Rotterdam Convention

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

Draft Decision Guidance Document

Azinphos-methyl

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

Introduction

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

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

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

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

Purpose of the decision guidance document

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

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

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

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

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

Disclaimer

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

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

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

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

STANDARD CORE SET OF ABBREVIATIONS	
<	less than
≤	less than or equal to
<<	much less than
>	greater than
≥	greater than or equal to
µg	microgram
µm	micrometre
ARfD	Acute Reference Dose
a.i.	active ingredient
ADI	Acceptable Daily Intake
b.p.	boiling point
bw	body weight
^{o}C	degree Celsius (centigrade)
CAS	Chemicals Abstract Service
CHO	Chinese Hamster Ovary
cm	centimeter
DMSO	Dimethyl sulfoxide
DT_{50}	50% degradation or dissipation time
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate
EC_{15}	Effective median Concentration, 15%
EC_{50}	Effective median Concentration, 50%
EEC	European Economic Community
EHC	Environmental Health Criteria
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
g	gram
h	hour
ha	hectare
i.m.	intramuscular
IMDG	International Maritime Dangerous Goods code
i.p.	intraperitoneal
IPM	Integrated Pest Management
IARC	International Agency for Research on Cancer
IPCS	International Programme on Chemical Safety
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts

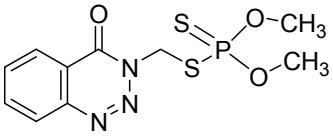
STANDARD CORE SET OF ABBREVIATIONS	
	on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)
k	kilo- (x 1000)
kg	kilogram
Kow	Octanol-water partition coefficient
L	Liter
LC_{50}	Lethal Concentration, 50%
LD_{50}	Lethal Dose, 50%
LOAEL	lowest observed adverse effect level
m	meter
m.p.	melting point
mg	milligram
mL	milliliter
mPa	Millipascal
MRL	Maximum Residue Level
NAIS	Norwegian Agricultural Inspection Service
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
OSPAR	Oslo and Paris Convention
PACR	Proposed Acceptability for Continuing Registration
PEC	Predicted Environmental Concentration
PHED	Pesticide Handler Exposure Database
PIC	Prior Informed Consent
PMRA	Pest Management Regulatory Agency
PPE	Personal Protective Equipment
ppm	parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/L are used).
RfD	Reference Dose for Chronic Oral Exposure (comparable to ADI)
RQ	Risk Quotient
RTECS	Registry of Toxic Effects of Chemical Substances
STCC	Standard Transportation Commodity Code
SBC	The Secretariat of the Basel Convention
TEC	Transport Emergency Card
TER	Toxicity Exposure Ratio
UNEP	United Nations Environment Programme
WHO	World Health Organization

Decision guidance document for a banned or severely restricted chemical

Azinphos-methyl

Published:

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

Common name	Azinphos-methyl
Chemical name and other names or synonyms	IUPAC: *S*-(3,4-dihydro-4-oxobenzo[d]-[1,2,3]-triazin-3-ylmethyl)-*O*,*O*-dimethyl phosphorodithioate CAS: *O*,*O*-dimethyl-*S*-[(4-oxo-1,2,3-benzotriazin-3(4*H*)-yl)methyl]phosphorodithioate
Molecular formula	$C_{10}H_{12}N_3O_3PS_2$
Chemical structure	
CAS-No.(s)	86-50-0
Harmonized System Customs Code	2933 99
Other numbers	EEC Number: 201-676-1 STCC Number: 4921527 Caswell Number: 374 RTECS Number: TE1925000
Category	Pesticide
Regulated category	Pesticide
Use(s) in regulated category	**Canada**: Azinphos-methyl is a broad spectrum organophosphate insecticide, which at the time of the regulatory action, was registered in Canada for use on a wide variety of feed, food and ornamental crops. The feed crops were alfalfa, clover and rye. Registered uses on food crops were apple, crab apple, pear, quince, cherry, peach, apricot, plum, prune, blackberry, boysenberry, loganberry, raspberry, blueberry, cranberry, grape, strawberry, walnut, broccoli, Brussels sprouts, cabbage (including tight heading varieties of Chinese cabbage), cauliflower, cucumber, potato, tomato, melons, pumpkin and turnip/rutabaga. Registered uses on outdoor ornamental crops included nursery plants, forest trees and shade trees. **Norway**: Azinphos-methyl was used as an insecticide on pome fruit, stone fruit, garden blueberries, strawberries, cabbage and ornamentals.
Trade names	Guthion Solupak 50% Wettable Powder Crop Insecticide Sniper 50W Clean Pak Insecticide Azinphos-methyl 240 EC Spray Concentrate Azinphos-methyl 50W Wettable Powder Insecticide Gusathion *This is an indicative list. It is not intended to be exhaustive.*
Formulation types	Dustable powder, emulsifiable concentrate, suspension concentration, wettable powder (Pesticide Manual, 2009).
Uses in other categories	No reported use as an industrial chemical.
Basic manufacturers	Bayer CropScience, Makhteshim-Agan, General Quimica, IPESA *This is an indicative list of current and former manufacturers. It is not intended to be exhaustive.*

2. Reasons for inclusion in the PIC procedure

Azinphos-methyl is included in the PIC procedure as a pesticide. It was listed based on final regulatory actions that severely restricted its use, notified by Canada, and banned its use, notified by Norway.

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

Canada The use of azinphos-methyl and associated end-use products entails an unacceptable risk of harm to the agricultural worker pursuant to Section 20 of the Canadian Pest Control Product (PCP) Regulations. The Pest Management Regulatory Agency (PMRA) has determined that all uses for azinphos-methyl are to be phased out as outlined below:

- Phase out of all uses of azinphos-methyl by the end of December 2005, for which alternatives exist (alfalfa, clover, rye, quince, potatoes, tomatoes, rutabagas, turnips, cabbages, broccoli, Brussels sprouts, cauliflowers, cucumbers, strawberries, boysenberries, loganberries, walnuts, melons, pumpkins, blueberries, outdoor ornamentals, nursery plants, forest trees and shade trees).

