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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**Final Decisions for the Remaining Uses of Azinphos-methyl  
November 16, 2006**

**Part I: Summary and Background**

**Final Decision**

Based on its reevaluation of the risks and benefits of the 10 remaining uses of azinphos-methyl (AZM), and taking into account public comments, the Agency has come to the conclusion that these uses must be phased out by 2012. The Agency has determined that AZM use on Brussels sprouts and nursery stock will be phased out in 2007; AZM use on almonds, walnuts, and pistachios will be phased out in 2009; and use on apples/crabapples, blueberries, cherries, pears and parsley will be phased out in 2012. In addition, use of AZM will be increasingly limited during the phase out period and mitigation measures to further reduce risk to workers and the environment will be implemented. The AZM registrants have conditionally agreed to put in place EPA's final decision by amending their pending applications for continued registration and requesting voluntary cancellation of their registrations. The purpose of this document is to outline the Agency's rationale for these decisions. All supporting documents, including the worker and ecological risk assessments, the crop-by-crop grower impact assessments, comments received to date, and EPA's response to comments can be found at: <http://www.regulations.gov> under docket number EPA-HQ-OPP-2005-0061.

**Regulatory Context/Background**

AZM, an organophosphate insecticide first registered in 1959, is currently used on orchard fruits, blueberries, nuts, parsley, nursery stock, and Brussels sprouts. In connection with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) reregistration and the Federal Food, Drug, and Cosmetic Act (FFDCA) tolerance reassessment processes, EPA issued an Interim Reregistration Eligibility Decision (IRED) for AZM in October 2001.

In the AZM IRED, the Agency concluded, based on evaluation of the risks and benefits of the use of AZM, that 35 uses should either be immediately canceled (Group 1) or phased out over a four-year period (Group 2).<sup>1</sup> The remaining ten time-limited AZM uses

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<sup>1</sup> Groups 1 and 2 uses have all been deleted from the AZM registrations.

(Group 3: almonds, apples/crabapples, highbush and lowbush blueberries, Brussels sprouts, cherries, nursery stock, parsley, pears, pistachios, and walnuts) were eligible for reregistration for a period of four years, contingent on the submission of additional data and pending completion of the cumulative risk assessment for OPs. Subsequent to the IRED, a Memorandum of Agreement (MOA) in 2002 between EPA and the AZM registrants, Bayer Corporation, Gowan Company, Makhteshim-Agan of North America, Inc, Micro-Flo Corporation, and Platte Chemical Company, provided among other things, that registrants could submit applications for amended registration to extend their AZM registrations beyond the four-year period. EPA would consider applications to remove the time limitation on the registrations taking into account additional data EPA required the registrants to submit. In July 2004, the AZM registrants submitted applications to remove the time limitation for the ten uses.

The Data Call-In associated with the 2001 IRED required usage information, ecological effects data as well as biomonitoring of agricultural workers. These data have been submitted by registrants, reviewed by the Agency, and incorporated into the revised grower impact, worker and ecological risk assessments. The Agency also updated ecological and worker exposure incident information, consulted with other EPA offices, USDA, states and stakeholders, and evaluated national water monitoring data.

The ecological assessment and grower impact assessments for the individual Group 3 crops were made available for public comment on December 7, 2005. Additionally, a revised worker assessment was made available for comment on June 9, 2006. The revised worker assessment includes a discussion of a repeat-dose human toxicity study conducted in 1999 that was submitted to the Human Studies Review Board in April, 2006. Before issuing this final decision, the Agency considered the public comments received on those documents.

In addition to the revised assessments, on June 9, 2006, the Agency issued a proposed decision on the remaining uses of AZM. The Agency received comments during the public comment period from growers, grower groups, university extension agents, worker and environmental advocacy groups, registrants, and other members of the public. Many comments received were from growers urging the Agency to retain the uses of AZM. EPA received numerous similar comments from worker advocacy groups asking the Agency to cancel AZM immediately. University extension agents and growers submitted practical information about crop practices and how AZM is used in the field. EPA personnel met with stakeholders in Michigan, California, Oregon, and Washington – areas of high AZM use. EPA considered all comments it received through the public comment period and in meetings with stakeholders in reaching this final decision.

This is the Agency's final decision on the ten remaining uses of AZM and the response to the registration amendment requests. Today's decision in large measure follows the Agency's June 9, 2006 proposal with the following exceptions: (1) Rather than phasing out all AZM uses over 4 years, EPA has decided to extend the phase-out period for some uses to 6 years while achieving yearly maximum application rate reductions on a faster schedule than proposed; (2) phase-out dates for nut crops have been moved from 2007 to

2009 with the adoption of extensive additional worker and ecological risk mitigation; (3) For most uses, EPA has decided to extend existing buffer zones around water from 25 to 60 feet, rather than to 100 feet as proposed, however, product labeling must require that such buffers be maintained, vegetative buffers; (4) Rather than seeking medical monitoring of post-application workers, the AZM registrants will develop an extensive worker education and product stewardship program designed to educate workers regarding (i) work practices that can reduce exposure to AZM, (ii) the recognition of symptoms associated with exposure to AZM, and (iii) how to seek medical attention in the event workers experience such symptoms. EPA believes this education program will provide a more effective and immediate means of reducing the potential for harmful exposures to AZM during the phase-out period than the submission of new medical monitoring information. As noted above, the AZM registrants have agreed to implement EPA's final decision by amending their pending applications for continued registration consistent with the terms of this decision. For the reasons set forth below, the Agency believes this decision adequately addresses the concerns of stakeholders while providing the necessary protection to human health and the environment.

The final decision also includes consideration of the results of the cumulative dietary risk assessment of the organophosphate (OP) pesticides. The OP cumulative risk assessment is available at the following website: <http://www.epa.gov/pesticides/cumulative/2006-op/index.htm>. Since there are no dietary risk concerns for AZM, current tolerances are not affected by this decision.

### **United Farm Workers v. Johnson**

This decision is also being issued in response to a settlement agreement with the United Farm Workers and the other plaintiffs who sued the Agency in January 2004 in the U.S. District Court for the Western District of Washington regarding the pesticides AZM and phosmet. The suit alleged that the AZM and phosmet Interim Reregistration Eligibility Decisions (IREDs) were inconsistent with the requirements of FIFRA because EPA did not appropriately consider the risks and benefits of these pesticides. The settlement agreement effectively stays the legal challenge pending EPA's reconsideration of the "time limited" uses of these pesticides. Prior to finalizing the settlement agreement, EPA took public comment on it.

The settlement agreement established milestones for EPA to propose decisions on the re-evaluation of the ten AZM time-limited uses, take comment, and finalize its decision on these remaining uses by August 3, 2006. EPA and the plaintiffs later agreed to a fall date for the finalization of the AZM decision.

This document explains the logic and considerations behind EPA's risk/benefit decisions in the crop-by-crop discussions in Part II. EPA also explains the crop-specific mitigation measures in Part II.

## Summary of Ecological Risk Concerns

(For more information, see the Ecological Risk Assessment for the Use of AZM, dated September 29, 2005, and located in the AZM docket (EPA-HQ-OPP-2005-0061) located on the internet at <http://www.regulations.gov>.)

EPA's ecological assessment explored multiple lines of evidence including laboratory toxicity data for surrogate species, modeled exposure estimates (taking into account buffer strips and application rates on current labels), field studies, and ecological monitoring information. The ecological assessment shows concerns for both aquatic and terrestrial animals, even taking into account the ecological risk mitigation implemented as a result of the IRED in 2001.

AZM is mobile and relatively persistent; aquatic exposures are predominantly driven by runoff from treated orchards. AZM is very highly toxic to freshwater and marine fish and invertebrates as well as to birds, mammals, and beneficial insects, such as honey bees. All of the assessed Group 3 uses are likely to result in AZM exposures that exceed known toxicity thresholds for fish (surrogate for aquatic-phase amphibians), aquatic invertebrates, birds (surrogate for reptiles and terrestrial-phase amphibians), mammals, and beneficial insects. Depending on the magnitude and duration of exposure, acute (*i.e.* mortality) and/or chronic (*i.e.* reproductive) effects are expected.

Further, five water bodies are listed as impaired by AZM under the Clean Water Act section 303(d). Section 303(d) requires states to identify impaired waters and develop allocations of the maximum amount of a pollutant each water body can receive and still meet water quality standards. The Agency considered these impairments in its decision on AZM.

Table 1. Impaired Water Bodies Associated with AZM Use

| State | Impaired Water Body                                 | Predominant Crops  | Listed |
|-------|---|--------------------|--------|
| CA    | Colusa Basin Drain (Central Valley)                 | Nuts, stone fruits | 2002   |
| CA    | Orestimba Creek—above Kilburn Road (Central Valley) | Nuts, stone fruits | 2002   |
| CA    | Orestimba Creek—below Kilburn Road (Central Valley) | Nuts, stone fruits | 2002   |
| OR    | Neal Creek  | Pears, apples      | 2002   |
| WA    | Mission Creek                                       | Apples             | 1998   |

A recently published USGS National Water Quality Assessment Program (NAWQA) 10-year report<sup>2</sup> indicates 14 of 83 agricultural watersheds monitored had AZM concentrations that exceeded EPA's levels of concern for aquatic species.

