Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Proposed Acceptability for Continuing Registration

PACR2003-07

Re-evaluation of Azinphos-methyl

The organophosphate active ingredient azinphos-methyl and associated end-use products were proposed for re-evaluation under Section 19 of the Pest Control Products (PCP) Regulations in June 1999.

As a result of the re-evaluation, it has been determined that all uses of azinphos-methyl are to be phased out in light of the identified risks to workers and to the environment. It is proposed that most uses of azinphos-methyl, for which alternatives exist, will be phased out by the end of 2003. The remaining uses, considered key in Canada, will be phased out by the end of 2005 to allow for a transition to alternatives.

This Proposed Acceptability for Continuing Registration (PACR) document provides a summary of the data reviewed and the rationale for the proposed regulatory decision for azinphos-methyl. The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document. Please forward all comments to the Publication Coordinator at the address below.

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Foreword

The re-evaluation of the active ingredient (a.i.) azinphos-methyl and the associated end-use products (EP), an insecticide developed by Bayer CropScience, for use on various orchard and field crops, has been completed by the Pest Management Regulatory Agency (PMRA).

The PMRA announced in June 1999 that organophosphate active ingredients, including azinphos-methyl, were subject to re-evaluation under authority of Section 19 of the Pest Control Products (PCP) Regulations.[1]

The PMRA has carried out an assessment of available information and has found it sufficient, pursuant to Section 20 of the PCP Regulations, to allow a determination of the safety, merit and value of azinphos-methyl and associated end-use products, manufactured by Bayer CropScience, Makhteshim Agan, Norac Concepts Inc., and United Agri Products. The Agency has concluded that the use of azinphos-methyl and associated end-use products in accordance with the current labels does entail an unacceptable risk of harm to agricultural workers pursuant to Section 20. Environmental concerns have also been identified. As a result, the PMRA has determined that all uses for azinphos-methyl are to be phased out. The PMRA is proposing that the uses of azinphos-methyl on apple, apricot, blackberry, cherry, cranberry, grape[2], pear, peach, plum, prune, and raspberry, be permitted until the end of 2005 to allow for transition to alternative pest management tools. In the interim, measures to mitigate occupational and environmental risks will be implemented for these crops. Sales by registrants of product labelled for all other uses will end as of September 30, 2003.

The PMRA will accept written comments on the proposed phase-out periods up to 60 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed re-evaluation decision for these products.

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1 Re-evaluation Document REV99-01, *Re-evaluation of Organophosphate Pesticides*

2 Provisional upon evaluation of data submitted to assess worker exposure

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1.0 Purpose

The Pest Management Regulatory Agency (PMRA) announced in June 1999 that organophosphate active ingredients, including azinphos-methyl, were subject to re-evaluation under authority of Section 19 of the Pest Control Products (PCP) Regulations.[3] The purpose of this document is to inform the registrants, pesticide regulatory officials and the Canadian public that the PMRA has completed a review of azinphos-methyl. The document includes a human health assessment, an environmental assessment and information on the value of azinphos-methyl to pest management in Canada. By way of this document, the Agency is soliciting comments from interested parties on the proposed regulatory decision.

2.0 General background on re-evaluation

The PMRA is re-evaluating, under Section 19 of the Regulations pursuant to the *Pest Control Products Act*, all pesticides, both active ingredients and formulated end-use products, that were registered prior to 1995, to ensure that their continued acceptability is examined using current scientific approaches. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, outlines the details of the re-evaluation activities. Azinphos-methyl is under reassessment in the United States (U.S.) as a result of the *Food Quality Protection Act* and is therefore being re-evaluated by the PMRA under Program 3. The following components are addressed and considered in this re-evaluation:

Risk to human health: The initial focus of the re-evaluation of a pest control product in Program 3 is the risk to human health. As indicated in DIR2001-03, the reassessment in Program 3 pays particular attention to:

- pest control products with a common mechanism of toxicity,
- aggregate exposure to a pesticide arising from its residues in food and in drinking water, and from non-occupational exposure, such as from treatments in and around homes, and
- susceptibility and exposure of infants and children that may be different from that of adults during critical developmental stages.

The re-evaluation of risks to human health also includes a re-examination of the acceptability of risks resulting from occupational exposure. Once the reassessments of all the individual organophosphates have been completed, a cumulative assessment of all the remaining uses of organophosphates will be conducted.

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[3] Re-evaluation Document REV99-01, *Re-evaluation of Organophosphate Pesticides*

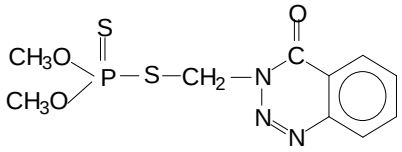
Risk to the environment: The environmental assessments will be tiered, with refined environmental risk assessments taking place only on those actives, products or uses that pass the cumulative health risk assessment or, for unique mechanisms of toxicity, that are acceptable from a human health perspective. At the first tier, based on an identification of hazards to non-target organisms, measures to reduce environmental exposure will be implemented where warranted. These measures may include removing uses that are obsolete, reducing the number of applications, requiring buffer zones to protect sensitive habitats and taking regulatory action against uses that have been determined to be extremely high risk to organisms in the environment. In general, uses that remain after the first tier assessment will be revisited when the results of refined environmental assessments are available.

Value: The PMRA seeks to understand, as early as possible in the process, the current uses of the products and their importance for pest management. The PMRA relies to a great extent on provincial and territorial government input. Registrants and users are also an important source of information. Environment Canada, the Department of Foreign Affairs and International Trade, the Canadian Food Inspection Agency and Agriculture and Agri-Food Canada are also contacted in the process for information specific to their areas of expertise.

The outcome of the re-evaluation of a pesticide, including proposed risk mitigation measures, will be published in a consultation document at the end of the aggregate human health risk assessment and the first tier environmental assessment. In some cases, the PMRA will implement changes in regulatory status of products prior to public consultation, especially where the PMRA considers risk mitigation not effective or practical, or where registrants have opted for voluntary discontinuation of sale of products.

3.0 Re-evaluation of azinphos-methyl

3.1 Azinphos-methyl



International Union of Pure and Applied Chemistry (IUPAC):
S-(3,4-dihydro-4-oxobenzo[d]-[1,2,3]-triazin-3-ylmethyl) O,O-dimethyl phosphorodithioate

Chemical Abstracts Service (CAS): O,O-dimethyl S-[(4-oxo-1,2,3-benzotriazin-3(4H)-yl)methyl] phosphorodithioate

Azinphos-methyl is one of the 27 organophosphate pesticides subject to re-evaluation in Canada. The re-evaluation of azinphos-methyl was announced in Re-evaluation Document REV99-01, *Re-evaluation of Organophosphate Pesticides*. Azinphos-methyl is a broad spectrum organophosphate insecticide which inhibits the enzyme acetylcholinesterase, interrupting the transmission of nerve impulses. It works by contact and ingestion action. Pest control products containing azinphos-methyl were first registered in Canada in 1958. Currently, eight end-use products containing azinphos-methyl are registered, all under the restricted classification.

