UNITED NATIONS

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

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Chemical Review Committee
Sixth meeting
Geneva, 15–19 March 2010
Item 5 (b) (ii) of the provisional agenda*

Listing of chemicals in Annex III to the Rotterdam Convention: review of notifications of final regulatory actions to ban or severely restrict a chemical: azinphos-methyl

Azinphos-methyl

Note by the Secretariat

1. Under Article 5 of the Rotterdam Convention, when the Secretariat has received at least one notification from each of two prior informed consent (PIC) regions containing the information required in Annex I to the Convention, it shall forward the notifications and accompanying documentation to the members of the Chemical Review Committee. The Committee shall review the documentation provided in such notifications and, in accordance with the criteria set out in Annex II to the Convention, recommend to the Conference of the Parties whether the chemical in question should be included in Annex III to the Convention and whether a decision guidance document should be drafted.

2. At its fifth meeting, the Committee reviewed two notifications of final regulatory action related to azinphos-methyl from two PIC regions: North America (Canada) and Asia (Thailand). It concluded that the notification from Canada met the requirements set forth in Annexes I and II to the Convention. The rationale for the Committee's conclusion may be found in document UNEP/FAO/RC/CRC.6/6/Add.1.

3. The Secretariat has since received another notification relating to the use of azinphos-methyl as a pesticide that meets the information requirements of Annex I from another PIC region: Europe (Norway). A summary of this notification was included in PIC Circular XXX of December 2009. The notifications, as received from the notifying countries, are set out in the annex to the present note.

4. The supporting documentation provided by Canada in support of its final regulatory action on azinphos-methyl was circulated for consideration at the Committee's fifth meeting in document UNEP/FAO/RC/CRC.5/4/Add.1. The supporting documentation provided by Norway is set out in document UNEP/FAO/RC/CRC.6/6/Add.2.

5. A list of other notifications for azinphos-methyl previously considered by the Committee is set out in document UNEP/FAO/RC/CRC.6/INF/4.

* UNEP/FAO/RC/CRC.6/1.

K0953654 211209

Annex

Notification of final regulatory action on azinphos-methyl by Canada

Notification of final regulatory action on azinphos-methyl by Norway

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

UNEP

FORM FOR NOTIFICATION OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

IMPORTANT: See instructions before filling in the form

COUNTRY: CANADA

PART I: PROPERTIES, IDENTIFICATION AND USES

1.	**IDENTITY OF CHEMICAL**	
1.1	**Common name**	Azinphos-methyl
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	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(4H)-YL)METHYL] PHOPHORODITHIOATE
1.3	**Trade names and names of preparations**	Guthion Solupak 50% Wettable Powder Crop Insecticide, Sniper 50W Clean Pak Insecticide, Azinphos-methyl 240 EC Spray Concentrate, and Azinphos-methyl 50W Wettable Powder Insecticide.
1.4	**Code numbers**	
1.4.1	**CAS number**	86-50-0
1.4.2	**Harmonized System customs code**	
1.4.3	**Other numbers (specify the numbering system)**	EEC No. 201-676-1, STCC Number 4921527, Caswell Number 374, RTECS Number TE1925000

1.5	**Indication regarding previous notification on this chemical, if any**
1.5.1	X☐ This is a first time notification of final regulatory action on this chemical.
1.5.2	☐ This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____ ☐ This notification replaces all previously submitted notifications on this chemical.

PLEASE RETURN THE COMPLETED FORM TO:

Secretariat for the Rotterdam Convention
Plant Protection Service
Plant Production and Protection Division, FAO
Viale delle Terme di Caracalla
00100 Rome, Italy

Tel: (+39 06) 5705 3441
Fax: (+39 06) 5705 6347
E-mail: pic@fao.org

OR

Secretariat for the Rotterdam Convention
UNEP Chemicals

11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland

Tel: (+41 22) 917 8183
Fax: (+41 22) 797 3460
E-mail: pic@unep.ch

	Date of issue of the previous notification: _____

1.6 Information on hazard classification where the chemical is subject to classification requirements	
International classification systems	**Hazard class**
UN/NA Number 2783	
WHO toxicity class (active ingredient)	1b
EPA (formulation)	I
EC risk	T+ (R24, R28)
Other classification systems	**Hazard class**
Development codes Bayer 17 147	
R 1582; E1582	
Official Codes ENT 23 233	
OMS 186	
Source: The Pesticide Manual, Eleventh Edition, 1997.	