<sup>2</sup> Gilliom, Robert J., Jack E. Barbash, Charles G. Crawford, Pixie A. Hamilton, Jeffrey D. Martin, Naomi Nakagaki, Lisa H. Nowell, Jonathan C. Scott, Paul E. Stackelberg, Gail P. Thelin, and David M. Wolock. 2006. The Quality of Our Nations Waters: Pesticides in the Nations's Streams and Groundwater, 1992-2001. U. S. Geological Survey Circular 1291. 172 p.

Because of the acute and chronic risks to aquatic animals identified in the IRED and subsequent litigation, a risk assessment<sup>3</sup> was conducted to determine whether AZM may affect threatened and endangered Pacific anadromous salmonids and their designated critical habitat. The endangered species assessment (conducted only for effects to salmonids in the Pacific North West) concluded that in spite of the mitigation measures taken (*i.e.* reduction of maximum application rates, cancellations, phase outs), AZM may affect 25 out of 26 salmonid evolutionarily significant units (ESUs) listed as threatened or endangered under the Endangered Species Act. One of those ESUs has since been delisted.

Agency records show that use of AZM has historically resulted in numerous adverse ecological incidents. EPA databases document reports of 148 fish kills and 15 honey bee kills. Reported ecological incidents have declined in the past several years, presumably in part because many of the use sites associated with a large number of incidents have been cancelled (*e.g.* cotton, sugar cane). Nevertheless, predicted environmental exposures, monitoring data, and field studies support EPA's risk conclusions for the Group 3 uses.

### Summary of Worker Risk Concerns

(For more information see the Revised Occupational Exposure and Risk Assessment for Azinphos-Methyl, dated June 6, 2006 and located in the AZM docket (EPA-HQ-OPP-2005-0061) located on the internet at <http://www.regulations.gov>.)

The toxicity endpoints used for estimating risks from short term dermal (0.56 mg/kg) and inhalation (0.2 mg/kg/day) exposures using PHED (Pesticide Handlers Exposure Database) data are the same as those used in the 2001 assessment. These endpoints are from route-specific toxicity studies in animals. The recent biomonitoring studies have allowed EPA to refine many of the exposure estimates. The toxicity endpoint used to estimate risks from worker exposures based on an internal dose from biomonitoring data is from an oral study in the dog (0.15 mg/kg/day). This is considered a protective endpoint, and is supported by a weight-of-evidence re-evaluation of the entire toxicity data base. In comparison, the endpoint in the repeat dose human study was 0.25 mg/kg/day, within the range of endpoints that have been selected for use in the occupational risk assessment. All worker endpoints used in the assessment are based on cholinesterase inhibition, a sensitive marker of exposure.

EPA's "level of concern" for AZM is a margin of exposure (MOE) of 100. That is, EPA believes there is some concern that workers may show cholinesterase inhibition when they are exposed to AZM at levels that are not at least 100-fold below the "no effect" level measured in animal data. EPA considered a repeat dose study with human subjects, and presented it to the Human Studies Review Board (HSRB). At the HSRB public meeting and in their final report, the HSRB advised EPA not to use the 28-day

<sup>3</sup> U.S.E.P.A., Office of Pesticide Programs, Environmental Field Branch. 2003. Azinphos methyl: Analysis of Risks to Endangered and Threatened Salmon and Steelhead.



study with human subjects to remove the interspecies uncertainty factor primarily because the study only established a no observed adverse effect level (NOAEL).

EPA used biomonitoring data for airblast application for all the Group 3 crops. MOEs using the biomonitoring-airblast study range from 14-18 for all open cab scenarios for mixing/loading/applying AZM to apple, pear, crabapple, almond, pistachio and walnut. For closed cab scenarios MOEs range from 80-102. MOEs for cherry and nursery stock range are 205 and 155 respectively, with closed cabs.

For post application workers, EPA used the 2003 AZM biomonitoring data for blueberry, apple, and walnut to estimate risk for all Group 3 uses except parsley. Walnuts and almonds are the only group 3 crops with MOEs of at least 100 for current REI (30 days). Other Group 3 crops would require significantly longer REIs for MOEs to reach 100. The MOEs for apples, cherries, blueberries, and pears range from 7 to 30. Currently labeled REIs are considered to be the maximum feasible for growers due to the need to perform certain crop maintenance tasks at specific stages in the growth cycle of the crops.

In addition to the risk estimates based on biomonitoring and other data, EPA has considered incidents reports and Washington state medical monitoring information. Limited information from Poison Control Centers shows a decline of about 50% in reported poisonings involving AZM from 1993-2003 or a reduction in average number of reported poisonings per year from 19 to 10. Washington state medical monitoring found two pesticide handlers with inhibition reported in 2004 related to AZM exposure alone out of 580 workers tested (% ChE inhibition was not provided nor is it known how many of the 580 workers were exposed to AZM). In 2005, the second year of Washington state's monitoring program, one worker was reported with inhibition related to AZM exposure alone, out of 611 workers tested. (It is not known how many of the 611 workers were exposed to AZM.) His red blood cell acetyl ChE inhibition varied from 8 to 21% over a 3 month period.

### Summary of Usage

Table 2. Comparison of AZM Usage Information in the 2001 and 2006 Assessments

| Crop                   | 2001 Assessment |                      | 2006 Assessment |                      |
|------------------------|-----------------|----------------------|-----------------|----------------------|
|                        | Pounds Applied  | Percent Crop Treated | Pounds Applied  | Percent Crop Treated |
| Apples                 | 932,792         | 72                   | 945,272         | 73                   |
| Sweet Cherries         | 30,200          | 44                   | 33,100          | 46                   |
| Tart Cherries          | 39,400          | 77                   | 33,700          | 68                   |
| Blueberries (lowbush)  | 2,700           | 36                   | no data         | no data              |
| Blueberries (highbush) | 8,300           | 44                   | 7,037           | 52                   |
| Pears                  | 65,552          | 42                   | 66,345          | 50                   |
| Almonds                | 83,076          | 10                   | 89,000          | 10                   |
| Pistachios             | 31,000          | 21                   | 35,000          | 24                   |
| Walnuts                | 33,123          | 10                   | 17,000          | 5                    |
| Brussels sprouts       | --              | 41                   | --              | 7                    |
| Nursery stock          | 1,400           | 1                    | 1,700           | 1                    |

|                      |             |         |             |                  |
|----------------------|-------------|---------|-------------|------------------|
| Parsley              | No data     | no data | ≈ 400       | <1               |
| Total Pounds Applied | ≈ 1,227,543 |         | ≈ 1,228,554 | Δ + 1,011 pounds |

## Revised Mitigation Measures

In the proposed decision published on June 9, 2006, EPA proposed several measures to mitigate ecological risks of concern as well as risks of concern to farm workers and members of the public. These mitigation measures included buffers around water bodies, buffer zones around houses and other dwellings, reduction of some application rates, and medical monitoring of post-application workers. Based on further analysis and stakeholder input EPA has modified some of the mitigation measures proposed in June and has added some new measures. The rationale for these changes is explained below. In Part II of this decision, EPA has laid out the final crop-specific mitigation required for each site.

*Buffer zones around water bodies* - The size of buffer zones around water bodies was determined using crop-specific, application equipment-specific, and geographically-specific ecological risk assessments. The size of buffer zones around water bodies will range from 60 to 500 feet, as determined from the risks and benefits of each AZM use. For apples, pears, cherries, and blueberries, a maintained vegetative buffer zone of 60 feet around water bodies is required for airblast applications. For parsley, a 60 foot buffer is required for ground applications. For aerial application to blueberries, a buffer zone of 150 feet is required around water bodies. A buffer zone of 60 feet for the fruit airblast uses was determined to be appropriate based on risk-benefit balancing. While a buffer zone of 60 feet does not reduce ecological risk of these uses below the Agency's level of concern for aquatic organisms, it does reduce the extent of risk to such organisms. A larger buffer for aerial application to blueberries was deemed appropriate because of greater spray drift that results from aerial applications compared to airblast applications, and therefore greater potential risk to non-target organisms.

For nut crops, (almonds, pistachios, and walnuts), a larger buffer of up to 500 feet is required around water bodies. AZM is used on a relatively small percentage of the total nut crop and a number of efficacious, cost-effective alternatives are available. Accordingly, these uses have considerably lower benefits than the fruit uses of AZM. For this reason, EPA could not make the risk-benefit finding to support use on nuts through 2009 absent additional risk reduction. At 500 feet, the estimated environmental concentration (EEC) just reaches the level of concern for brook trout if applications to nut crops occur during the dry months of June, July, August, or September. When considering a buffer zone of 500 feet during these dry months, the EEC is 0.61. The LC50 for brook trout, northern pike, and invertebrates (scud) are 1.2 ppb, 0.36 ppb, and 0.16, respectively. The ecological risk assessments discussing buffer zones are available in the AZM docket (EPA-HQ-OPP-2005-0061) located on the internet at <http://www.regulations.gov>. A booklet available from USDA (<http://www.in.nrcs.usda.gov/technical/agronomy/newconbuf.pdf>) provides information on how runoff buffers should be maintained to ensure that they are most effective. Registrants have agreed to amend their labels to include the following label language:



“A vegetative buffer zone of 60 feet must be maintained around water bodies or aquatic habitat, including, but not limited to, lakes, reservoirs, rivers, streams, marshes, natural ponds, estuaries, and commercial fish ponds.”

