhibitor. Continued exposure to small amounts may inhibit blood cholinesterases to hazard levels.

#### 5.1.2 Symptoms and signs

Initial symptoms of poisoning may include excessive sweating, headache, weakness, giddiness, nausea, copious and prolonged vomiting, stomach pains, muscle and joint pains, blurred vision, slurred speech, muscle twitching and hypersalivation. More advanced symptoms of poisoning may include laboured respiration, cyanosis, coma, loss of sphincter control and loss of reflexes.

#### 5.1.3 Laboratory

The most important laboratory finding is reduction in activity of blood cholinesterases. Direct measurement can be made of metabolites in urine and faeces.

## 5.1.4 Treatment

If the pesticide has been ingested, unless the patient is vomiting, rapid gastric lavage should be performed using 5% sodium bicarbonate, if available. For skin contact the skin should be washed with soap and water. If the compound has entered the eyes, they should be washed with isotonic saline or water.

Persons without signs of respiratory inefficiency but with manifest peripheral symptoms should be treated with 2-4 mg of atropine sulfate and 1000-2000 mg of pralidoxime chloride or 250 mg of toxogonin (adult dose) by slow intravenous injection. More atropine may be given as needed. Persons with severe intoxication with respiratory difficulties, convulsions and unconsciousness should immediately be given atropine and a reactivator. In such severe cases 4-6 mg of atropine sulfate should be given initially followed by repeated doses of 2 mg at 5-10 minute intervals. The patient's condition, including respiration, blood pressure, pulse frequency, salivation and convulsions should be carefully observed as a guide to further administration of atropine. If the patient is cyanotic, artificial respiration should be given first and then atropine sulfate.

The airways should be kept free and artificial respiration should be applied, if required, preferably by mechanical means. If necessary, intubation should be performed.

Contraindications are morphine, barbiturates, phenothiazine, tranquillizers and central stimulants of all kinds.

## 5.1.5 Prognosis

If the acute toxic effects are survived and these may be prolonged, and adequate artificial respiration has been given, the chances of complete recovery are good. However, in very severe cases, particularly if artificial respiration has been inadequate, prolonged hypoxia may give rise to permanent brain damage.

## 5.1.6 References of previously reported cases

Case histories and methods of treatment can be found in:

Dean et al. (1967) So. African Med. J., 1017-1019

Von Clarmann, M. et al. (1966) Arch. Toxik., 22, 2-11

Pickering, E. N. (1966) Can. J. Med. Tech., p. 174

## 5.2 SURVEILLANCE TESTS

| Test                       | Normal level* | Action level**† | Symptomatic level* |
|----------------------------|---------------|-----------------|--------------------|
| Plasma cholinesterase      | 100%          | 50%             | variable           |
| Erythrocyte cholinesterase | 100%          | 70%             | usually < 40%      |

†The level at which action has to be taken to terminate exposure of the men until recovery of cholinesterase occurs.

\*Expressed as percentage of pre-exposure activity.

## 5.3 LABORATORY METHODS

References only are given.

### 5.3.1 Detection and assay of compound

It is unlikely that unchanged fenthion will be detectable in human tissues after exposure. Determination of the level of blood cholinesterase is probably the most suitable method in cases of suspected poisoning. Levels of metabolites can be measured in urine or faeces. Most methods of residue analysis involve gas-liquid chromatography.

Thornton, S. S. Chemagro Corp., Research Department, Report No. 20.420 (revised 21 October, 1968)

Bowman & Beroza (1968) J. Ag. Food Chem., 16, 399-402

Additional information will be found in:

Analytical methods for pesticides, Plant Growth Regulations and Food Additives, ed. Zweig, G., Vol. II, 1964, Academic Press

### 5.3.2 Other tests in cases of poisoning

Levels of cholinesterase in the blood provides the most useful diagnosis of poisoning for methods of estimation. See:

Michel, N. O. (1969) J. Lab. Clin. Med., 34, 1566-1568

Ellman et al. (1961) Biochem. Pharmacol. I., 88-95

\* \* \*

## Annex IV Further information on the pesticide active ingredient

### Introduction

This annex provides further information on the physico-chemical, toxicological and environmental properties of the pesticide active ingredient fenthion. This information has been taken from the documents collected by the secretariat in line with part 2 of Annex IV of the Convention and made available to the Chemical Review Committee in documents UNEP/FAO/RC/CRC.9/4/Add.2, including the review of fenthion by the European Union (2003), information from the US EPA and Australia and FAO Specifications and evaluations for Fenthion (2004).