1.7	Use or uses of the chemical
1.7.1	X☐ **Pesticide**
	Describe the uses of the chemical as a pesticide in your country:
	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 ornamental crops included nursery plants, forest trees and shade trees. Source: - Proposed Acceptability for Continuing Registration (PACR 2003-07), Pest Management Regulatory Agency (PMRA) Re-evaluation of Azinphos-methyl, March 31, 2003.
1.7.2	☐ **Industrial**
	Describe the industrial uses of the chemical in your country:

1.8	**Properties**
1.8.1	**Description of physico-chemical properties of the chemical**

Molecular Weight:	317.3
Molecular Formula	$C_{10}H_{12}N_3O_3PS_2$
Melting Point:	73°C
Specific Gravity/Density:	1.518 at 21°C
Water Solubility:	28 mg/L (20°C)
Solubility in Other Liquids:	in dichloroethan, acetone, acetonitrile, ethyl acetate, dimethyl sulfoxide >250, n-heptane 1.2, xylene 170 (all in g/L, 20°C)
Vapour Pressure	5 x 10^{-4} mPa (20°C)
Kow log P	2.96

Source:
- The Pesticide Manual, Eleventh Edition, 1997.

1.8.2	**Description of toxicological properties of the chemical**

In laboratory animals, azinphos-methyl was found to be extremely toxic following acute oral and dermal exposures. Azinphos-methyl was moderately toxic via the inhalation route and was a dermal sensitizer. With oral exposure, azinphos-methyl was readily absorbed and rapidly eliminated with little tissue retention. The metabolism in rats proceeds largely through the action of glutathione-S-transferase and mixed function oxidases. Phosphorylated metabolites were not present to any significant degree in urine or feces. There was no major sex or dose-related differences in the disposition or metabolism of azinphos-methyl.

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. With short- and long-term dosing, reduced body weight gain is also observed. Assessment of the relative sensitivity of cholinesterase activity reveals no appreciable differences between mice, rats and dogs. Studies of various durations in rat indicate that the female may be more sensitive than the male. A comparison of the results of subchronic and chronic studies demonstrates that duration of dosing has little impact on toxicity. Although frank neurobehavioral observations are associated with azinphos-methyl, there was no evidence of histopathological effects on the central nervous system in any of the available studies. Azinphos-methyl did not cause any apparent delayed neurotoxicity in hens following acute exposure.

Azinphos-methyl demonstrated no evidence of tumorigenicity in rats or mice following chronic dosing. The overall weight of evidence from a battery of in vitro and in vivo studies indicates that azinphos-methyl is not genotoxic.

The developmental toxicity studies in rats and rabbits showed no evidence of teratogenic effects and no additional sensitivity of the fetus following in utero exposure to azinphos-methyl; maternal no observed adverse effect levels (NOAELs) are lower than NOAELs in the offspring. Azinphos-methyl did not cause reproductive toxicity in rats other than reduced viability of the young at doses that were maternally toxic. Thus, the overall evidence from the developmental and reproductive toxicity studies indicates that there is no increased sensitivity of the young to azinphos-methyl relative to adult animals. There was no evidence in the available database to suggest that azinphos-methyl has an adverse effect on the endocrine system in mammals.

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.

Acute oral LD_{50} for rats c. 9, male guinea Pigs 80, mice 11-20, dogs >10 mg/kg.
Skin and eye acute percutaneous LD_{50} for rats 150-200 mg/kg (24 h).
Not a skin irritant, mild eye irritant (rabbits).
Inhalation LC_{50} (4 h) for rats 0.15 mg/L air (aerosol).
NOEL (2 y) for rats and mice 5 mg/kg diet for (1 y) for dogs 5 mg/kg diet.