*Buffer zones around houses and occupied dwellings* – EPA determined the size of buffer zones around houses and other occupied structures based on a human health risk assessment using labeled maximum application rates and drift behavior based on application equipment. EPA is requiring a buffer zone of 60 feet around houses and other occupied dwellings for all uses of AZM. This assessment is available in the AZM docket (EPA-HQ-OPP-2005-0061) located on the internet at <http://www.regulations.gov>. Registrants have agreed to amend their labels to include the following label language:

“Do not apply this product within 60 feet of (1) buildings occupied by humans for residential, commercial, or business purposes, including, but not limited to, homes, farmworker housing, or other residential buildings, schools, daycare centers, nursing homes, hospitals, and (2) outdoor recreational areas such as school grounds, athletic fields, and parks. Non-residential agricultural buildings, including barns, livestock facilities, sheds, and outhouses are not included in this prohibition.”

*Rate Reductions* – EPA has developed graduated rate reductions for each of the remaining AZM uses during the phase out period. EPA’s previous proposal included only a rate reduction on apples. Rate reductions are outlined for each crop in Part II of this Decision Document.

*Medical monitoring/Stewardship* – In the proposed decision document of June 9, 2006, EPA proposed a medical monitoring requirement for postapplication workers exposed to AZM. In lieu of medical monitoring, the registrants have agreed to develop a stewardship program that will provide education to postapplication workers on ways to reduce their exposure to all pesticides, including AZM. The education program will take place in areas of the country where AZM is used most. The program will include an AZM-specific component that educates workers on (1) work practices that can reduce exposure to AZM (2) the symptoms of AZM exposure and organophosphate exposure, and (3) the steps that should be taken if symptoms of organophosphate poisoning are experienced. Registrants will submit a program protocol by June 2007 for EPA review. EPA determined that a broad-scale stewardship program will provide a more effective and immediate means of reducing potential AZM exposure during the phase out than medical monitoring would achieve. Further, the benefits of this program could well extend to the use of many other pesticides.

### **Transition Strategy**

To facilitate the transition to safer alternatives, it is EPA’s desire to have growers, registrants and other stakeholders meet periodically during the phase out and discuss available alternatives, as well as newer pesticides in the pipeline to replace AZM. This workgroup will be headed by EPA and the United States Department of Agriculture (USDA) and will be discussed at a future Pesticide Program Dialogue Committee (PPDC) meeting.

A key grower concern during the phase out period is that maximum residue levels (MRLs) will not be established in foreign markets to allow for lawful export of American commodities treated with AZM alternatives. EPA believes it is likely that by 2012, in export countries, additional MRLs will be in place covering AZM alternatives for the Group 3 crops, including apples, pears, cherries, and blueberries. These new MRLs will eliminate the concern for possible impacts to the U.S. export market. Should that not be the case, however, the EPA will consider appropriate remedies.

In light of the uncertainties concerning the alternatives, EPA has agreed to continue to assess the need for use of AZM during the phase-out period and to evaluate, under risk-benefit principles, whether to amend the cancellation order that phases out all AZM use if EPA concludes there remains a demonstrated need for AZM to address key pests.

#### **Implementation of AZM Decision**

The registrants will implement EPA's decision voluntarily by means of modifications to the terms and conditions of the AZM product registrations and revised product labeling.

## Part II: Crop Specific Considerations, Final Decisions and Rationale

(For more information on usage, alternatives and impacts, see the crop-specific grower impact assessments located in the AZM docket (EPA-HQ-OPP-2005-0061) located on the internet at <http://www.regulations.gov>.)

### Apples

#### Current Use Parameters

**Label rate:** 1.0 - 1.5 lbs ai/A per application

**Max application rate:** 4.0 lbs ai/A per season; 7 days between applications

**Typical rate:** 0.78 lbs ai/A per application, 3 applications per season

**Current REI:** 14 days

**Current PHI:** 14 days ( $\leq 1.0$  lb ai/A), 21 days ( $> 1.0$  lb ai/A)

#### Worker Risks

Of particular concern are the relatively low margins of exposure (MOE) for post application activities in apple orchards. As explained above in the summary of worker risk, the target MOE for these activities is 100. After 14 days, the MOE for thinning apples in Oregon is 24 and the MOE is 7 for harvesting apples in either New York or Oregon. These results are based on refined data, including consideration of actual biomonitoring of workers performing these activities. Based on the grower impact assessment, setting the REI longer than 14 days, to achieve an MOE that does not present risks of concern, would not be feasible for this chemical on apples due the need to perform critical crop maintenance activities at specific times in the crop's growth cycle. Further, additional worker protection measures such as more clothing or gloves for these activities are not considered feasible due to heat stress and other factors associated with these activities.

Also, EPA has calculated an MOE of 18 for applicators using an open cab airblast application to apples and an MOE of 90 with a closed cab. This result was also based on biomonitoring data of current use practices.

#### Ecological Risks

(See the above Summary of Ecological Risk Concerns for more information.)

The use of AZM on apples poses the most significant ecological risks of all the remaining uses due to application rate, timing, volume of use, and use pattern. At nearly 1 million pounds applied yearly, the apple use is the largest remaining use of AZM.

Aquatic exposures were estimated for western (OR and WA) and eastern (PA) apples and

took into account the current label rate and buffer strips. Air blast exposures from use on apples in the Pacific Northwest (OR) are estimated to be 8 times the median lethal concentration for brook trout (a salmonid species), and 32 times the chronic no-effect concentration for a common freshwater invertebrates species. Even if spray drift could be completely eliminated from apple orchard applications, runoff of the pesticide into aquatic environments would still result in acute and chronic risk quotients for aquatic animals that exceed the Agency's levels of concern at 2 times the median lethal concentration for brook trout, and 7 times the chronic no-effect concentration for freshwater invertebrates. Risks to aquatic animals are even greater for eastern (PA) apples due to increased runoff potential. As a result, EPA believes there is a high risk of mortality for aquatic species.

EPA's modeling predictions are confirmed by recent NAWQA monitoring data indicate that there continue to be AZM detections above the level of concern in areas where apples and other orchard crops on which AZM may be used are located (See the following website for more information:

<http://infotrek.er.usgs.gov/traverse/f?p=NAWQA:HOME:4416958071450237443>).

Also, states have identified impaired water bodies associated with AZM applications to apples and other uses, as noted in Table 1 above.

Further, the endangered salmonid species assessment concluded that counties where apples are grown in the Pacific Northwest overlap with the spawning, rearing, and/or migration corridors for more than 20 listed salmon groups.

The use of AZM on apples also poses acute and chronic risks to terrestrial animals, such as mammals, birds, and beneficial insects, particularly honey bees. Predicted dietary exposures for animals in and around apple orchards exceed known acute and chronic toxicity thresholds. Further, field studies in Washington and Michigan apple orchards have documented the poisoning of a variety of terrestrial animals following exposure to spray applications of AZM at rates that are very similar to the current label rate. These studies also show that there is concordance between EPA's predicted dietary exposures and actual measured field residues. In addition, there are six known honey bee kills specifically associated with the use of AZM on fruit orchards in Washington State.

#### Grower Impacts

AZM use on apples accounts for 76% of the total current use of AZM; 73% of the apple crop is treated with AZM. If AZM were not available the estimated biological and economic impact of each alternative scenario varies by region. The following is a summary of EPA's evaluation of grower impacts for eastern and western US apple production.

In the Eastern US, 49% of apples grown go to the fresh market and 51% are processed. EPA considered two alternative scenarios:

1. Phosmet as an alternative resulted in 3 % quality loss plus increase in control costs, and a 12 % reduction in per acre net revenue.

2. Using a combination of phosmet and non-OP alternatives (thiacloprid, novaluron, acetamiprid) resulted in no yield or quality loss but significant increase in control costs, and a 6% reduction in per acre net revenue.

Estimated aggregate losses to growers in the Eastern U.S. range from \$9 million to \$31 million across all scenarios.

In the Western US 70% of apples grown go to the fresh market and 30% are processed.

1. Phosmet as an alternative resulted in 1 % yield and 5 % quality loss plus increase in control costs, and 23% reduction in net revenue.
2. Using a combination of phosmet and non-OP alternatives showed no yield or quality loss but significant increase in control costs, and a 4% reduction in net revenue.

Estimated aggregate losses to growers in the Western U.S. range from \$9 million to \$50 million across all scenarios.

Estimated losses to the apple industry nationally range from \$18 million to \$81 million across all scenarios. Total national impacts are estimated to range from 5% - 18% of current net revenues.

In addition to grower impacts for domestic apple production, EPA also evaluated the effect the loss of AZM would have on the export market. In order for US growers to export apples that have pesticide residues to most export markets, there must be established maximum residue levels (“MRL”) which are similar to the requirements of US tolerances. The Agency researched whether there are established MRLs for the alternatives to AZM in the countries that receive US apples. The absence of MRLs for multiple AZM alternatives could have major impacts that are not included in the loss estimates given above. The following is a summary of the current status of MRLs in key export markets.

#### Status of MRLs for AZM Alternatives

- The US Apple trade association indicates that leading markets for US apples include Canada, Mexico, Taiwan, Hong Kong, and Malaysia.
- The main alternatives discussed by BEAD in its 2005 assessment are phosmet, acetamiprid, novaluron, and thiacloprid.
- Phosmet has an MRL in all apple export markets. The largest single export market, Mexico, has an MRL for all key alternatives. However, the other countries have few MRLs established for materials other than phosmet.

Table 3. Apples: Available MRLs for selected alternatives to AZM

| Country | Phosmet        | Acetamiprid    | Novaluron | Thiacloprid |
|---------|----------------|----------------|-----------|-------------|
| Mexico  | 10             | 1              | 2         | 0.3         |
| Canada  | 10             | 1 <sup>b</sup> | 2         | 0.3         |
| Taiwan  | 2 <sup>a</sup> | 1 <sup>a</sup> | -         | -           |

|                    |                 |   |     |     |
|--------------------|-----------------|---|-----|-----|
| Hong Kong          | 10              | - | -   | -   |
| Malaysia           | 10 <sup>a</sup> | - | -   | -   |
|                    |                 |   |     |     |
| US                 | 10              | 1 | 2   | 0.3 |
| Codex <sup>c</sup> | 10              | - | {3} | -   |

**Sources:** USDA Foreign Agricultural Services (FAS), Agricultural and Tropical Products Division ([www.mrlatabase.com](http://www.mrlatabase.com)); Northwest Horticultural Council ([www.nwhort.org](http://www.nwhort.org)).

**Notes:**

<sup>a</sup> From Northwest Horticultural website.

<sup>b</sup> Proposed as per the Canadian PMRA Website <http://www.pmra-arla.gc.ca/english/legis/max-re-e.html>.

<sup>c</sup> From the Codex Alimentarius website: [http://www.codexalimentarius.net/mrls/pestdes/jsp/pest\\_q-e.jsp](http://www.codexalimentarius.net/mrls/pestdes/jsp/pest_q-e.jsp).

{ } = under development according to the Report of the Thirty Eighth Session of the Codex Committee on Pesticide Residues, Fortaleza Brazil, 3-8 April, 2006. Available at <http://www.codexalimentarius.net>.

- = MRL not listed.

\* MRL figures are given in parts per million (ppm); Codex values, are in mg/kg, which are equivalent

## Final Decision/Mitigation

As explained above, EPA believes there is a high risk of mortality to numerous aquatic and terrestrial species from the apple use of AZM. Additional label mitigation can reduce this risk but EPA's assessment indicates it is insufficient to reduce the risk below EPA levels of concern. The worker risk assessment indicates that existing MOEs at current label rates are insufficient to ensure that there is not a concern that workers will be exposed to levels of AZM that will result in cholinesterase depression – a precursor of adverse neurological effects. Current label restricted entry intervals cannot be extended in light of the need for field re-entry to conduct necessary cropping practices.

In the short term, EPA believes that the benefits of AZM use on apples are high and with the additional mitigation measures outlined below, these benefits outweigh the risks during the phase out, largely for four reasons: (1) While there are now numerous efficacious registered alternatives to AZM, many of the alternatives that are the most likely to be used lack maximum residue level regulations (known as "MRLs") that allow for residues of these pesticides on apples sold in countries to which U.S. apples are exported, leaving growers at risk, in some cases, of losing the export market for lack of an appropriate alternative. EPA's "worst-case" estimate is that loss of certain export markets could result in a loss to the apple industry of well over \$100 million. (2) Development of effective alternative pest control practices using new pesticides often takes multiple use seasons to perfect. With 73% of apples treated with AZM, most growers will need to switch to new practices and may not have the necessary experience or guidance regarding such practices were EPA to cancel this use immediately or allow only for a more limited phase out. Without prior development of such practices, there is a risk that grower impacts would exceed EPA's estimates. (3) While EPA believes the risk concerns from AZM use are significant, EPA is not aware of incident information, monitoring data or other sources of information that suggest AZM is having immediate large-scale environmental impacts (such as a clear link to species population declines or extirpations) or that severe worker poisoning incidents are occurring. Although incident and monitoring databases are not sufficiently robust to capture the full extent of likely adverse effects, EPA believes that if severe adverse human health were occurring on a broad scale, these databases would reflect that fact. (4) EPA believes the risk mitigation



measures outlined below are feasible and will reduce the existing risks to some extent.

EPA believes, however, that with the development of MRLs for newer pesticides, new registrations for use on apples, and with the adoption of and experience in using alternative pest control practices, this risk-benefit balance for apples changes. EPA believes it is reasonable to assume that a number of export countries will adopt additional MRLs for the newer pesticides within 6 years, and that growers will have at their disposal appropriate guidance and practice with using these alternatives effectively by that time. At that point, EPA believes the benefits of AZM will track the grower impact scenarios outlined above and that the risk associated with AZM will outweigh those benefits. While these impacts will remain in the millions of dollars nationally, it is important to note that the overall impact on grower revenue is relatively small. These numbers should decline further as additional alternatives become available over the next few years. Further, EPA has not reviewed any information that suggests there will be a measurable impact on consumers in the price or availability of apples from the cancellation of AZM. Indeed, the loss of a single agricultural pesticide rarely translates into consumer-level impacts.

In EPA's June 9, 2006 proposed decision, the Agency had concluded that the appropriate phase-out period for transition to AZM alternatives for the fruit crops was four, rather than six years. EPA has now concluded that a six year phase-out for the fruit uses that reduces use rates sooner is appropriate for the following reasons: (1) By reducing some application rates sooner, this approach allows for earlier risk reduction; (2) In addition, by lowering the rates used to a greater degree than proposed, the overall use of AZM over six years only represents a modest increase (15%) over the amount that could have been used under the proposed decision while giving growers more time to develop effective transition strategies for alternatives; (3) EPA was convinced by grower and registrant comments that six years was likely a more accurate estimate for the time period in which a number of proven, cost-effective alternatives for which MRLs have been established will become available to growers; and (4) Registrants will voluntarily request amendments to their registrations to conform to this decision. In the absence of the registrants voluntary actions, EPA would have had to initiate a cancellation action, with the possibility of protracted cancellation hearings. In addition to the legal risk associated with taking such matters to a hearing, lengthy cancellation proceedings could have put in jeopardy EPA's ability to institute in a timely manner the near term risk mitigation provisions of this decision, including rate reductions, buffer zones and the early phase-out of certain uses.

As discussed above, EPA believes it is likely that by 2012 there will be in place additional MRLs for AZM alternatives in export countries for apples that will eliminate the concern for possible impacts to the US export market as well as cost-effective alternatives to replace AZM for the domestic market. As indicated above, however, EPA will continue to assess the need for use of AZM during the phase out period and to evaluate, under risk-benefit principles, whether to amend the cancellation order that phases out all AZM use if EPA concludes there remains a demonstrated need for AZM.

During the phase out period, EPA will require the following mitigation measures:

#### Rate Reduction for Apples

| Apples             | 2007                  | 2008, 2009            | 2010                  | 2011, 2012            |
|--------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| Limit Seasonal Max | 4.0 lbs ai/A per year | 3.0 lbs ai/A per year | 2.0 lbs ai/A per year | 1.5 lbs ai/A per year |

- Use on apples/crabapples will be cancelled as of September 30, 2012
- Aerial application will be prohibited. There is currently one 24(c) registration for aerial application on apples. EPA has been notified that this 24(c) will be cancelled.
- Buffer zone for homes and occupied dwellings: 60 feet
- Vegetative buffer zone for water bodies: 60 feet
- “Pick your own” / “U-pick” harvesting REIs: For rates of 1.01 – 1.5 lbs ai/A per application, a U-pick REI of 44 days must be observed. For rates of 0.61 – 1.0 lbs ai/A per application, a U-pick REI of 39 days must be observed. For rates of 0.60 lbs ai/A per application or less, a REI of 33 days must be observed.

#### Pears

##### Current Use parameters

**Label rate:** 1.0 – 1.5 lbs ai/A per application

**Max application rate:** 3.0 lbs ai/A per year; 7 days between applications

**Typical rate:** 1.05 lbs ai/A, 3 applications per season

**Current REI:** 14 days

**Current PHI:** 14 days (< 1.0 lbs ai/A), 21 days (>1.0 lbs ai/A)

##### Worker Risks

Like apples, of particular concern are the relatively low margins of exposure (MOE) for post application activities on pears. As explained above, the target MOE for these activities is 100. After 14 days, the MOE for thinning pears in Oregon is 24 and only 7 for harvesting pears in either New York or Oregon. These results are based on refined data, including consideration of actual biomonitoring of workers performing these activities. Although the biomonitoring study used for pears was conducted with apples, the Agency believes that apples are appropriate surrogates for pears.

Also of concern is the MOE of 18 for open cab airblast applications to pears, based on apple biomonitoring data of current use practices. The MOE for closed cab airblast application to pears is 90.

##### Ecological Risks

(See the above Summary of Ecological Risk Concerns for more information.)

The use of AZM on pears poses acute and chronic risks to all aquatic and terrestrial animals. Aquatic exposures were estimated for Oregon pears, and predicted exposures exceed known toxicity thresholds.

States have identified impaired water bodies associated with AZM applications, including pears and other uses, as noted in Table 1 above.

The endangered salmonid species assessment concluded that counties where pears are grown in the Pacific Northwest overlap with the spawning, rearing, and/or migration corridors for more than 20 listed salmon groups.

### Grower Impacts

Pears are produced on about 64,500 total bearing acres in the U.S. Washington, Oregon, and California represent about 94% of the national production of pears. Washington State alone accounts for 40 percent of the total acreage. Approximately 66,000 pounds of AZM are applied annually to pears with 50 % of the pear crop treated with this pesticide.

AZM is applied to pears primarily for the control of codling moth (*Cydia pomonella*) and, to a lesser extent, for the suppression of grape mealybug (*Pseudococcus maritimus*) populations.

Several new insecticides have been registered on pears since the 2001 AZM IRED. The following insecticides are potential alternatives to AZM: abamectin, acetamiprid, buprofezin, diflubenzuron, indoxacarb, lambda cyhalothrin, methoxyfenozide, novaluron, pyriproxyfen, spinosad, thiacloprid, and thiamethoxam. With the exception of diflubenzuron, indoxacarb, lambda cyhalothrin, novaluron, and spinosad all of these insecticides have been adopted to some degree by pear growers for control of codling moth and/or grape mealybug.

Based on the latest information available with respect to alternative insecticides for AZM, no yield or quality losses are expected if AZM is not available for use on pears. However, alternative pest control scenarios (phosmet or acetamiprid and methoxyfenozide) are more expensive than AZM. Nationally, the increased control costs are estimated to decrease the value of production by less than 1% for pear growers. Regionally, the Pacific Northwest will experience the greatest losses with a reduction in per acre net revenues from 1.5% to 1.6% if AZM is not available.

These new alternatives give growers more treatment options and may be useful for resistance management when rotated with phosmet, the primary alternative to AZM.

### **Status of MRLs for AZM Alternatives**

- The leading export markets for pears include Mexico, Canada, Brazil, Sweden, and Russia.

- The main alternatives listed by BEAD in its 2005 assessment are phosmet, acetamiprid, novaluron, and methoxyfenozide.
- Mexico has established MRLs for all the main alternatives to AZM. Canada has MRLs established or proposed for 3 of the 4 main alternatives.

Table 4. Pears: Available MRLs for selected alternatives to AZM \*

| Country            | Phosmet        | Acetamiprid    | Novaluron        | Methoxyfenozide |
|--------------------|----------------|----------------|------------------|-----------------|
| Mexico             | 10             | 1              | 2                | 1.5             |
| Canada             | 10             | 1 <sup>a</sup> | -                | 1.5             |
| Brazil             | -              | -              | -                | -               |
| Sweden             | 2 <sup>c</sup> | -              | -                | -               |
| Russia             | -              | -              | -                | -               |
|                    |                |                |                  |                 |
| US                 | 10             | 1              | 2                | 1.5             |
| Codex <sup>b</sup> | 10             | -              | {3} <sup>d</sup> | 2               |

Sources: USDA Foreign Agricultural Services (FAS), Agricultural and Tropical Products Division ([www.mrlatabase.com](http://www.mrlatabase.com)); Northwest Horticultural Council ([www.nwhort.org](http://www.nwhort.org)).

**Notes:**

<sup>a</sup> From Northwest Horticultural website only.

<sup>b</sup> From the Codex Alimentarius website: [http://www.codexalimentarius.net/mrls/pestdes/jsp/pest\\_q-e.jsp](http://www.codexalimentarius.net/mrls/pestdes/jsp/pest_q-e.jsp).

<sup>c</sup> EU MRL

<sup>d</sup> Proposed per PMRA Website <http://www.pmra-arla.gc.ca/english/legis/max-re-e.html>

{ } = under development according to the Report of the Thirty Eighth Session of the Codex Committee on Pesticide Residues, Fortaleza Brazil, 3-8 April, 2006. Available at <http://www.codexalimentarius.net>.

- = MRL not listed.

\* MRL figures are given in parts per million (ppm): Codex values are in mg/kg, which are equivalent.

## Final Decision/Mitigation

For the reasons outlined above in the discussion regarding apples, EPA believes that AZM use on pears should similarly be phased out in 2012. While the Agency assessment indicates that there will be fewer domestic impacts on pear growers than apple growers, the concerns regarding MRLs for pears in export markets are similar, and in some cases greater, than the concern for apples.

As discussed above, EPA believes it is likely that by 2012 there will be in place additional MRLs for AZM alternatives in export countries for pears that will eliminate the concern for possible impacts to the US export market. EPA has, however, agreed to continue to assess the need for use of AZM during the phase-out period and to evaluate, under risk-benefit principles, whether to amend the cancellation order that phases out all AZM use if EPA concludes there remains a demonstrated need for AZM.

During the phase out period, labeling will be amended to require the following mitigation measures:

### Rate Reduction for Pears

| Pears              | 2007, 2008            | 2009, 2010            | 2011, 2012            |
|--------------------|-----------------------|-----------------------|-----------------------|
| Limit Seasonal Max | 3.0 lbs ai/A per year | 2.0 lbs ai/A per year | 1.5 lbs ai/A per year |

- Use on pears will be cancelled as of September 30, 2012
- Aerial application is prohibited
- Buffer zone for homes and occupied dwellings: 60 feet
- Vegetative buffer zone for water bodies: 60 feet
- “Pick your own” / “U-pick” harvesting is prohibited on pears if AZM is applied to pears

### **Blueberries (lowbush and highbush)**

#### *Current Use parameters*

**Label rate:** 0.5 – 0.75 lbs ai/A per application (lowbush and highbush)

**Max application rate:** 1.5 lbs ai/A per season

**Typical rate:** 0.25 lbs ai/A for lowbush and 0.564 lbs ai/A for highbush,  
2 applications per crop per season

**Current REI:** 10 days for lowbush and 7 days for highbush, u-pick is 30 days

**Current PHI:** 10 days for lowbush and 7 days for highbush

#### *Worker Risks*

Of particular concern are the relatively low margins of exposure (MOEs) for post application activities on blueberries. As explained above, the target MOE for these activities is 100. After seven days, the MOE for harvesting highbush blueberries is 30. These results are based on refined data, including consideration of actual biomonitoring or workers performing these activities.

Based on PHED data, the MOEs for mixing/loading for aerial or groundboom, with a closed system, are 9 to 40. For groundboom application of AZM to blueberries the MOE is 25 for open cab applications and 80 for closed cabs.

#### *Ecological Risks*

(See the above Summary of Ecological Risk Concerns for more information.)

Blueberries are grown across the U.S., and fresh- and saltwater ecosystems may be exposed to AZM by runoff and spray drift. Aquatic exposures were modeled for Michigan blueberries and various drift scenarios were considered. Aerial application of AZM to blueberries is particularly concerning due to the increased likelihood of drift to aquatic resources. Even if drift could be reduced to 1%, there still would be acute and chronic concerns.

For terrestrial animals, modeled dietary exposures for small, medium and large birds and mammals are at risk regardless of preferred food items. Mean dietary residues are also likely to exceed known acute and chronic thresholds for birds and mammals.

Based on these multiple lines of evidence, EPA considers the ecological risk of AZM on blueberries to be high.

### Grower Impacts

There are two primary types of blueberries (*Vaccinium* spp.), lowbush and highbush. The U.S. production of lowbush (also called “wild”) blueberries occurs almost entirely in Maine, while highbush blueberry production occurs primarily in three regions: the Pacific Northwest (Oregon and Washington), the North Central (Michigan and Indiana), and the East (New York, New Jersey, Florida, Georgia, North Carolina, Alabama, and Arkansas).

Approximately 7,000 pounds of AZM are applied to highbush blueberries. There are no data on the amount of AZM applied to lowbush blueberries. However, information from crop experts indicates that AZM use has decreased since 2001 and it appears that most growers have already switched to other alternatives, primarily phosmet. In the absence of AZM, the likely pest management scenarios indicate that lowbush blueberry producers in the absence of AZM should be able to substitute phosmet with low losses in net cash returns since it is comparable to AZM in terms of cost and efficacy.

There appears to be virtually no use of AZM in Pacific Northwest blueberries. Highbush blueberry growers in the North Central region (primarily Michigan) will have to use more treatments of a set of alternative insecticides to substitute for the average of approximately 2 applications of AZM they have been using. Similarly, growers in the other major highbush blueberry producing region, the Eastern US (represented by New Jersey), will also have to use multiple alternatives in place of AZM. EPA’s 2005 grower impact assessments concluded that in both regions pest management costs will rise, along with an estimated 1-2 % yield loss and 1-2 % quality loss. Therefore, for both regions, losses ranging from \$51 to \$116 per acre at the grower level (in terms of returns above variable costs per acre) are predicted, while at the regional level losses of approximately \$ 2.3 million are expected.

