UNITED NATIONS

PIC

UNEP/FAO/PIC/INC.11/4

Distr.: General
26 January 2004

Original: English

United Nations Environment Programme

Food and Agriculture Organization of the United Nations

Intergovernmental Negotiating Committee for an International Legally Binding Instrument for the Application of the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
Eleventh session
Geneva, 18 September 2004
Item 5 (b) (i) of the provisional agenda*

Implementation of the interim prior informed consent procedure: inclusion of chemicals: parathion

Inclusion of the chemical parathion in the interim prior informed consent procedure and adoption of the draft decision guidance document on parathion

Note by the secretariat

Introduction

1. In paragraph 8 of its resolution on interim arrangements,[1] the Conference of Plenipotentiaries decided that the Intergovernmental Negotiating Committee would decide, between the date on which the Convention was opened for signature and the date of its entry into force, on the inclusion of any additional chemicals under the interim prior informed consent procedure in accordance with the provisions of articles 5, 6, 7 and 22 of the Convention.

2. Paragraph 5, subparagraph (a), of article 22 provides that amendments to Annex III of the Convention must be proposed and adopted according to the procedure laid down in articles 5 to 9 and paragraph 2 of article 21. Under paragraph 2 of article 21, amendments to the Convention must be adopted at a meeting of the Conference of the Parties and the text of any proposed amendment must

* UNEP/FAO/PIC/INC.11/1.

[1] Final Act of the Conference of Plenipotentiaries on the Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, Rotterdam, Netherlands, 10-11 September 1998 (UNEP/FAO/PIC/CONF/5), annex I, resolution 1.

K0470274 120304

be communicated to the Parties by the secretariat at least six months before the meeting at which it is proposed for adoption.

3. At its fourth session, the Interim Chemical Review Committee reviewed two notifications of final regulatory action from two PIC regions to ban or severely restrict the chemical parathion and, taking into account the criteria set forth in Annex II of the Convention, concluded that the requirements of that Annex had been met. Accordingly, the Interim Chemical Review Committee recommended to the Intergovernmental Negotiating Committee that parathion should become subject to the interim prior informed consent procedure,[2] noting that the Interim Chemical Review Committee would develop a draft decision guidance document and forward it to the Intergovernmental Negotiating Committee in accordance with article 7 of the Convention.

4. At its fifth session, the Interim Chemical Review Committee finalized the draft decision guidance document and decided to forward it and the recommendation for inclusion of parathion in the interim prior informed consent procedure to the Intergovernmental Negotiating Committee. The text of that recommendation, a summary of the deliberations of the Committee, including a rationale for the inclusion of parathion based on the criteria listed in Annex II of the Convention, and a tabular summary of comments received and how they were addressed are attached as annex I to the present note.[3] The draft decision guidance document is reproduced as annex II to the present note.[4]

5. At its fifth session, the Interim Chemical Review Committee also noted that there was currently an entry in Annex III of the Rotterdam Convention for certain severely hazardous formulations of parathion. The entry includes all formulations of parathion: aerosols, dustable powder (DP), emulsifiable concentrate (EC), granules (GR) and wettable powders (WP), except capsule suspensions (CP). In line with a decision by the Intergovernmental Negotiating Committee at its ninth session, the Interim Chemical Review Committee amended the introduction to the decision guidance document to invite countries to make a single response regarding future imports that would apply to all forms of parathion, including the severely hazardous formulations listed in Annex III of the Convention.

6. In accordance with decision INC-7/6, which sets out the process for drafting decision guidance documents, and in line with the time frame specified in paragraph 2 of article 21, the secretariat circulated the present note to all Parties and observers on 15 March 2004.

Suggested action by the Committee

7. The Committee may wish to make parathion subject to the interim prior informed consent procedure as defined in paragraph 2 of the resolution on interim arrangements and to approve the draft decision guidance document on parathion.

[2] See UNEP/FAO/PIC/ICRC.4/18, para. 61 and annex III.

[3] In part, annex I to the present note reproduces annex IV of the report of the Interim Chemical Review Committee on its fifth session (UNEP/FAO/PIC/ICRC.5/15).

[4] Version of December 2003, circulated as the annex to document UNEP/FAO/PIC/INC./ICRC.5/14.

Annex I

Parathion

The Interim Chemical Review Committee,

Noting that at its fourth session it had reviewed the notifications of final regulatory actions by Australia and the European Community on parathion and, taking into account the requirements set forth in Annex II of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, had come to the conclusion that the requirements of that Annex had been met,

Recalling that, in line with paragraph 6 of Article 5 of the Convention, at its fourth session it had accordingly decided to recommend to the Intergovernmental Negotiating Committee that parathion should become subject to the interim prior informed consent procedure and noting (Annex III of its report of its fourth session UNEP/FAO/PIC/ICRC.4/18) that it was to develop a draft decision guidance document and forward it to the Intergovernmental Negotiating Committee in accordance with Article 7 of the Convention,

Recalling also that, in accordance with the operational procedures for the Interim Chemical Review Committee, set forth in decision INC-7/6 of the Intergovernmental Negotiating Committee on the process for drafting decision guidance documents, it had established a task group to draft a decision guidance document on parathion and that that task group, upon fulfilling the requirements of the operational procedures and in accordance with paragraph 1 of Article 7 of the Convention, had developed a draft decision guidance document on parathion (UNEP/FAO/PIC/ICRC.5/14, annex) and had submitted it to the Committee at its fifth session for further action

Noting that the draft decision guidance document was based on the information specified in Annex I of the Convention, as required by paragraph 1 of Article 7 of the Convention,

Recalling that in accordance with step 7 of the process for drafting decision guidance documents, final documentation forwarded by the Secretariat to all Parties and observers in advance of Intergovernmental Negotiating Committee sessions must include a draft decision guidance document, a recommendation by the Interim Chemical Review Committee for inclusion in the prior informed consent procedure, a summary of the deliberations of the Interim Chemical Review Committee including a rationale for inclusion based on the criteria listed in Annex II to the Convention, and a tabular summary of comments received by the Secretariat and how they had been addressed,

Adopts the following recommendation to the Intergovernmental Negotiating Committee:

Recommendation ICRC-5/2: Inclusion of parathion in the interim prior informed consent procedure

The Interim Chemical Review Committee

Recommends, in line with paragraph 6 of Article 5 of the Convention, that the Intergovernmental Negotiating Committee should make the following subject to the interim prior informed consent procedure:

Chemical	Relevant CAS Number(s)	Category
Parathion	56-38-2	Pesticide

Forwards, in line with paragraph 2 of Article 7 of the Convention, this recommendation, together with the draft decision guidance document on parathion to the Intergovernmental Negotiating Committee for a decision on the inclusion of parathion in the interim prior informed consent procedure and adoption of the draft decision guidance document.

Appendix I

Rationale for the recommendation that parathion (parathion ethyl) (56-38-2) should become subject to the interim prior informed consent procedure and to establish an intersessional drafting group to prepare a draft decision guidance document

In reviewing the notifications of final regulatory actions by Australia and the European Community, together with the supporting documentary information provided by those Parties, the Committee was able to confirm that those actions had been taken in order to protect human health and the environment. The European Community action was based on a risk evaluation, which concluded that there were concerns about the safety of operators and environmental fate and behaviour and the possible impact on non-target organisms. The action by Australia was based on a risk evaluation of pesticide uses of parathion (parathion ethyl) that concluded that there were unacceptable risks to operators, to aquatic ecosystems and bees. In both cases the main concerns related to the acute toxic effect of the substance as a result of inhibition of acetylcholinesterase activity in the nervous system.

The Committee established that the final regulatory actions had been taken on the basis of risk evaluations and that those evaluations had been based on a review of scientific data. The available documentation demonstrated that the data had been generated in accordance with scientifically recognised methods, and that the data reviews had been performed and documented in accordance with generally recognised scientific principles and procedures. It also showed that the final regulatory actions had been based on chemical-specific risk evaluations taking into account the conditions prevailing within Australia and the European Community.

The Committee concluded that the final regulatory actions provided a sufficiently broad basis to merit including all formulations of parathion (parathion ethyl) in the interim PIC procedure in the category of pesticide. It noted that those actions had led to a significant decrease in the quantities and uses of the chemical and the risks for human health and the environment. There was no indication that there were any industrial chemical uses of parathion (parathion ethyl). The Committee also took into account that the considerations underlying the final regulatory actions were not of limited applicability but of broader relevance. On the basis of information provided by the Secretariat at the fourth session of the Interim Chemical Review Committee, the Committee concluded also that there was ongoing international trade in parathion (parathion ethyl).

The Committee noted also that concern about intentional misuse of parathion (parathion ethyl) had not been a reason for the final regulatory actions.

The Committee concluded that the notifications of final regulatory actions by Australia and the European Community met the information requirements of Annex I and the criteria set out in Annex II to the Convention. It recommended that all formulations of parathion (parathion ethyl) (CAS No. 56-38-2) be included in the interim PIC procedure as a pesticide.

Comments Received on the Internal Proposal for Parathion

SECTION	AUTHOR	COMMENT	RESPONSE
Abbreviations			
	Switzerland	Page 6: Adding Log P Logarithm of octano/water partition coefficient	Agreed
	Switzerland	page 6: NOAEL: no observed (better: observable) adverse effect level NOEL: no observed (better: observable) effect level	Disagree
Annex I further information on the substance			
2. Toxicological properties	Switzerland	page 18: ..., it was fund that oral doses of 0.05-0.7 mg **parathion** /kg bw	Agreed
	Switzerland	page 19: The lowest **NOEL** was reported ...	Agreed
3. Human exposure/Risk evaluation	Switzerland	page 22, lines 23-25: This sentence is incomprehensible, possible out of context.	Amended as: "The 400% value took into account estimates of beer consumption, but the calculation in this case was based on the residues in barley because no data were available on the fate of parathion during brewing."
	Switzerland	page 22, line 26: 0-140% the ~~acute~~ **A**RfD	Agreed
	Germany	page 21: Quoting MRLs as set by Commission Directive 2002/66/EC of 16 July 2002.	Agreed
4. Environmental fate and effects	Switzerland	page 25, lines 39-40: "The bioconcentration factor in whole fish tissues varied between 92-140 µg/kg." 92-140 µg/kg is most probably not the factor, but the concentration in the fish tissue. The bioconcentration factor is in the order of 63 -462 (USEPA Aquire Data Base)	The paragraph amended as "A bioaccumulation study with bluegill sunfish has shown that parathion residues in water are rapidly taken up by fish, extensively metabolised and rapidly excreted, with little potential to bioacumulate. The steady-state bioconcentration factor for whole body tissues was calculated as 430. During the depuration phase, the calculated half-life was 0.76 days for whole body tissues."