Further information on the physico-chemical, toxicological and environmental properties of pesticide formulations containing fenthion may be found in safety data sheets for the respective products via the internet.

| <b>1. Physico-Chemical properties</b> |   |
|---------------------------------------|---|
| <b>1.1</b>                            | <b>Common name</b> Fenthion   |
|                                       | <b>Chemical names</b> <i>O,O</i> -dimethyl <i>O</i> -(4-(methylthio)- <i>m</i> -tolyl)phosphorothioate (IUPAC)<br><i>O,O</i> -dimethyl <i>O</i> -[3-methyl-4-(methylthio)phenyl] phosphorothioate (CA)  |
| <b>1.2</b>                            | <b>Formula</b> C <sub>10</sub> H <sub>15</sub> O <sub>3</sub> PS <sub>2</sub>   |
| <b>1.3</b>                            | <b>Molar mass</b> 278.3 g/mol   |
| <b>1.4</b>                            | <b>Appearance</b> Pure fenthion is a colourless, almost odourless liquid. Technical fenthion is a yellow or brown oily liquid with a weak garlic odour. (Extension Toxicology Network 1993)   |
| <b>1.5</b>                            | <b>Density</b> 1.250 g/cm <sup>3</sup> (at 20 °C / 4 °C)  |
| <b>1.6</b>                            | <b>Melting point</b> 7 °C, 280 K, 45 °F   |
| <b>1.7</b>                            | <b>Boiling point</b> 87 °C, 360 K, 189 °F (at 0.01 mmHg)  |
|                                       | <b>Flash point</b> >82°C, 180°F (Extension Toxicology Network 1993)   |
| <b>1.8</b>                            | <b>Solubility</b> in water: 4.2 mg/l (at 20 °C)<br>in glyceride oils, methanol, ethanol, ether, acetone, and most organic solvents, especially chlorinated hydrocarbons: soluble (FAO 2004)   |
| <b>1.9</b>                            | <b>Vapor pressure</b> 7.4 x 10 <sup>-4</sup> Pa at 20°C, extrapolated, purity 99.7 % w/w (FAO 2004)   |
| <b>2 Toxicological properties</b>     |   |
| <b>2.1</b>                            | <b>General</b>  |
| <b>2.1.1</b>                          | <b>Mode of Action</b> Cholinesterase inhibition after conversion into the more toxic oxygen analogue in the body (Data Sheets on Pesticides No. 23, IPCS).  |
| <b>2.1.2</b>                          | <b>Symptoms of poisoning</b> Fenthion is moderately toxic if ingested, inhaled, or absorbed through the skin. It affects the central nervous, cardiovascular, and respiratory systems, and may irritate eyes and mucous membranes. As with all organophosphates, fenthion is readily absorbed through the skin. While symptoms of poisoning may be delayed in animals, in cases of human poisonings, symptoms have generally been immediate. Deaths are primarily due to respiratory failure. Several cases of intentional or accidental human poisonings via ingestion and/or dermal exposure are known.<br><br>The organophosphate insecticides are cholinesterase inhibitors. They are highly toxic by all routes of exposure. When inhaled, the first effects are usually respiratory and may include bloody or runny nose, coughing, chest discomfort, difficult or short breath, and wheezing due to constriction or excess fluid in the bronchial tubes. Skin contact with organophosphates may cause localized sweating and involuntary muscle contractions. Eye contact will cause pain, bleeding, tears, pupil constriction, and blurred vision. Following exposure by any route, systemic effects may begin within a few minutes or be delayed for up to 12 hours. These may include pallor, nausea, vomiting, diarrhea, abdominal cramps, headache, dizziness, eye pain, blurred vision, constriction or dilation of the eye pupils, tears, salivation, sweating, and confusion. Severe poisoning will affect the central nervous system, producing incoordination, slurred speech, loss of reflexes, weakness, fatigue, involuntary muscle contractions, twitching, tremors of the tongue or eyelids, and eventually paralysis of the body extremities and the respiratory muscles. In severe cases there may also be involuntary defecation or urination, psychosis, irregular heart beats, unconsciousness, convulsions and coma. Death may be caused by respiratory failure or cardiac arrest (UNEP/FAO/RC/CRC.9/4/Add.2, source: Extension Toxicology Network 1993). |

Poisoning occurs when the inhibition of cholinesterase leads to accumulation of acetylcholine at the nerve synapses, resulting in muscarinic, nicotinic, and central nervous system effects. Symptoms of poisoning are acute but also later caused by an accumulation of acetylcholine. Poisoning is characterized by miosis, hypersecretion, nausea, vomiting, diarrhea, abdominal pain, bronchial constriction, respiratory depression, and muscle twitching. The treatment consists of improving tissue oxygenation and administration of atropine intravenously.