### **Status of MRLs for AZM Alternatives**

- The leading export markets for blueberries include Japan, Canada, Australia, Korea, and the UK.
- The main alternatives are phosmet, esfenvalerate, and tebufenozide.
- Japan and Canada have an established MRL for phosmet and Japan also has an established MRL for tebufenozide.

Table 5. Blueberries (lowbush and highbush): Available MRLs for selected alternatives to AZM

| Country   | Phosmet | Esfenvalerate | Tebufenozide |
|-----------|---------|---------------|--------------|
| Japan     | 10      | -             | 3            |
| Canada    | 5       | -             | -            |
| Australia | -       | -             | -            |



|                    |    |                |   |
|--------------------|----|----------------|---|
| Korea              | -  | -              | - |
| UK                 | -  | -              | - |
|                    |    |                |   |
| US                 | 10 | 3 <sup>b</sup> | 3 |
| Codex <sup>a</sup> | 10 | 1 <sup>c</sup> | 3 |

**Sources:** USDA Foreign Agricultural Services (FAS), Agricultural and Tropical Products Division ([www.mrlatabase.com](http://www.mrlatabase.com)).

**Notes:** UK defers to EU MRL levels for pesticides if the country has not set its own MRL. In the same context, Korea defers to CODEX MRL levels. Australia follows only its own MRL levels.

- = MRL not listed.

<sup>a</sup> From the Codex Alimentarius website: [http://www.codexalimentarius.net/mrls/pestdes/jsp/pest\\_q-e.jsp](http://www.codexalimentarius.net/mrls/pestdes/jsp/pest_q-e.jsp).

<sup>b</sup> Listed in CFR but not in FAS.

<sup>c</sup> Expressed as fenvalerate in CODEX database.

\* MRL figures are given in parts per million (ppm); Codex values, are in mg/kg, which are equivalent.

### Final Decision / Mitigation

For the reasons outlined above in the decision regarding apples, EPA believes that AZM use on blueberries should similarly be phased out in 2012. AZM use on blueberries presents high ecological risks and potentially high risk to workers, especially re-entry workers engaged in harvesting activities. While the impact to growers of losing AZM is less than with the apple and pear uses, there will be some impacts felt from the loss of AZM. The absence of MRLs for alternatives in certain blueberry export markets could have an impact on growers selling for the export market. Accordingly, as with apples and pears, EPA is proposing to phase-out the use of AZM on blueberries in 2012.

As discussed above, EPA believes it is likely that by 2012 there will be in place additional MRLs for AZM alternatives in export countries for blueberries that will eliminate the concern for possible impacts to the US export market. EPA has, however, agreed to continue to assess the need for use of AZM during the phase-out period and to evaluate, under risk-benefit principles, whether to amend the cancellation order that phases out all AZM use if EPA concludes there remains a demonstrated need for AZM.

During the phase out period, product labels will be amended to include the following mitigation measures:

#### Rate Reduction for Blueberries

| Blueberries        | 2007                  | 2008, 2009             | 2010, 2011, 2012       |
|--------------------|-----------------------|------------------------|------------------------|
| Limit Seasonal Max | 1.5 lbs ai/A per year | 1.25 lbs ai/A per year | 0.75 lbs ai/A per year |

- Use on blueberries will be cancelled as of September 30, 2012
- Aerial application will be permitted through September 30, 2009. After September 30, 2009, aerial application will be prohibited.
- Based on benefits, maintain highbush blueberry REI of 7 days
- Buffer zone for homes and occupied dwellings: 60 feet
- Vegetative buffer zone for water bodies: 60 feet for airblast applications and 150

feet for aerial applications.

- “Pick your own” / “U-pick” harvesting REIs: For rates of 0.626 – 0.75 lbs ai/A per application, a U-pick REI of 42 days must be observed. For rates of 0.51 – 0.625 lbs ai/A per application, a U-pick REI of 35 days must be observed. For rates of 0.50 lbs ai/A per application or less, a REI of 30 days must be observed.
- Restrict application to the following states: Alabama, Arkansas, Florida, Georgia, Indiana, Michigan, New Jersey, New York, and North Carolina. (Currently on labels)

### **Cherries (sweet and tart)**

#### *Current Use parameters*

**Label rate:** 0.75 lbs ai/A per application

**Max application rate:** 1.5 lbs ai/A per season

**Minimum** 14 days between applications

**Typical rate:** 0.64 lbs ai/A for tart cherries, 2.7 applications per year

0.46 lbs ai/A for sweet cherries, 2 applications per year

**Current REI:** tart cherries: 2 days

sweet cherries: 15 days and 30 days for u-pick

**Current PHI:** 15 days

#### *Worker Risks*

Of particular concern are the relatively low margins of exposure (MOE) for post application activities in cherry orchards. As explained above in the summary of worker risk, the target MOE for these activities is 100. After 14 days, the MOE for harvesting cherries in New York or Oregon is 14. These results are based on refined data, including consideration of actual biomonitoring of workers performing these activities. Based on the grower impact assessment, setting the REI longer than 14 days would not be feasible for this chemical on cherries. Further, additional worker protection mitigation measures such as more clothing or gloves for these activities are not considered feasible due to heat stress and other factors associated with these activities.

Also EPA has estimated an MOE of 36 for mixer/loader/applicators using an open cab for airblast application to cherries. This result was also based on biomonitoring data of current use practices.

#### *Ecological Risks*

(See the above Summary of Ecological Risk Concerns for more information.)

The use of AZM on cherries poses risks to aquatic and terrestrial animals. Aquatic exposures were modeled for Michigan cherries, and various drift scenarios were considered. Even if drift could be reduced to 1%, there still would be acute and chronic concerns.

For terrestrial animals, modeled dietary exposures for small, medium and large birds and mammals are at risk regardless of preferred food items. Mean dietary residues are also likely to exceed known acute and chronic thresholds for birds and mammals.

States have identified impaired water bodies associated with AZM applications to cherries (a stone fruit) and other uses, as noted in Table 1, above.

The endangered salmonid species assessment concluded that counties where cherries are grown in the Pacific Northwest overlap with the spawning, rearing and/or migration corridors for more than 20 listed salmon groups.

#### Grower Impacts - Sweet Cherries

Sweet cherries are primarily produced in four states: California, Michigan, Oregon, and Washington.

The cost of currently available AZM alternatives and recent efficacy data on these pesticides suggests that grower-level (per acre) impacts of the loss of AZM for eastern (largely Michigan) sweet cherry growers may be as high as 11 % loss in net cash returns, while in Washington such losses are approximately 2 %. It appears that effective new pest control alternatives (such as thiamethoxam, multiple sprays of synthetic pyrethroids, and spinosad) now exist that should allow growers to meet the stringent quality standards required by the sweet cherry market. However, increases in production costs are potentially significant for individual growers, at least in the eastern U.S. Calculated losses reflect the increased production costs incurred by the need to apply multiple treatments of some alternatives, or the much higher costs of other materials. Unlike the other crops mentioned above, phosmet is not an alternative to AZM for sweet cherries because of phytotoxicity concerns.

#### Grower Impacts - Tart Cherries

Michigan is the primary producer of tart cherries, accounting for over 70 percent, followed by Washington, Utah, and New York. Less than one percent of production is marketed as fresh; the primary processed use is frozen cherries although a significant portion is canned. Bearing acreage of tart cherries have been declining steadily in the U.S. for at least the past decade, although the decline has lessened in recent years and may even have stabilized.

Based on the current availability of efficacious alternatives to AZM to control plum curculio and cherry fruit fly in tart cherries the benefits derived from the use of AZM are likely to be small. In the absence of AZM, growers would most likely use phosmet to maintain the local, state, and federal mandated zero tolerance for these pests. Use of phosmet would likely raise production costs by around \$10 to \$25 per acre. This could amount to two to four percent of a grower's net cash returns (gross revenue minus

operating costs). However, recent increases in the price of tart cherries may mean that the benefits of AZM as a percent of net cash returns are smaller.

### Status of MRLs for AZM Alternatives

- The leading export markets for cherries include Japan, Canada, Taiwan, the United Kingdom, and Australia.
- The main alternatives listed by BEAD in its 2005 assessment are phosmet, lambda cyhalothrin, imidacloprid, spinosad, and thiamethoxam.
- The top 5 export countries have an MRL established for phosmet. Japan has MRLs established for all the main AZM alternatives. Australia and Canada have MRLs established or proposed for 4 of the 5 main alternatives.