Acute Reference Dose: 0.007 mg/kg bw
ADI : 0.0015 mg/kg bw/day

Source:
- Proposed Acceptability for Continuing Registration (PACR 2003-07), Pest Management Regulatory Agency (PMRA) Re-evaluation of Azinphos-methyl, March 31, 2003.
- The Pesticide Manual, Eleventh Edition, 1997.

1.8.3 Description of ecotoxicological properties of the chemical

The PMRA currently conducts a deterministic assessment of the environmental risk of pest control products. Environmental risk is characterized using the quotient method, which uses the ratio of the estimated environmental concentrations to the effects end point of concern. Quotient values less than one are considered indicative of a low hazard to non-target organisms, whereas values greater than one are considered to indicate that some degree of hazard exists for effects on non-target organisms.

Available data indicated that azinphos-methyl is expected to be slightly persistent to moderately persistent in soil (DT_{50} = 27–66 days) under terrestrial field conditions. On soil, the phototransformation of azinphos-methyl is slow (half-life = 180 days). Azinphos-methyl has low volatility from moist soil evident by its vapour pressure (1.8×10^{-4} Pa) and Henry's Law Constant (2.0×10^{-8} atm 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). Azinphos-methyl has a potential for bioaccumulation as its octanol-water partition coefficient, log Kow was 2.96.

The fate of azinphos-methyl in aquatic systems was not fully characterized due to an absence of data on aerobic and anaerobic aquatic biotransformation. Available data, however, indicated 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). By contrast, under basic conditions (pH 9), hydrolysis is a 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).

Toxicity studies indicated that azinphos-methyl was acutely toxic to a wide range of non-target organisms including birds (LD_{50} = 32–136 mg ai/kg bw), mammals (LD_{50} = 7.8–48 mg ai/kg bw), honeybees (LD_{50} = 0.15, 0.06–0.42 μg ai/bee), fish (LC_{50} = 0.36–4810 μg ai/L), aquatic invertebrates (EC_{50} = 0.16–4800 μg ai/L) and amphibians (LC_{50} = 109–3200 μg ai/L).

Azinphos-methyl poses a high risk to terrestrial organisms. In birds and mammals, there is a high risk through consumption of azinphos-methyl-contaminated food sources. In orchards, there is a high risk, since it was shown that the application of azinphos-methyl in apple orchards was responsible for 12–52% of the mortalities in birds and mammals. There is also the concern of secondary toxicity, as azinphos-methyl was responsible for kills in birds due to feeding on dead or dying fish that were exposed (azinphos-methyl was detected in bird tissue). In addition, there is the concern that azinphos-methyl poses a high risk to terrestrial invertebrates through spray deposit.

Azinphos-methyl poses an even greater risk to aquatic organisms. In fish and aquatic invertebrates, the risk is extremely high and in amphibians, the risk is very high. These risks were verified by incident reports in which fish kills in receiving waters were associated with azinphos-methyl. In Canada, azinphos-methyl has been implicated in fish kills in Prince Edward Island where heavy rainstorms washed soil from nearby treated fields. In orchards, there is a similar risk as azinphos-methyl was detected at concentrations within the range of LC_{50}s for fish in nearby streams during periods of application. Given these reports of fish kills, the PMRA has significant concerns with the surface runoff of azinphos-methyl from treated fields.

Source:
- Proposed Acceptability for Continuing Registration (PACR 2003-07), Pest Management Regulatory Agency (PMRA) Re-evaluation of Azinphos-methyl, March 31, 2003.