(UNEP/FAO/RC/CRC.9/4/Add.2, p. 186, source: Haavik TK - Ihlen H (1974): Alkyl phosphate poisoning. A case of Lebaycid (Fenthion) poisoning. *Nor Laegeforen* (94(19):1251-3, 1974 Jul 10).

Ingestion has proved to be the important cause of severe poisoning with this compound. It may also be absorbed through the skin and by inhalation of dust particles.

Fenthion has been widely used in many parts of the world for control of household pests and mosquitos. Twenty-seven out of 28 workers, who sprayed fenthion as residual indoor application for 15 days in a malaria control operational trial without taking adequate precautions, demonstrated various degrees of poisoning. These included headache, vertigo, blurred vision, muscle and abdominal pains, cramps, diarrhoea and prolonged vomiting. Very severe reduction of whole blood cholinesterase activity was observed, and it was still reduced a month after the end of spraying. However, in a second smaller spraying operation when precautions were more stringent, only one out of 12 men showed mild symptoms. In mosquito larviciding operations, dermal exposure was found to average 3.6 mg/h with both power and hand sprayers and 12.3 mg/h using a granular formulation dispersed by hand. Some workers showed some plasma cholinesterase depression but in no case was erythrocyte cholinesterase depressed (UNEP/FAO/RC/CRC.9/4/Add.2, source: Data Sheets on Pesticides No. 23, IPCS).

### 2.1.3 Absorption, distribution, excretion and metabolism in mammals

Absorbed by the intact skin as well as by inhalation and from the gastro-intestinal tract. Cholinesterase inhibition after conversion into the more toxic oxygen analogue in the body.

In rats 86% of an oral dose is eliminated in seven days (urine 45% and faeces 40%). Metabolites include the sulfone and sulfoxide of both the parent compound and its oxygen analogue.

In animals, fenthion is quickly absorbed into the bloodstream through the digestive tract, lungs, and skin, and then broken down. Its breakdown products are eliminated through the urine and the feces in a three-day period. A single dose of the insecticide has prolonged action, suggesting that much of it is stored and later released for metabolism. Fenthion has 'lipophilic' properties and tends to be deposited in fatty tissue. Fenthion and its metabolites were found in the fat of steers slaughtered 3 days after dermal application of fenthion. When cows were given a dermal application of 9 mg radio-labeled fenthion per kg, 45-55% of the dose was excreted in the urine, 2.0 to 2.5% in the feces, and 1.5 to 2.0% was recovered in the milk (Extension Toxicology Network 1993).

Patterns of absorption, distribution, metabolism and elimination of administered fenthion are broadly comparable between rats, pigs, cows and goats. Absorption is rapid after any route of exposure, distribution is extensive particularly into lipid stores, metabolism is extensive and can generate active anti-ChE intermediates, and elimination is almost complete. Tissue residues were low in all species.

Metabolism of fenthion generally commences with desulphuration of thiophosphoric ester portion of fenthion (PS) to yield the phosphoxone oxygen analog (fenthoxone; POS).

Both fenthion and fenthoxone can be oxidised to the corresponding sulphoxides (PSSO, POSO) and sulphones (PSSO<sub>2</sub>, POSO<sub>2</sub>) by oxidation of the ring -SCH<sub>3</sub> group. Further metabolites can be formed by demethylation of one of the two oxymethyl groups. Hydrolysis of the ring P-O bond leads to loss of the OP moiety and gives rise to a fenthion "phenol" (PhS) which can also be oxidised to the corresponding sulphoxide (PhSO) and sulphone (PhSO<sub>2</sub>) forms. The oxygen analogue of fenthion and

its sulphoxide and sulphone derivatives are generally regarded as principal active metabolites, rather than fenthion itself.