Table 6. Cherries (sweet and tart): Available MRLs for selected alternatives to AZM

| Country            | Phosmet        | Lambda Cyhalothrin | Imidacloprid     | Spinosad         | Thiamethoxam      |
|--------------------|----------------|--------------------|------------------|------------------|-------------------|
| Japan              | 0.1            | 0.5                | 3                | 0.2              | 5                 |
| Canada             | 7              | -                  | 3                | 0.1 <sup>b</sup> | 0.02 <sup>b</sup> |
| Taiwan             | 2 <sup>a</sup> | -                  | -                | -                | -                 |
| UK                 | 2 <sup>d</sup> | -                  | -                | 0.2 <sup>a</sup> | -                 |
| Australia          | 1 <sup>a</sup> | 0.1                | 0.5 <sup>a</sup> | 1.0 <sup>a</sup> | -                 |
|                    |                |                    |                  |                  |                   |
| US                 | 10             | 0.5                | 3                | 0.2              | 0.5               |
| Codex <sup>c</sup> | 10             | -                  | {0.5}            | 0.2              |                   |

**Sources:** USDA Foreign Agricultural Services (FAS), Agricultural and Tropical Products Division ([www.mrlatabase.com](http://www.mrlatabase.com)); Northwest Horticultural Council ([www.nwhort.org](http://www.nwhort.org)).

**Notes:**

<sup>a</sup> From Northwest Horticultural website only.

<sup>b</sup> Proposed per PMRA Website <http://www.pmra-arla.gc.ca/english/legis/max-re-e.html>.

<sup>c</sup> From the Codex Alimentarius website: [http://www.codexalimentarius.net/mrls/pestdes/jsp/pest\\_q-e.jsp](http://www.codexalimentarius.net/mrls/pestdes/jsp/pest_q-e.jsp).

<sup>d</sup> EU MRL

{ } = under development according to the Report of the Thirty Eighth Session of the Codex Committee on Pesticide Residues, Fortaleza Brazil, 3-8 April, 2006. Available at <http://www.codexalimentarius.net>.

- = MRL not listed in the databases examined.

\* MRL figures are given in parts per million (ppm); Codex values are in mg/kg., which are equivalent.

### Final Decision / Mitigation

For many of the same reasons outlined above in the decision regarding apples, EPA believes that AZM use on cherries should similarly be phased out in 2012. The cherry use of AZM presents high ecological risks and potentially high risk to workers, especially re-entry workers. While the impact to growers of losing AZM is less than with the apple and pear uses it is still significant. Further, as noted above, while MRLs are in place for numerous export markets for the alternatives, the absence of certain MRLs in certain important export markets could have an impact on growers selling to those markets. Even though the MRL situation is better for cherries than apples, pears, and blueberries, a six-year phase-out is necessary because of the need to transition to the newer alternatives. EPA was convinced by grower and registrant comments that six years was

likely a more accurate estimate for the time period in which a number of proven, cost-effective alternatives will become available to growers for use on cherries.

EPA will continue to assess the need for use of AZM during the phase-out period and to evaluate, under risk-benefit principles, whether to amend the cancellation order that phases out all AZM use if EPA concludes there remains a demonstrated need for AZM.

EPA believes the risk mitigation measures outlined below are feasible and will reduce the existing risks to some extent. During the phase out period, product labels will be amended to require the following mitigation measures:

#### Rate Reduction for Cherries

|                       |                          |                           |
|-----------------------|--------------------------|---------------------------|
| Cherries              | 2007, 2008,<br>2009      | 2010, 2011,<br>2012       |
| Limit Seasonal<br>Max | 1.5 lbs ai/A per<br>year | 0.75 lbs ai/A<br>per year |

- Use on cherries will be cancelled as of September 30, 2012
- Aerial application is prohibited
- Buffer zone for homes and occupied dwellings: 60 feet
- Vegetative buffer zone for water bodies: 60 feet
- “Pick your own” / “U-pick” harvesting is prohibited on cherries after AZM applications

#### **Parsley**

##### *Current Use Parameters*

**Label rate:** 0.5 lb ai/A per application; maximum of 3 applications per season

**Current REI:** 30 days

**Current PHI:** 7 days

**Use restrictions:** Restricted to New Jersey and Ohio

##### *Worker Risk*

As explained in the summary of worker risk, the target MOE is 100. For occupational handlers, the calculated MOEs for mixer/loaders supporting groundboom applications on parsley are 93 with engineering controls. For applicators applying sprays for groundboom application, the MOE with engineering controls (enclosed cabs) is 191. These estimates are based on default Agency assumptions and may overestimate risk.

For post application activities on parsley, the MOE at 42 days is 100. The labeled REI is currently 30 days. These estimates are based on default Agency assumptions as no appropriate biomonitoring data were available.

### Ecological Risks

See the above Summary of Ecological Risk Concerns for more information. Due to the small acreage of this crop, ecological risk is of somewhat less concern than for larger acreage crops.

### Grower Impacts

AZM is used on less than 1% of the national parsley crop. Most of the nation's domestic parsley crop is grown in California, with scattered production in other states, such as Ohio and Arizona. In parsley, AZM is labeled for the control of the carrot weevil (*Listronotus oregonensis*), which is a pest unique to parsley in the eastern U.S. There are few alternative insecticides with the carrot weevil specifically listed on their labels. For example, spinosad does not list the weevil as a target pest, but may have efficacy for its control. Pyrethrin-containing products list the weevil, but apparently these are effective only during cold weather. Cultural controls also play a role in reducing the survival of the carrot weevil. Based on the very low recent usage of AZM, and the availability of alternative chemical and cultural controls, for the majority of U.S. parsley production, the impact of the loss of AZM will be minimal, with possibly greater impacts in Ohio due to constraints on available alternatives.

EPA does not anticipate any export issues for parsley due to the loss of AZM.

### **Final Decision / Mitigation**

The parsley use of AZM presents risks to re-entry workers as well as some ecological risks of concern. Given the limited use of AZM on parsley, however, the extent of that risk is fairly limited in scope both geographically and in the number of potentially affected persons and species. While the overall impact to parsley growers nationwide of losing AZM is likewise quite small, in those areas where it is used there are few alternative insecticides currently available for the key target pest. Given the value of AZM to parsley growers in the eastern U.S., EPA believes that with the additional mitigation outlined in this decision, the benefits of AZM use on parsley outweigh the risks. EPA believes, however, that by 2012 transition strategies for use of AZM alternatives are likely to have been developed that will significantly reduce parsley grower impacts in the eastern U.S. Accordingly, the parsley use will be cancelled as of September 30, 2012. EPA has, however, agreed to continue to assess the need for use of AZM during the phase-out period and to evaluate, under risk-benefit principles, whether to amend the cancellation order that phases out all AZM use if EPA concludes there remains a demonstrated need for AZM.

#### Rate Reduction for Parsley

|                |                  |                     |                  |
|----------------|------------------|---------------------|------------------|
| Parsley        | 2007             | 2008, 2009,<br>2010 | 2011, 2012       |
| Limit Seasonal | 1.5 lbs ai/A per | 1.25 lbs ai/A       | 1.0 lbs ai/A per |



|     |      |          |      |
|-----|------|----------|------|
| Max | year | per year | year |
|-----|------|----------|------|

- Use on parsley will be cancelled as of September 30, 2012
- Buffer zone for homes and occupied dwellings: 60 feet
- Vegetative buffer zone for water bodies: 60 feet

## **Almonds**

### **Current Use Parameters**

**Label rate:** 1.5 – 2.0 lbs ai/A per application, maximum of one application per season

**Typical rate:** 1.85 lbs ai/A per application

**Current REI:** 30 days

**Current PHI:** 30 days

### **Worker Risks**

For post application activities on almonds, MOEs range from 170 to 790 for rakers, sweepers, and shakers at the labeled restricted entry interval (REI) of 30 days. These results are based on refined data, including consideration of actual biomonitoring of workers performing these activities.

The calculated MOE of 14 for open cab applications to almonds is of concern. This estimate is also based on biomonitoring of current use practices. With closed cabs, the MOEs for these pesticide handlers would be 80.

### **Ecological Risks**

(See the above Summary of Ecological Risk Concerns for more information.)

The use of AZM on almonds poses risks to aquatic and terrestrial animals. Aquatic exposures were modeled for California almonds, and various drift scenarios were considered. Even if drift could be reduced to 1%, there would still be acute and chronic concerns.

Recent NAWQA monitoring data show that there continue to be AZM detections above the level of concern in nut-growing areas. States have identified impaired water bodies associated with AZM applications to nut crops and other uses, as noted in Table 1, above.

The endangered salmonid species assessment concluded that counties where almonds are grown in California overlap with the spawning, rearing and/or migration corridors for four listed salmon groups.

### Grower Impacts

The loss of AZM use is unlikely to have significant impacts on the almond industry because there are several alternative chemicals that can be used for the pests of concern. AZM is applied to about 10% of the total almond acreage in the US. Almond growers have several alternatives to AZM that are currently being used, and the Agency's economic analysis shows minimal loss if growers switch to these alternatives.

The main alternatives for AZM use on almonds listed by BEAD in its scenarios in 2005 assessment are chlorpyrifos, phosmet, spinosad, esfenvalerate, and permethrin. The Agency's economic analysis shows minimal loss if growers switch to these alternatives. The following is a summary of the impacts on revenue as a result of switching to each of these alternatives.

1. Phosmet alternative: 0.1% - 0.3% reduction in per acre net revenue.
2. Chlorpyrifos alternative: 2.0% - 2.8% increase in per acre net revenue.
3. Non-OPs (spinosad, esfenvalerate, permethrin): 0.2% reduction in per acre net revenue to 5.3% increase in per acre net revenue.