Much of the scientific information used by the PMRA in its assessment of azinphos-methyl came from reviews conducted by the U.S. Environmental Protection Agency (EPA). The EPA reviews for azinphos-methyl can be referenced for further details regarding the scientific studies used by the PMRA. These reviews, as well as other information on the regulatory status of azinphos-methyl in the U.S., can be found at the website of the EPA (http://www.epa.gov/pesticides/reregistration/status.htm).

3.2 Existing use pattern

Azinphos-methyl is a broad spectrum organophosphate insecticide which is registered in Canada for use on a wide variety of feed, food and ornamental crops. The feed crops are alfalfa, clover and rye. Registered uses on food crops are 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 include nursery plants, forest trees and shade trees.

In the U.S., azinphos-methyl is registered for the same crops as in Canada with the exception of pumpkins, rutabagas and turnips (registered in Canada but not the U.S.), and cotton, nectarine, almond, hazelnut (filbert), pecans, pistachios, eggplant, peppers, celery, spinach, parsley, snap beans, birdsfoot trefoil, onions, oranges, grapefruit, lemons and other citrus fruit (registered in the U.S. but not Canada).

Currently registered formulations include wettable powders in water soluble packets and emulsifiable concentrates. In agriculture, azinphos-methyl can be applied aerially or from the ground (airblast sprayer, hydraulic sprayer). Application to ornamentals is by ground equipment only.

3.3 Status in the United States

The U.S. EPA recently completed an assessment for azinphos-methyl and has announced an Interim Reregistration Eligibility Decision (IRED). The EPA concluded that acute and chronic dietary risk from ingestion of azinphos-methyl was not of concern. However, the EPA concluded that the margins of exposure for handlers of azinphos-methyl and those who work in treated fields and orchards are significantly lower than the margins generally considered acceptable, and that with the exception of certain soil applications, the imposition of practical mitigation measures would not result in achievement of the desired margins of exposure. In addition, the EPA raised significant concerns regarding the potential for azinphos-methyl to cause negative effects to non-target organisms in terrestrial and aquatic environments.

As an outcome of this assessment, the EPA reached an agreement with the registrants of azinphos-methyl in the U.S. for the cancellation of certain uses (i.e., uses for which the economic benefits were determined to be minimal and alternatives exist). Certain other uses (i.e., uses for which the economic benefits were determined to be significant but did not outweigh the risks) are to be phased out by 2005. Certain other uses (i.e., use for which economic benefits were determined to outweigh the risks) are to be phased out by 2005 unless additional data are submitted to the EPA which result in a change to the risk and benefit assessments and would support continued registration for these uses. For all uses to be phased out, measures are to be implemented to mitigate the occupational and environmental risks. Further information regarding the EPA's assessment of azinphos-methyl and the regulatory decisions in the U.S. can be found at the EPA's website (http://www.epa.gov/pesticides/reregistration/status.htm).

4.0 Effects having relevance to human health

4.1 Toxicology summary

The toxicology database supporting azinphos-methyl is primarily based on studies available from the registrant. In laboratory animals, azinphos-methyl was found to be extremely toxic following relatively 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 were 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 the rat indicate that the female may be more sensitive than the male. A comparison of the results of subchronic and chronic studies demonstrate 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.

Although human studies were available for azinphos-methyl, they were only considered supplementary information. These studies confirmed that the animal species selected in the risk assessment were considered conservative surrogates with respect to acute exposures to adult humans.

Reference doses have been set based on NOAELs for the most sensitive indicator of toxicity, namely cholinesterase inhibition or clinical signs of cholinergic toxicity. These reference doses incorporate various uncertainty factors to account for extrapolating between rats and humans and for variability within human populations.

4.1.1 Acute reference dose (ARfD)

To estimate acute dietary risk (1 day), the **lowest observed adverse effect level (LOAEL) of 2.0 mg/kg bw** from the acute neurotoxicity study in rats was selected for risk assessment. This LOAEL is established based on erythrocyte and brain cholinesterase inhibition in male rats. An overall **safety factor of 300** was required to account for inter-species extrapolation (10×) and intra-species variability (10×), as well as an additional 3× uncertainty factor due to the lack of a NOAEL in this study. The ARfD was calculated to be 0.007 mg/kg bw (2.0 mg/kg bw ÷ 300). This value was considered to be protective of all populations including infants and children.

4.1.2 Acceptable daily intake (ADI)

To estimate dietary risk from the repeat or chronic exposure, the NOAEL of 0.15 mg/kg bw/day from the 52-week dog toxicity study was selected for risk assessment. The NOAEL is based on clinical signs of toxicity (diarrhea) at 0.73 mg/kg bw/day. Standard uncertainty factors of 10× for interspecies extrapolation and 10× for intraspecies variability were used. The ADI was calculated to be 0.0015 mg/kg bw/day (0.15 mg/kg bw/day ÷ 100). This value was considered to be protective of all populations including infants and children.

4.1.3 Occupational endpoints

For **short-term dermal exposure (days 1–7)**, the toxic endpoint selected was from a dermal absorption study in rats with a NOAEL of 0.56 mg/kg bw/day based on minimal inhibition of erythrocyte cholinesterase (EChE) activity at 5.6 mg/kg bw (LOAEL). **A target margin of exposure (MOE) of 100** is required for short-term dermal occupational risk assessment and includes the conventional uncertainty factor of 100× (10× for interspecies extrapolation and 10× for intraspecies variability).

For **short-term inhalation risk assessment (days 1–7)** the selected toxic endpoint was from a 90-day inhalation study in rats (6 hr/day, 5 days/wk) with a NOAEL of 0.0012 mg/L (0.32 mg/kg/day) based on EChE inhibition at 0.0047 mg/L (1.28 mg/kg/day). **A target MOE of 100** is required for short-term inhalation occupational risk assessment and includes the conventional uncertainty factor of 100×.

For **intermediate-term dermal/inhalation risk assessments** (one week to several months) the selected toxic endpoint was from the 52-week capsule study in the dog with a NOAEL of 0.15 mg/kg bw/day based on clinical signs of toxicity (diarrhea) at 0.73 mg/kg bw/day (LOAEL). As there is no route-specific unique toxicity associated with azinphos-methyl, the overall use of an oral toxicity study in the risk assessment addresses the systemic hazards resulting from intermediate dermal and inhalation exposure scenarios. **A target MOE of 100** is required and includes the conventional uncertainty factor of 100×.

4.2 Occupational risk assessment

As described in the Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, where available, recent Reregistration Eligibility Decision (RED) documents meeting certain criteria form the basis of the PMRA's re-evaluation. Further details on the occupational exposure and risk assessments are described in the EPA IRED found at http://www.epa.gov/oppsrrd1/REDs/azinphosmethyl_ired.pdf.

Workers can be exposed to a pesticide through mixing, loading, or applying the pesticide, and re-entering a treated site to conduct agronomic activities. Worker risk is measured by an MOE which determines how close the occupational exposure comes to the no observed effect level (NOEL) taken from animal studies. Generally, MOEs that are greater than the target MOE do not pose a risk concern. For workers entering a treated site, restricted entry intervals (REIs) are calculated to determine the minimum length of time required before workers or others can safely re-enter.