PART II: FINAL REGULATORY ACTION

2.	**FINAL REGULATORY ACTION**			
2.1	**The chemical is:**	❑ **banned**	**OR**	X❑ **severely restricted**
2.2	**Information specific to the final regulatory action**			
2.2.1	**Summary of the final regulatory action**			

The use of azinphos-methyl and associated end-use products (EP) entails an unacceptable risk of harm to the agricultural worker pursuant to Section 20 of the Canadian Pest Control Product (PCP) Regulations. Environmental concerns have also been identified. As a result, 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 as of end of December 2005, for which alternatives exist (alfalfa, clover, rye, quince, potatoes, tomatoes, rutabagas, turnips, cabbage, broccoli, brussels sprouts, cauliflowers, cucumbers, strawberries, boysenberries, longan berries, 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 program and uses for which no alternatives exist) until end of December 2012.

2.2.2 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 2004-05), 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 Web Site, Re-evaluation Summary Table (http://www.pmra-arla.gc.ca/).

2.2.3 Date of entry into force of the final regulatory action

No further uses were allowed after December 2005 for all uses except for apples, crab apples, apricots, blackberries, cherries, cranberries, grapes, pears, peaches, plums, prunes, raspberries.

2.3	Was the final regulatory action based on a risk or hazard evaluation?	X☐ Yes ☐ No
	If yes, give information on such evaluation	
	The PMRA has concluded that the use of azinphos-methyl and its associated end-use products entails an unacceptable risk of harm to the agricultural worker pursuant to Section 20 of the Pest Control Product (PCP) Regulations.	
	Reference to the relevant documentation	
	- 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 2004-05), Azinphos-methyl, 29 March 2004.	

2.4	Reasons for the final regulatory action	
2.4.1	Is the reason for the final regulatory action relevant to the human health?	X☐ Yes ☐ No
	If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers	
	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 routes and following exposures of various durations. 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. The PPE, engineering controls and use pattern changes required to mitigate worker exposure during the phase-out period are described in PACR 2003-07, Appendix II.	
	Reference to the relevant documentation	
	- 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 2004-05), Azinphos-methyl, 29 March 2004.	

Expected effect of the final regulatory action

Reducing the risk of occupational exposure to azinphos-methyl. In the interim, 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 minimize exposure, and
- Increase the margins of safety for agricultural workers.

Details of the mitigative measures are listed in the Use Standard in PACR 2003-07, Appendix II.

Source:
- Proposed Acceptability for Continuing Registration (PACR 2003-07), Pest Management Regulatory Agency (PMRA) Re-evaluation of Azinphos-methyl, March 31, 2003.

2.4.2	**Is the reason for the final regulatory action relevant to the environment?**	☐ Yes	X ☐ No
	If yes, give summary of the known hazards and risks to the environment		
	Reference to the relevant documentation		

	Expected effect of the final regulatory action

2.5	Category or categories where the final regulatory action has been taken	
2.5.1	Final regulatory action has been taken for the chemical category	☐ Industrial
	Use or uses prohibited by the final regulatory action	
	Use or uses that remain allowed	

2.5.2	Final regulatory action has been taken for the chemical category	X☐ Pesticide
	Formulation(s) and use or uses prohibited by the final regulatory action	
	Phase-out of all uses of azinphos-methyl as end of December 2005, for which alternatives exist (alfalfa, clover, rye, quince, potatoes, tomatoes, rutabagas, turnips, cabbage, broccoli, brussels sprouts, cauliflowers, cucumbers, strawberries, boysenberries, longan berries, walnuts, melons, pumpkins, blueberries, outdoor ornamentals, nursery plants, forest trees and shade trees).	

	Formulation(s) and use or uses that remain allowed
	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 program and uses for which no alternatives exist) until end of December 2012.

2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.		
	Quantity per year (MT)	Year
Produced		
Imported		
Exported		
Used		

2.6	Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions
	Conditions of occupational exposure are likely to occur in other regions.

2.7	Other relevant information that may cover:

2.7.1	Assessment of socio-economic effects of the final regulatory action
	- 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.