There are minimal estimated losses from the elimination of AZM as a pesticide on almonds. The Agency did not assess the availability of MRLs for AZM alternatives used on almonds. However, because only 10 percent of the crop is currently treated with AZM and the crop is being treated with numerous other alternative insecticides, EPA assumes that the loss of AZM will have no significant impact on the almond export market.

### **Final Decision / Mitigation**

In the absence of enclosed cabs for applicators, extensive buffer zones, and seasonal timing limitations on use, AZM use on almonds presents significant worker and ecological risks. The risk mitigation described in the previous sentence (and as outlined below) can significantly reduce these risks; it will not, however, eliminate risk concerns entirely. While the benefits of AZM use on almonds are generally quite limited, EPA has learned through public comments and meetings with grower groups that AZM is an important tool for some growers in controlling insect pests that cause crop damage resulting in the spread of the aflatoxin fungus. While the aflatoxin concern is not widespread, growers who use AZM to control the spread of naval orange worm need additional time to develop effective strategies for using alternatives to address this concern. Given the continued risk concerns and the relatively limited extent of the aflatoxin problem, EPA does not believe the benefits of continued use merit a 6-year phase out, as with the fruit crops, but the Agency is persuaded that these concerns do merit extending the cancellation date for an additional two years to give affected growers some time to develop alternative strategies.

The following measures apply to almonds:

- Use on almonds will be cancelled as of October 30, 2009
- Limit to one application of 2.0 lbs ai/A per year
- Only apply AZM to almonds during the months of June, July, or August
- All applications must occur in closed cabs
- Buffer zone for homes and occupied dwellings: 60 feet
- Buffer zone for water bodies: 300 feet for Butte, Colusa, Glenn, Madera, Merced, San Joaquin, Solano, Stanislaus, Sutter, Tehama, Yolo, and Yuba counties in California, and 500 feet for all other counties.

## **Pistachios**

### **Current Use Parameters**

**Label rate:** 2.0 lbs ai/A per application, maximum of one application per season

**Typical rate:** 1.85 lbs ai/A per application

**Current REI:** 21 days

**Current PHI:** 21 days

### **Worker Risks**

For post application activities on pistachios, the MOE for rakers, sweepers, and shakers at 18 days is 102. As explained in the summary of worker risk, the target MOE is 100. The labeled REI requirement for pistachios is 21 days, so there are no risks of concern for workers as long as they adhere to the labeled REI. These results are based on refined data, including consideration of actual biomonitoring of workers performing these activities.

The calculated MOE of 14 for open cab applications to pistachios is of concern. This estimate is also based on biomonitoring of current use practices. With closed cabs, the MOEs for these pesticide handlers would be 80.

### **Ecological Risks**

(See the above Summary of Ecological Risk Concerns for more information.)

The use of AZM on pistachios poses risks to aquatic and terrestrial animals. Aquatic exposures were modeled for California pistachios and various drift scenarios were considered. Even if drift could be reduced to 1%, there would still be acute and chronic concerns.

States have identified impaired water bodies associated with AZM applications to nut crops and other uses, as noted in Table 1, above.

The endangered salmonid species assessment concluded that counties where pistachios are grown in California overlap with the spawning, rearing and/or migration corridors for one listed salmon group.

### Grower Impacts

The loss of AZM use is unlikely to have a large impact on the pistachio industry because there are several alternative chemicals that can be used for pests of concern and are less expensive than AZM. Although AZM is applied to about 24% of the total pistachio acreage in the US, pistachio growers have several alternatives to AZM that are currently being used. Because efficacious alternatives exist, EPA assumes there will be no yield or quality loss from using another chemical in place of AZM. The Agency's economic analysis shows no loss if growers switch to these alternatives.

The main alternatives listed by BEAD in its 2005 impact assessment are permethrin, phosmet, tebufenozide, and methoxyfenozide.

There are no estimated losses from the elimination of AZM as a pesticide on pistachios.

### **Final Decision / Mitigation**

In the absence of enclosed cabs for applicators, extensive buffer zones, and seasonal timing limitations on use, AZM use on pistachios presents significant worker and ecological risks. The risk mitigation described in the previous sentence (and as outlined below) can significantly reduce these risks; it will not, however, eliminate risk concerns entirely. While the benefits of AZM use on pistachios are generally quite limited, EPA has learned through public comments and meetings with grower groups that AZM is an important tool for some growers in controlling insect pests that cause crop damage resulting in the spread of the aflatoxin fungus. While the aflatoxin concern is not widespread, growers who use AZM to control the spread of naval orange worm need additional time to develop effective strategies for using alternatives to address this concern. Given the continued risk concerns and the relatively limited extent of the aflatoxin problem, EPA does not believe the benefits of continued use merit a 6-year phase out, as with the fruit crops, but the Agency is persuaded that these concerns do merit extending the cancellation date for an additional two years to give affected growers some time to develop alternative strategies.

The following measures apply to pistachios:

- Use on pistachios will be cancelled as of October 30, 2009
- Limit to one application of 2.0 lbs ai/A per year
- Application is limited to California and Arizona
- Only apply AZM to pistachios during the months of June through October
- All applications must occur in closed cabs
- Buffer zone for homes and occupied dwellings: 60 feet
- Buffer zone for water bodies: 500 feet

### Walnuts

### Current Use Parameters

**Label rate:** 1.5 - 2.0 lbs ai/A per application, maximum of one application per season

**Typical rate:** 1.23 lbs ai/A per application

**Current REI:** 30 days

**Current PHI:** 30 days

### Worker Risks

For post application activities on walnuts, MOEs range from 170 to 790 for rakers, sweepers, and shakers at the labeled REI requirement of 30 days. These results are based on refined data, including consideration of actual biomonitoring of workers performing these activities.

The calculated MOE of 14 for open cab applications to walnuts is of concern. This estimate is also based on biomonitoring of current use practices. With closed cabs, the MOEs for these pesticide handlers would be 80.

### Ecological Risks

(See the above Summary of Ecological Risk Concerns for more information.)

The use of AZM on walnuts poses risks to aquatic and terrestrial animals. Aquatic exposures were modeled for California walnuts, and various drift scenarios were considered. Even if drift could be reduced to 1%, there would still be acute and chronic concerns.

Recent NAWQA monitoring data indicate that there continue to be AZM detections above the level of concern in nut-growing areas. States have identified impaired water bodies associated with AZM applications to nut crops and other uses, as noted in Table 1, above.

The endangered salmonid species assessment concluded that counties where walnuts are grown in California overlap with the spawning, rearing and/or migration corridors for more than 20 listed salmon groups.

### Grower Impacts

The loss of AZM is unlikely to have a large impact on the walnut industry because there are several alternative chemicals that can be used for pests of concern and are less expensive than AZM. Additionally, AZM is only applied to about 5% of the total walnut acreage in the U.S. Walnut growers have several alternatives to AZM that are currently being used. Because efficacious alternatives exist, in some cases at lower prices, EPA assumes there will be no significant yield or quality loss from using other chemicals in place of AZM. The Agency's economic analysis shows little to no loss if growers switch

to these alternatives. Additionally, walnut acreage in the U.S. has increased in recent years, and AZM use has decreased in recent years, indicating that growers have decreased reliance on AZM.

The main alternatives listed by BEAD in its scenarios in 2005 are methyl parathion, methidathion, phosmet, carbaryl, esfenvalerate, permethrin, lambda-cyhalothrin, spinosad, *Bt*, tebufenozide, methoxyfenozide, and diflubenzuron.

The elimination of AZM as a pesticide on walnuts may result in an increase or decrease in per acre net revenue depending upon the alternative chosen.

### **Final Decision / Mitigation**

In the absence of enclosed cabs for applicators, extensive buffer zones, and seasonal timing limitations on use, AZM use on walnuts presents significant worker and ecological risks. The risk mitigation described in the previous sentence (and as outlined below) can significantly reduce these risks; it will not, however, eliminate risk concerns entirely. While the benefits of AZM use on walnuts are generally quite limited, EPA has learned through public comments and meetings with grower groups that AZM is an important tool for some growers in controlling insect pests that cause crop damage resulting in the spread of the aflatoxin fungus. While the aflatoxin concern is not widespread, growers who use AZM to control the spread of aflatoxin need additional time to develop effective strategies for using alternatives to address this concern. Given the continued risk concerns and the relatively limited extent of the aflatoxin problem, EPA does not believe the benefits of continued use merit a 6-year phase out, as with the fruit crops, but the Agency is persuaded that these concerns do merit extending the cancellation date for an additional two years to give affected growers some time to develop alternative strategies.

The following measures apply to walnuts:

- Use on walnuts will be cancelled as of October 30, 2009
- Limit to one application of 2.0 lbs ai/A per year
- Only apply AZM to walnuts during the months of June, July, or August
- All applications must occur in closed cabs
- Buffer zone for homes and occupied dwellings: 60 feet
- Buffer zone for water bodies: 500 feet

Debra Edwards, Ph.D., Director  
Special Review and Reregistration Division