- Continued registration for use on apples, crab apples, apricots, blackberries, cherries, cranberries, grapes, pears, peaches, plums, prunes, raspberries (uses that are part of an established IPM programme and uses for which no alternatives exist) until end of December 2012.

Reason Human health

Norway All uses were phased out by 31 December 2005.

Reason Environment (concerns with regard to ecotoxicity and detection of the substance via a national water monitoring programme in surface water at several occasions, despite limited use in the catchment area under restriction of 30 metre buffer).

2.2 Risk evaluation (see Annex 1 for further details)

Canada

Human health

Two key factors are considered when assessing health risks: the dose levels where no health effects occur and the dose levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (*e.g.* children and nursing mothers). Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

Azinphos-methyl is extremely toxic following acute oral and dermal exposures. Azinphos-methyl is moderately toxic via the inhalation route and is a dermal sensitizer.

Acute toxic signs induced by azinphos-methyl are consistent with cholinesterase inhibiting chemicals and include tremors, convulsions, salivation and respiratory distress. Dose-related inhibition of plasma, erythrocyte and brain cholinesterase activity occurs by all exposure.

Occupational risk estimates associated with application, mixing and loading for current label uses exceed the level of concern for most exposure scenarios, even after consideration of maximum feasible engineering controls and personal protective equipment (PPE) and clothing. Therefore, azinphos-methyl in its present use entails an unacceptable risk of harm to agricultural workers.

Norway

Environment

Azinphos-methyl poses a high risk to terrestrial and aquatic organisms. Azinphos-methyl is toxic to non-target arthropods and exposure evaluation did not demonstrate that areas where organisms are exposed by spray drift will be sufficiently recolonized within acceptable periods, which is normally one year.

For earthworms, the estimated chronic Toxicity Exposure Ratio (TER) is below the trigger value, indicating high risks to earthworms, in particular in orchards, where suggested application rates were higher than in most other crops.

Azinphos-methyl is extremely toxic to aquatic organisms. Even with buffer zones of 30 metres TER values for aquatic invertebrates are below the trigger values, indicating high risk to the aquatic environment.

Azinphos-methyl has been detected via the National Water Monitoring Programme in several locations at concentrations up to 0.64 µg/L. When comparing this value to NOEC values from chronic fish test (rainbow trout; 0.18-0.39 µg/L), indoor microcosm (rainbow trout NOEC: 0.64 µg/L) and outdoor microcosm studies (NOEC: 0.32 µg/L), the risk was deemed unacceptable for use under Norwegian conditions.

3. Protective measures that have been applied concerning the chemical

3.1 Regulatory measures to reduce exposure

Canada It is expected that the final regulatory action will reduce the risk of occupational exposure to azinphos-methyl. Until registrations end on December 31, 2012, the registrant must implement a specific product stewardship plan and a number of mitigative measures to:

- Ensure that field workers are provided with double notification (*i.e.* written notice on posted signs and verbal notification to those re-entering a field) that the area has been treated with azinphos-methyl and that azinphos-methyl is a cholinesterase inhibitor. This should include a brief description of the signs and symptoms of cholinesterase inhibition and ways to minimise exposure, and
- Increase the margins of safety for agricultural workers.

Norway The ban of azinphos-methyl will reduce the risk of environmental exposure to azinphos-methyl.

3.2 Other measures to reduce exposure

None reported by the notifying Parties.

3.3 Alternatives

It is essential that before a country considers substituting alternatives, 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.

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

Advice may be available through National IPM focal points, the FAO, IFOAM (International Federation of Organic Movements) and agricultural research or development agencies. Where it has been made available by governments, additional information on alternatives to azinphos-methyl may be found on the Rotterdam Convention website www.pic.int.

Canada Alternatives for azinphos-methyl exist for alfalfa, clover, rye, quince, potatoes, tomatoes, rutabagas, turnips, cabbages, broccoli, Brussels sprouts, cauliflowers, cucumbers, strawberries, boysenberries, loganberries, walnuts, melons, pumpkins, blueberries, outdoor ornamental crops, nursery plants, forest trees and shade trees. However, currently, no efficient alternatives for azinphos-methyl exist for the use on apples, crab apples, apricots, blackberries, cherries, cranberries, grapes, pears, peaches, plums, prunes or raspberries.

Norway At the time of the decision, it was concluded that there were no real alternatives to azinphos-methyl.

However, chemical alternatives are available for some uses: in ornamentals this includes phosalone, dimethoate, esfenvalerate, fenpropathrin, lambda-cyhalothrin and alpha-cypermethrin, along with the nematode *Heterorhabditis megidis*. For pome fruit and stone fruit, alternatives include diflubenzuron, thiacloprid, indoxacarb and phosalone. Chemical alternatives in strawberries include methiocarb, thiacloprid and esfenvalerate. There were no alternatives for azinphos-methyl in blueberries and cabbage.

3.4 Socio-economic effects

Canada Significant challenge for PMRA is a regulatory decision that moves towards the goal of eliminating azinphos-methyl in a manner that is the least disruptive to the need to protect agricultural crops from pests. To meet its challenge, the PMRA has considered the availability of alternatives and the need for a transition period for those uses for which no or limited alternatives are available.

Significant challenge for industry is to develop alternatives in the relatively short time frame of proposed phase-out.

Significant challenge for the agricultural sector is to reduce use during the transition period and be open to using alternatives.

Norway No information available.