Annex 4. Reference			
	Germany	page 32: Adding Commission Directive 2002/66/EC in the list of reference	Agreed
General Comments			
	Bangladesh	Agree with the internal proposal	Noted
	Brazil	Agree with the internal proposal	Noted
	Romania	Providing information on regulatory status of parathion in Romania	Noted
	Sudan	No further comments	Noted

Annex II

Operation of the interim Prior Informed Consent procedure
for banned or severely restricted chemicals

Draft Decision Guidance Document

PARATHION

Secretariat for 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 co-operative 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 interim secretariat of the Convention is provided jointly by the United Nations Environment Programme (UNEP) and the Food and Agriculture Organisation of the United Nations (FAO).

Candidate chemicals[5] for the Rotterdam Convention include those that have been banned or severely restricted by national regulatory actions in two or more Parties[6] in two different regions. Inclusion of a chemical in the Convention is based on regulatory actions taken by Parties that have addressed the risks associated with the chemical by banning or severely restricting it. Other ways might be available to control/reduce such risks. However, inclusion does not imply that all Parties to the Convention have banned or severely restricted this chemical. 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.

In the period before the Convention enters into force the interim PIC procedure is in operation which follows the obligations of the Convention. During this period chemicals are approved for inclusion in the interim PIC procedure by the Intergovernmental Negotiating Committee (INC).

At its XXXX session, held in XXXX on XXXX, the Intergovernmental Negotiating Committee adopted the decision guidance document for parathion with the effect that this chemical became subject to the interim PIC procedure.

The Committee also decided that with the circulation of this decision guidance document, countries would be invited to submit a single decision regarding future imports that would apply to all forms of parathion, including the severely hazardous formulations listed in Annex III of the Convention[7] unless explicitly exempted in the submitted import response.

The present decision guidance document was communicated to the Designated National Authorities on [xxxx] in accordance with Articles 7 and 10 of the Rotterdam Convention.

Purpose of the Decision Guidance Document

For each chemical included in the interim PIC procedure a decision guidance document has been approved by the Intergovernmental Negotiating Committee. Decision guidance documents are sent to all Parties with a request that they provide a decision regarding future import of the chemical.

The decision guidance document is prepared by the Interim Chemical Review Committee (ICRC). The ICRC is a group of government designated experts established in line with Article 18 of the Convention, that evaluates

[5] "'Chemical' means a substance whether by itself of in a mixture or preparation and whether manufactured or obtained from nature, but does not include any living organism. It consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial."

[6] "'Party' means a State or regional economic integration organization that has consented to be bound by this Convention and for which the Convention is in force."

[7] All formulations – aerosols, dustable powders (DP), emulsifiable concentrate (EC), granules (GR) and wettable powders (WP) – of this substance are included, except capsule suspensions (CS)

candidate chemicals for possible inclusion in the Convention. The decision guidance document reflects the information provided by two or more Parties in support of the national regulatory actions to ban or severely restrict the chemical. It is not intended as the only source of information on a chemical nor is it updated or revised following its adoption by the Intergovernmental Negotiating Committee.

There may be additional Parties that have taken regulatory actions to ban or severely restrict the chemical as well as others that have not banned or severely restricted it. Such risk evaluations or information on alternative risk mitigation measures submitted by Parties may be found on the Rotterdam Convention web-site.

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 this 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 this document.

While the information provided is believed to be accurate according to data available at the time of preparation of this Decision Guidance Document, the Food and Agriculture Organization of the United Nations (FAO) and the United Nations Environment Programme (UNEP) disclaim any responsibility for omissions or any consequences that may flow 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.

ABBREVIATIONS	
<	less than
≤	less than or equal to
<<	much less than
>	greater than
≥	greater than or equal to
>>	much greater than
µg	microgram
µm	micrometer
AChE	acetylcholinesterase
ADI	acceptable daily intake
ADP	adenosine diphosphate
a.i.	active ingredient
AOEL	acceptable operator exposure level
ARfD	acute reference dose
ATP	adenosine triphosphate
b.p.	boiling point
bw	body weight
^{o}C	degree Celsius (centigrade)
CA	chemical association
CAS	chemical abstract service
cc	cubic centimetre
ChE	cholinesterase
CHO	Chinese hamster ovary
cm	centimetre
d	day(s)
DNA	Deoxyribose nucleic acid
DT_{50}	time 50% of a chemical to degrade
E.C.	European Community
EC_{50}	effect concentration, 50% (median effective concentration)
ED_{50}	effect dose, 50% (median effective dose)
EEC	European Economic Community
EINECS	European inventory of existing commercial substances
EHC	Environmental Health Criteria
FAO	Food and Agriculture Organisation of the United Nations
g	gram
GEMS/Food	Global Environment Monitoring System - Food contamination monitoring and assessment programme
h	hour
ha	hectare
i.m.	intramuscular
i.p.	intraperitoneal

ABBREVIATIONS	
IARC	International Agency for Research on Cancer
IC_{50}	inhibition concentration, 50%;
IESTI	international estimate of short-term dietary intake
ILO	International Labour Organisation
IPCS	International Programme on Chemical Safety
IPM	Integrated Pest Management
ISO	International Organisation for Standardisation
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)
kg	kilogram
Koc	organic carbon-water partition coefficient
l	litre
LC_{50}	lethal concentration, 50%
LD_{50}	lethal dose, 50%
LOAEL	lowest observed adverse effect level
LD_{LO}	lowest lethal dose
LOEL	lowest observed effect level
Log P	logarithm of the octanol/water partition coefficient
m	metre
m.p.	melting point
mg	milligram
ml	millilitre
MOE	margin of exposure
mPa	milliPascal
MRL	maximum residue level (or limit)
MTD	maximum tolerated dose
ng	nanogram
NOAEL	no-observed-adverse-effect level
NOEL	no-observed-effect level
NRA	National Registration Authority for Agricultural and Veterinary Chemicals (Australia)
NTP	National Toxicology Program
OECD	Organisation for Economic Co-operation and Development
OHS	Occupational Health and Safety
PCM	phase contrast microscopy
Pow	octanol-water partition coefficient
PPE	personal protective equipment
RfD	reference dose for chronic oral exposure (comparable to ADI)

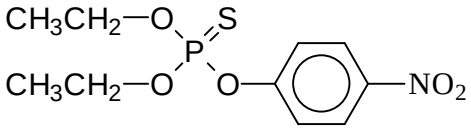
ABBREVIATIONS

SMR	standardized mortality ratio
STEL	short term exposure limit
STMR	supervised trials median residues
TER(s)	toxicity/exposure ratio(s)
TLV	threshold limit value
TWA	time weighted average
UNEP	United Nations Environment Programme
US EPA	United States Environmental Protection Agency
UV	ultraviolet
WHO	World Health Organization
wt	weight

Decision guidance document for a banned or severely restricted chemical

Parathion **Published:**

1. Identification and uses (see Annex 1)

Common name	**Parathion (ISO)**
Chemical name	IUPAC: *O,O*-Diethyl *O*-(4-nitrophenyl) phosphorothioate
Other names/ synonyms	CAS: *O,O*-diethyl *O*-(4-nitrophenyl) phosphorothioate Synonym(s): Parathion ethyl, thiophos, ethyl parathion
CAS-No.	56-38-2
Harmonised System Customs Code	29.2010.00 – active ingredient. 3808.10.40 – formulated product put up as insecticide.
Other numbers:	European Community number: 200-271-7
Molecular formula	$C_{10}H_{14}NO_5PS$
Structural formula	
Category	Pesticide
Regulated Category	Pesticide
Use(s) in regulated category	Insecticide/acaricide used in agriculture, horticulture, and viticulture notably to protect pome and stone fruit, vegetables, citrus fruits, vines and lucerne.
Trade names	Ethyl parathion 100 EC; Ethyl parathion 500 EC; Farmoz; Pacol 4,5 (EO, 45 g/l, Aventis Optimagro); Parathion E Insecticide; Novafos E Insecticide; Oléon Bladan (EC, 93 g/l, Bayer SA); Oléoparatior (EO, 45 g/l Capiscol); Parafor ethyl (EC, 100 g/l, Capiscol); Paretox 10 (WP, 10%, Bourgeois); Rhodiatox liquide 10% (EC, 100 g/l, Flexagri); Tebing Parathion Insecticide; Ugécoil 10 (EC, 100 g/l, Sopcam-phyteurop); Ugécoil P (EC, 30 g/l, Sopcam-phyteurop). *Parathion is widely distributed under numerous commercial names. This list is an indicative list of trade names. It is not intended to be exhaustive.*
Formulation types	Available in a variety of formulations such as emulsifiable concentrate (EC), emulsion (water in oil) (EO) or wettable powder (WP). The concentration of active ingredient (a.i.) in these formulations ranges from 30 to 500 g/l. Also available in mixtures with other active ingredients.
Uses in other categories	No reported use as an industrial chemical.
Basic manufacturers	Cheminova, Shenzhen Jiangshan. *This is an indicative list of current and former manufacturers of Parathion. It is not intended to be exhaustive.*

2. Reasons for inclusion in the PIC procedure

Parathion is included in the interim PIC procedure as a pesticide. It is listed on the basis of the final regulatory actions to ban all uses of parathion notified by Australia and the European Community.

Previously all formulations (aerosols, dustable powder, emulsifiable concentrate, granules and wettable powders) of this substance (except capsule suspensions) were included in Annex III of the Rotterdam Convention as severely hazardous pesticide formulations on the basis of the recommendation of the 3rd FAO/UNEP Joint Expert Group

Meeting. This action was taken because of their acute hazard classification and concern as to their impact on human health under conditions of use in developing countries.

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

Australia

The active constituent approval, all product registrations, and associated label approvals for products containing parathion, were cancelled as from 11 June 1999. Wholesale supply to cease by 31 December 1999; retail sale to cease by 30 June 2000 and maximum residue levels (MRL) withdrawn from 30 June 2001.

Reason: Human Health and Environment (Concerns with regard to operator exposure and aquatic ecosystems).

European Community

The authorisations for plant protection products containing parathion had to be withdrawn by 8 January 2002. From that date, no authorisations for plant protection products containing parathion could be granted or renewed.