4.2.1 Operator exposure and risk assessment

The following equipment may be used to apply azinphos-methyl: aircraft, groundboom and airblast.

Short and intermediate term dermal and inhalation exposure estimates were based on the Pesticide Handlers' Exposure Database (PHED 1.1). The PHED is a database of generic mixer/loader/applicator passive dosimetry data which facilitate the generation of scenario specific exposure estimates. No chemical-specific mixer/loader/applicator data were submitted.

Mixer/loader/applicator exposure estimates are based on the best available data at this time. The assessment might be refined with exposure data representative of modern spray equipment and engineering controls. Biological monitoring data could also further refine the assessment.

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 Appendix II.

4.2.2 Worker post-application risk assessment

Post-application activities include pruning, thinning, propping, harvesting and any other activities involving contact with foliage following pesticide applications. Exposure to workers re-entering treated areas is calculated using dislodgeable foliar residue (DFR) values, which are crop-specific, and transfer coefficients (TC), which are activity-specific in the following equation:

$$\text{Exp. (mg/kg/day)} = \frac{\text{DFR } (\mu\text{g/cm}^2) \times \text{TC } (\text{cm}^2/\text{hr}) \times 8 \text{ hr/day}}{\text{body weight (kg)}} \times 0.001 \text{ mg}/\mu\text{g}$$

Dislodgeable foliar residue data are available for tomatoes, potatoes, apples and grapes and are described in the U.S. EPA Human Health Risk Assessment Chapter for Azinphos Methyl (May 19, 1999). All DFR studies were based on sampling following 3–4 applications at various intervals, using either wettable powder (WP) or emulsifiable concentration (EC) formulations, at various geographic locations within the U.S. Activity-specific transfer coefficients, together with the above-noted DFR data, were used to estimate exposure and are described in the U.S. EPA IRED.

Post-application exposure estimates are based on the best available data. Data being generated by the Agricultural Re-entry Task Force (ARTF) and (or) other data such as passive dosimetry, biological monitoring and additional DFR data might permit refinement of the assessment.

The post-application risks to re-entry workers greatly exceed the level of concern based on current re-entry intervals (REIs) 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. To achieve MOEs that are not a concern for post-application workers based on the current use pattern, most REIs would need to be significantly increased in length.

Revised REIs and use pattern reductions required to further mitigate worker exposure during the phase-out period are described in Appendix II.

4.3 Dietary risk assessment

In a dietary exposure assessment, the PMRA determines how much of a pesticide residue, including residues in fruit, vegetables, milk, meat, eggs and processed products, may be ingested with the daily diet. These dietary assessments are age-specific and incorporate the different eating habits of the population at various stages of life (infants, children, adolescents, adults and seniors). For example, assessments take into account childrens' greater consumption of fruit, vegetables and juices for their body weight compared with adults.

4.3.1 Residue of concern

The residue of concern (ROC) in plants and animals was defined as azinphos-methyl. This ROC was consistent with that adopted by U.S. EPA and Codex. Adequate analytical methods exist for crop and livestock matrices. Azinphos-methyl was shown to be stable in plant and livestock matrices in frozen storage for two years and four weeks, respectively. Raw agricultural commodity (RAC) maximum residue limits (MRLs) will cover off potential residues in processed fractions.

4.3.2 Acute dietary (food) risk

Acute dietary risk is calculated using food consumption and food residue values. A probabilistic statistical analysis allows all possible combinations of food consumption and residue levels to be combined to estimate a distribution of the amount of azinphos-methyl residue that might be eaten in a day. An exposure value representing the high end (99.9^{th} percentile) of this distribution is compared with the ARfD, which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the calculated intake from residues, called the potential daily intake (PDI), is less than the ARfD, the intake is not considered to be of concern.

The acute dietary risk from foods treated with azinphos-methyl was not a concern for the general Canadian population and all population subgroups (i.e., less than 100% of the ARfD is consumed). The assessment has been conducted using market basket survey, monitoring, and residue data, as well as MRLs. Percent crop treated data 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, children (1–6 years old), consume 65% of the ARfD in their food. All other subpopulations had potential daily intakes less than 48% of the ARfD.

4.3.3 Chronic dietary (food) risk

The chronic dietary risk was calculated by using the average consumption of different foods, and average residue values on those foods, over a 70-year lifetime. This expected intake of resides is compared with the ADI, which is the dose at which an individual could be exposed over the course of a lifetime and expect no adverse health effects. When the expected intake from residues is less than the ADI, the expected intake is not considered to be of concern. The risk assessment was conducted using MRLs, average residues, percent crop treated data and processing factors.

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 (ie., less than 100% of the ADI is consumed). The most highly exposed population subgroup, children (1–6 years old), consumes 88% of the ADI in their food.

4.3.4 Aggregate risk

Aggregate risk assessment looks at the combined potential risk associated with exposures from food, drinking water, and residential uses of a pesticide. Generally, when the risks from these exposures are combined, and are still less than 100% of the ARfD and ADI, the aggregate risk is not considered of concern. As residential use of azinphos-methyl is not permitted, the aggregate risk assessment considers food and water only.

Concentrations in drinking water were estimated using drinking water exposure models, and high-end ground water and surface water concentrations were estimated from monitoring data in Canada and the U.S. (see Section 5.3). A drinking water level of comparison (DWLOC) is derived from the overall allowable risk from residues permitted in the diet after considering the contribution by food. The DWLOC is 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.

For acute risk, the DWLOCs range from 35 to 40 μg/L for children 1–6 years old and for infants <1 year old, and from 180 to 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. Thus, acute aggregate risk is not of concern.

For chronic risk, the calculated DWLOCs range from 2.7 to 59 μg/L, the most sensitive population subgroup being children 1–6 years old. Chronic concentrations estimated from surface water monitoring were estimated as 0.3 μg/L. Thus, chronic aggregate risk is not of concern when considering surface water. Groundwater monitoring data are limited, however the average concentration in the most highly exposed well was less than 2 μg/L. Available groundwater data do not indicate exceedances of the chronic DWLOC.

5.0 Environmental assessment

The data cited in this assessment were obtained largely from the U.S. EPA re-evaluation of azinphos-methyl (*Preliminary Environmental Fate and Effects Division (EFED) Chapter of the Reregistration Eligibility Decision (RED) Document for Azinphos-methyl, List A Case 0235, 1998*).

In characterizing the environmental risk of azinphos-methyl, the PMRA used a deterministic approach which characterizes the risk by the quotient method, in which a risk quotient (RQ) is calculated as the ratio of the estimated environmental concentration (EEC) to the toxicity endpoint of concern. RQs less than one are considered as a low risk to non-target organisms, whereas RQs greater than one indicate some degree of risk.

In this screening-level assessment, EECs for aquatic and terrestrial ecosystems were based on maximum label rates. Toxicity endpoints (acute or chronic) were chosen for the most sensitive species and used as surrogates for the range of species which can potentially be exposed following treatment with azinphos-methyl.

5.1 Environmental fate

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•m3/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 K_{ow} 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).