2.7.2	Information on alternatives and their relative risks
	Currently no efficient alternatives for azinphos-methyl exist for the use on apples, crab apples, apricots, blackberries, cherries, cranberries, grapes, pears, peaches, plums, prunes, raspberries.
2.7.3	Relevant additional information

PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
Institution	Pest Management Regulatory Agency, Health Canada
Address	2720 Riverside Drive Ottawa, Ontario K1A 0K9 Canada
Telephone	+ 1 613 736-3660
Telefax	+ 1 613 736-3659
E-mail address	Trish_MacQuarie@hc-sc.gc.ca
Designated National Authority	
Institution	Pest Management Regulatory Agency, Health Canada
Address	2720 Riverside Drive Ottawa, Ontario K1A 0K9 Canada
Name of person in charge	Trish MacQuarrie
Position of person in charge	Director General , Policy, Communications and Regulatory Affairs Directorate
Telephone	+ 1 613 736-3660
Telefax	+ 1 613 736-3659
E-mail address	Trish_MacQuarie@hc-sc.gc.ca

Date, signature of DNA and official seal: Sept 3, 2008

ROTTERDAM CONVENTION

SECRETARIAT FOR THE ROTTERDAM CONVENTION
ON THE PRIOR INFORMED CONSENT PROCEDURE
FOR CERTAIN HAZARDOUS CHEMICALS AND PESTICIDES
IN INTERNATIONAL TRADE

PL 36/11

FORM FOR NOTIFICATION
OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

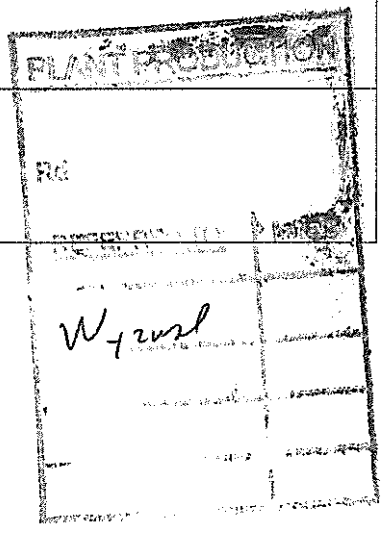
Country: Norway

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1	**Common name**	**Azinphos-methyl**
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	**s-(3,4-dihydro-4-oxobenzo[d]-[1,2,3]-triazin-3-ylmethyl)-o,o-dimethyl-phosphorodithioate**
1.3	**Trade names and names of preparations**	**Gusathion**

1.4 Code numbers

1.4.1	CAS number	86-50-0
1.4.2	Harmonized System customs code	
1.4.3	Other numbers (specify the numbering system)	EEC No. 201-676-1



1.5 Indication regarding previous notification on this chemical, if any

1.5.1 ☒ This is a first time notification of final regulatory action on this chemical.

1.5.2 ☐ This notification replaces all previously submitted notifications on this chemical.
Date of issue of the previous notification:

SECTION 2 FINAL REGULATORY ACTION

2.1 The chemical is: ☒ **banned** **OR** ☐ **severely restricted**

2.2 Information specific to the final regulatory action

2.2.1 Summary of the final regulatory action

Phase out of all uses by 31.12.2005. The underlying reasons were the ecotoxicological toxicity and the fact that the substance had been detected in the national water monitoring program at several occasions despite limited use in the catchment area.

2.2.2 Reference to the regulatory document, e.g. where decision is recorded or published

Decision by the Norwegian Agricultural Inspection Service 22.10.2002 (200200430 IP/hmo)

2.2.3 Date of entry into force of the final regulatory action

22.10.2002

2.3 Category or categories where the final regulatory action has been taken

2.3.1 All use or uses of the chemical in your country prior to the final regulatory action

Insecticide use in pome fruit, stone fruit, garden blueberries, strawberries, cabbage, and ornamentals.