The administration of fenthion by the oral, dermal, subcutaneous or intraperitoneal routes to various species (rat, pig, cow, goat and rabbits) resulted in a comparable pattern of absorption and metabolism in all animals. Single doses are readily absorbed after all routes of administration and rapidly excreted in urine (approx. 90%) and faeces. For example, in several studies using rats treated with <sup>14</sup>C-labelled fenthion orally or intravenously, no major differences were seen in metabolite profiles with route of administration, dose, sex, or pretreatment with unlabelled fenthion for 14 days. No unchanged parent compound was detected in the urine and very little (< 2%) in the faeces. Fourteen urinary metabolites were identified which represented 93-96% of the total recovered label. The major group of metabolites (about 60% of the total label) was composed of the three phenol thioethers resulting from hydrolysis of the OP moiety (phenol fenthion, phenol sulfoxide, and phenol sulfone) and their glucuronide, sulfoxide, and sulfone conjugates. Four desmethyl metabolites were also identified, accounting for about 30% of the label, while the oxygen analogue sulfoxide constituted only 1-4%. Mean tissue-residue levels of fenthion or metabolites were generally low except at the actual site of dermal or subcutaneous administration, suggesting that there is no tendency for fenthion to bioaccumulate in the rat or domestic animals.

Oral dosing results in an earlier onset of ChE inhibition and more rapid recovery compared to dermal and subcutaneous administration, which have a later onset and more prolonged effect (Emteres et al 1985; Christenson 1990c, APVMA 2012a).

## 2.2 Toxicology studies

### 2.2.1 Acute toxicity

Rat LD<sub>50</sub> oral: ca. 250 mg/kg bw (FAO 2004), 140-615 mg/kg bw (APVMA 2012a)

Mouse LD<sub>50</sub> oral: 150-290 mg/kg bw (APVMA 2012a)

Rat LD<sub>50</sub> dermal: ca. 586 (males) / ca. 800 (females) mg/kg bw (FAO 2004); 325 - >5000 mg/kg (APVMA 2012a)

Mouse LD<sub>50</sub> dermal: 500 - 2000 mg/kg bw (APVMA 2012a)

Rat LC<sub>50</sub> inhalation ca. 507 (males) / ca. 454 (females) mg/m<sup>3</sup> (dust, 4 h exposure) (FAO 2004)

Rabbit skin irritation and eye irritation: non-irritant (FAO 2004, APVMA 2012a)

Guinea-pig skin sensitization: non-sensitizing (FAO 2004, APVMA 2012a)

The acute oral and intraperitoneal toxicity of the oxygen analogue of fenthion and its sulphoxide and sulphone derivatives, thought to be the principal active metabolites were 5-10 times that of fenthion (APVMA 2012a).

Fenthion potentiated the acute toxicity of malathion, dioxathion and coumaphos in the rat, whereas in the dog fenthion potentiated malathion and coumaphos but not dioxathion (APVMA 2012a).

### 2.2.2 Short term toxicity

Critical effect: cholinesterase inhibition (EU 2002)

Oral, lowest relevant NOAEL: 0.1 mg/kg bw/d, 1 year dog (EU 2002)

Dermal, lowest relevant NOAEL: 0.1 mg/kg bw/d, 21 day rabbit (EU 2002)

Inhalation, lowest relevant NOAEL: 1 mg/m<sup>3</sup>/d, 21 day rat (EU 2002)

### 2.2.3 Genotoxicity (including mutagenicity)

Tests on mice did not show mutagenic effects from fenthion (Extension Toxicology Network 1993, APVMA 2012a)

Clastogenic potential at doses exhibiting cytotoxicity (EU 2002)