5.2 Environmental toxicology

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

5.3 Drinking water assessment

Initially, residues of azinphos-methyl in drinking water resulting from surface runoff were estimated using the GENEEC model. With this model, the drinking water concentrations in a farm dugout were estimated to be: 245 μg/L (peak conc.); 232 μg/L (mean 4-day conc.); 174 μg/L (mean 21-day conc.) and 110 μg/L (mean 56-day conc.). These concentrations were based on the maximum application rate on raspberries and blackberries (2.25 kg a.i./ha), the number of applications per season (2) and the application interval (14 days).

More recently, the surface runoff models, PRZM/EXAMS (Level 1), were used to estimate the drinking water concentrations in a reservoir. These concentrations were estimated to be: 86.5 μg/L (acute) and 13.3 μg/L (chronic) and were based on the maximum application rate on grapes (2.80 kg a.i./ha), the number of applications per season (3) and the application interval (14 days).

Water monitoring data from both Canada and the United States recently collected by the PMRA indicate that azinphos-methyl is likely to contaminate potential drinking water sources in Canada. An estimated groundwater concentration, representing the 95th percentile of the maximum concentrations detected, was determined as 5.1 μg/L. Acute and chronic concentrations estimated from surface water monitoring were estimated as 3.4 μg/L and 0.3 μg/L, respectively. The acute concentration represents the 95th percentile of the maximum concentrations detected in surface water monitoring and the chronic concentration represents the 95th percentile of the arithmetic means of the surface water monitoring data, including all non-detects.

5.4 Terrestrial assessment

Birds could be exposed to azinphos-methyl by ingestion of contaminated food (e.g. seeds, fruits, insects or grasses). Based on the acute oral toxicity of azinphos-methyl in birds (LD_{50} = 32 mg a.i./kg; estimated NOEL = 3.2 mg a.i./kg) and using standard PMRA exposure scenarios, it was determined that birds would have to consume contaminated food sources for 0.7–1.4 days for their population to be reduced by 50% (LD_{50}). For no observable effects on a population, birds can consume contaminated food for up to 0.07–0.14 days (NOEL). As the number of feeding days required for an adverse effect is less than one, there is a risk to birds consuming contaminated food sources.

Based on the dietary toxicity of azinphos-methyl to birds (no observed adverse effect concentration (NOAEC) = 15.6 mg a.i./kg diet) and using standard PMRA exposure scenarios, the RQs ranged from 18 to 38. These values are classified as a high risk in birds on a chronic basis. The available dietary toxicity data are for waterfowl (mallard duck) and upland game birds (bobwhite quail) and thus, did not allow for an assessment based on smaller avian species such as songbirds which are more typical in agricultural areas where azinphos-methyl is used. These smaller species are typically more sensitive than the mallard or bobwhite.

It should also be noted, however, that these assessments were based on the assumption that birds would be feeding exclusively on contaminated food. In addition, the assessment does not consider feeding preference or avoidance behaviour toward contaminated food as these data are not currently available. Thus, more realistic exposure scenarios are required to refine the risk assessment for birds.

Similarly, wild mammals could be exposed to azinphos-methyl by ingestion of contaminated food (e.g., grass, grain, seeds, forage crops and leafy crops). Based on the acute oral toxicity of azinphos-methyl in small mammals (LD_{50} = 7.8 mg a.i./kg; estimated NOEL = 0.78 mg a.i./kg) and using standard PMRA exposure scenarios, it was determined that animals would have to consume contaminated food sources for 0.09–0.19 days for their population to be reduced by 50% (LD_{50}). For no observable effects on a population, animals can consume contaminated food for up to 0.009–0.019 days (NOEL). As the number of feeding days required for an adverse effect is less than one, there is a risk to small mammals consuming contaminated food sources.

On a dietary toxicity basis (NOAEC = 5.0 mg a.i./kg diet), the RQs in mammals were 160–338. These values are classified as very high risk on a chronic basis.

It should be noted, however, that these assessments were based on the assumption that small mammals would be feeding exclusively on contaminated food. In addition, the assessment does not consider feeding preference or avoidance behaviour toward contaminated food as these data are not currently available. Thus, more realistic exposure scenarios are required to refine the risk assessment for small mammals.

In field studies, however, it was demonstrated that the application of azinphos-methyl in apple orchards (3–4 applications of 1.68 kg a.i./ha), posed a substantial risk to birds and small mammals. It was determined that 12–52% of the casualties were probably treatment-related with an additional 22–68% that were possibly treatment-related. Furthermore, a substantial number of casualties were observed along the orchard perimeter (45% of casualties) and in areas outside the orchards (13–17% of casualties).

Bees and other beneficial insects may be exposed to azinphos-methyl through spray deposit. Based on the acute contact toxicity in bees (NOEC = 0.0071 kg a.i./ha), the RQs were 22–47 and were classified as a high risk.

The results of the initial terrestrial assessment identified moderate to very high risk to birds, mammals and beneficial insects.

5.5 Aquatic assessment

Aquatic organisms can be exposed to azinphos-methyl that enters aquatic systems through spray drift. In the initial assessment, the potential exposure was determined using a screening-level model to obtain expected environmental concentrations for the different rates and number of applications.

For laboratory-derived data, RQ values were based on estimates of the acute NOEC for the most sensitive species (i.e., 0.10 LC_{50}). In freshwater fish, the RQs were 158–15 792 based on an estimated acute NOEC (0.12 μg a.i./L). Similarly, in freshwater aquatic invertebrates, the RQs were 1188–118 437 based on an estimated acute NOEC (0.016 μg a.i./L). These values for fish and aquatic invertebrates are classified as an extremely high risk. The RQs in freshwater amphibians were 2–174 which indicated a moderate to very high risk.

At the ecosystem level, the toxicity of azinphos-methyl was examined in a mesocosm that consisted of fish, benthic macroinvertebrates, emergent insects and zooplankton. Overall, the community structure was adversely impacted as lesser sensitive species (plants, copepods, snails, rotifers and cladocerans) became more abundant as highly-sensitive species were reduced (fish and some insects). The most sensitive species were adult bluegill fish with an estimated EC_{50} of 0.20 μg/L based on mortality. Thus, the RQs were 95–9475 which indicated a very high to extremely high risk.

From incident reports (Canada and U.S.), it was evident that the high toxicity of azinphos-methyl was manifested under environmental conditions. These data showed: 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.

In Canada, azinphos-methyl was suspected as the cause of several fish kills in rivers in Prince Edward Island following heavy rainstorms that washed soil from nearby fields where the insecticide was applied. As early as 1999 and as recently as 2002, there were reports of several fish kills: one kill of 3000 in 1999 and another of 4500 in 2002. In one report, water analysis indicated that azinphos-methyl was detected in high concentrations in samples from pools of standing water at the edge of treated fields and adjacent to the stream. In addition, azinphos-methyl was detected in dead fish in some cases but not in all incidents.

Similarly, in the Niagara fruit belt (1996 and 1997), azinphos-methyl was detected during periods of application in 30% of water samples from streams at concentrations up to 7.79 μg/L, which is within the range of LC_{50}s for fish.

The data from these incident reports confirm the high levels of risk that were identified in the initial assessment based on laboratory-derived data and screening-level exposure scenarios, and thus, is a further indication that mitigative measures are required for the protection of non-target aquatic organisms.

5.6 Environmental assessment conclusions

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.