Reason: Human Health and Environment (Concerns with regard to operator exposure and non-target organisms).

2.2 Risk evaluation (see Annex 1 for details)

Australia:

The Australian National Registration Authority for Agricultural and Veterinary Chemicals (NRA) selected parathion for review because of concerns about its high mammalian toxicity, occupational exposure concerns and potential for adverse environmental impacts. The main issues are detailed below.

Parathion was registered for use on citrus, pome fruit, stone fruit, vines, vegetables, pastures and lucerne, with the major use being in orchards. It was used to control mites, scale insects, aphids, moths, mealy bugs, lucerne fleas and thrips. As the major use of parathion at the time of the review was to control moths as part of integrated pest management (IPM) in pome fruit orchards, this was the use pattern used in the assessment. The application rate was 50 ml per 100 l of spray, which corresponds to 750-1500 ml/ha (375-750 g a.i./ha) for typical high volume spray of 1500 – 3000 l/ha.

Occupational Health and Safety (OHS):

The OHS risk assessment utilised measured worker exposure studies, published literature and predictive exposure modelling to estimate the risk to workers using parathion. The risk assessment found that the health risk to workers during ground spraying (airblast, electrostatic and boom spraying) of parathion products using prevailing practices in all crops was not supported.

The OHS risk was not acceptable under the prevailing conditions of use for pastures and lucerne where parathion was applied aerially. The OHS risk assessment concluded that field workers were at risk when re-entering parathion treated areas. Re-entry restrictions on parathion product labels at the time of the assessment were inadequate. No data were available to assess hand-held uses and greenhouse uses of parathion. Parathion and the products under review are hazardous substances and were covered by regulations to control workplace hazardous substances. Tank mixing with parathion was part of current practice at the time. The OHS risk assessment indicated unacceptable risk when using parathion alone. The additional risk posed by tank mixing with other anticholinesterase products was unacceptable.

Environmental Impact

Parathion was found to be hazardous to sensitive freshwater crustacea and other organisms, including bees. Spray drift was identified as extremely hazardous to aquatic ecosystems.

European Community:
Pursuant to Article 8 (2) of the Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, parathion was reviewed to determine whether or not it should be included in Annex I to this Directive (the list of active ingredients that can be used in plant protection products).

Parathion is a broad spectrum insecticide used on a large variety of crops. In the Member States, parathion-containing pesticides were registered for applications on apples, cereals, citrus fruit, grape, peach, pear, pome and stone fruit by means of spray/foliar spray applications, which were considered in the risk evaluation. Application rates considered in the risk assessment ranged from 0.2 to 0.3 kg a.i./ha.

Based on the information available and the proposed conditions of use, it was concluded from the evaluation that parathion could not fulfil the safety requirements set out in Article 5 (1) (a) and (b) of Council Directive 91/414/EEC. The evaluation identified concerns with regard to the safety of parathion, in particular with regard to operator exposure and non-target organisms. The main issues are detailed below.

Human Health and Safety
From the toxicological assay results available, the following conclusions on parathion health hazards were reached: parathion is very toxic by inhalation or if swallowed and toxic by contact with skin. This active ingredient also exhibits a danger of serious damage to health by prolonged exposure. The critical effect of this organophosphate pesticide is inhibition of cholinesterase (ChE) activity.

No monitoring data for operator exposure under normal conditions were provided. Therefore, the German model was used to evaluate operator exposure to a representative formulation, Ethylparathion EC 500, Toxicological data were missing in a number of key areas, but when using an Acceptable Operator Exposure Level (AOEL) of 0.006 mg/kg bw/d, determined on the basis of the available data, acceptable exposure levels for operators were exceeded in all scenarios of exposure. Even if traditional personal protective equipment (PPE) were to be worn, the AOEL would have still been exceeded in two exposure scenarios: tractor-mounted and hand-held applications in high crops.

Environmental Impact
Based on the registered uses of parathion in orchards, vines and arable land (0.2 – 0.3 kg a.i./ha) high risks were identified for aquatic invertebrates after acute and chronic exposure to the substance and for fish after chronic exposure. Risks were unacceptable when using buffer zones of 5 and 15 meters between the arable crop and the adjacent surface water bodies. In addition unacceptable risks were identified for bees and birds.

3. Protective measures that have been applied concerning the chemical

3.1 Regulatory measures *to reduce exposure*

Australia: Under conditions of use in Australia, it was not shown that parathion could be used in a manner that ensured the safety of people exposed to it during its handling. Its use also could have an unintended effect that was harmful to the environment. It was concluded that conditions of registrations and approvals could not be varied in such a way to allow continued use and as a result, registration for all parathion products was cancelled.

European Community: From the assessments made, it was concluded parathion did not satisfy the safety requirements laid down in Directive 91/414/EEC, in particular with regard to acceptable operator exposure and exposure of non-target organisms. As a result, authorisations for all parathion products had to be withdrawn.

Banning parathion has eliminated exposure and the associated risks to human health or the environment. Australia and the European Community adopted the same risk management strategy to deal with the existing stocks, by allowing a phase-out period:

- Australia: use was phased out over 2 years;
- E.C. Member States may have granted a period of grace of no longer than 18 months for disposal, storage, placing on the market, and use of existing stocks.

This was seen as the lowest risk option for disposing of existing stocks in the light of the risks associated with product recall, storage and disposal. It also allowed users time to adopt other pest management practices.

3.2 Other measures to reduce exposure

None.

3.3 Alternatives

It is essential that before a country considers substituting alternative pesticides, it ensures that the use is relevant to its national needs, and the anticipated local conditions of use. The hazards of the substitute materials and the controls needed for safe use should also be evaluated.

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

Advice may be available through National IPM focal points, the FAO, agricultural research or development agencies. Where it has been made available by governments, additional information on alternatives to parathion may be found on the Rotterdam Convention website www.pic.int.

Australia
The following alternatives were considered at the time of the notification to pose lower risks to workers and the environment. World Health Organisation hazard classifications are provided as an aid to consideration of relative risks. These classifications are for the active ingredient only. Actual hazard depends on the way in which the active ingredient is formulated.

- Moderately hazardous: carbaryl, dimethoate, fenthion;
- Slightly hazardous: fenoxycarb, malathion.

European Community
The European Community did not provide any specific information on alternatives to parathion.

3.4 Socio-economic effects

Australia

Parathion has been an important component of integrated pest management in pears in one Australian State. It was expected that the action would have a significant effect on these growers in the short term. The phase-out period (two years) would reduce the impact and allow time for development of alternatives.

European Community

No detailed assessment of socio-economic effects was undertaken by the European Community.

Countries should consider the results of this information in the context of their own national conditions.

4. Hazards and Risks to human health and the environment

4.1 Hazard Classification

WHO / IPCS	**Technical a.i.:**	**Ia (extremely hazardous)**, classification based on **oral toxicity in rats LD_{50}: 13 mg a.i./kg bw** of liquid parathion (WHO 2000).			
	Formulations	Oral toxicity		Dermal toxicity	
		LD_{50}: 13 mg a.i./kg bw		**LD_{50}: 73 mg a.i./kg bw**[8]	
		a.i. (%)	hazard class	a.i. (%)	hazard class
	Liquid	≥ 20 ≥ 8 ≥ 1 ≥ 0.5	Ia Ib II III	≥ 20 ≥ 2	Ib II
	Solid	≥ 30 ≥ 3 ≥ 1	Ib II III	≥ 80 ≥ 10 ≥ 3	Ib II III
IARC	Group 3: The agent is not classifiable as to its carcinogenicity to humans. (IARC Subsequent evaluation: Suppl. 7 (1987), p. 69)				
European Community	Classification of the active substance is (Commission Directive 93/72/EEC, 1 September 1993): T+ very toxic, N dangerous for the environment, R27/28 very toxic in contact with skin and if swallowed, R50/53 very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment				
US EPA	Category 1 (highly toxic) (EPA 1985) Group C (possible human carcinogen)				

[8] Source of dermal LD_{50} value : JMPR, Australia and E.C. (Annex I Section 2.2.1)

4.2 Exposure limits

Food

The FAO/WHO Joint Meeting on Pesticide Residues (JMPR) established an Acceptable Daily Intake (ADI) of 0.005 mg/kg bw at its first 3 reviews of parathion in 1963, 1965 and 1967. In its fourth and latest review in 1995, the ADI was lowered to 0.004 mg/kg bw. An acute reference dose (ARfD) of 0.01 mg/kg bw was established in 1995.

The JMPR re-evaluated all food residues in 2000 (FAO/WHO 2001) and recommended maximum residue limits on cereal grains, oil seeds and apples ranging between the limit of analytical detection of 0.05 mg/kg and 7 mg/kg.

The Codex Committee on Pesticide Residues at its 34th session in May 2002 recommended withdrawal of all maximum residue limits as parathion was no longer supported by the manufacturer in the Codex system (CCPR 2002 paragraph 94 ALINORM03/24).

A dietary risk assessment was performed by the JMPR in 2000. For the commodities on which Codex maximum residue limits were proposed, it concluded that the acute intake of residues of parathion from uses, other than on barley and apples, was unlikely to present a public health concern. The JMPR also concluded that based for the commodities it considered the long-term intake of residues of parathion were unlikely to present a public health concern. Further details can be found in Annex I (Section 3.1) and in JMPR report, 2000.

Drinking water

The WHO has not established a drinking water guideline for parathion.
The European Community has proposed a drinking water limit of 18 µg/l (For further details, see Annex I, Section 3.3).

4.3 Packaging and labelling

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

Hazard Class:	6.1 poisonous substance
Packing Group:	Packing Group I: substances and preparations presenting a very severe risk of poisoning, when the content of the active ingredient is 40-100%. Packing Group II: substances and preparations presenting a serious risk of poisoning, when the content of the active ingredient is 4-40%. Packing Group III: substances presenting a relatively low risk of poisoning in transport, when the content of the active ingredient is 1-4% (solid) or 0.4-4% (liquid).
International Maritime Dangerous Goods (IMDG) Code	Severe marine pollutant. Do not transport with food and feedstuffs.
Transport Emergency Card	TEC (R)-61GT6-I NFPA Code: H4; F1; R2.

For further specific guidance on appropriate symbols and label statements regarding formulations of parathion, countries should also consult the *FAO Guidelines on Good Labelling Practice for Pesticides (1995)*.