- 2.2.4 Long term toxicity and carcinogenicity**
- 23 months chronic oral study, Rhesus monkey: NOAEL 0.2 mg/kg bw/d (FAO 2004)  
 52 weeks chronic feeding study, dog: NOAEL 0.05 mg/kg bw/d (FAO 2004)  
 24 months chronic feeding study, rat: NOAEL 0.15 mg/kg bw/d, no evidence of carcinogenicity (FAO 2004)  
 24 months oncogenicity feeding study, mouse: NOAEL 2 mg/kg bw/d (5 ppm), no evidence of carcinogenicity (FAO 2004)  
 The National Cancer Institute performed carcinogenicity tests on fenthion that indicated that this insecticide may be a carcinogen in male mice. However, no carcinogenic effects were observed in other two-year feeding studies of rats and mice, (Extension Toxicology Network 1993).  
 Chronic dietary studies in mice and rats showed no evidence of oncogenicity and therefore, fenthion is not considered to pose a carcinogenic risk to humans (APVMA 2012a).
- 2.2.5 Effects on reproduction**
- 2-generation reproduction toxicity, rat: NOAEL 0.16 mg/kg bw/d (FAO 2004)  
 Developmental toxicity, rat: NOAEL (developmental, maternal) 4.2 mg/kg bw/d (FAO 2004)  
 Developmental toxicity, rabbit: NOAEL (developmental) 2.75 mg/kg bw/d, NOAEL (maternal) 1 mg/kg bw, no evidence of teratogenicity (FAO 2004)  
 Reproductive effects: Single injections of 40 or 80 mg/kg of fenthion into the abdominal cavities of pregnant female mice caused poisoning in the developing fetuses, particularly when administered on days 10 through 12 of gestation. There were significantly more abnormalities in the offspring of female mice that had received 40 mg/kg on days 8 or 10 of pregnancy. Fetuses were injured primarily by dosages that caused toxicity in the maternal mouse. No influence was seen on reproduction in other 3- generation studies of mice. After administration of 0.5 mg/kg/d for 30 days, the eggs laid by surviving mallards had markedly reduced fertility. Once in the bloodstream, fenthion may cross the placenta (Extension Toxicology Network 1993).  
 Teratogenic effects: Some reduction in fetal weight occurred, but no defects were found in mice that were given intraperitoneal doses of up to 80 mg/kg of fenthion in single day or 3-day periods during the period of gestation in which organs are formed. Other tests on mice and rats did not show teratogenic effects from fenthion. No teratogenic effects were seen in five generations of mice that drank water containing 60 parts per million (ppm) fenthion (Extension Toxicology Network 1993).  
 Fenthion did not induce major malformations or significant effects on most reproductive parameters in experimental animals. The single reproduction study in rats reported epididymal changes in parental males, and RBC and plasma ChE inhibition in both parental sexes at high doses. However, the study demonstrated a clear NOEL of 1.16 mg/kg bw/d for reproductive parameters and foetotoxicity. Developmental studies with fenthion in rats and rabbits revealed no teratogenic effects and foetotoxicity only at maternotoxic levels; there was inhibition of maternal but not foetal brain ChE activity (APVMA 2012a).
- 2.2.6 Neurotoxicity/delayed neurotoxicity, Special studies where available**
- Sub-chronic delayed neurotoxicity (hen, 3 months): no evidence of organophosphate-induced delayed neuropathy (FAO 2004)  
 Unlikely to pose a risk of delayed neurotoxicity in humans (EU 2005)  
 There was no evidence that fenthion causes delayed neuropathy (REF) or significant Neurotoxicity Target Esterase inhibition in the studies using single oral or dermal doses at or above the LD<sub>50</sub>. As expected, dose-related, reversible inhibition of ChE activity was observed, but this effect was not accompanied by any microscopic changes in nerve tissues, even in those animals that displayed gross clinical signs. On occasion, some impairment of motor activity was reported at higher doses, but this effect was transient and reversible (APVMA 2012a).