5.7 Environmental risk mitigation

Mitigation of potential impacts on terrestrial ecosystems is difficult given that the non-target organisms frequent treated areas. In the case of bees, it may be possible to reduce the risk by restricting the application of azinphos-methyl to when bees are not actively foraging. For birds and small mammals, there are no available options that would effectively reduce the risk that results from ingestion of contaminated food sources in treated areas.

Azinphos-methyl can enter aquatic ecosystems through spray drift and surface runoff. For mitigating surface runoff, there are no known accepted methods or measures for reducing entry into aquatic systems. The observance of buffer zones, however, can effectively mitigate the entry of spray drift into aquatic systems. Pesticide spray drift from aerial application of azinphos-methyl was predicted using the AgDrift Model (Spray Drift Task Force; 1998). The data of Nordby and Skuterud (1975) were utilized for predicting the spray drift from ground boom sprayers. The data of Ganzelmeier *et al.* (1995) were used to estimate spray drift from airblast sprayers used in orchards and vineyards. Based on these model predictions and the most sensitive aquatic organism at the ecosystem level (bluegill sunfish; EC_{50} = 0.20 μg/L), buffer zones were calculated for mitigating the entry of spray drift into aquatic systems. In addition, the buffer zone estimation was based on the maximum application rate, the number of applications per season and the interval between applications.

For ground spraying in field crops, a buffer zone of 59 m is required for the protection of aquatic habitats. With the use of shrouds and cones on ground spray booms, however, it has been estimated that the buffer zone can be reduced by 70% and 30%, respectively. Thus, with the use of shrouds or cones, the recommended buffer zones are 18 and 41 m, respectively. For airblast spraying in orchards/vineyards, buffer zones of 78 m are required for the protection of aquatic habitats.

For aerial application, the buffer zones were calculated to be 1014 m. Such a large buffer zone precludes the feasability of applying azinphos-methyl by air, as it would be impractical in agricultural practices.

Guidance to spray drift management practices and the observance of buffer zones are outlined in the Use Standard in Appendix II.

6.0 Value

6.1 Evaluation method

Agricultural uses
The importance of azinphos-methyl end-use products for managing specific pests on specific crops in Canada was evaluated based on the availability of registered alternative pesticides that are potential substitutes. The recent field use of azinphos-methyl in agriculture in Canada was assessed by a survey of organophosphate (OP) use conducted in 1998 (the "1998 OP Survey") with the cooperation of provincial governments, and from consultations with crop production specialists, and expert opinion of provincial agricultural officials, grower groups, and other stakeholders.

Uses of azinphos-methyl were classified into two value classes as follows:

Key uses:
Some uses of azinphos-methyl were considered "key uses" because they matched one or more of the following criteria:

- there was reported use of approximately 10% and there are no registered alternatives, OR
- there was reported use of at least 10% and alternative active ingredients are registered but azinphos-methyl is the preferred active ingredient (e.g., due to more favourable performance characteristics compared with alternatives), OR
- maintaining registration was considered key for resistance management and (or) plays an important role in IPM programs, OR
- the site of use is of large importance to the economy of Canada.

Non-key uses:
Uses of azinphos-methyl were considered to be "non-key uses" either because they did not match the "key use" criteria, or because the information available to the PMRA indicated little or no use in Canada.

Non-agricultural uses of azinphos-methyl
Information regarding the extent of non-agricultural use of azinphos-methyl was obtained from consultation with provincial governments and crop protection specialists. These uses were also categorized into "key uses" and "non-key uses" based on the above criteria.

6.2 Evaluation results

Crops with key uses of azinphos-methyl
The following crops were identified as having "key uses" of azinphos-methyl.

Apple:
Azinphos-methyl is reported to be key in integrated pest management (IPM) programs in apples. It is the only active ingredient registered to control the European apple sawfly, and is the only active ingredient registered that can provide effective control of codling moth, plum curculio and apple maggot. While alternative non-OPs are available to control some pests (codling moth), there are no effective non-OPs registered for control of other pests (apple maggot and plum curculio). Azinphos-methyl is also a key pest management tool in British Columbia, where it is used to reduce codling moth populations prior to commencement of a sterile insect release program in new areas of British Columbia.

Pear:
Azinphos-methyl is a preferred active ingredient for the Ontario and British Columbia pear IPM programs for control of codling moth and pear psylla. Applications of azinphos-methyl against pear psylla also control plum curculio.

Apricot, peach, plum, prune:
Azinphos-methyl is generally regarded as the only effective active ingredient available for control of plum curculio on apricots, peaches, plums and prunes although less effective non-OPs are registered for controlling these pests.

Cherry:
For control of cherry fruit fly for exports to Taiwan, Taiwan has indicated it wants older chemistries such as azinphos-methyl and other OPs.

Raspberry, blackberry:
There are no non-OP active ingredients registered for control of raspberry crown borer, which is a major pest (for this use azinphos-methyl is applied as a soil drench pre- and post-harvest). Azinphos-methyl is the only registered active ingredient than can be applied as a post-harvest treatment to control raspberry crown borer. A significant portion of the crop is also treated with azinphos-methyl to control leafrollers. Azinphos-methyl is considered to be the only effective pre-harvest clean up spray for machine harvested raspberries.

Cranberry:
There are no registered alternatives to azinphos-methyl for control of cranberry tipworm.

Grape:
Azinphos-methyl plays an important role in the Ontario IPM program for grapes for two reasons. When grape berry moth populations are high, azinphos-methyl is used to reduce pest numbers to a level where pheromone mating disruption is practical. Secondly, azinphos-methyl is rotated with synthetic pyrethroids in management of grape berry moth insecticide resistance.

Crops with non-key uses of azinphos-methyl
The following crops were identified as having no "key uses" of azinphos-methyl: alfalfa, clover, rye, crab apple, quince, potato, tomato, rutabaga, turnip, cabbage (including tight heading varieties of Chinese cabbage), broccoli, Brussels sprouts, cauliflower, cucumber, strawberry, boysenberry, loganberry, walnut, melons, pumpkin, blueberry, outdoor ornamentals, nursery plants, forest trees, and shade trees.

7.0 Other assessment considerations

During the review of azinphos-methyl, the PMRA has taken into account the federal Toxic Substances Management Policy (TSMP)[4] and has followed its Regulatory Directive DIR99-03[5]. It has been determined that this active does not meet all the TSMP criteria for a Track-1 substance based on the following:

- Azinphos-methyl does not meet the criteria for bioaccumulation. The octanol-water partition coefficient (log K_{ow}) is 2.96, which is below the TSMP Track-1 cut-off criterion of log $K_{ow} \geq 5.0$.

[4] The federal Toxic Substances Management Policy is available through Environment Canada's Web Site at: www.ec.gc.ca/toxics

[5] *The PMRA's Strategy for Implementing the Toxic Substances Management Policy*, DIR99-03, is available through the Pest Management Information Service: Phone 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); Fax (613) 736-3798; E-mail pminfoserv@hc-sc.gc.ca or through our Web site at www.hc-sc.gc.ca.pmra-arla

- Azinphos-methyl does not meet the criteria for persistence as its half-life values in water (7–38 days), and soil (27–66 days) are above the TSMP Track-1 cut-off criteria for water (≥182 days) and soil (≥182 days).
- The toxicity of azinphos-methyl is addressed in Sections 4.0 and 5.2.