4.4 First aid

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

Signs and symptoms of acute parathion poisoning are typical of organophosphorus pesticides acting through ChE inhibition and include pupillary constriction, muscle cramp, excessive salivation, sweating, nausea, vomiting, dizziness, headache, convulsions, diarrhoea, weakness, laboured breathing, wheezing, unconsciousness, abdominal cramps, respiratory failure, and death.

First aid personnel should wear rubber or plastic gloves to avoid contamination. Contaminated clothing and contact lenses should be removed as quickly as possible to prevent further absorption. If skin contact occurs, the area should be washed with soap and water. Eyes should be washed for 15–20 minutes with running water or saline solution. In the case of ingestion, if the victim is conscious and not convulsing, give 1 or 2 glasses of water to dilute the chemical. If the victim is unconscious or convulsing, do NOT give anything by mouth and do NOT induce vomiting. The stomach should be emptied as soon as possible by careful gastric lavage, preferably within one hour of ingestion. In massive overdoses, acute respiratory failure may occur. It is important to keep the airway open and to prevent aspiration if nausea and vomiting occur.

Persons who have been poisoned (accidentally or otherwise) must be transported immediately to a hospital and placed under the surveillance of properly trained medical staff. Where possible show the label of the parathion container when the patient/affected person is presented for medical attention.

If the substance is formulated with solvent(s), also consult the International Chemical Safety cards (ICSC) of the solvent(s). Carrier solvents used in commercial formulations may affect the toxicity of the active ingredient by altering its extent of absorption from the gastrointestinal tract or through the skin.

Atropine and oxime reactivator compounds, such as Toxogonin, are well known antidotes to parathion poisoning. Use and effectiveness of these antidotes in cases of human poisoning are well documented in the scientific literature.

Further information may be found on the website of the IPCS/WHO at ***www.inchem.org***

4.5 Waste management

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

Australia and the European Community adopted the same risk management strategy to deal with the existing stocks, by allowing a phase-out period. This period was two years in Australia and 18 months for E.C. Member States. This was seen as the lowest risk option for disposing of existing stocks in the light of risk associated with product recall, storage and disposal. It also allowed users time to change over to other pest management practices (see Annex 2)

In all cases waste should be disposed of in accordance with the provisions of the *Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (1996)*, any guidelines thereunder (*Secretariat of the Basel Convention*, 1994) and any other relevant regional agreements.

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

Annexes

Annex 1 **Further information on the substance**

Annex 2 **Details on Final regulatory action**

Annex 3 **Address of designated national authorities**

Annex 4 **References**

Annex 1 Further information on the substance

Introductory text to Annex I

The information presented in this Annex reflects the conclusions of the two notifying parties: Australia and the European Community. In a general way, information provided by these two parties on the hazards are synthesised and presented together, while the risk assessments, specific to the conditions prevailing in these parties, are presented separately. This information is contained in the documents referenced in the notifications in support of their final regulatory actions banning parathion. The notification from Australia was first reported in the PIC Circular XII of December 2000 and the notification from the European Community in PIC Circular XVI of December 2002.

The FAO/WHO Joint Meeting on Pesticide Residues (JMPR) reviewed parathion in 1963, 1965, 1967, 1995 and 2000. The last review of toxicity data was in 1995 while residues were re-evaluated in 2000. The conclusions of the JMPR were not substantially different from those reported here. As a result, details of the evaluations are not included though their relevant conclusions, e.g. regarding acceptable daily intake (ADI) and acute reference dose (ARfD), have been included in the interest of completeness.

The results of international reviews, such as that of WHO/IPCS (IPCS Health and Safety Guide, 1992) and IARC (1983) have also been considered while drafting the document. They do not differ substantially from the information provided by the notifying countries, and details of these evaluations have not been included though the IPCS conclusions regarding acute toxicity endpoints have been included in section 2.2.7.

Annex 1 – Further information on parathion

1. Physico-Chemical properties

1.1	**Identity**	ISO: Parathion IUPAC: *O,O*-diethyl-*O*-(4-nitrophenyl) phosphorothioate CAS:, *O,O*-diethyl *O*-(4-nitrophenyl) Phosphorothioate [56-38-2]
1.2	**Formula**	$C_{10}H_{14}NO_5PS$
1.3	**Chemical type**	Organophosphorus compound
1.4	**Colour and Texture**	Pure parathion: pale yellow liquid with phenol like odour
1.5	**Decomposition temperature**	Isomerises to O,S-diethyl isomer on heating above 130°C
1.6	**Density (g/cm^3)**	1.2694
1.7	**Solubility**	In water: 11 mg/l at 20°C; 12.4 ± 0.7 mg/l at 25 ± 1°C Completely miscible with most organic solvents.
1.8	**Log P**	1598 (log K_{ow} = 3.15 ± 0.27)
1.9	**Vapour pressure**	0.89 mPa at 20 °C
1.10	**Melting point**	6.1 ºC
1.11	**Boiling point**	150°C/80 Pa
1.12	**Reactivity**	Hydrolysis: Rapidly hydrolyses in alkaline media, more slowly in acidic media pH 4: DT_{50} = 272 d, pH 7: DT_{50} = 247-356 d, depending on the buffer pH 9: DT_{50} = 102-130 d (several tests)
1.13	**Stability**	Not highly flammable. Non-explosive
1.14	**Molecular Weight**	291.3 g/mol

2 Toxicological properties

2.1 General

2.1.1	**Mode of Action**	The biological mode of action of parathion is by cholinesterase (ChE) inhibition. The transmission of nerve impulses is blocked at the nerve synapses. In brief, nerve impulses are transmitted to the next fibre (or to a muscle) by acetylcholine being released from the transmitting nerve, which stimulates the receiving nerve (muscle). The acetylcholine is then immediately catabolised by the enzyme acetylcholinesterase (AchE). The organophosphorus insecticides bind to AchE so that acetylcholine cannot be catabolised. Consequently control via the nervous system is blocked by nerves being permanently stimulated. Specifically, the toxicity of parathion is directly related to the inhibition of ChEs by the major parathion activation product, paraoxon.
2.1.2	**Symptoms of poisoning**	The symptoms of parathion poisoning are typical of organophosphorus pesticides acting through cholinesterase inhibition and include: pupillary constriction, weakness, nausea, vomiting, excessive sweating, headache, tightness in the chest, laboured breathing, dizziness, excessive salivation, muscle cramp, difficulty in walking, convulsions, diarrhoea, wheezing, abdominal cramps, miosis, muscle fasciculation, unconsciousness, coma, respiratory failure, and death.

2.1.3 Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption

The absorption of parathion is rapid and extensive (more than 90%) in rats following oral administration.

Studies of the absorption of parathion through the skin in mice, rats and humans have shown that the substance is readily absorbed and metabolised, but with a high variability among species, gender, application site and individuals.

Distribution and excretion

Parathion does not accumulate in tissues. It is generally excreted very rapidly, more than 99% within 48 hours, mainly via the urine (86-94%). There are only very low concentrations of residues (about 2% of the administered dose) remaining in tissues such as fat, lung, liver and brain 48 hours after oral administration.

Metabolism in animals

The metabolism is well defined and proceeds through a process of desulphurisation, dealkylation, conjugation and oxidation. The process is common across mammalian species, the key metabolite is paraoxon-ethyl which is of similar acute toxicity to the parent compound.

Human data:

Studies in human volunteers indicate that approximately 10% of a parathion dose applied to human skin is absorbed, with approximately a 5-fold difference between individuals.

As in other mammalian species, paraoxon-ethyl (paraoxon) is the major degradation product of parathion.

2.2 Toxicology studies

2.2.1 Acute toxicity

Oral: Parathion is very acutely toxic by the oral route, with LD_{50} values ranging from 2 to 22 mg/kg bw for rats, 12 mg/kg bw for mice, 10 mg/kg bw for pigs.

The estimated human oral lethal dose for parathion is 1.43 mg/kg.

Dermal: Parathion is acutely toxic following percutaneous application, with LD_{50} values ranging from 71 to 100 mg/kg bw for rats.

A microencapsulated form of parathion was of low-moderate toxicity to rats when tested by the oral and dermal routes.

Inhalation: Parathion is very toxic by the inhalation route. The LC_{50} (aerosol, 4h, nose only) is 0.03 mg /l for male and female rats.

Irritation: Parathion is not / slightly irritant to rabbit's skin and to rabbit's eyes. The microencapsulated product is a slight eye irritant and a slight skin irritant in rabbits, and is a weak skin sensitiser in guinea pigs.

Sensitisation: Parathion does not induce skin sensitisation in guinea pigs tested according to the method of Magnusson and Kligman.

Human data:

Australia: Several acute/short-term studies conducted on human volunteers were reported. In these early studies, it was found that oral doses of 0.05 – 0.07 mg parathion/kg bw may be asymptomatic. Doses of 0.1 mg/kg bw and above gave signs and symptoms typical of cholinesterase inhibition, as well as measured reductions in plasma and whole blood cholinesterase activity. In later studies, oral intake of up to 0.1 mg/kg bw/d for up to 14 weeks produced no clinical signs but inhibited plasma cholinesterase markedly and erythrocyte cholinesterase slightly with significant individual variability. From these studies NOELs in the range 0.05 - 0.1 mg/kg bw/d were established for plasma ChE inhibition. The lowest NOEL was used for the human risk assessment.

European Community:

In one study, a group of five volunteers were given parathion by capsule, firstly at 3

mg/person/d for 28 days, then at 4.5 mg/person/d for 28 days and finally at 6 mg/person/d for 43 days. The administration at 3 and 4.5 mg/person/d did not affect plasma or erythrocyte cholinesterase activity. The highest dose of 6 mg/person/d produced a slight depression (10 - 15%) of plasma and erythrocyte cholinesterase activity. No adverse clinical symptoms were observed.

In a second study, groups, each consisting of five male subjects, were given parathion by capsule at doses of 3, 4.5, 6 or 7.5 mg/person/d for 35 days. There was no effect on plasma or erythrocyte cholinesterase activity at the two lower dose levels. At 6 mg/person/d there was a slight, but not significant, depression of plasma cholinesterase activity. At the highest dose level of 7.5 mg/person/d, plasma cholinesterase on average was depressed by 15%, although, in some individuals, this depression was 50%. A slight inhibition of erythrocyte cholinesterase activity was also seen at this dose level.

The 'no-effect' level in humans, as a result of the above studies was, therefore, 4.5 mg/person/d, equal to 0.06 mg/kg bw/d. This value was used for the human risk assessment (Section 3).