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| 2.2.7      | <b>Summary of mammalian toxicity and overall evaluation</b> | Fenthion is moderately toxic if ingested, inhaled, or absorbed through the skin. It affects the central nervous, cardiovascular, and respiratory systems, and may irritate eyes and mucous membranes. As with all organophosphates, fenthion is readily absorbed through the skin. The organophosphate insecticides are cholinesterase inhibitors. They are highly toxic by all routes of exposure. (Extension Toxicology Network 1993).  |
|            |   | The potential for genotoxicity, teratogenicity/reproductive toxicity and carcinogenicity is low.  |
| <b>3</b>   | <b>Human exposure/Risk evaluation</b>                       |   |
| <b>3.1</b> | <b>Food</b>   | The 20th Australian Total Diet Survey (ATDS) (2003) performed under the auspices of Food Standards Australia New Zealand (FSANZ) estimated that the mean dietary intake of fenthion residues was 0.0022 µg/kg bw/d for adult males and females, 0.0025 and 0.0023 µg/kg bw/d for boys and girls, respectively, 0.0033 g/kg bw/d for toddlers and 0.0025 µg/kg bw/d for infants (APVMA 2012a).   |
|            |   | Generally, a dietary risk estimate that is less than 100% of the acute or chronic Population Adjusted Dose does not exceed the Agency's risk concerns. The fenthion acute and chronic dietary risks from food exceed the US Environmental Protection Agency's level of concern for the general U.S. population and various population subgroups, including infants and children. The most highly exposed subgroup is children 1-6 years, with approximately 800% of the acute Population Adjusted Dose (PAD) (at the 99.9th percentile of exposure) and 270% of the chronic PAD consumed.                           |
|            |   | In the chronic analysis, infants were the only population subgroup for which chronic dietary risk was below the level of concern, at approximately 60% of the chronic PAD. The acute critical exposure contribution and the chronic critical commodity analyses demonstrate that estimated dietary risk is due largely to potential residues in beef meat and fat and that milk is a minor contributor to acute and chronic dietary risk (USEPA 2001).  |
| <b>3.2</b> | <b>Air</b>  | -   |
| <b>3.3</b> | <b>Water</b>  | Based on its current pattern of use, exposure of the general population to fenthion residues in drinking water is considered negligible in Australia (APVMA 2012a).   |
|            |   | The environmental fate data base for fenthion is incomplete. However, it is reported that fenthion degrades by aerobic microbial metabolism with a half-life of <1 day in aerobic soil and 11 days under anaerobic aquatic conditions. Although no clear degradation rates are available, fenthion also probably degrades by photolysis in water. No mobility studies with unaged fenthion have been submitted; however, since fenthion degrades rapidly and thermal fogs and ULV are the only terrestrial uses of fenthion, there probably would be no serious groundwater contamination from the parent compound. |
|            |   | In terms of livestock uses, since fenthion is either contained within an ear tag or is spot treated to livestock, these uses are not expected to result in significant exposures to drinking water sources. However, the use of fenthion as a mosquito adulticide requires the active ingredient to remain suspended in air for a period of time, rather than quickly depositing on the ground. This application technique facilitates drift, reduces deposition, and widens the area of deposition. Therefore, there is potential for this use to result in surface water exposure from spray drift.               |
|            |   | Limited groundwater monitoring data are available for fenthion but the utility of these data are limited by the fact that only the parent compound was analyzed; fenthion is not as persistent as the five regulated metabolites of toxicological concern (USEPA 2001).   |



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| <b>3.4</b> | <b>Occupational and dietary exposure</b>                | <p>Occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Residents or homeowners can be exposed to fenthion by entering or performing other activities on treated areas. Occupational handlers of fenthion include: mixers/loaders, applicators, and flaggers for mosquito control uses; applicators for livestock use; and applicators for the aquaculture use. Although there are no homeowner uses of fenthion in the United States, residential exposure to adults and children can occur from the use of fenthion as a wide area mosquito adulticide.</p> <p>Risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE), which determines how close the occupational or residential exposure comes to a No Observed Adverse Effect Level (NOAEL). Generally, MOEs greater than 100 do not exceed the United States Environmental Protection Agency's risk concern. However, in the case of fenthion, 300 is the target MOE for intermediate exposure because of a lack of a definitive NOAEL in the 2-year oral monkey study (USEPA 2001).</p> <p>AOEL: 0.001 mg/kg bw/d (oral), 0.2 mg/kg bw/d (dermal), 0.02 mg/kg bw/d (inhalation) (EU 2005)</p> <p>ADI: 0.007 mg/kg bw/d (uncertainty factor 10) (EU 2005)</p> <p>An ADI of 0.0003 mg/kg bw/d was set in 1996, in Australia, based on a NOEL for plasma ChE inhibition in a chronic mouse study and using a 100-fold safety factor. This was amended by the Advisory Committee on Pesticides and Health (ACPH) in 1997 who recommended an ADI of 0.002 mg/kg bw/d and a 10-fold safety factor based on a NOEL of 0.02 mg/kg bw/d for plasma ChE inhibition seen at 0.07 mg/kg bw/d in a 4-week 1979 human study (APVMA 2012a).</p> <p>ARfD: 0.01 mg/kg bw/d (EU 2005); ARfD of 0.007 mg/kg bw based on the NOEL for red blood cell ChE inhibition (0.07 mg/kg bw) and applying a tenfold safety factor (APVMA 2012a).</p>                            |
| <b>3.5</b> | <b>Medical data contributing to regulatory decision</b> | -  |
| <b>3.6</b> | <b>Public exposure</b>                                  | -  |
| <b>3.7</b> | <b>Summary-overall risk evaluation</b>                  | <p>EU:</p> <p>In its evaluation of a bait use the Scientific Committee for Plants considered that it was not possible to complete a full assessment in the absence of data that even the limited intended use as bait application was safe for human health. After the evaluation of additional information, it was however concluded that, although the risk to operators when applying fenthion was high, the risk can be reduced to an acceptable level if personal protective equipment is worn.</p> <p>USA:</p> <p>Fenthion is no longer registered in the USA, and the risk summary below reflects the last risk assessments prior to cancellation. The USEPA issued preliminary risk assessments for fenthion in August 1998 and revised human health and environmental effects risk assessments for fenthion in October 1999. Based on the comments received, and on the additional data received from the registrant, the USEPA completed its review and issued an Interim Reregistration Eligibility Decision for fenthion in January 2001. In the interim decision, the USEPA stated that the current use of fenthion posed unreasonable adverse effects to human health and the environment and that it should not be registered unless steps were taken to mitigate these risks. The USEPA identified risks to workers who mixed, loaded and/or applied fenthion for mosquito control and livestock and aquaculture applications. In its occupational assessment, the USEPA indicated the lack of exposure data for workers who applied the pesticide to kill mosquitoes and requested mixer/loader/applicator exposure data for all mosquito pesticide applicators. In the interim, the following risk mitigation measures were proposed by the USEPA: use of closed systems for all types of mosquito control applications, prohibition on using human flaggers, use of the highest rate for public health uses only, use of a handheld sprayer instead of backpack sprayer method of application in aquaculture.</p> |

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| <b>4</b>     | <b>Environmental fate and effects</b>  |  |
| <b>4.1</b>   | <b>Fate</b>                            |  |
| <b>4.1.1</b> | <b>Soil</b>                            | <p>Degradation in nature: Photodegradation and biodegradation are common mechanisms of fenthion degradation in the environment (Extension Toxicology Network 1993).</p> <p>The aerobic degradation of fenthion is rapid and independent of the concentration used. The half-life in soil under aerobic conditions in the lab is low (less than 2 days at 22 °C) and DT<sub>90</sub> values do not exceed 10 days under these conditions. This implies that fenthion does not persist and accumulate in the soil (EU 2005).</p> <p>In soil, fenthion degradation ranges from 4 to 6 weeks and it occurs through photodegradation as well as anaerobic or non-photolytic organisms. However, soil particles strongly adsorb fenthion that makes it less susceptible to percolate with water through the soil (Extension Toxicology Network 1993).</p>  |
| <b>4.1.2</b> | <b>Water</b>                           | <p>The half-life of fenthion in a natural pond water ranged from 1 to 1.5 days. The DT<sub>50</sub> in river water was about 7 days while the DT<sub>90</sub> was 14 days. However there is no data about the fate of the metabolites. The DT<sub>50</sub> value for fenthion in water/sediment systems was less than 7 days (EU 2005).</p> <p>Under normal aquatic environment, half-life of fenthion in water is 3 to 21 days. It may be photodynamically, chemically or biologically degraded. The degradation mechanisms can be hydrolysis, oxidation, and/or alkylation-dealkylation, which are dependent on the presence of light, temperature, alkali, or enzymatic activity (Extension Toxicology Network 1993).</p>   |
| <b>4.1.3</b> | <b>Air</b>                             | <p>In the atmosphere, vapor phase fenthion reacts rapidly with photochemically produced hydroxyl radicals, and its half-life is about 5 hours. (Extension Toxicology Network 1993) Photochemical oxidative degradation in air, DT<sub>50</sub>: 2-4 hours (EU 2002).</p>   |
| <b>4.1.4</b> | <b>Bioconcentration</b>                | <p>Log P<sub>ow</sub>: 4.84 (EU 2002)</p> <p>Bioconcentration factor (BCF, fish): 33 (EU 2002)</p>   |
| <b>4.1.5</b> | <b>Persistence</b>                     | <p>Soil DT<sub>50</sub> (lab, aerobic): 7 to &lt; 2 days; not persistent (EU 2002)</p>   |
| <b>4.2</b>   | <b>Effects on non-target organisms</b> | <p>Despite short half-life in the environment, fenthion toxicity is highly significant to birds and estuarine/marine invertebrates. Even though fenthion is used in some parts of the world to control pest birds, such as weaver bird, many non-targeted wild birds are victim of fenthion poisoning. Acute symptoms of fenthion poisoning in birds include tearing of the eyes, foamy salivation, lack of movement, tremors, congestion of the windpipe, lack of coordination in walking, and an abnormally rapid rate of breathing or difficult breathing. Fenthion has been found toxic to fish and other aquatic invertebrates. Bees are also found to be greatly affected by fenthion contamination (UNEP/FAO/RC/CRC.9/4/Add.2, p. 90).</p>  |
| <b>4.2.1</b> | <b>Terrestrial vertebrates</b>         | <p>Mammalian toxicity see point 2.</p> <p>Acute toxicity to bobwhite quail: LD<sub>50</sub>: 7.2 mg/kg bw (FAO 2004, EU 2002)</p> <p>Dietary (subacute) toxicity to bobwhite quail: LC<sub>50</sub>: 60 ppm feed (FAO 2004, EU 2002)</p> <p>Dietary (subacute) toxicity to mallard duck: LC<sub>50</sub>: &gt; 1259 ppm feed (FAO 2004)</p> <p>Reproductive toxicity to birds: NOEC: 10 mg/kg bw (EU 2002)</p> <p>Fenthion is highly toxic to birds. It is more toxic to fowl than to mammals. Acute symptoms of fenthion poisoning in birds include tearing of the eyes, foamy salivation, lack of movement, tremors, congestion of the windpipe, lack of coordination in walking, and an abnormally rapid rate of breathing or difficult breathing. Chickens developed leg weakness when they were fed 25 mg/kg doses of fenthion. The acute oral LD<sub>50</sub> in poultry is 15 to 30 mg/kg.</p> <p>The LC<sub>50</sub> for fenthion in mallards is 250 to 299 ppm, 180 to 220 ppm in pheasants, and 25 to 35 ppm or 60 mg/kg in bobwhites. In these tests, fenthion was included in diets of two-week-old birds for five days and was followed by untreated feed for three days (Extension Toxicology Network 1993).</p> |