8.0 Proposed regulatory action

The PMRA has carried out an assessment of available information and has found it sufficient pursuant to Section 20 of the PCP Regulations, to allow a determination of the safety, merit and value of azinphos-methyl and associated end-use products, manufactured by Bayer CropScience, Makhteshim Agan, Norac Concepts Inc., and United Agri Products. The Agency has concluded that the use of azinphos-methyl and associated end-use products in accordance with the label does entail an unacceptable risk of harm to agricultural workers, pursuant to Section 20. Environmental concerns have also been identified.

As a result, the PMRA has determined that all uses of azinphos-methyl are to be phased out. In determining the phase-out period, while considering the worker risk concerns identified above, the key uses as identified in Section 6.0 were further screened against the following criteria: uses that are part of an established provincial IPM program; uses for which no effective alternatives exist.

Uses meeting these criteria are as follows:

- apples (European apple sawfly, apple maggot, codling moth, plum curculio)
- pears (codling moth, pear psylla)
- apricots and peaches, plum and prune (plum curculio)
- raspberries and blackberries (raspberry crown borer)
- cranberries (cranberry tipworm)
- grapes[6] (grape berry moth)
- cherries (cherry fruitfly) export to South East Asia—only older chemistries such as OPs are accepted as effective control of cherry fruit fly.

The uses for azinphos-methyl are to be phased out according to the schedule noted below:

A) Uses on alfalfa, clover, rye, crab apple, quince, potato, tomato, rutabaga, turnip, cabbage (including tight heading varieties of Chinese cabbage), broccoli, Brussels sprouts, cauliflower, cucumber, strawberry, boysenberry, loganberry, walnut, melons, pumpkin, blueberry, outdoor ornamentals, nursery plants, forest trees, and shade trees

[6] Provisional upon evaluation of data submitted to assess worker exposure

The PMRA is proposing that the use of azinphos-methyl on alfalfa, clover, rye, crab apple, quince, potato, tomato, rutabaga, turnip, cabbage (including tight heading varieties of Chinese cabbage), broccoli, Brussels sprouts, cauliflower, cucumber, strawberry, boysenberry, loganberry, walnut, melons, pumpkin, blueberry, outdoor ornamentals, nursery plants, forest trees, and shade trees, be phased out as follows:

- Last date of sale by registrants of product labelled for these uses: September 30, 2003
- Last date for use of any carry-over product labelled for these uses: December 31, 2005

Product labelled with these uses which remains in the possession of retailers and users after September 30, 2003 is permitted to be sold and used until December 31, 2005. In order to ensure that carry-over of such product is minimal, sales of currently labelled product by registrants for the 2003 season (up to September 30, 2003) will be restricted to the average annual sales of each product based on the previous 5 years of sales.

B) Uses on apple, apricot, blackberry, cherry, cranberry, grape[6], pear, peach, plum, prune, and raspberry

The PMRA proposes that the use of azinphos-methyl on identified key pests of apple, apricot, blackberry, cherry, cranberry, grape[6], pear, peach, plum, prune, and raspberry be phased out as follows:

- Last date of sale of products by the registrant: June 30, 2005
- Last date for use of product by users and growers: December 31, 2005

The longer phase-out period for grapes can only be considered after evaluation of dislodgeable foliar data for grapes and the corresponding EPA data evaluation report (DER) for these data. Further characterization of worker activities that take place within 60 days after treatment are also required. Bayer CropScience has recently submitted these data. These data will be considered by the PMRA prior to finalizing a decision regarding the longer phase-out period for grapes.

Details of insect pests, use instructions, and precautionary statements for the extended uses are listed in the Use Standard in Appendix II.

The uses of azinphos-methyl remaining until 2005 will be by ground application only. The large buffer zones for aerial application from water bodies would make aerial use impractical, and application on these crops is normally by ground.

In the interim, until registrations end on December 31, 2005, the registrant must design, submit to the PMRA for approval, and implement a specific product stewardship plan 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.

Furthermore, until registrations end on December 31, 2005, the registrant must implement a number of mitigative measures to increase the margins of safety for agricultural workers and environmentally sensitive aquatic areas including:

- longer intervals before workers may re-enter treated areas
- establishment of a product stewardship program by the registrant; for example,
  - rate reductions
  - posting of treated sites to protect re-entry workers
  - availability of wash stations for all re-entry workers
- increased PPE for mixer/loader applicators and re-entry workers
- limiting the number of applications per season
- prohibiting aerial applications (application to these crops is currently limited to ground equipment, and will remain so for the duration of the phase-out period)
- establishment of buffer zones around aquatic habitat

Details of the mitigative measures are listed in the Use Standard in Appendix II.

C) Use in Prince Edward Island (P.E.I.)

All registrants of azinphos-methyl products have informed the PMRA that they will cease marketing azinphos-methyl products for sale in P.E.I. effective March 7, 2003. The use of azinphos-methyl in P.E.I. is governed by a provincial permitting system that was implemented to mitigate the risk of fish kills from specific pest control products. This decision by registrants, together with the permitting system administered by the province of P.E.I., reflects the unique circumstances of geography and agronomic practices in P.E.I., and is seen as a prudent measure to address concerns regarding use of azinphos-methyl in that province.

8.1 Azinphos-methyl MRLs

Current MRLs for azinphos-methyl are listed in Appendix I. All other potential food residues for azinphos-methyl from domestic uses and imports are currently covered under the 0.1 ppm default regulation (B.15.002 (1) of the *Food and Drugs Act*.

When pesticide active ingredients are no longer registered for use in Canada, the PMRA intends to protect the food supply from unwanted residues associated with continued use of the pesticide by revoking any existing MRLs and setting new residue limits at the limit of quantification. The U.S. EPA undertakes similar action in such circumstances. A proposal to amend the MRLs will appear in the Canada Gazette, taking into consideration the last date of legal use of products and the expected time for treated commodities to clear the channels of trade, usually one year.

Parties interested in supporting an MRL to allow imports of specific commodities treated with azinphos-methyl should contact the PMRA as soon as possible to discuss the submission of appropriate toxicology, residue chemistry and food residue data or suitable rationales as to why the submission of these data are not necessary to allow an assessment of the safety of the proposed import MRLs.

8.2 Consultation

By way of this document, the Agency is soliciting comments from interested parties on the proposed regulatory decision. The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document.