Acute reference dose (ARfD):

European Community: An acute reference dose of 0.005 mg/kg bw was established based on acute neurotoxic effects observed in rats, with a safety factor of 100 (see point 2.2.6).

JMPR (1995): An acute reference dose of 0.01 mg/kg bw was established by applying a 10-fold safety factor to a NOAEL of 7.5 mg/d (highest oral dose), corresponding to about 0.1 mg/kg bw per day, in humans. This was based on the absence of inhibition of erythrocyte AChE.

Australia: An acute reference dose of 0.01 mg/kg bw was established by applying a 10-fold safety factor to a NOEL of 0.125 mg/kg bw in humans. This was based on the absence of inhibition of erythrocyte AChE in a 35-d study (five males), at the highest dose tested of 7.5 mg/person/d.

2.2.2 Short term toxicity

Oral

Short term studies

In rats (14 d) and mice (28 d) inhibition of erythrocyte ChE was the most sensitive endpoint, with death occurring at the highest doses. A NOEL (oral, 14 d) = 1 mg/kg in the diet was established in rats.

Sub-chronic studies

In several studies performed on rats (90 d), mice (90 d) and dogs (90 d – 6 months) inhibition of erythrocyte ChE was also observed with additional inhibition of plasma ChE and in the longer studies brain ChE activities. The lowest NOEL was reported by Australia: NOEL (oral, dogs, 6 months) = 0.0024 mg/kg bw/d based on plasma ChE inhibition.

Dermal

Lowest relevant NOEL (Rabbits, 21-day) = 0.1 mg/kg bw (inhibition of erythrocyte, plasma and brain ChE at 2 mg/d).

Inhalation:

In a 21-d inhalation (nose only) study in rats, there were no effects at the low dose of 0.25 mg/m^3 (NOEL), reductions in plasma, erythrocyte or brain ChE activity at the mid dose (0.92 mg/m^3) or high dose (3.9 mg/m^3), and clinical signs of poisoning and deaths at the high dose. LOEL (rats, 30 x 7 h/d) = 0.01 mg/m^3 air (inhibition of erythrocyte ChE).

2.2.3 Genotoxicity

The weight of the evidence indicates no genotoxic potential.

	(including mutagenicity)	Parathion does not interact with genetic material and has been shown not to cause: mutations in bacterial or mammalian cells, chromosomal damage in mouse or human blood cells or mouse germ cell cells, inhibition or stimulation of DNA repair. Parathion did not exhibit mutagenic activity in *in vivo* mouse bone marrow micronucleus or dominant lethal assays
2.2.4	**Long term toxicity and carcinogenicity**	In general for **long term toxicity** studies, at the highest dose levels, the toxic effects were consistent with exposure to cholinesterase inhibiting compounds, namely increased mortality, reduced body weight gain, cholinergic and clinical signs, peripheral neuropathy and reduced red cell count. At these levels, cholinesterase activity in erythrocytes, plasma and brain were all markedly inhibited. In rats: - the lowest NOEL (diet, 24 months) was 0.01 mg/kg bw/d (plasma ChE inhibition) (Australia); - the lowest NOEL (diet, 24 months) was 0.1 mg/kg bw/d (erythrocyte/plasma ChE inhibition) (E.C.) In dogs, the lowest NOEL (diet, dogs, 12 months) was 0.01 mg/kg bw/d (erythrocyte/plasma ChE inhibition) (Australia, E.C.) **Carcinogenicity:** Under the conditions of the available studies parathion did not show carcinogenic potential (rat, two years).
2.2.5	**Effects on reproduction**	*Reproduction* In 2 two-generation reproduction studies in rats (dosed with 0.05 to 2.3 mg/kg bw/d parathion by gavage) and a third where rats were fed (1, 5, 10, 20 mg/kg in diet – 1 mg/kg being equivalent to 0.05 mg/kg bw/d) with parathion in the diet the NOELs for parental toxicity ranged from 0.05 to 0.9 mg/kg bw/d and from 0.6 to 1 mg/kg bw/d for reproductive effects. *Developmental effects* In two studies in rats dosed with parathion at levels ranging from 0.1 to 1.5 mg/kg bw/d and one in rabbits dosed at levels ranging from 0.03 to 0.3 mg/kg bw/d effects were only observed at maternotoxic doses. In rats the NOEL for maternal toxicity ranged from 0.3 to 1 mg/kg bw/d and in rabbits the NOEL for maternal toxicity was 4 mg/kg bw/d. Under the conditions of these studies parathion did not show teratogenic potential.
2.2.6	**Neurotoxicity/ delayed neurotoxicity, Special studies where available**	Acute neurotoxicity study, rats single oral doses between 0.025 and 10 mg/kg. At 10 mg/kg there were deaths and clinical signs of toxicity. Neurological effects were typical of acute cholinesterase inhibition and were seen at doses that caused significant inhibition of plasma, erythrocyte and brain cholinesterase activity. Substantial recovery of cholinesterase levels was seen at day 14 post treatment. The NOEL for the study was 0.5 mg/kg bw/d based on inhibition of plasma, erythrocyte and brain cholinesterase and acute neurological effects seen at 2.5 mg/kg and above. This study was used by the EC to derive the ARfD. There was no evidence of delayed neurotoxic effects in rats or hens in studies up to 13 weeks. **Human data:** Neither single or repeated exposure to parathion in humans appears to lead to delayed neuropathy, but the possibility of neuropsychiatric effects cannot be completely eliminated.
2.2.7	**Summary of**	Parathion is rapidly absorbed by the major routes of exposure (oral, dermal and

mammalian toxicity and overall evaluation

inhalation) with some interindividual/interspecies or gender variations in the case of dermal contact. Parathion does not accumulate in tissues, and is quickly excreted, mainly via urine. Parathion is metabolised mainly in the liver where its major metabolite (paraoxon) is formed.

Parathion has a high acute toxicity:
LD_{50} (oral, rats) = 2 - 22 mg/kg bw (Australia, European Community)
LD_{50} (oral, rats) = 2 - 22 mg/kg bw (JMPR, 1995)
LD_{50} (oral, rats) = about 13 mg/kg bw (IPCS, 1992)

LC_{50} (inhalation, aerosol, 4h, nose only) = 0.03 mg /l (Australia, European Community)
LC_{50} (inhalation, 4h) = 0.03 mg /l (JMPR, 1995, study from 1986)
LC_{50} (inhalation, 4h) = 24 - 91mg /l (JMPR, 1995, study from 1972)
LC_{50} (inhalation) = no data (IPCS, 1992)

LD_{50} (dermal, rats) = 71 - 100 mg/kg bw (Australia, European Community)
LD_{50} (dermal, rats) = 73 mg/kg bw (JMPR, 1995)
LC_{50} (dermal) = no data (IPCS, 1992)
LD_{50} (dermal, rabbits) = 910 – 1400 mg/kg bw (JMPR, 1995)

Parathion was not highly irritating to the skin or the eyes of rabbits, and was not a skin sensitiser in guinea pigs (Australia, European Community, JMPR, 1995).

The major toxic effect of parathion (organophosphorus compound) is cholinesterase inhibition.

Short-term studies
Lowest NOEL (oral, dogs, 6 months) = 0.0024 mg/kg bw/d (plasma ChE inhibition) (Australia)

Long term studies:
Lowest NOEL (diet, dogs, 12 months) = 0.01 mg/kg bw/d (erythrocyte/plasma ChE inhibition) (Australia/E.C.)
Lowest NOEL (diet, rats, 24 months) = 0.01 mg/kg bw/d (plasma ChE inhibition) (Australia)
Lowest NOEL (diet, rats, 24 months) = 0.1 mg/kg bw/d (erythrocyte/plasma ChE inhibition) (E.C.)

Human oral study
Lowest NOEL = 0.05 mg/kg (plasma ChE) (Australia)
= 0.06 mg/kg bw/d (erythrocyte/plasma ChE) (E.C.)

Parathion was not found to be genotoxic (Australia, E.C.).

Parathion was not found to be carcinogenic, in several two years dietary studies.

Acute reference dose (ARfD):
Australia: ARfD = 0.01 mg/kg bw (applying a 10-fold safety factor to a NOEL of 0.125 mg/kg bw/d for inhibition of erythrocyte AChE in humans).

European Community: ARfD = 0.005 mg/kg bw based on acute neurotoxic effects observed in rats, with a safety factor of 100.

JMPR (1995)*:* ARfD = 0.01 mg/kg bw (10-fold safety factor, NOAEL = 0.1 mg/kg bw/d, in humans (highest oral dose), based on the absence of inhibition of erythrocyte AchE.

Acceptable Daily Intake (ADI)

Australia

ADI of 0.001 mg/kg bw/d based on the human NOEL of 0.05 mg/kg bw/d (plasma ChE), and application of a 50-fold safety factor to account for the reported variability in human populations.

European Community

ADI of 0.006 mg/kg bw/d based on the human NOEL of 0.06 mg/kg bw/d (erythrocyte/plasma ChE), and application of a 10-fold safety factor.

JMPR, 1995

ADI of 0-0.004 mg/kg bw/d based on a NOAEL of 0.4 mg/kg bw/d in the two-year study in rats for retinal atrophy and inhibition of brain acetylcholinesterase at the higher dose and application of a 100-fold safety factor.

Lower NOAELs in animals, based only on inhibition of erythrocyte or brain AchE, were not considered relevant because of the availability of an NOAEL for erythrocyte AchE inhibition in humans, which was 0.1 mg/kg bw per day.

3 Human exposure/Risk evaluation

3.1 Food

Australia

No Australian residue trial data were presented for review. However, using available data several maximum residue levels (MRLs) were set ranging from 0.05 to 1 mg/kg (withdrawn June 2001). The risk for consumers was not assessed.

European Community

MRLs were set by Commission Directive 2002/66/EC of 16 July 2002 at the following levels:
Meat, milks, eggs: 0.05 mg/kg (LOD = lower limit of analytical determination)
Fruits, vegetables, pulses, oilseeds, potatoes, cereals: 0.05 mg/kg (LOD)
Tea, hops: 0.1 mg/kg (LOD).

JMPR

The JMPR performed a dietary risk assessment for short-term and chronic exposure in 2000. The Codex Committee on Pesticide Residues at its 34th session in May 2002 recommended withdrawal of all MRLs as parathion was no longer supported by the manufacturer in the Codex system (CCPR 2002 paragraph 94 ALINORM03/24). However, in the absence of any other information on dietary risk, results from this dietary risk assessment (JMPR report, 2000) are reported below.