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	1b
IARC	Not evaluated
European Union	**Classification of the active substance (including risk phrases) pursuant to Directive 67/548/EEC**: **T+** (Very Toxic); **R26/28** - Very toxic by inhalation and if swallowed **T** (Toxic); **R24** - Toxic in contact with skin **R43** - May cause sensitization by skin contact **N** (Dangerous for the environment); **R50/53** - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment **Classification of the active substance (including risk phrases) pursuant to Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures**: Acute Tox. 2 * - H330 (Fatal if inhaled) Acute Tox. 2 * - H300 (Fatal if swallowed) Acute Tox. 3 * - H311 (Toxic in contact with skin) Skin Sens. 1 - H317 (May cause an allergic skin reaction) Aquatic Acute 1 - H400 (Very toxic to aquatic life) Aquatic Chronic 1 - H410 (Very toxic to aquatic life with long lasting effects)
US EPA	Toxicity Class 1

4.2 Exposure limits

Maximum Residue Levels

CODEX maximum residue levels (MRL) in food (FAO/WHO Food Standards (2010)) are as follows:

Commodity	MRL (mg/kg)
Alfalfa fodder	10
Almond hulls	5
Almonds	0.05
Apple	2
Blueberries	5
Broccoli	1
Cherries	2
Clover hay or fodder	5
Cotton seed	0.2
Cranberry	0.1
Cucumber	0.2
Fruits (except as otherwise listed)	1
Melons, except watermelon	0.2
Nectarine	2
Peach	2
Pear	2
Pecan	0.3
Peppers, Chili (dry)	10
Peppers, Sweet	1
Plums (including prunes)	2
Potato	0.05
Soya bean (dry)	0.05
Sugar cane	0.2
Tomato	1
Vegetables (except as otherwise listed)	0.5
Walnuts	0.3
Watermelon	0.2

http://www.codexalimentarius.net/pestres/data/pesticides/details.html?id=2

Acceptable Daily Intake

The FAO/WHO Joint Meeting on Pesticide Residues (JMPR) set an ADI of 0-0.0025 mg/kg bw (JMPR, 1973).

An additional RfD of 0.03 mg/kg bw has been identified by JMPR (2007).

Canada established an ADI of 0.0015 mg/kg bw/day.

Acute Reference Dose

Canada established an Acute Reference Dose (ARfD) of 0.007 mg/kg bw/day.

An additional ARfD of 0.1 mg/kg bw/day has been identified by JMPR (2007).

4.3 Packaging and labelling	
The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:	
Hazard Class and Packing Group:	United Nations number: 2783 UN Hazard Class: 6.1 Poisonous substance UN Pack Group: II
International Maritime Dangerous Goods (IMDG) Code	Not available
Transport Emergency Card	TEC (R)-61G41b

Further specific guidance on appropriate symbols and label statements for individual pesticides and formulations is available in the FAO Guidelines on Good Labelling Practice for Pesticides.

4.4 First aid

NOTE: The following advice is based on information available from the World Health Organization 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. This information should be in compliance with any national standards that may exist.

Early symptoms of poisoning may include excessive sweating, headache, weakness, giddiness, nausea, vomiting, hypersalivation, stomach pains, blurred vision, slurred speech and muscle twitching. Later there may be convulsions and coma.

First aid procedures:
Inhalation: Fresh air, rest. Artificial respiration if indicated. Refer for medical attention.
Skin: Remove contaminated clothes. Rinse and then wash skin with water and soap. Refer for medical attention.
Eyes: First rinse with plenty of water for several minutes (remove contact lenses if easily possible), then take to a doctor.
Ingestion: Induce vomiting (ONLY IN CONSCIOUS PERSONS!). Refer for medical attention.

International Programme on Chemical Safety (IPCS) (2005). International safety card on azinphos-methyl, available at www.inchem.org/pages/icsc.html.

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* (1999).

In all cases waste should be disposed in accordance with the provisions of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (1996), any guidelines there under (SBC, 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

Introduction

The information presented in the present annex reflects the conclusions of the two notifying Parties, namely Canada and Norway. Where possible, information provided by these two Parties on hazards has been presented together, while the risk assessments, which are specific to the conditions prevailing in the Parties, are presented separately. This information is taken from the documents referenced in the notifications in support of the final regulatory actions severely restricting and banning azinphos-methyl. The notification from Canada was first reported in PIC Circular XXVIII of December 2008 and the notification from Norway in PIC Circular XXX of December 2009.

There have been reviews on azinphos-methyl, published by the Joint FAO/WHO meeting on Pesticide Residues in Food (1991, 2007) and by the EU as a Pesticide monograph (1996). These reviews had been taken into consideration in the final regulatory actions of Canada and Norway and are referenced in the present document. Some conclusions from these reviews have been used in the present document, for example, those relating to risk assessment. These do not differ substantially from the information provided by the notifying Parties.

Annex 1 – Further information on azinphos-methyl

1.	**Physico-Chemical properties**	
1.1	**Identity**	Azinphos-methyl
1.2	**Formula**	$C_{10}H_{12}N_3O_3PS_2$
1.3	**Molecular weight**	317.3
1.4	**Appearance**	Yellowish crystals
1.5	**Melting point**	73°C
1.6	**Vapour pressure**	5 x 10^{-4} mPa (at 20°C) (Pesticide Manual, 2009; EU Pesticide Monograph, 1996) 1.8 x 10^{-4} mPa (PMRA, 2003)
1.7	**Henry's Law Constant**	5.7 x10^{-6} Pa m^3/mol (Pesticide Manual, 2009; calculated) 2.3 x 10^{-3} Pa m^3/mol (2 x 10^{-8} atm m^3/mol) (EU Pesticide Monograph, 1996; PMRA, 2003)
1.8	**Solubility in water**	28 mg/L (at 20°C)
1.9	**Solubility in organic solvents**	Dichloroethane: >250 g/L (at 20°C) Acetone: >250 g/L (at 20°C) Acetonitrile: >250 g/L (at 20°C) Ethyl acetate: >250 g/L (at 20°C) DMSO: >250 g/L (at 20°C) *n*-heptane: 1.2 g/L (at 20°C) xylene: 170 g/L (at 20°C)
1.10	**Decomposition temperature**	200°C
1.11	**Relative Density (g/cm^3)**	1.518 (20°C)
1.12	**log Kow**	2.96 (Pesticide Manual, 2009).

2	**Toxicological properties**	
2.1	**General**	
2.1.1	**Mode of Action**	Azinphos-methyl is a non-systemic broad spectrum organophosphate insecticide and acaricide with contact and stomach action, acting as cholinesterase inhibitor (Pesticide Manual, 2009).
2.1.2	**Symptoms of poisoning**	Acute toxic signs induced by azinphos-methyl are consistent with cholinesterase inhibiting chemicals and include: tremors, convulsions, salivation and respiratory distress. Dose-related inhibition of plasma, erythrocyte and brain cholinesterase activity occurs by all routes and following exposures of various durations (PMRA, 2003).
2.1.3	**Absorption, distribution, excretion and metabolism in mammals**	Azinphos-methyl is rapidly and almost completely absorbed when administered via the oral route (90-100%) (EU Pesticide Monograph, 1996; NAIS, 2002; JMPR, 1991). Azinphos-methyl undergoes enterohepatic recirculation. Metabolism in rats is largely through the action of glutathione-S-tranferase and mixed function oxidases. Phosphorylated metabolites were not present to any significant degree in urine or faeces. There are no major sex- or dose-related differences in the disposition or metabolism of azinphos-methyl. It is excreted mainly via the urine (PMRA, 2003).
2.2	**Toxicology studies**	
2.2.1	**Acute toxicity**	LD_{50} (rat, oral): 4-20 mg/kg bw depending on solvent used. LD_{50} (guinea-pig, oral): 80 mg/kg bw LD_{50} (mouse, oral): 11-20 mg/kg bw LD_{50} (dog, oral): >10 mg/kg bw LC_{50} (rat, inhalation): 0.132 mg/L (4-5 hours exposure).

LC_{50} (rat, inhalation): 0.15 mg/L air (aerosol)

LD_{50} (rat, dermal): 72-250 mg/kg bw depending on solvent used.

(PMRA, 2003; EU Pesticide Monograph, 1996; NAIS, 2002; JMPR, 1991).

Canada Azinphos-methyl is extremely acutely toxic via the oral and dermal routes and moderately toxic via the inhalation route (PMRA, 2003).

However, the R26 Hazard Classification states that it is very toxic by inhalation and this is supported by the rat LC_{50} values.

It is not irritating to the skin or eyes of rabbits. However, azinphos-methyl is a sensitizer in guinea pigs (PMRA, 2003; EU Pesticide Monograph, 1996; NAIS, 2002; JMPR, 1991, 2007).

2.2.2 Short term toxicity

In an inhalation toxicity study, Wistar rats (10/sex/dose) were administered dose rates of 0, 0.195, 1.24 and 4.72 mg/m³ azinphos-methyl in the air for 6 hours a day, 5 days a week for 12 weeks. Body weight gain and erythrocyte cholinesterase activity were decreased at the top dose group and therefore there was a NOAEL of 1.24 mg/m³ (JMPR, 1991).

Rats (strain unknown) were administered 0, 1 or 2 mg/kg bw/day to determine acute neurotoxicity. At a dose of 2 mg/kg bw, significant inhibition of acetylcholinesterase activity in erythrocytes of male rats was observed, but not at 1 mg/kg bw in female rats. The NOAEL was stated to be 2 mg/kg bw on the basis of inhibition of cholinesterase activity in the brain (JMPR, 2007).

In a dermal toxicity study, rabbits (6/sex/dose) were administered 0, 2 or 20 mg/kg bw/day 6 hours a day, 5 days/week for 3 weeks. Erythrocyte activity was decreased by approximately 30% in the top dose group. A no observed adverse effect level (NOAEL) of 20 mg/kg bw/day was identified since the brain cholinesterase activity was not reduced (JMPR, 1991).

Beagle dogs (4/sex/dose) were administered 0, 5, 25, or 125 ppm (0, 0.15, 0.74 and 3.7 mg/kg bw/day, respectively), via the diet, for 52 weeks. Plasma and erythrocyte cholinesterase inhibition occurred in the mid and top dose test groups and brain cholinesterase inhibition in the top dose test group. A NOAEL of 0.15 mg/kg bw/day was identified and used in the Canadian risk evaluation (PMRA, 2003). However, the JMPR document determines the NOAEL at 25 ppm (0.74 mg/kg bw/day) based on reduced weight gain and inhibition of cholinesterase in the brain (JMPR, 1991).

In a randomized double-blind study in human volunteers (7 of each sex) given ascending single oral doses, azinphos-methyl did not induce cholinergic signs or changes in erythrocyte acetylcholinesterase activity at the highest doses tested, up to 1 mg/kg bw in males and 0.75 mg/kg bw in females. JMPR (2007) used this NOAEL of 1 mg/kg bw and a safety factor of 10 to derive an ARfD of 0.1 mg/kg bw.

Eight male volunteers were given a daily oral dose of 0.25 mg/kg bw/day for 28 days without effect on cholinergic signs or erythrocyte acetylcholinesterase activity. This results has been repeated in two further studies with similar doses (0.23-0.29 mg/kg bw/day) taken orally over 30 days (JMPR, 2007). The NOAEL from these studies of 0.29 mg/kg bw/day and a safety factor of 10 was used to establish an ADI of 0.03 mg/kg bw/day (JMPR, 2007).

2.2.3 Genotoxicity (including mutagenicity)

Azinphos-methyl is not regarded as genotoxic (JMPR, 2007).

The overall weight of evidence for a battery of *in vitro* and *in vivo* studies indicates that azinphos-methyl is not genotoxic (PMRA, 2003).

Positive results were obtained in two chromosome aberration tests *in vitro* (CHO cells and human lymphocytes). However, negative results were obtained in other *in vitro* studies and all *in vivo* tests (EU Pesticide Monograph, 1996; NAIS, 2002; JMPR, 1991).

2.2.4 Long term toxicity and carcinogenicity

Wistar rats (60/sex/dose) were administered dietary levels of 0, 0.3, 0.9 or 2.6 mg/kg bw/day (0, 5, 15, 45 ppm) for two years. Brain cholinesterase was reduced in the mid and top dose groups. A NOAEL of 0.9 mg/kg bw/day (15 ppm) was identified from this study (JMPR, 1991).

CD-1 mice (50/sex/dose) were administered dietary levels of 0, 0.9, 3.5 or 7/14 mg/kg bw/day (0, 5, 20 or 40/80 ppm) for two years. Females exhibited a dose related decrease in brain cholinesterase at the mid and top dose groups. A NOAEL of 0.9 mg/kg bw/day was determined (JMPR, 1991).

Effects included a dose dependent inhibition of cholinesterase in plasma, erythrocytes and brain, with other symptoms of cholinergic toxicity such as convulsions, reduced body weight or body weight gain. Assessment of the relative sensitivity of cholinesterase activity reveals no appreciable differences between mice, rats and dogs. Studies of various durations in the rat indicate that the female may be more sensitive than the male. A comparison of the results of sub-chronic and chronic studies demonstrates that duration of dosing has little impact on toxicity. Azinphos-methyl is not considered to be a carcinogen (PMRA, 2003; EU Pesticide Monograph, 1996; NAIS, 2002; JMPR, 1991, 2007).

Azinphos-methyl does not appear to have any carcinogenic potential (JMPR, 2007)

2.2.5 Effects on reproduction

Azinphos-methyl is not toxic to reproduction or development in rats or rabbits. Effects were only observed at doses where maternal toxicity was evident. There was no evidence in the available database to suggest that azinphos-methyl has an adverse effect on the endocrine system in mammals (PMRA, 2003; EU Pesticide Monograph, 1996; NAIS, 2002; JMPR, 1991, 2007).

2.2.6 Neurotoxicity/delayed neurotoxicity, Special studies where available

Delayed neuropathy was not observed in hens following acute exposure (PMRA, 2003; EU Pesticide Monograph, 1996; NAIS, 2002; JMPR, 1991, 2007).

2.2.7 Summary of mammalian toxicity and overall evaluation

Azinphos-methyl is rapidly and almost completely absorbed. It undergoes enterohepatic recirculation. There are no major sex- or dose-related differences in the disposition or metabolism of azinphos-methyl. It is excreted mainly via the urine.

The Canadian notification states that azinphos-methyl is extremely toxic via the oral and dermal routes, and moderately toxic via the inhalation route. However, azinphos-methyl has a Hazard Classification of R26, very toxic by inhalation. It is not irritating to the skin or eyes of rabbits. However, azinphos-methyl is a sensitizer in guinea pigs. Azinphos-methyl is not considered to be genotoxic. Long term effects include a dose dependent inhibition of cholinesterase in plasma, erythrocytes and brain, with other symptoms of cholinergic toxicity such as convulsions, reduced body weight or body weight gain. Azinphos-methyl is not considered to be a carcinogen. Azinphos-methyl is not toxic to reproduction or development in rats or rabbits. Delayed neuropathy was not observed in hens following acute exposure.

3 Human exposure/Risk evaluation

3.1 Food

Canada

The Lowest Observed Adverse Effect Level (LOAEL) was set at 2 mg/kg bw/day based on an acute neurotoxicity study in rats. The uncertainty factor used was 300.
The ARfD was set at 0.007 mg/kg bw/day (PMRA, 2003).

The NOAEL was set at 0.15 mg/kg bw/day based on a 52 week dog study. The uncertainty factors used were 100.
The ADI was set at 0.0015 mg/kg bw/day

An additional ADI of 0.03 mg/kg bw based on human volunteer studies has been identified by JMPR (2007).

Acute:
The acute dietary risk from foods treated with azinphos-methyl was not a concern for the general Canadian population and all population subgroups. The assessment has been conducted using market basket survey, monitoring, and residue data, as well as Maximum Residue Levels (MRLs). Data assuming a percentage treatment of a crop with azinphos-methyl were used for domestic and imported crops, and processing factors were used where relevant. At the 99.9th percentile of exposure, the most highly exposed population subgroup, which was 1-6 years old children, consumed 65% of the ARfD in their food. All other subpopulations had potential daily intakes less than 48% of the ARfD (PMRA, 2003).

Chronic:
Chronic dietary exposure from foods treated with azinphos-methyl is not a concern for the general Canadian population and all population subgroups including children and infants (*i.e.* less than 100% of the ADI is consumed). The most highly exposed population subgroup, which was 1-6 years old children, consumed 88% of the ADI in their food (PMRA, 2003).

3.2 Air

No data available.

3.3 Water

Canada

Drinking Water Level of Comparison (DWLOC, i.e. the maximum concentration in drinking water which, when considered together with dietary exposure, does not exceed a level of concern, based on the respective reference dose) range from 35-40 µg/L for 1-6 years old children and for infants who are <1 year old, and from 180-400 µg/L for all other subpopulations. The 95th percentile of the maximum concentrations of azinphos-methyl detected in ground water and surface water are less than the DWLOCs (PMRA, 2003).

For chronic risk, the calculated DWLOCs range from 2.7-59 µg/L, the most sensitive population subgroup being 1-6 years old children. Chronic concentrations estimated from surface water monitoring were estimated at 0.3 µg/L, thus, chronic aggregate risk is not of concern when considering surface water. Ground water monitoring data are limited. The average concentration in the most highly exposed well was less than 2 µg/L (PMRA, 2003).

3.4 Occupational exposure

Canada

Workers short and intermediate term dermal and inhalation exposure was estimated using the Pesticide Handlers' Exposure Database (PHED 1.1). PHED is a database of generic mixer/loader/applicator passive dosimetry data, which facilitates the generation of scenario specific estimates. The estimates were based on the best data available at the time.

Occupational risk assessments associated with application, mixing and loading for current label uses exceeded the level of concern for most exposure scenarios, even after consideration of maximum feasible engineering controls and personal protective equipment and clothing (PMRA, 2003). Following this assessment new occupational exposure data was received. However, review of this data did not result in significant changes to the occupational risk assessment and risks still exceeded the level of concern (PMRA, 2007).

Post-application activities include pruning, thinning, propping, harvesting and any other activities involving contact with foliage following pesticide application. The post-application risks to re-entry workers greatly exceed the level of concern based on current re-entry intervals and label use pattern. Documented incident data on reported cases of azinphos-methyl exposure from re-entering treated fields support occupational exposure and risk estimates.

3.5 Medical data contributing to regulatory decision

The JMPR (2007) reported regular examination of workers involved in formulating products containing azinphos-methyl had revealed no effects, except for one case of possible dermatosis resulting in sensitive dry skin.

Canada

No cases of health effects were observed in male and female workers subjected to regular medical monitoring and employed in formulating azinphos-methyl. In one case, handling of azinphos-methyl possibly led to exacerbation of existing dry skin (PMRA, 2003).

Published reports from the pesticide incident monitoring system in the US indicate that 5-12 incidents per year have been associated with azinphos-methyl. Workers experienced headaches, nausea, weakness and vomiting upon entering the field to pick peaches 3 days after crop treatment (PMRA, 2003).

3.6 Public exposure

No data available.

3.7 Summary-overall risk evaluation

Canada

Occupational risk estimates associated with application, mixing and loading for current label uses exceeded the level of concern for most exposure scenarios, even after consideration of maximum feasible engineering controls and personal protective equipment (PPE) and clothing (PMRA, 2003).

4 Environmental fate and effects

4.1 Fate

4.1.1 Soil

Available data indicate that azinphos-methyl is slightly to moderately persistent in soil (DT_{50}: 27-66 days) under field conditions. On soil, the phototransformation of azinphos-methyl is slow (half life = 180 days). Azinphos-methyl has low volatility from moist soil, evidenced by its vapour pressure (1.8×10^{-4} mPa) and Henry's Law constant (2.3×10^{-3} Pa m^3/mol). Although, based on its chemical properties, it has a low potential for leaching in soil, azinphos-methyl has been detected in both water and eroded soil in surface runoff (0.18 - 3.5% of the amount applied) (PMRA, 2003).

4.1.2 Water

Available data indicate that under acidic (pH 4) and neutral (pH 7) conditions, hydrolysis is not a major route in the transformation of azinphos-methyl (half lives of 38 and 37 days, respectively). Under basic conditions (pH 9) hydrolysis is a major route of transformation (half life = 6.9 days). Similarly, phototransformation in water is a route of transformation for azinphos-methyl (half-life = 3.2 days) (PMRA, 2003).

Azinphos-methyl has been found in creeks and rivers in Norway on several occasions (Ludvigsen and Lunde, 2002).

Fish kills in USA and Canada have been associated with azinphos-methyl in water at concentrations of 0.30-18.6 µg/L (PMRA, 2003).

4.1.3 Air

No data are available.

4.1.4 Bioconcentration

Azinphos-methyl has a potential for bioaccumulation as its octanol-water partition coefficient, Log Kow is 2.96 (PMRA, 2003).

Soil adsorption distribution coefficient of a substance between the dissolved and solid phase (Kd): 4.0-28.5 L/kg (EU Pesticide Monograph, 1996; NAIS, 2002).

4.1.5 Persistence

The half-lives of azinphos-methyl in water (7-38 days) and soil (27-66 days) do not meet the criteria of the Canadian Toxic Substances Management Policy Track-1 cut-off criteria for water (≥ 182 days) and soil (≥ 182 days). Therefore it does not meet the criteria for persistence (PMRA, 2003).

4.2 Effects on non-target organisms

4.2.1 Terrestrial vertebrates

Azinphos-methyl has a high acute toxicity to birds: LD_{50} 8.5-136 mg/kg bw (study duration unknown) (EU pesticide monograph, 1996; NAIS, 2002; PMRA, 2003).

4.2.2 Aquatic species

Azinphos-methyl is toxic to fish:

Rainbow trout (*Oncorhynchus mykiss*): 96 hour LC_{50} = 3 µg/L, NOEC: 0.18-0.39 µg/L (EU Pesticide Monograph, 1996; NAIS, 2002).

Bluegill sunfish (*Lepomis macrochirus*) estimated EC_{50} = 0.20 µg/L based on mortality (PMRA, 2003).

Azinphos methyl is extremely toxic to aquatic invertebrates (*Daphnia magna*): 48 hour EC_{50}: 1.1 µg/L, NOEC: 0.25 µg/L (EU Pesticide Monograph, 1996; NAIS, 2002).

Green algae (*Scenedesmus subspicatus*) 96 hour EC_{50}: 3.61 mg/L, NOEC: 0.25 µg/L.

Midge (*Chironomus riparius)* EC_{15}: 0.3 µg/L. (EU Pesticide Monograph, 1996; NAIS, 2002).

Midge (*Chironomus riparius*) 28 days EC_{50}: 0.55 µg/L (EU Pesticide Monograph, 1996; NAIS, 2002).

Outdoor microcosm NOEC: 0.32 µg/L (EU Pesticide Monograph, 1996; NAIS, 2002).

4.2.3 Honeybees and other arthropods

Azinphos-methyl is extremely toxic to honeybees: oral and contact LD_{50}: 0.1 µg/bee and 0.06-0.42 µg/bee (EU Pesticide Monograph, 1996; NAIS, 2002; PMRA, 2003).

Azinphos-methyl is harmful to non target arthropods like parasitoids, predatory mites, ladybirds, lacewings, hoverflies and beetles (EU Pesticide Monograph, 1996; NAIS, 2002).

4.2.4 Earthworms

Azinphos-methyl is toxic to earthworms: 14 day acute LC_{50}: 59 mg/kg soil (EU Pesticide Monograph, 1996; NAIS, 2002).
The NOEC for earthworms from a reproduction test <0.5 kg a.i./ha (EU Pesticide Monograph, 1996).

4.2.5 Soil microorganisms

No effects on soil microorganisms up to 8 kg a.i./ha were detected, in terms of nitrogen and carbon mineralization (EU List of endpoints, 2004; EU Pesticide Monograph, 1996; NAIS, 2002).

4.2.6 Terrestrial plants

No data available.

5 Environmental Exposure/Risk Evaluation

5.1 Terrestrial vertebrates

Norway

The Toxicity Exposure Ratio (TER) is a ratio of the toxicity, as measured by LD_{50} or no effect values of sensitive organisms, and the predicted exposure to the substance. TER values are compared with trigger values, which reflect the margin of precaution. Risks are considered acceptable if the TER value is above the respective trigger value.

Azinphos-methyl poses a high risk to terrestrial organisms according to the assessment summarized in Table 1 below.

Table 1 Critical TER (Toxicity Exposure Ratio) values for sensitive terrestrial organisms (EU List of endpoints, 2004)

Application rate (kg a.i./ha)	Crop/Time scale	Species	TER value	Trigger value
0.12	Potatoes/acute	Small insectivorous bird	1.3	10
0.12	Potatoes/long-term (reproduction)	Small insectivorous bird	0.5	5
0.12	Potatoes/acute	Medium herbivorous mammal	0.95	10
0.12	Potatoes/long-term	Medium herbivorous mammal	0.22	5
0.12	Potatoes/acute	Yellow wagtail	3.95	10
0.7	Arable crops/long-term	Medium grazing mammal (hare) estimated half-life on plants 3 d, 25% food from treated area	2.9	5

5.2 Aquatic species

General

Toxicity exposure ratios for the most sensitive aquatic species also indicate a risk for fish, *Daphnia* and other invertebrates (Table 2; EU List of endpoints, 2004).

Table 2 Critical TER (Toxicity Exposure Ratio) values for aquatic organisms (EU List of endpoints, 2004)

Application rate (kg a.i./ha)/Distance	Crop/Time scale	Species	TER value	Trigger value
0.5/50	Potatoes/acute	*O. mykiss*	30	100
0.75/50	Apples/acute		5.5	100
0.5/50	Potatoes/acute	*O. mykiss*	6.4	10
0.75/50	Apple/21 d NOEC	*O. mykiss*	1.2	10
0.12/50	Potatoes/acute	*D. magna*	46	100
0.5/50	Potatoes/acute	*D. magna*	11	100
0.75/50	Apples/acute	*D. magna*	2.0	100
0.5/50	Potatoes/NOEC community	Invertebrates	3.2	5
0.75/50	Apples/NOEC community	Invertebrates	0.6	5

Norway
Azinphos-methyl was detected on 5 occasions in rivers and streams and on one occasion in ditches. Azinphos-methyl has been detected at a maximum concentration of 0.64 µg/L (in 1998) and as recently as 2002 at a concentration of 0.55 µg/L.

The following endpoints were found in ecotoxicological studies:
NOECs for fish (rainbow trout) range from 0.18-0.39 µg/L.
NOEC for invertebrates (*Daphnia magna*) is established at 0.25 µg/L.
EC_{15} for *Chironomus riparius* is established at 0.3 µg/L.
NOEC of 0.32 µg/L was established in an outdoor microcosm study.

Using the calculation method used at the time of the evaluation, a maximum predicted environmental concentration (PEC) of 1.53 µg/L in surface water was calculated, taking into account a 30 metres buffer zone. This was based on the application rate for apple fruit moths. This value was then compared to the NOEC of 0.32 µg/L established from a microcosm study. The TER based on these two data is 0.2, which is less than the trigger value of 10 and therefore indicating an unacceptable risk for aquatic organisms.

This conclusion was also supported by actual measured concentrations in Norway that were twice as high as the acceptable concentration for the protection of aquatic species (EU Pesticide Monograph, 1996; Ludvigsen and Lunde, 2002).

Canada
In Canada, estimated environmental exposure data were obtained for a number of different rates and numbers of applications and compared with the most sensitive ecotoxicological endpoints for aquatic organisms to give a Risk Quotient (RQ). The RQs for fish and aquatic invertebrates were 1188-118437 and classified as extremely high risk and 2-174 for freshwater amphibians which indicated a moderate to very high risk. These assessments were confirmed for fish at the ecosystem level, when measured in a mesocosm (PMRA, 2003).

In incident reports from USA and Canada; azinphos-methyl was detected at substantial distances from the target area (drifts up to 914 m) following aerial application; fish kills were associated with azinphos-methyl in water at concentrations of 0.30-18.6 µg/L; indirect kills in birds were due to feeding on dead or dying fish that were exposed to azinphos-methyl; azinphos-methyl was detected in bird tissue (PMRA, 2003).

5.3 Honey bees and other arthropods

Norway
A risk assessment based on laboratory tests and application rates of 1.5 kg a.i./ha on tree fruit gave Hazard Quotients of 15000 by both the contact and oral route. Being far above the Annex VI Trigger of 50, this indicates a high risk to bees via oral and contact routes (EU List of endpoints, 2004; EU Pesticide Monograph, 1996).

5.4 Earthworms

Norway
A high long-term risk to earthworms based on adverse effects on reproduction was identified when comparing the toxicity value (NOEC from a reproduction test) with the exposure value (calculated soil PEC value). The TER did not meet the trigger value in particular in orchards, where higher application rates were suggested. (EU Pesticide Monograph, 1996; EU List of endpoints, 2004).

5.5 Soil microorganisms

No effect on soil microorganisms (EU Pesticide Monograph, 1996).

5.6 Summary – overall risk evaluation

Norway
Azinphos-methyl poses a high risk to terrestrial and aquatic organisms. TER values are below the trigger value for birds, mammals, fish, *Daphnia* and other aquatic invertebrates. Even a 30-50 metres buffer zone to surface water is not sufficient to protect the aquatic environment. By repeated use of azinphos-methyl it is possible that some populations of invertebrates are knocked out for a longer period. It is toxic to bees, earthworms and to non-target arthropods and exposure evaluation shows that areas where organisms are exposed by spray drift will not be recolonized. (EU Pesticide Monograph, 1996; EU List of endpoints, 2004).

Azinphos-methyl has been detected in the Norwegian National Water Monitoring Program at levels which are deemed unacceptable for use under Norwegian conditions (NAIS, 2002).

Annex 2 – Details on final regulatory actions reported

Country Name: Canada

1	**Effective date(s) of entry into force of actions**	All uses were banned as from 1 January 2006, except uses on apples, crab apples, apricots, blackberries, cherries, cranberries, grapes, pears, peaches, plums, prunes, raspberries.
	Reference to the regulatory document	Proposed acceptability for continuing registration (PACR 2003-07), Pest Management Regulatory Agency (PMRA) Re-evaluation of Azinphos-methyl, March 31, 2003. Re-evaluation Decision Document (RRD 2004-5) Azinphos-methyl, 29 March 2004. Re-evaluation Note, REV2006-04, Update on Re-evaluation of Azinphos-methyl, 13 April 2006. Re-evaluation Note, REV2007-08, Update on Re-evaluation of Azinphos-methyl, 17 July 2007. PMRA Website, Re-evaluation summary table (http://www.pmra-arla.gc.ca/).
2	**Succinct details of the final regulatory action(s)**	The use of azinphos-methyl and associated end-use products entails an unacceptable risk of harm to the agricultural worker pursuant to Section 20 of the Canadian Pest Control Product Regulations. The Pest Management Regulatory Agency has determined that all uses for azinphos-methyl are to be phased out.
3	**Reasons for action**	Two key factors are considered when assessing health risks: the dose levels where no health effects occur and the dose levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (*e.g.* children and nursing mothers). Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration. Occupational risk estimates associated with application, mixing and loading for current label uses exceeded the level of concern for most exposure scenarios, even after consideration of maximum feasible engineering controls and personal protective equipment (PPE) and clothing. Therefore, this entails an unacceptable risk of harm to the agricultural worker.
4	**Basis for inclusion into Annex III**	Final regulatory action that severely restricts the use of azinphos-methyl, based on a risk evaluation.
4.1	**Risk evaluation**	The review of uses of plant protection products containing azinphos-methyl concluded that there was unacceptable risk to workers.
4.2	**Criteria used**	Risks to workers.
	Relevance to other States and Region	Conditions of occupational exposure are likely to occur in other regions; therefore, these measures will mitigate the associated risks.
5	**Alternatives**	No efficient alternatives for azinphos-methyl for the use on apples, crab apples, apricots, blackberries, cherries, cranberries, grapes, pears, peaches, plums, prunes or raspberries existed at the time of notification.
6	**Waste management**	Production limits have been put in place to minimize potential disposal issues resulting from phase out of azinphos-methyl.
7	**Other**	None

Country Name: Norway		
1	**Effective date(s) of entry into force of actions**	22 October 2002
	Reference to the regulatory document	Decision by the Norwegian Agricultural Inspection Service 22 October, 2002 (200200430 IP/hmo)
2	**Succinct details of the final regulatory action(s)**	Phase out of all uses by 31 December, 2005.
3	**Reasons for action**	Azinphos-methyl poses high risk to terrestrial and aquatic organisms. Azinphos-methyl is toxic to non-target arthropods and exposure evaluation show that areas where organisms are exposed by spray drift will not be recolonized. For earthworms, the estimated chronic Toxicity Exposure Ratio (TER) is below the trigger value, indicating a high risk to earthworms (for all uses except fruit trees). Azinphos-methyl is extremely toxic to several aquatic organisms. TER values for invertebrates are below the trigger values (even with buffer zones of 30 metres) indicating high risk to the aquatic environment. Azinphos-methyl has been detected in the national water monitoring programme at several locations at concentrations up to 0.64 µg/L. When comparing this value to NOEC values from chronic fish test (0.18-0.39 µg/L), indoor microcosm (rainbow trout NOEC: 0.64 µg/L) and outdoor microcosm studies (NOEC: 0.32 µg/L), the risk was deemed unacceptable for use under Norwegian conditions.
4	**Basis for inclusion into Annex III**	Final regulatory action that bans the use of azinphos-methyl, based on a risk evaluation.
4.1	**Risk evaluation**	The review of uses of plant protection products containing azinphos-methyl concluded that there was unacceptable risk to the environment.
4.2	**Criteria used**	Risks to the environment.
	Relevance to other states and region	Conditions of environmental exposure (contamination of surface water and exposure of aquatic organisms) are likely to occur in other states and regions. Azinphos-methyl is included in the OSPAR list of priority substances agreed by the Third North Sea Conference (Annex 1A to the Hague Declaration).
5	**Alternatives**	At the time of the decision, it was concluded that there were no real alternatives to azinphos-methyl. Chemical alternatives in ornamentals include phosalone, dimethoate, esfenvalerate, fenpropathrin, lambda-cyhalothrin and alpha-cypermethrin, along with the nematode, *Heterorhabditis megidis*. For pome fruit and stone fruit alternatives include diflubenzuron, thiacloprid, indoxacarb and phosalone. Chemical alternatives in strawberries include methiocarb, thiacloprid and esfenvalerate. There were no alternatives for azinphos-methyl in blueberries and cabbage.
6	**Waste management**	No specific measures outlined.
7	**Other**	None

Annex 3 – Addresses of designated national authorities	
CANADA **P**	
Pest Management Regulatory Agency, Health Canada 2720 Riverside Drive Ottawa, Ontario K1A 0K9 Canada *Trish MacQuarrie* *Director General, Policy, Communication and Regulatory Affairs Directorate*	**Phone** +1 613 736 3660 **Fax** + 1 613 736 3659 **Email** trish_macquarie@hc-sc.gc.ca
NORWAY **P**	
Norwegian Food Safety Authority Regional Office for Oslo, Akershus and Ostfold National Registration Section Felles postmottak P.O.Box 383 N-2381 Brumunddal Norway *Marit Randall* *Senior Executive Officer*	**Phone** + 47 64 94 43 63 **Fax** + 47 64 94 44 10 **Email** marit.randall@mattilsynet.no

C Industrial chemicals
CP Pesticides and industrial chemicals
P Pesticides

Annex 4 – References

Regulatory actions

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