List of abbreviations

a.i.	active ingredient
ADI	acceptable daily intake
bw	body weight
d	day
EFED	Environmental Fate and Effects Division (U.S. EPA)
EPA	Environmental Protection Agency
g	grams
h	hour
ha	hectare
IPM	integrated pest management
kg	kilogram
L	litres
LD_{50}	mean lethal dose
LOAEL	lowest observed adverse effect level
m	metre
mg	milligram
MOE	margin of exposure
MRL	maximum residue limit
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OP	organophosphate insecticide
PCP	pest control products
PHED	Pesticide Handlers' Exposure Database
PHI	pre-harvest interval
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
RED	Reregistration Eligibility Decision
REI	re-entry interval
ROC	residue of concern
TSMP	Toxic Substances Management Policy
U.S.	United States of America

Appendix I Existing MRLs for azinphos-methyl

Commodity*	Canada (ppm)
Apples, apricots, beans, blackberries, blueberries, boysenberries, citrus fruits, loganberries, peaches, pears, quinces, raspberries, spinach.	2
Artichokes, cauliflower, celery, cucumbers, onions (dry bulb).	0.5
Broccoli, Brussels sprouts, cabbage, cherries, cranberries, currants, onions (green), plums, tomatoes, strawberries.	1
Grapes	5
Kiwi fruit (edible portion)	0.4
Peppers	0.2

*If no MRL is listed, the general Regulation applies with 0.1 ppm; no data evaluated.

Appendix II Use standard for RESTRICTED class products containing azinphos-methyl for the interim period until phase-out of all uses at the end of 2005

(Note: The information in this appendix summarizes the uses, limitations and precautions for the restricted class products containing azinphos-methyl, but does not identify all label requirements for such products. Registrants are referred to the PMRA Registration Handbook for further guidance on label requirements for pest control products.)

COMMON NAME: azinphos-methyl

CHEMICAL NAME: *S*-(3,4-dihydro-4-oxobenzo [*D*]-[1,2,3] triazin-3-ylmethyl) *O,O*-dimethyl phosphorodithioate

FORMULATION TYPE: WP: wettable powder
EC: emulsifiable concentrate

SITE CATEGORIES: USC# 14, Terrestrial Food Crops

NOTE: All uses of azinphos-methyl fall under RESTRICTED classification.

NATURE OF RESTRICTION: This product is to be stored, displayed and distributed in the manner authorized. Provincial and federal regulations are in effect.

USE LIMITATIONS: Do not use on other crops used for food or forage. Use only according to label directions. Application at rates above those shown may result in illegal crop residues. Do not graze livestock in treated orchards or groves for 21 days after treatment. USE OF THIS PRODUCT IN GREENHOUSES OR ENCLOSED AREAS IS PROHIBITED. Backpack and hand-wand spraying is prohibited.

TOXICOLOGICAL INFORMATION: Azinphos-methyl is a cholinesterase inhibitor. Typical symptoms of overexposure to cholinesterase inhibitors include headache, nausea, dizziness, sweating, salivation, runny nose and eyes. This may progress to muscle twitching, weakness, tremor, incoordination, vomiting, abdominal cramps and diarrhea in more serious poisonings. A life-threatening poisoning is signified by loss of consciousness, incontinence, convulsions and respiratory depression with a secondary cardiovascular component. Treat symptomatically. If exposed, plasma and red blood cell cholinesterase tests may indicate degree of exposure (baseline data are useful). Atropine, only by injection, is the preferable antidote. Oximes, such as pralidoxime chloride, may be therapeutic if used early; however, use only in conjunction with atropine. In cases of severe acute poisoning, use antidotes immediately after establishing an open airway and respiration. With oral exposure, the decision of whether to induce vomiting or not should be made by an attending physician.

For those products which contain more than 10% petroleum distillates, the following text should also be added to the Toxicological Information section (placed at the end of the paragraph presented above), as an additional aid to the attending physician:

"NOTE: Product contains a petroleum distillate solvent."

PRECAUTIONS: KEEP OUT OF REACH OF CHILDREN: Poisonous if swallowed, inhaled, or absorbed through the skin. Do not get in eyes or on skin. Do not breathe fumes or spray mist. Spray operator should work to windward to stay out of drift or mist. Keep all unprotected persons out of the operating area or vicinity where there may be danger of drift. Do not contaminate feed or foodstuffs. Keep out of reach of children and domestic animals.

Personal protective equipment (PPE):
See Engineering controls for additional requirements.

Mixers and loaders must wear the following during mixing, loading, clean-up and repair activities:

- Coveralls over long-sleeved shirt and long-legged pants
- Chemical-resistant gloves, such as barrier laminate or viton
- Chemical-resistant footwear plus socks
- Protective eyewear
- Chemical-resistant apron when mixing or loading
- Chemical-resistant headgear
- For exposure in enclosed areas, a respirator with either an organic vapour-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)
- For exposure outdoors, dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC23-C).

Airblast applicators must be in fully enclosed cabs or if not in fully enclosed cabs, applicators must wear:

- Chemical-resistant coveralls over long-sleeved shirt and long-legged pants
- Chemical-resistant hood
- Full-face respirator or half-faced respirator with a face shield (respirators can have either an organic vapour-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)
- Chemical-resistant footwear plus socks.
- Chemical-resistant gloves

Applicators (other than airblast) must wear:

- Coveralls over long-sleeved shirt and long-legged pants
- Chemical-resistant gloves, such as barrier laminate or viton
- Chemical-resistant footwear plus socks
- Protective eyewear
- For exposure in enclosed areas, a respirator with either an organic vapour-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)
- For exposure outdoors, dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC23-C)

Information as to suitable types of respirators is available from your dealer.

Discard clothing and other absorbent materials if accidentally drenched or heavily contaminated with concentrated product. Do not reuse contaminated clothing. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User safety recommendations:
User should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash skin thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing gloves or clothing. As soon as possible, wash skin thoroughly and change into clean clothing.

Engineering controls
Liquid formulations: Mixers and loaders must use a fully closed mixing and loading system. The system must be capable of removing the pesticide from the shipping container and transferring it into mixing tanks and (or) application equipment. At any disconnect point, the system must be equipped with a dry disconnect or dry couple shut-off device that is warranted by the manufacturer to minimize drippage to not more than 2 ml per disconnect point.
In addition, mixers and loaders must:

- wear the equipment required in the PPE section of this labelling for mixer/loaders,
- wear protective eyewear if the system operates under pressure.

Wettable powder formulations: Wettable powder formulations are permitted only when marketed in water-soluble packages. Water-soluble packets qualify as a closed mixing/loading system when used correctly. Mixers and loaders using water-soluble packets must:

- wear the personal protective equipment required above for mixers/loaders

RESTRICTED ENTRY INTERVAL (REI): Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) listed in the chart below:

Crop	REI	
apple, plum, prune, pear, apricot, peach	14 days	The PPE required for early entry to treated areas that involves contact with anything that has been treated, such as plants, soil, or water, is: • Chemical-resistant coveralls over long-sleeved shirt and long pants • Chemical-resistant gloves • Chemical-resistant footwear plus socks • Protective eyewear • Chemical-resistant headgear for overhead exposure Workers performing activities that involve foliar contact following the REI must wear clean long sleeved shirts and protective gloves. Notify workers of the pesticide application by warning them orally and by posting warning signs at entrances to treated areas. Wash stations must be available in the field for all re-entry workers. Do not apply this product in a way that will come into contact with workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.
Raspberry, cranberry, blackberry	7 days	
cherry (sweet and tart)	15 days	
grape[1]	28 days[2]	

[1] Provisional upon evaluation of data submitted to assess worker exposure

[2] Will be refined based on review of worker exposure data

Persons other than agricultural workers, such as members of the general public involved in "pick-your-own," "U-pick," or similar operations, are not permitted to enter a treated area for 30 days after application.