Short-term intake

The International Estimate of Short-Term Dietary Intake (IESTI)of parathion was calculated for the food commodities (and their processing fractions) for which maximum residue levels and supervised trials median residues (STMR) values have been estimated and for which data on consumption were available. The IESTI represented 0– 400% of the ARfD for the general population. The 400% value took

into account estimates of beer consumption, but the calculation in this case was based on the residues in barley because no data were available on the fate of parathion during brewing. The IESTI represented 0–140% of the ARfD for children. The value of 140% represents the estimated short-term intake of residues in apples, but the Meeting was informed that the large portion size (679 g) of apple consumption by children may represent total apple consumption (including apple juice) rather than consumption of whole apples only.

The JMPR concluded that the acute intakes of residues of parathion from uses, other than on barley and apples, were unlikely to present a public health concern.

Chronic intake

The review of parathion at this time resulted in recommendations for new and revised MRLs and new STMR values for raw and processed commodities. Data on consumption were available for 10 food commodities and were used in calculating dietary intake. The international estimated daily intakes from the five GEMS/Food regional diets, based on estimated STMR values, represented 7–20% of the ADI.

The JMPR concluded that long-term intake of residues of parathion from uses that it considered is unlikely to present a public health concern.

3.2 **Air**

Not relevant.

Parathion formulations are normally used at times when re-entering the crops shortly after spraying is not necessary. The half-life of the active ingredient in air is less than 1 day.

3.3 **Water**

European Community: Field studies demonstrated that parathion is not mobile below 10 cm soil depth, indicating that under normal agricultural use there is no potential risk of contaminating drinking water supplies. On the basis that exposure through drinking water should not account for more than 10% of ADI, assuming average consumption of 2 litres of water per person per day and body weight of 60 kg, a limit of 18 µg/l is proposed.

3.4 **Occupational exposure**

In line with internationally accepted practices, the occupational risk evaluation was based on hazard characteristics and worker exposure. The latter took into consideration the mixing, loading and applications activities involved in the use of pesticides.

Australia

The OHS risk assessment utilised measured worker exposure studies, published literature and predictive exposure modelling (UK Predictive Operator Exposure Model – POEM) to estimate the risk to workers using parathion.

Parathion was applied in Australia to the following crops: stone and pome fruit, citrus, vines, vegetables, and pastures and lucerne.

The maximum parathion concentration in working strength spray was 0.05% in horticultural crops and 0.088% in field crops.

It was assumed that maximum PPE (personal protective equipment) was worn (*i.e.* gloves, overalls and waterproof clothing).

Assessment of health risk to workers

In estimating health risk to workers from exposure data, an average body weight of 60 kg per worker and a skin penetration rate of 10% for parathion were used.

Assessment of risk was based on calculations of margins of exposure (MOE). MOE

for Australian use patterns were calculated by comparing the NOEL of 0.05 mg/kg bw/d with measured and/or predicted worker exposure. An MOE of 50 or more was considered acceptable. The NOEL of 0.05 mg/kg bw/d determined in humans based on erythrocyte ChE inhibition was selected for the occupational health and safety risk assessment of parathion (see section 2.2.1).

Assessment - ground application
Worker health risk was assessed from measured exposure data including the study conducted in Australian orchards and model data. A range of control measures was considered including maximum PPE, closed mixing systems and closed cabs.
Stone and pome fruit The critical uses of parathion were ground application in stone and pome fruit. In the Australian study, MOE generated for parathion were unacceptable, at ≤ 2. This was for workers performing combined functions and using high-pressure airblast and electrostatic equipment with and without air-conditioned cabs. Biological monitoring results indicated that one out of seven workers in the parathion group exceeded the Biological Exposure Index (BEI) for parathion defined by the American Conference of Governmental Industrial Hygienists (ACGIH).
Both measured exposure data and modelled data indicated unacceptable exposures, under the then prevailing use conditions in stone and pome fruit. The data on the influence of mixer/loader exposure on overall exposure was conflicting. Predicted applicator exposure appeared acceptable for low volume and ultra low volume spraying. Further data would be required to assess whether use is safe with closed mixing/loading systems and closed cabs.
Other crops The assessment of parathion use in other crops found an unacceptable level of risk during ground spraying. Further data would be required to assess whether use is safe with closed mixing/loading systems and closed cabs.
Assessment - aerial application: Limited measured exposure data indicated that worker exposure and risk during aerial application of parathion in field crops was acceptable. However, further data would be required to show that exposures are acceptable for aerial loading teams.
Bystander exposure: human flagging during aerial application was not acceptable, unless workers had additional protection.
Re-entry assessment: For all uses, an interim minimum re-entry period of 14 days was recommended.

Summary
The risk assessment found that the health risk to workers during ground spraying (airblast, electrostatic and boom spraying) of parathion products using prevailing practices in all crops was not supported. The OHS risk was not acceptable in the uses at the time of the assessment for pastures and lucerne where parathion was applied aerially. The OHS risk assessment concluded that field workers were at risk when re-entering parathion treated areas.

European Community
There were no measured worker exposure studies for mixing, loading or application of parathion. Therefore the German model was used to estimate exposure for the proposed uses.

Acceptable operator exposure level (AOEL)
The NOEL of 0.06 mg/kg bw determined in human volunteer studies (see section 2.2.1) was used to calculate the AOEL, with a 2.5-fold Safety Factor (intraspecies variability). However, a higher Safety Factor of 10 was deemed necessary to take into account the fact that this NOEL is based on an acute end-point (cholinesterase inhibition), and that this study had been performed at times when analytical methods for cholinesterase determination were rather poor. On this basis, the AOEL = 0.006 mg/kg bw/d.

Operator exposure risk assessment:

The risk of systemic effects arising from operator exposure to the active substance during mixing and application activities was estimated for Ethyl parathion EC 500. Ethyl parathion EC 500 is a broad-spectrum insecticide used on a variety of crops including vegetables, fruit trees, field crops, protected crops and ornamental plants. It is applied using field crop sprayers, portable or hand-held sprayers and air assisted fruit-tree sprayers.

Operator exposure estimates, calculated using the experimentally determined specific exposures provided by the German Generic Database indicated that, when no personal protective equipment (PPE) is worn, the AOEL will be exceeded in all scenarios of exposure, whether assuming a 20% or a 10% skin absorption.

When traditional personal protective equipment is worn, the AOEL will still be exceeded in two exposure scenarios: tractor-mounted and hand-held applications in high crops.

Therefore, the margins of safety obtained by calculation are inadequate, and the risk is not acceptable.

The results of risk evaluation based on Generic Databases to predict operator exposure indicate the need to proceed to a Tier-III risk assessment, based on actual measurements of exposure, rather than on exposure estimates.

3.5 Medical data contributing to regulatory decision

Humans may be among the more sensitive species to parathion, with marked individual variations. A 60-fold variation was observed in the activity of the enzyme responsible for parathion metabolism in humans.

The estimated human oral lethal dose for parathion is 1.43 mg/kg (Section 2.2.1).

4 Environmental fate and effects

4.1 Fate

4.1.1 Soil

Biodegradation: In a soil metabolism study a DT_{50}-value of about 58 days was established whilst laboratory degradation studies revealed DT_{50}-values of 150 to 170 days based on the first 20 days of the study. These studies were carried out in 3 different soils with different pH at 22 – 25 ˚C. Degradation mainly took place to CO_2 (43%), non-extractable residues in the soil (maximum of 49.1% of the initial dose after 92 days incubation and 36.6% after 366 days) and some minor metabolites (2.9% 4-nitrophenol, 1.6% paraoxon and 2.1% *O,O*-bis(4-nitrophenol) ethylphosphate). In field studies with application rates of 1.1 and 0.35 kg/ha, dissipation is faster. DT_{50}-values of 3 – 32 days were determined depending on soil and temperature. Parathion is fairly degradable and is not considered as persistent (field DT_{50} < 3 months).

Degradation of parathion in sterile soils was not investigated.

Photodegradation of parathion showed no additional enhancement compared to biodegradation. A DT_{50} of 73 days was determined.

Degradation under anaerobic conditions has not been investigated because exposure to anaerobic conditions was not considered likely based on the low DT_{50}-values of the substance.

Mobility: Parathion may be classified as slightly mobile to immobile. In sorption experiments in four different soils Koc-values of 1700 – 1100 dm^3/kg were determined at organic carbon contents of 0.1 – 2.1%. In soil column aged leaching

studies only small amounts were found in the leachate: 0.23 – 0.28% after 135 days of ageing and leaching with 200 mm in 2 days. Also in a field leaching study no leaching of parathion could be demonstrated. Furthermore, no leaching properties were found for the metabolites in these studies.

4.1.2

Water

***Hydrolysis**: The hydrolysis of parathion is expected to be slow in the environment. At 25°C and pH 7, there was little hydrolysis with half-lives of 247-356 days. The half-life due to hydrolysis ranged from 100-102 days at pH 9 to 133 days at pH 5.*

Photolysis: Half-lives of parathion of 203, 30 and 4.4 days were obtained for dark controls, non-sensitised samples and samples sensitised with acetone (1% v/v), respectively. These studies were carried out in clear waters. It is expected that in turbid waters photolysis does not play a significant role.

Biodegradation: Parathion can be rated as readily degradable. The aerobic aquatic metabolism shows that the first half-life of parathion is approximately 2 days in the aquatic phase with an overall half-life of 5.2 days. These results were obtained from water / sediment studies with natural water taken from a ditch and a small lake. The mineralisation to CO_2 was negligible (< 3%) and the amount found in the sediment varied between 13 and 70 %, whilst in one study the amount of unextractable residues increased up to 60%.

***Mobility**: It was shown that parathion is readily absorbed by sediment. Within one day of application approximately 70% of the chemical was absorbed to the sediment with the remainder either degraded or remaining in the aquatic phase. No sorption constant however was determined.*

4.1.3

Air

***Volatilisation**: Parathion is classified as slightly volatile. The vapour pressure of parathion is 1.29 x 10^{-3} Pa at 25°C, whilst the Henry's Law constant is 0.0302 Pa.m^3/mol. Therefore the dimensionless air / water distribution constant is 5.2x10^{-7}. Based on the Henry's Law constant volatilisation of parathion is not expected.*

Photolysis: In a laboratory experiment, parathion had a half-life of about 60 days in the exposed sample and about 1100 days in the dark control at 30°C.

Based on the findings on volatilisation and photolysis in air, parathion is not expected to be found in significant amounts in air.

4.1.4

Bioconcentration

A bioaccumulation study with bluegill sunfish has shown that parathion residues in water are rapidly taken up by fish, extensively metabolised and rapidly excreted, with little potential to bioacumulate. The steady-state bioconcentration factor for whole body tissues was calculated as 430. During the depuration phase, the calculated half-life was 0.76 days for whole body tissues.

4.1.5

Persistence

Based on the DT_{50}-values found in soil (ca. 58 days) and water (5.2 days) parathion is not considered a persistent substance. Therefore, any accumulation in an environmental compartment is not expected (See Sections 4.1.1 and 4.1.2).

4.2

Effects on non-

target organisms

4.2.1		**Mammals:** LD_{50} (rat, oral) = 2.4 mg/kg bw
	Terrestrial vertebrates	**Birds**: LD_{50} (acute, bobwhite quail) = 2.7 mg/kg bw Lowest LC_{50} (dietary, 4 species) = 76 – 336 mg/kg **NOEC (reproductive toxicity, mallard duck) = 2.85 mg/kg bw**
4.2.2		**Fish:**
	Aquatic species	Parathion is acutely highly toxic to fish. LC_{50} (golden orfe, 96h) = 0.58 – 0.69 mg/l. LC_{50} (rainbow trout, 96h) = 1 – 1.5 mg/l. Parathion may be classified for chronic toxicity as highly toxic. NOEC (sheepshead minnow, 28d) = 0.72 µg/l. **Crustaceans**: Parathion is acutely highly toxic to daphnids. EC_{50} (*Daphnia magna*, 48h) = 2.5 µg/l. Parathion may be classified for chronic toxicity as highly toxic to daphnids. NOEC (*Daphnia magna*, 21d) = 0.1 - 0.56 µg/l. **Algae**: Also for algae Parathion is classified acutely as highly toxic. **EC_{50} (*Scenedesmus subspicatus*, 48h) = 0.5 mg/l.**
4.2.3		**Bees:**
	Honeybees and other arthropods	Parathion is classified as highly toxic to bees. **LD_{50} (contact) = 0.066 µg/bee; LD_{50} (oral) = 0.1 µg/bee.**
4.2.4		Parathion may be classified as moderately toxic to earthworms.
	Earthworms	**14-d LC_{50} = 65 mg/kg; 14-d NOEC = 32 mg/kg.**
4.2.5		**Nitrogen mineralisation**:
	Soil microorganisms	No significant effect up to 20 kg a.i. /ha in silty sand and loamy silt soil, up to 2.5 kg a.i. /ha in loamy sand and sandy silt soil **Carbon mineralisation**: **No significant effect up to 20 kg a.i. /ha in silty sand and loamy silt soil, up to 2.5 kg a.i. /ha in loamy sand and sandy silt soil**
4.2.6		
	Terrestrial plants	**No quantitative information available**

5 Environmental Exposure/Risk Evaluation

5.1		**Mammals**
	Terrestrial vertebrates	**Australia:** As the applications are normally made by tractor- powered equipment, accidental direct spraying of larger non-target organisms, such as marsupials, is considered unlikely as it is expected that these animals will move some distance from the area where spray operations are occurring, while smaller mammals will be undercover. Thus they are unlikely to be exposed. **European Community: A** worst-case assessment was first performed and indicated that mammals may be at risk (mammals eating 100% short grass, in the treated area). However, under practical conditions the risk to mammals from the use of parathion as an insecticide in grapes, orchards and field crops appeared to be lower. **Birds**

Australia: For fruit sprayed at 750 g a.i./ha the concentration of parathion residues on the fruit was calculated as 10 mg/kg wet weight. This concentration indicated a low hazard to birds from the toxicity data reviewed (Section 4.2.1).
European Community: The risk evaluation of the use of parathion in the European Community was performed taking into account the intended applications notified for authorisation. Application rates of 0.2 to 0.3 kg a.i./ha were considered in the case of arable land and in vines and orchards. For calculations, the LD_{50} values of 2.4 mg/kg bw for mammals and 2.7 mg/kg bw for birds were used as reference for the acute toxicity.

The Toxicity/Exposure Ratios (TER) were calculated for small, medium-sized and relatively large herbivorous mammals and birds. These TERs must be greater than the trigger value (10) established in the European Community.
For small birds TER-values are 0.6 – 24, for small herbivorous birds TERs are 0.08 – 3.4 and for large herbivorous birds TERs are 0.53 – 22.

5.2 Aquatic species

Australia:
The application of parathion directly to a body of water 15 cm deep at the lowest rate of 0.375 kg a.i./ha was calculated to give a concentration in water of 250 $\mu g.l^{-1}$. As this is above the EC_{50}'s for all aquatic organisms tested, except algae, there is a potential hazard to all other aquatic organisms.

Effects on daphnids and other aquatic insects/invertebrates from direct overspray are likely to be severe, with the concentration in water approximately 65 times the EC_{50} for daphnia from the lowest application rate. While the then prevailing use pattern would not be expected to cause direct overspray, aerial application could. Furthermore, even with precautions, the hazard to aquatic invertebrates and macro-crustacea from spray drift was considered to be unacceptably high. Despite the rapid degradation, chronic effects are possible on sensitive organisms at application rates > 500 g a.i./ha.

European Community:
The risk evaluation of the use of parathion in the European Community was performed taking into account application rates of 0.2 kg a.i./ha for arable land and 0.3 kg a.i./ha for vines and orchards. The exposure levels were calculated using buffer zones of 5 m for arable land and 15 m for vines and orchards . The toxicity data concerning the most sensitive species in each trophic level were used.

The TERs were calculated for fish, daphnids and algae in acute exposure and for fish and daphnids in chronic exposure. For fish and daphnids, these TERs must be greater than the trigger values (100 for acute and 10 for chronic exposure) established in the European Community. The trigger value for algae is 10.

The results of the acute and chronic studies with *Daphnia magna* indicate significant levels of toxicity. The resultant acute TER and long-term TER values are very low, all being less than 100 and less than 10, respectively. The results of the studies assessing the acute toxicity of parathion to fish and to green algae indicate a moderate level of acute toxicity. The resultant acute TER values for the organisms are all greater than 100 and so a low risk can be assigned. However, the results of the studies assessing the chronic toxicity of parathion to fish indicate a somewhat higher level of toxicity (early life stage study). This is confirmed by the long-term TER values, which in the most severe case (orchards application) are less than 10. The results are summarised in the following table.

Application rate (kg a.i./ha)	Crop	Organism	Time-scale	Distance (m)	TER	Trigger values
0.2	Arable crops	Rainbow trout	96 h	5	1450	100
0.3	Vines	Rainbow trout	96 h	15	725	100
0.3	Orchards	Rainbow trout	96 h	15	232	100
0.2	Arable crops	*Daphnia magna*	48 h	5	**6.3**	100
0.3	Vines	*Daphnia magna*	48 h	15	**3.1**	100
0.3	Orchards	*Daphnia magna*	48 h	15	**1**	100
0.2	Arable crops	*Scenedesmus subspicatus*	96 h	5	1250	10
0.3	Vines	*Scenedesmus subspicatus*	96 h	15	625	10
0.3	Orchards	*Scenedesmus subspicatus*	96 h	15	200	10
0.2	Arable crops	Sheepshead minnow	21 d	5	**1.8**	10
0.3	Vines	Sheepshead minnow	21 d	15	**0.9**	10
0.3	Orchards	Sheepshead minnow	21 d	15	**0.3**	10
0.2	Arable crops	*Daphnia magna*	21 d	5	**1.4**	10
0.3	Vines	*Daphnia magna*	21 d	15	**0.7**	10
0.3	Orchards	*Daphnia magna*	21 d	15	**0.2**	10

5.3 Honey bees

Australia: Bees are at risk if spraying occurs when they are present in the crop. Even at the lowest rate, 375 g a.i./ha, the estimated dose (2.25 µg a.i./bee) is significantly above the contact EC_{50} (= 0.131 µg/bee). Spray drift from orchard application is also likely to be toxic to bees.

European Community: Based on the hazard quotient, defined as the ratio of application rate and LD_{50}-value, in the European Community a value less than the trigger value of 50 is considered safe. Hazard quotients established for parathion are > 3000 g ha^{-1}/(µg bee^{-1}). Therefore parathion is considered very dangerous for bees.

5.4 Earthworms

Australia: following an application rate of 750 g a.i./ha, the top 5 cm of soil would contain parathion residues at 1.1 mg/kg of soil (assumes no crop cover, density of soil 1300 kg/m3, direct application). As the concentration of pesticide in the soil due to direct application is significantly below the EC50 for earthworms (65 mg/kg of soil), effects on earthworms from orchard spraying are not expected.

European Community: Based on the normal application rates of parathion resulting in concentrations in the upper soil of 0.13 – 0.2 mg a.i./kg soil are considered not to cause risk to earthworms.

5.5 Soil microorganisms

Normal agricultural use of parathion will not cause effects on the carbon and nitrogen mineralisation cycle in soil.

5.6 Summary – overall risk evaluation

The two notifying parties performed risk assessments for the use of parathion in the conditions prevailing in their countries. The main difference in use pattern was the aerial application of parathion in Australia, which was not intended in the European Community. It should be noted that the risk assessments were performed on the recommended applications rates, which were higher in Australia than in the European Community. Despite these differences in agricultural practices, the two notifying parties reached similar conclusions on the environmental risks.

Australia concluded that there were unacceptable risks to aquatic ecosystems, especially to fish and macro-invertebrates, and to bees.

In the European Community, although there were a number of deficiencies in the data package submitted that prevented a complete evaluation being carried out, it was clear that the data already available indicated:

- for all applications, a high acute risk to birds and bees,
- for all applications (with a 5 or 15 meter buffer zone), a high acute and chronic risk to daphnids, and also a chronic risk for fish.