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| <b>4.2.2</b> | <b>Aquatic species</b>                     | <p>Acute toxicity to fish: LC<sub>50</sub>: 2.7 mg/L (golden orfe, 96 hour study) (FAO 2004)<br/> LC<sub>50</sub>: 0.83 mg/L (rainbow trout, 96 hour study) (FAO 2004)</p> <p>Acute toxicity invertebrate: EC<sub>50</sub>: 5.7 µg /L (<i>Daphnia magna</i>, 48 hour study) (FAO 2004)</p> <p>Chronic toxicity invertebrate: 21 day EC<sub>50</sub> 0.059 µg/L, NOEC: 0.042 µg/L (FAO 2004)</p> <p>Chronic toxicity algae: E<sub>r</sub>C<sub>50</sub>: 1.79 mg/L (<i>Scenedesmus subspicatus</i>, 72 hour study) (FAO 2004)</p> |
| <b>4.2.3</b> | <b>Honeybees and other arthropods</b>      | <p>Honey-bee LD50 contact (48 hour acute study): 0.16 ng/bee (FAO 2004); 0.31 µg/bee (EU 2002)</p>   |
| <b>4.2.4</b> | <b>Earthworms and other soil organisms</b> | <p>Earthworm LC<sub>50</sub> 750 mg/kg dry soil (14 days, EC50 formulation) (FAO 2004, EU 2002)</p>  |
| <b>4.2.5</b> | <b>Soil microorganisms</b>                 | <p>Nitrogen mineralisation: &gt;25% effect</p> <p>Carbon mineralisation: No significant adverse effect (Dose: 10 µL/kg soil, 20 °C) (PPDB)</p>   |
| <b>4.2.6</b> | <b>Terrestrial plants</b>                  | -  |

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## 5 Environmental Exposure/Risk Evaluation

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EU:

The risk evaluation carried out by the EU Member States identified a high risk to birds by application of fenthion as a bait in orchards. These concerns were confirmed by the Scientific Committee for Plants which considered that it was not possible to complete a full assessment in the absence of data that even the limited intended use as bait application was safe for the environment. The evaluation of additional information still resulted in the conclusion that the risk to birds from the proposed uses of fenthion remained uncertain.

As a consequence, in the EU, plant protection products containing fenthion shall not be authorised as of 30 June 2007 in order to ensure a high level of protection of the environment.

Australia:

Insufficient data were provided to the APVMA to allow for assessment of the effect of the uses of pest bird control products on non-target bird species. Therefore, the APVMA is not satisfied that fenthion products for non-native pest bird control would not have an unintended effect that is harmful to animals, plants or to the environment. The environmental assessment found that there was inadequate information to assess what effects, if any, there are on non-target birds due to exposure to the product itself or the effects on predatory birds that may eat dead or dying birds. To address the concerns with the bird control products, further data will be required to address the possible effects on non-target bird species. However, the environmental assessment has found that additional label statements to reduce the risk to the environment would satisfy the environmental concerns in the short term.

**Annex V      References**

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