ENVIRONMENTAL HAZARDS: This pesticide is extremely toxic to fish and wildlife. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning equipment and container or disposing of waste. Drift and runoff from treated areas are hazardous to aquatic organisms in neighbouring areas. This product is highly toxic to bees exposed to direct treatment, drift, or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area. Protective information may be obtained from your local government extension specialist. It is suggested that when treating fruit during the bloom period, bee keepers should be warned well in advance to remove hives a safe distance from orchards to be treated.

Drift resulting from applications of azinphos-methyl has been determined to be a hazard to aquatic ecosystems. For the purposes of determining buffer zones for azinphos-methyl, aquatic ecosystems consist of any form of water, such as, but not limited to, a lake, pond, stream, river,

creek, slough, canal, coulee, prairie pothole, or reservoir. For details on required buffer zones, refer to Spray Drift Management for Ground Applications.

SPRAY DRIFT MANAGEMENT FOR GROUND APPLICATIONS

General information

Use good pesticide practices and apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and parks is minimal. Take into consideration wind speed, wind direction, temperature, application equipment and sprayer settings used for application.

For the protection of non-target habitats, overspray or drift to any body of water or other environmentally sensitive habitats must be avoided. The interaction of many equipment- and weather-related factors determines the potential for spray drift. The applicator is responsible for considering all these factors when making application decisions.

Ground application

Avoid overspray or drift to sensitive aquatic habitats. An appropriate buffer zone is required between the downwind point of direct application and the closest edge of sensitive aquatic habitats including sloughs, coulees, ponds, prairie potholes, lakes, rivers, streams, reservoirs and wetlands that are situated on the periphery of the treated area.
Do not apply during periods of dead calm or when winds are gusty.

For ground spray booms, a buffer zone of 59 m is required for protection of aquatic habitats (as indicated above) if shrouds or cones are not used on the boom spray equipment. With the use of shrouds or cones on boom spray equipment, buffer zones of 18 m and 41 m, respectively, are required for protection of aquatic habitats (as indicated above).

Orchard airblast application

Do not direct spray above trees/vines and turn off outward pointing nozzles at row ends and outer rows.

Do not apply during periods of dead calm, when winds are gusty or when wind speed is greater than 16 km/hour at the application site as measured outside of the orchard/vineyard on the upwind side.

For orchard airblast applications, a buffer zone of 78 m is required for protection of aquatic habitats (as indicated above)

USES FOR AZINPHOS-METHYL (In product sold after September 30, 2003 until December 31, 2005, when registration for all uses ends):

Nature of Restriction: This product is to be stored, displayed and distributed in the manner authorized - provincial and federal regulations are in effect.

Do not apply by air.

SPRAYING: Work to windward. Protect sprayer operators from drift or mist. Additional information on spray drift management for GROUND APPLICATION is provided in the section "SPRAY DRIFT MANAGEMENT FOR GROUND APPLICATIONS". When low volumes of spray are applied, complete coverage and thorough application are essential for most effective results. Schedule applications in accordance with local conditions. Consult your local agricultural authorities for specific use information.

EXTENDED USES[7] FOR AZINPHOS-METHYL FROM OCTOBER 1, 2003 to DECEMBER 31, 2005

Site	Pests	Rate (g a.i.)	Application instructions and limitations
APPLE, PEAR			Maximum 4 applications for apples and 3 applications for pears per crop season.
	apple maggot, codling moth, pear psylla, European apple sawfly	300–373.3 g/1000 L Apply 1000–3000L of water per hectare per spray. (Maximum application rate: 1120 g a.i./ha	Ground application only. Apply specified dose in sufficient water to ensure complete coverage. Up to 4480 g a.i. for apples, 3360 g a.i./ha for pears) may be applied per hectare per crop (4 applications for apples and 3 applications for pears per crop season). Allow at least 7 days between applications. If last application is less than 1120 g a.i./ha, allow at least 14 days between last application and harvest. If last application is equal to 1120 g a.i./ha allow 21 days between last application and harvest. Use during dormant season is prohibited. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. Do not graze livestock in treated orchards.

[7] In product sold after September 30, 2003

Site	Pests	Rate (g a.i.)	Application instructions and limitations
	plum curculio	300–373.3 g/1000 L Apply 1000–3000L of water per hectare per spray. (Maximum application rate: 1120 g a.i./ha	Ground application only. Apply specified dose in sufficient water to ensure complete coverage. Apply as a border spray in sufficient water for thorough coverage. Up to two applications per year. Up to 2000 g a.i. maximum may be applied per hectare sprayed per crop season. Allow at least 7 days between applications. Allow 14 days between last application and harvest. Use during dormant season is prohibited. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. Do not graze livestock in treated orchards.
APRICOT, PEACH	plum curculio	300–333.3 g/1000 L	Ground application only. Apply specified dose in sufficient water to ensure complete coverage. Apply as a border spray in sufficient water for thorough coverage. Up to two applications per year. Up to 2000 g a.i. maximum may be applied per hectare per crop season. Allow at least 14 days between applications. Allow at least 21 days between last application and harvest. Use during dormant season is prohibited. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. Do not graze livestock in treated orchards.
BLACKBERRY, RASPBERRY	raspberry crown borer	1125 g a.i./ha	Ground application only. Post-harvest application: for control of raspberry crown borer, apply specified dosage per hectare to the lower portion of the canes and to soil beneath the plants in approximately 1600 L water. One application only.

Site	Pests	Rate (g a.i.)	Application instructions and limitations
CHERRY	cherry fruit fly	300–1125 g a.i./ 1000 L	Ground application only. Apply specified dosage in 1000 L of water as a full coverage spray. Limit to two applications to a maximum of 1680 g a.i./ha per year. Allow at least 14 days between applications and at least 15 days between last application and harvest. Use during dormant season is prohibited. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. Do not graze livestock in treated orchards.
CRANBERRY	tipworm	560–1125 g a.i./ha	Ground application only. Apply specified dosage in approximately 1600 L of water per hectare. A total of 2 applications may be made per crop season. Allow at least 14 days between applications and at least 21 days between last application and harvest.
GRAPE[8]	grape berry moth	312.5–625 g a.i./ 1000 L	Ground application only. Apply specified dosage in 1000 L of water as a full coverage border spray. A total of 2 applications is permitted per crop per season, regardless of rate. Use in conjunction with a grape berry moth mating disruption pheromone. Allow at least 14 days between applications Allow at least 21 days between last application and harvest for rates up to 437.5 g a.i./1000 L. Allow at least 28 days between last application and harvest when more than 437.5 g a.i./1000 L is applied.

[8] Provisional upon evaluation of data submitted to assess worker exposure

Site	Pests	Rate (g a.i.)	Application instructions and limitations
PLUM, PRUNE	plum curculio	300–333.3 g a.i./ 1000 L	Ground application only. Apply as a border spray in sufficient water for thorough coverage. Up to two applications per year. Up to 2000 g a.i. may be applied per hectare per crop season. Allow at least 10 days between applications. Allow at least 15 days between last application and harvest. Use during dormant season is prohibited. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. Do not graze livestock in treated orchards.