Annex 2 – Details on final regulatory actions reported

Country Name: Australia

1	**Effective date(s) of entry into force of actions**	From 11 June 1999: registration of parathion cancelled. Use phased-out according to the following schedule: **Whole sale supply:** to cease by 31 December 1999 **Retail sales:** to cease by 30 June 2000 **MRLs:** withdrawn from 30 June 2001
	Reference to the regulatory document	National Registration Authority for Agricultural and Veterinary Chemicals (NRA) Board Resolution 752, Action 99-29, 11 June 1999 The NRA Review of parathion, Volume I, February 2000. NRA Review Series 00.2. National Registration Authority for Agricultural and Veterinary Chemicals.
2	**Succinct details of the final regulatory action(s)**	The active constituent approval, all product registrations and associated label approvals for products containing parathion, were cancelled.
3	**Reasons for action**	Unacceptable occupational health and safety risks, and unacceptable risk for the environment.
4	**Basis for inclusion into Annex III**	Decision followed a review of parathion under Australian National Registration Authority for Agricultural and Veterinary Chemicals' (NRA) Existing Chemical Review Program, which failed to satisfy the NRA that continued use of parathion products, in accordance with the recommendations for its use, would not harm people or the environment.
4.1	**Risk evaluation**	The review concluded that continued use of parathion would pose an unacceptably high risk to workers and wildlife.
4.2	**Criteria used**	Risks to the environment, to occupational health and safety, and to public health.
	Relevance to other States and Region	The action has minimal relevance as parathion is already subject to the PIC procedure.
5	**Alternatives**	The following alternatives were considered at the time of the notification to pose lower risks to workers and the environment. World Health Organisation hazard classifications are provided as an aid to consideration of relative risks. These classifications are for active constituents. Actual hazard depends on formulation. Moderately hazardous: carbaryl, dimethoate, fenthion; Slightly hazardous: fenoxycarb, malathion. It is suggested that if any of these chemicals are to be considered as alternatives, advice should be sought from product manufacturers concerning the suitability for the proposed use and for local conditions.
6	**Waste management**	Phase-out of existing stocks following the regulatory action.
7	**Other**	Australian Classification: Parathion is listed in Australian National Occupational Health and Safety Commission (NOHSC) List of Designated Hazardous substances. It is included in Schedule 7 (Dangerous poisons) of Australia's 'Standard for the Uniform Scheduling of Drugs and Poisons'.

Country Name: European Community

1	**Effective date(s) of entry into force of actions**	The measures laid down by Commission Decision 2001/520/EC of 9/07/2001 had to be put into effect by 08/01/2002 at the latest.
	Reference to the regulatory document	Commission Decision 2001/520/EC of 9/07/2001 concerning the non-inclusion of parathion in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance (Official Journal of the European Community L187 of 10/07/2001, p. 47)
2	**Succinct details of the final regulatory action(s)**	Parathion is not included as an active ingredient in Annex I to Directive 91/414/EEC. It is therefore prohibited to place on the market or to use plant protection products containing parathion. The authorisations for plant protection products containing parathion had to be withdrawn within a period of 6 months from the date of the final regulatory action, *i.e.* 08/01/2002. From that date, no authorisation for plant protection products containing parathion could be granted or renewed.
3	**Reasons for action**	The Decision followed the review of parathion pursuant to Article 8 (2) of the Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. In accordance with that Directive, the Commission initiated a programme of work for the gradual examination of active substances available on the market. Parathion was one of the 90 active substances included in the list of substances covered by the first stage of the work programme. The main notifier submitted a dossier, which was reviewed by the Member States and the Commission within the Standing Committee on Plant Health. This review was finalised on 7 February 2001 in the form of a Commission review report for parathion. From the assessments made, it was concluded that the submitted information had not demonstrated that the safety requirements laid down in Article 5(1)(a) and (b) and 5(2)(b) of Directive 91/414/EEC were met, in particular with regard to operator exposure and non-target organisms.
4	**Basis for inclusion into Annex III**	None of the intended uses were considered to present an acceptable risk as regards operator exposure and the environment.
4.1	**Risk evaluation**	It was concluded that continued use of parathion would pose an unacceptably high risk to human health and the environment.
4.2	**Criteria used**	Exposure/effects ratios for occupational use, public health and the environment.
	Relevance to other States and Region	Of special concern to developing countries due to the high risk associated with spraying of parathion, even when rigorous Good Agricultural Practices (GAP) are employed and protective equipment is used.
5	**Alternatives**	No alternatives are proposed.
6	**Waste management**	Member States were allowed to grant a limited period of grace for disposal, storage, placing on the market and use of existing stocks in accordance with the provisions of Article 4(6) of Directive 91/414/EEC. This period was set at not longer than a maximum of 18 months from the date of adoption of Commission Decision 2001/520/EC of 9/07/2001 (*i.e.* by 8/1/2003).
7	**Other**	

Annex 3 – Addresses of designated national authorities

AUSTRALIA

P

Senior Manager
Agricultural and Veterinary Chemicals
Product Integrity, Plant and Animal Health
Department of Agriculture, Fisheries and Forestry, Australia
GPO Box 858
Canberra Act 2601
Australia
Mr André MAYNE

Phone ***+61 2 6272 5391***
Fax + ***+61 2 6272 5697***
Telex ---
e-mail andre.mayne@affa.gov.au

C
Assistant Secretary
Environment Quality Division
Environment Australia
GPO Box 787
CANBERRA ACT 2601
Mr Peter Burnett

Phone ***+61 2 6274 1841***
Fax ***+61 2 6274 2060***
Telex
e-mail ***peter.burnett@ea.gov.au***

EUROPEAN COMMUNITY

CP
Administrator
European Commission
DG Environment
Rue de la Loi, 200
B-1049, Brussels – Belgium
Mr Klaus BEREND

Phone +322 299 48 60
Fax +322 295 61 17
Telex
e-mail Klaus.Berend@cec.eu.int

C Industrial chemicals
CP Pesticides and industrial chemicals
P Pesticides

Annex 4 – References

Regulatory actions

Australia:

- National Registration Authority for Agricultural and Veterinary Chemicals (NRA) Board Resolution 752, Action 99-29, 11 June 1999.
- The NRA Review of parathion, Volume I, February 2000. NRA Review Series 00.2. National Registration Authority for Agricultural and Veterinary Chemicals. Available at www.apvma.gov.au/chemrev/parathio.shtml
  [Note the NRA is now known as the Australian Pesticides and Veterinary Medicines Authority (APVMA)]

European Communities

- Commission Decision 2001/520/EC of 9/07/2001 concerning the non-inclusion of parathion in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance (Official Journal of the European Community L187 of 10/07/2001, p. 47).
  Available at http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_187/l_18720010710en00470048.pdf

Other Documents

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). Australia

Review report for the active substance parathion – Finalised to support European Commission decision concerning the non-inclusion of parathion as active substance in the Annex I to the Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance. European Commission – Directorate General Health for consumer Protection (2001).

Full Report on Parathion, ECCO Peer Review Meetings, 2000 (*The table of contents of the report and excerpt (page 1 to 48))*

Monograph on the Review of Parathion, European Community (*Volume 1 of the monograph, which contains report and proposed decision)*

Commission Directive 2002/66/EC of 16 July 2002 amending the Annexes to Council Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC as regards the fixing of maximum levels for pesticide residues in and on fruit and vegetables, cereals, foodstuffs of animal origin and certain products of plant origin, including fruit and vegetables respectively (Official Journal of the European Community L 192 of 20/7/2002, p 47). Available at http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_192/l_19220020720en00470053.pdf

FAO/WHO, 1965. Pesticide Residues in Food – 1965 - Evaluation of the toxicity of pesticide residues in food. Joint Meeting of the FAO Committee on Pesticides in Agriculture and the WHO Expert Committee on Pesticide Residues, Rome, 15-22 March 1965. FAO Meeting Report No. PL/1965/10/1 WHO/Food Add./27.65 (available at http://www.inchem.org/documents/jmpr/jmpmono/v065pr34.htm)

FAO/WHO, 1967. Pesticide Residues in Food – 1967 - Evaluations of some pesticide residues in food. The monographs. Joint Meeting of the FAO Working Party of Experts and the WHO Expert Committee on Pesticide Residues, Rome, 4 - 11 December, 1967. (FAO/WHO, 1968). FAO/PL:1967/M/11/1 WHO/Food Add./68.30 (available at http://www.inchem.org/documents/jmpr/jmpmono/v067pr29.htm)

FAO/WHO, 1969. Pesticide Residues in Food – 1969 - Evaluations of some pesticide residues in food. The monographs. Joint Meeting of the FAO Working Party of Experts and the WHO Expert Committee on Pesticide Residues, Rome, 8 - 15 December 1969. (FAO/WHO, 1968). FAO/PL:1969/M/17/1 WHO/FOOD ADD./70.38 (available at http://www.inchem.org/documents/jmpr/jmpmono/v069pr24.htm)

FAO/WHO, 1995. Pesticide Residues in Food – 1995 - Parathion (Pesticide residues in food: 1995 evaluations Part II Toxicological & Environmental)
(available at http://www.inchem.org/documents/jmpr/jmpmono/v95pr13.htm)

International Agency for Research on Cancer (IARC) - Summaries & Evaluations PARATHION. VOL.: 30 (1983) (p. 153) and Subsequent evaluation: Suppl. 7 (1987) (p. 69: Group 3)
(available at http://www.inchem.org/documents/iarc/vol30/parathion.html)

FAO/WHO, 2001. Pesticide Residues in Food - 2000, Report 2000
FAO Plant Production and Protection Paper 163 (Rome 2001) available at
http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Default.htm

CCPR 2002 Report of the Thirty Fourth Session of the Codex Committee on Pesticide Residues May 2002 (Alinorm 03/24) available at ftp://ftp.fao.org/codex/alinorm03/Al03_24e.pdf

PARATHION HEALTH AND SAFETY GUIDE (1992) (IPCS International Programme On Chemical Safety Health and Safety Guide No. 74, available at http://www.inchem.org/documents/hsg/hsg/hsg74.htm)

Tomlin, Clive 2000. The Pesticide Manual: A World Compendium (12th ed.), British Crop Protection Council, United Kingdom

WHO, 2000. Recommended classification of pesticides by hazard and guidelines to classification 2000-01. WHO/PCS/01.5. World Health Organization, IPCS, Geneva**.**

RELEVANT GUIDELINES AND REFERENCE DOCUMENTS

Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal 1996.

FAO, 1990. Guidelines for personal protection when working with pesticides in tropical countries. FAO, Rome.

FAO, 1995. Revised guidelines on good labelling practices for pesticides. FAO, Rome.

FAO, 1995. Guidelines on Prevention of Accumulation of Obsolete Pesticide Stocks. FAO, Rome.

FAO, 1996. Technical guidelines on disposal of bulk quantities of obsolete pesticides in developing countries. FAO, Rome.

FAO, 1996. Pesticide Storage and Stock Control Manual. FAO, Rome.