2.3.2 Final regulatory action has been taken for the category ☐ Industrial

Use or uses prohibited by the final regulatory action

Use or uses that remain allowed (only in case of a severe restriction)

2.3.3 Final regulatory action has been taken for the category ☒ Pesticide

Formulation(s) and use or uses prohibited by the final regulatory action

All uses

Formulation(s) and use or uses that remain allowed
(only in case of a severe restriction)

2.4 **Was the final regulatory action based on a risk or hazard evaluation?**

☒ **Yes**

☐ **No** (If no, you may also complete section 2.5.3.3)

2.4.1 If yes, reference to the relevant documentation, which describes the hazard or risk evaluation

Holistic evaluation of Gusathion - azinphos-methyl. The Norwegian Agricultural Inspection Service. 05.09.2002

2.4.2 Summary description of the risk or hazard evaluation upon which the ban or severe restriction was based.

2.4.2.1 Is the reason for the final regulatory action relevant to human health?

☐ Yes

☒ No

If yes, give summary of the hazard or risk evaluation related to human health, including the health of consumers and workers

Expected effect of the final regulatory action

2.4.2.2 Is the reason for the final regulatory action relevant to the environment?

☒ Yes

☐ No

If yes, give summary of the hazard or risk evaluation related to the environment

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) exceeds the trigger value, indicating high risk to earthworms (for all uses except fruit trees).

Azinphos-methyl is extremely toxic to several aquatic organisms. TER values for invertebrates exceed the trigger values (even with buffer zones of 30 meters), indicating high risk to the aquatic environment.

Azinphos-methyl has been detected in the national water monitoring program at several locations at concentrations up to 0,64 ug/l. When comparing this value to NOEC values from chronic fish tests (0,18-0,39 ug/l), indoor microcosm (rainbow trout) (NOEC: 0,64 ug/l) and outdoor microcosm studies (NOEC: 0,32 ug/l), the risk was deemed unacceptable for use under Norwegian condition.

Expected effect of the final regulatory action

Reducing the risk of environmental exposure to azinphos-methyl.

2.5 Other relevant information regarding the final regulatory action

2.5.1 Estimated quantity of the chemical produced, imported, exported and used

	Quantity per year (MT)	Year
produced	0	
imported	1.576	2001
exported	0	
used		

2.5.2 Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions

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).

2.5.3 Other relevant information that may cover:

2.5.3.1 Assessment of socio-economic effects of the final regulatory action

2.5.3.2 Information on alternatives and their relative risks, e.g. IPM, chemical and non-chemical alternatives

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

Chemical alternatives in ornamentals include fosalon, dimethoate, esfenvalerate, fenpropathrin, lambda cyhalothrin, and alphacypermethrin, along with the nematode Heterorhabditis megidis. For pome fruit and stone fruit, alternatives include diflubenzuron, thiacloprid, indoxacarb and fosalon. Chemical alternatives in strawberries include methiocarb, thiaclopprid, and esfenvalerate. There were no alternatives for azinphos-methyl in blueberries and cabbage.

2.5.3.3 Basis for the final regulatory action if other than hazard or risk evaluation

2.5.3.4 Additional information related to the chemical or the final regulatory action, if any

SECTION 3 PROPERTIES

3.1 Information on hazard classification where the chemical is subject to

classification requirements

International classification systems **e.g. WHO, IARC, etc.**	**Hazard class**
WHO	1b

Other classification systems **e.g. EU, USEPA**	**Hazard class**
EU	T+; R28. T; R24 (At the time of the decision)

3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

Formula C10H12N3O3PS2
Molecular weight 317,3
Solubility 28 mg/l
logKow 2,96
Vapour pressure 5 x 10-4 mPa
Dissociation constant -
Henry's law constant 5,7 x 10-6 Pa m3 mol-1

Reference

The Pesticide Manual, Twelfth Edition, 2000

3.2.2 Description of toxicological properties of the chemical

Kinetics: Rapid uptake (90-100%) by oral route. Excretion mainly via urine. enterohepatic recirculation. Same excretion pattern from different administration routes. T1/2= 10 h.

Acute toxicity: Very toxic by swallowing. Rat LD50: 4-20 mg/kg bw depending on

solvent used. Very toxic by inhalation. Rat LC50: 0.132 mg/L (4-5 hrs exposure). Toxic by dermal exposure. Rat LD50: 72-250 mg/kg bw depending on solvent used.

Irritation: Not irritant to eyes or skin in rabbit.

Allergy: Dermal sensitizer in guinea pigs.

Genotoxicity:Positive responses in two chromosome aberration tests in vitro (CHO-cells and human lymphocytes). Negative in other in vitro tests and all in vivo tests. Not regarded as genotoxic.

Subchronic/chronic toxicity: Dose dependent inhibition of cholinesterase in plasma, erytrocytes and brain were seen along with symptoms of cholinergic toxicity such as convulsions, reduced body weight or bodyweight gain. No delayed neuropathy was seen in hens. Azinphos-methyl was considered not to be a carcinogen.

Reprotoxicity: Azinphos-methyl is not regarded as a reprotoxicant or a teratogen. Effects were only seen at dose levels with maternal toxicity.

Reference

Monograph, 18 September 1996, Azinphos-methyl, Rapporteur Member State: Germany

Holistic evaluation of Gusathion - azinphosmethyl. The Norwegian Agricultural Inspection Service. 05.09.2002

WHO/PCS/92.52 JMPR Toxicology evaluations 1991

3.2.3 Description of ecotoxicological properties of the chemical

Fate and behaviour in the environment:

Soil degradation: DT50: 23 days (average)

Soil adsorption: Kd: 4,0-28,5

Degradation in water/sediment systems: DT50: 1,3-10 days.

Environmental monitoring:

Azinphos-methyl has been found in creeks and rivers in Norway at several occasions

Potential for bioaccumulation.

Extremely toxic to fish, LC50: 3 µg/l (rainbow trout), NOEC: 0,18-0,39 µg/l

Extremely toxic to Daphnia magna, 48 hr EC50: 1,1 µg/l, NOEC 0,25µg/l

96 hr EC 50 for Scenedesmus subspicatus: 3,61 mg/l, NOEC: 1,8 mg/l.

28 d EC50 for Chironomus riparius: 0,55 µg/l.

Acutely toxic to eartworms, 14 d LC50: 59 mg/kg soil.

Honeybees:Extremely toxic, oral and contact LD50: 0,1 µg/bee Arthropods:Harmful to parasitoids, predatory mites, ladybirds, chrysopa, syrphus, ground beetles. Birds: Extremely acute toxic, LD50: 8,5 mg/kg. Mammals: Extremely acutely toxic to rat, oral LD50: 4,4 mg/kg bw.

Reference

Monograph, 18 September 1996, Azinphos-methyl, Rapporteur Member State: Germany Holistic evaluation of Gusathion - azinphosmethyl. The Norwegian Agricultural Inspection Service. 05.09.2002

SECTION 4 DESIGNATED NATIONAL AUTHORITY

Institution	Norwegian Food Safety Authority
Address	Regional Office for Oslo, Akershus and Østfold National Registration Section Felles postmottak P.O. Box 383 N-2381 Brumunddal Norway
Name of person in charge	Marit Randall
Position of person in charge	Senior Executive Officer
Telephone	+ 47 64 94 43 63
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E-mail address	Marit.Randall@mattilsynet.no

Date, signature of DNA and official seal: June 21, 2009 Matti Lauri Jan Randall

PLEASE RETURN THE COMPLETED FORM TO:

Secretariat for the Rotterdam Convention
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Viale delle Terme di Caracalla
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Tel: (+39 06) 5705 3441
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United Nations Environment
Programme (UNEP)
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E-mail: pic@pic.int

Definitions for the purposes of the Rotterdam Convention according to Article 2:

(a) '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;

(b) 'Banned chemical' means a chemical all uses of which within one or more categories have been prohibited by final regulatory action, in order to protect human health or the environment. It includes a chemical that has been refused approval for first-time use or has been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process and where there is clear evidence that such action has been taken in order to protect human health or the environment;

(c) 'Severely restricted chemical' means a chemical virtually all use of which within one or more categories has been prohibited by final regulatory action in order to protect human health or the environment, but for which certain specific uses remain allowed. It includes a chemical that has, for virtually all use, been refused for approval or been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment;