Reregistration Decisions on Nine Phosmet "Time-Limited" Uses

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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Decision and Rationale

This document presents the Agency's regulatory decision on the nine "time-limited" uses of phosmet: high bush blueberries, peaches, nectarines, apples (including crabapples), pears, plums, prunes, grapes, and apricots.

The Agency has determined that the time-limited uses of phosmet should be retained with extended restricted entry intervals (REIs) and additional risk mitigation, as outlined below, to be included on product labels sold or distributed by the registrant after June 2008. Most of these additional restrictions or similar measures were included in the Agency's June 9, 2006, proposal for the reevaluation of the time-limited uses of phosmet. EPA has determined that with the additional mitigation outlined in this decision, the benefits of these uses outweigh the risks in the near term. While, in general, there are effective, alternative pesticides registered for these uses, current pesticide pricing information suggests that grower impacts in some states could be significant, depending on the crop, were they required to switch to these alternatives today. In addition, many of these alternatives are currently used by relatively few growers, thus requiring the development of untested alternative control regimes, leading to additional near-term transitional costs were the Agency to extend phosmet REIs beyond those outlined in this document.

While the Agency's current human health assessment indicates that workers are at some risk of experiencing cholinesterase inhibition — a precursor to neurological effects — when working with phosmet and in areas treated with phosmet, EPA believes phosmet presents fewer risks than azinphos- methyl (AZM), a likely alternative in the near-term for growers for many of these uses. Further regulation of these uses of phosmet now could have the unintended consequence of pushing some growers to switch to AZM while it is still available (all remaining uses of AZM are subject to cancellation by 2012), given AZM's cost and effectiveness. In addition, the significant international markets have approved maximum residue level (MRL) regulations for AZM, but generally have not for newer alternatives.

The Agency remains concerned, however, that the calculated margins of exposure for phosmet are low, and therefore indicative of some measure of worker risk from exposure to phosmet, as stated above. It should be noted that the phosmet human health database supporting this decision is not as refined as that for some other compounds. A biomonitoring study submitted in November 2005, was evaluated for EPA's proposed

decision. Although EPA considered that study in its proposed decision, the Agency nonetheless noted that it had numerous technical flaws which limited its utility. The Agency determined that the study did not fulfill the IRED biomonitoring data requirement and would need to be repeated. Since June 2006, when EPA issued its proposed decision, the Agency determined that it could not further consider the November 2005, study in developing its final decision for phosmet, because one of the study subjects was a minor. EPA's regulations regarding testing conducted on human subjects precludes EPA from considering intentional dosing studies that include minors. Post-application risk estimates have been revised and now rely solely on animal studies, as did the 2001 risk assessment.

In addition to mitigation, EPA is requiring additional biomonitoring or other relevant data to further refine the phosmet worker risk assessment. In the Agency's experience, additional refinement of the human health database (e.g., development of worker biomonitoring data) has generally served to demonstrate that risks are lower than estimated using only laboratory data. This is not uniformly true, however, and the Agency is therefore not prepared to make an open-ended determination that the benefits of phosmet outweigh the risks based on the current risk assessment, especially in light of the fact that new alternatives may become available. The Agency believes that with the development of additional data to be completed in 2008, there will be greater clarity on the extent of the risks workers face from phosmet. The Agency therefore intends to revisit this decision in 2008 upon the submission of such data and consider, in light of that data (and any new information regarding the benefits of phosmet) whether the mitigation outlined in this decision should be retained, strengthened, or reduced.

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 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 these pesticides. Prior to committing to the settlement agreement, EPA took public comment.

The settlement agreement established milestones for EPA to propose decisions on the re-evaluation of the ten AZM and nine phosmet time-limited uses, take comment, and then finalize a decision on these remaining uses by August 3, 2006. EPA and plaintiffs agreed on amendments to the settlement, and EPA informed the plaintiffs that the phosmet decision would be issued by January 17, 2007.

Regulatory History

Phosmet, an organophosphate insecticide first registered in 1966, is currently used on a variety of orchard fruits, berries, nuts, and other crops. In connection with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) reregistration requirements and the Federal Food, Drug, and Cosmetic Act (FFDCA) tolerance reassessment processes, EPA issued an Interim Reregistration Eligibility Decision (IRED) for phosmet in October 2001.

In the phosmet IRED, the Agency concluded, based on evaluation of the risks and benefits of the use of phosmet, that three uses would be cancelled, 36 uses were eligible for reregistration, and nine uses would be time-limited for a period of five years, contingent on the submission of additional data and pending completion of the cumulative risk assessment for OPs. Concurrent with the IRED in 2001, EPA and the sole technical registrant of phosmet, Gowan Company, signed a Memorandum of Agreement (MOA). The MOA provided that the registrant would develop and submit a biomonitoring study and other data, and that based on these data and any other available information, EPA would reevaluate the restricted entry intervals (REIs) of the nine time-limited uses in 2006.

In June 2006, the Agency released its proposed decision for public comment (at www.regulations.gov under docket number EPA-HQ-OPP-2002-0354). The revised decision presented in this document is based on (1) comments submitted during the June-August comment period, (2) updated post-application worker risk calculations (excluding the biomonitoring data), (3) calculations of risks to the general public participating in "pick-your-own" harvesting activities, (4) calculations of health-protective buffer zone distances from treated areas to occupied structures, and (5) updated (quantitative) grower impact assessments. In updated grower impact assessments, EPA estimated the costs to growers of switching from phosmet to other available alternatives. This decision document will be available on the phosmet website at http://www.epa.gov/oppsrrd1/op/phosmet.htm. Other supporting documents will be available in the docket phosmet docket at www.regulations.gov, under docket number EPA-HQ-OPP-2002-0354.

Summary of Usage

Table 1 presents the most recently available statistics on usage from USDA National Agricultural Statistics Service. In fully assessing usage patterns, EPA also uses other data sources, including proprietary data.

Table 1. Current Phosmet Usage, 2001-2005 National Averages.

Crop	lb Applied	% Crop Treated	No. of Applications	Rate (lb/acre)	Seasonal Rate (lb/acre/year)
Apple	346,100	31	2.4	1.57	3.68
Apricot [1]	1,900	5	1.1	2.42	2.72
Blueberry	31,100	47	2.2	0.83	1.78

Grape [2]	9,400	1	1.8	1.26	2.21
Nectarine [3]	38,100	40	1.3	1.94	2.43
Peach	238,800	41	3.3	1.43	4.73
Pear	68,500	23	1.5	3.37	5.06
Plum [3]	25,500	26	1.2	2.8	3.36

Source: USDA NASS Agricultural Chemical Usage, Fruit Summary (2002, 2004, 2006)

[1] Data from the California Dept of Pesticide Regulation (2001, 2003, 2004). USDA NASS did not report statistics on phosmet use in apricots. Over 90% of apricot acreage is in California.

[2] California dominates national grape statistics. USDA NASS does not report phosmet usage for any other state except for Michigan in 2001. EPA proprietary data indicate that phosmet is used on about 20% of grape acreage is the Northeast.

[3] California is the only reporting state in USDA NASS statistics. Most nectarine and about 95% of plum acreage is in California. However, phosmet usage on peaches may be more representative of usage in the eastern U.S.

Summary of the Phosmet Risk Assessments

For phosmet, the primary risks of concern are related to applicators and re-entry workers. There are also potential ecological risks to birds, mammals, fish, and aquatic invertebrates; however, these risks are substantially lower than those posed by azinphos-methyl (AZM), particularly for aquatic organisms (see section on ecological risk, below). Phosmet is an alternative to AZM for apples and pears (particularly in the eastern U.S.), and for highbush blueberries.

Human Health Assessment

The following is a summary of the updated risk assessment for post-application workers and members of the general public exposed to phosmet in Pick-your-own harvesting operations, or as bystanders in homes or other occupied structures near phosmet-applied fields. The complete assessment, "Phosmet: Revisions To The Occupational and Residential Post-Application Exposures and Risk Calculations and Determination of Buffer Zones for Phosmet Applications," dated November 16, 2006, can be found on the phosmet website at http://www.epa.gov/oppsrrd1/op/phosmet.htm.

Risks were estimated using the Margin of Exposure (MOE) approach, which is a ratio of the body burden (exposure) to the toxicological endpoint(s) of concern. EPA believes an MOE of 100 or greater (that is, an exposure that is at least 100 times greater than the level at which no effects are seen) is not of concern for phosmet.

The toxicological endpoint of concern is cholinesterase (ChE) inhibition. For the short-term risk calculations (up to 30 days exposure), EPA selected a 21-day dermal study in rats (MRID 44795801). The no observable adverse effect level (NOAEL) in this study was 15 mg/kg/day; the lowest observed adverse effect level (LOAEL) in this study was 22.5 based on brain (females) and plasma (males) cholinesterase inhibition.

A NOAEL of 1.1 mg/kg/day from a chronic (two-year) toxicity/carcinogenicity study in rats (MRID 41916401) was used to calculate intermediate term risks (over 30 days exposure). The LOAEL in this study was 1.8 mg/kg/day based on red blood cell and serum cholinesterase inhibition. In order to use this oral endpoint to calculate risks from dermal exposure, EPA used a 10% dermal absorption factor.

Further analysis of the toxicity data for phosmet indicates that the doses at which clinical signs occur (in animals) are approximately an order of magnitude higher than doses at which cholinesterase inhibition occur. The relatively few incident reports support the prediction that clinical signs are rare.

Handler Risk

Risk to phosmet handlers (mixers, loaders and applicators) was not reassessed for this current evaluation of restricted entry intervals. The handler risk assessment supporting EPA's 2001 Phosmet IRED indicated risks to airblast applicators are below the level of concern (MOE > 100), provide closed cabs are used. Current labels provide for the use of maximum personal protective equipment (PPE) as an alternative to closed cabs. This maximum PPE includes double-layer clothing, chemical resistant headgear, and a respirator, and results in airblast applicator MOEs would be <100 in many instances. EPA is currently evaluating the protection provided by various types of chemical resistant headgear in an effort to further refine risk estimates for applicators. Results of these evaluations will be included in subsequent assessments of phosmet handler risk.

Post-application worker risk

For all the tree crops, post-application workers could be expected to experience intermediate-term exposure, primarily during the 4-6 week thinning season. Thinning is the highest exposure activity in tree crops (transfer coefficient (TC) = 3,000). Post-application workers hand harvesting blueberries (and conducting other high exposure activities for blueberries, TC = 1,100) could also experience intermediate-term exposure. For grapes, workers conducting the highest exposure activity of grape girdling (TC = 10,000) are expected to experience less than 30 days of exposure; however, workers training vines, hand harvesting, and thinning (high exposure activities, TC = 5,000) could be exposed to phosmet residues for more than 30 days. The dislodgeable foliar residue (DFR) values used in the current assessment were taken from a study on pear trees (phosmet applied at 5 lbs/ai/A), and a study on grapes (phosmet applied at 1 lbs/ai/A), the same DFR studies used in the 2001 IRED. The pear DFR values were used to calculate post-application risks for all tree crops, and the grape DFR values were used to calculate post-application risks for grapes and highbush blueberries.

During the comment period, registrants and others contended that the transfer coefficient for thinning fruit trees (3000 cm^2/hour), used by EPA in its assessment, was not realistic and that the thinning TC should be the same as that for harvesting (1500 cm^2/hour). Were the lower TC to be used, MOEs for thinners would increase by 2-fold.

EPA's interpretation of the existing data is that thinners, because of the nature of the activity--grasping branches and selecting and removing immature fruits, can indeed be subject to greater pesticide exposure than harvesters. The only specific study designed to measure the surface area contacted during the thinning activity shows an average value of 3000 cm^2/hour. Five harvesting studies yielded an average of 1500 cm^2/hour. Until more thinning-specific data are available, EPA finds the 3000 cm^2/hour figure to be the most appropriately protective for this activity.

Also, commenters noted that in calculating exposure, EPA assumes that workers re-enter each field on the day corresponding to the REI for 30 or more consecutive days. EPA agrees in principle that assuming that maximum residues are available every day of exposure is conservative, especially for intermediate (>30 days) exposures. For this reason, in this assessment EPA is focusing on short term exposures for workers, as the most representative of actual phosmet risk, although intermediate term MOEs are also given for the sake of completeness. Using intermediate term exposure and maximum residue values for every day of exposure would likely overestimate risk. However, EPA believes that averaging residues for short term exposures is not appropriate in this instance, since thinning must occur in a relatively short time frame in order to be effective, in some crops phosmet is applied frequently, and it is likely that thinning crews reenter treated fields soon after treatment.

Risks to the general public: "pick-your-own" harvesting

EPA calculated risks to members of the general public (youths and adults) conducting "pick-your-own" harvesting activities in commercial peach, nectarine, apple, pear, plum, and apricot orchards, as well as highbush blueberry fields. "Pick-your-own" harvesting is not expected to occur in grape vineyards. For this assessment, EPA selected a rat acute neurotoxicity study (MRID 446733-01) with a NOAEL of 4.5 mg/kg/day, and a LOAEL of 22.5 based on plasma, red blood cell, and brain cholinesterase inhibition, and decreased motor activity. A 10% dermal absorption factor was used to adjust this acute dietary endpoint for dermal exposure. Risks were calculated based on 2 hours of harvesting by youths and 4 hours of harvesting by adults, as per the U.S. EPA 1996 Residential SOP. The transfer coefficient (TC) for the tree crops was derived from a homeowner dermal exposure study (MRID 401223-01). The TC used for highbush blueberries was the ARTF blueberry harvesting TC (ARF-020), modified to reflect the reduced clothing that might be worn by members of the general public (shorts and a short-sleeved shirt), as compared with WPS mandated field-worker clothing (long pants and a long-sleeved shirt).

Risks to the general public: bystanders near phosmet-applied fields

EPA also conducted a spray drift assessment, to calculate the risks to bystanders (children) in the vicinity of orchards, fields and vineyards treated with phosmet by airblast sprayer and aerial application. The AgDRIFT® model was used to calculate spray deposition at 25, 50, and 100 feet from treated areas. Risks were calculated for children

(as the most sensitive population) based on dermal, incidental oral, and combined (dermal and oral) routes of exposure as per the U.S. EPA 1996 Residential SOP 12.

Summary of Worker Incidents

Relatively few recent agricultural worker incidents have been reported for phosmet. From 1998 to 2003, five phosmet-related worker incidents that were definitively linked to agriculture were reported to the nationwide NIOSH-SENSOR worker incident database (out of 5,899 reported cases). Of these, one case involved a worker in Oregon, washing equipment in a confined space. Another involved a worker in New York who was exposed to phosmet during an accidental spill while unloading packages of phosmet from the back of a truck. Two cases involved apple thinners in Washington State, and another involved a farm worker in California (no further information was available regarding this incident).

In California, three phosmet-related worker incidents were reported to the California Pesticide Illness Surveillance Program from 1998 to 2004. In one case, an applicator who sprayed phosmet in peach and nectarine orchards reported flu-like symptoms; two days later, he reported nausea, body aches, and a headache and was treated by a physician. In the second, two brothers got sick after thinning nectarines on a hot day in an orchard that had been treated the previous month with phosmet. They reported stomach pain, diarrhea, and vomiting. In the third case, an applicator reported a headache while applying phosmet. Three days later, he was treated by a physician.

EPA also conducted a review of the 2004 and 2005 Washington State Biomedical Monitoring reports, for cases involving 30 days or more of handling phosmet. EPA also obtained worker inspection case follow-up notes directly from Washington State staff. A total of over 600 pesticide applicators were monitored for plasma and red blood cell cholinesterase each year. Of the 54 cholinesterase depression cases that had State follow-up, 16 involved phosmet. These 16 cases likely involved workers applying phosmet in fruit orchards, and this (fruit tree application) was confirmed for the three cases with field follow-up. In Washington State, insecticide application to fruit trees is typically by air blast. No cases involved phosmet alone: all involved chlorpyrifos (lorsban) and other compounds also known to depress cholinesterase. No workers showed overt symptoms of pesticide poisoning in either year.

Follow-up consultations with the Washington State Department of Public Health incident staff identified a total of twelve phosmet-related poisoning cases in the last three years. This is in addition to the cholinesterase monitoring cases that did not have overt poisoning symptoms. There were seven poisoning cases in 2003, three in 2004 (two “suspected” and one “probable”), and two in 2005 (one “possible” and one “insufficient”).

Ecological Assessment

In February 2006, EPA completed a limited update to the April 1998, "Environmental Fate and Ecological Risk Assessment" that had been completed for the phosmet IRED. This limited update focused only on the nine time-limited uses of phosmet, taking into account the most recent use parameters. For a complete discussion, please see the document, **"**Comparison of Currently Supported Phosmet Use Rates to those Assessed Previously," dated February 2, 2006, on the phosmet website (http://www.epa.gov/oppsrrd1/op/phosmet.htm).

To evaluate the potential risk to non-target organisms from the use of pesticide products, the Agency calculates a Risk Quotient (RQ), which is the ratio of the estimated pesticide exposure to the most sensitive ecological toxicity endpoint values, such as the median lethal dose (LD_{50}) or the median lethal concentration (LC_{50}) for a particular species. These RQ values are then compared to the Agency's levels of concern (LOCs), which indicate whether a pesticide, when used as directed, has the potential to cause adverse effects to non-target organisms. When the RQ exceeds the LOC for a particular category, the Agency presumes a risk of concern. EPA further characterizes ecological risk based on any reported incidents to non-target terrestrial or aquatic organisms in the field (e.g., fish or bird kills). Ecological LOCs are listed Table 2.

Table 2. EPA's Levels of Concern and Associated Risk Presumptions

Risk Presumption	**LOC Terrestrial Animals**	**LOC Aquatic Animals**	**LOC Plants**
Acute Risk - there is potential for acute risk	0.5	0.5	1
Acute Endangered Species - endangered species may be adversely affected	0.1	0.05	1
Chronic Risk - there is potential for chronic risk	1	1	N/A

Table 3, below, summarizes the risk quotients (RQs) and level of concern (LOC) exceedences at maximum labeled rates.

Table 3: Summary of Phosmet Risk Quotients and LOC Exceedences

Species	**LOC Summary (acute)**	**LOC Summary (chronic)**
Freshwater fish	1/9 uses exceed Pear RQ = 2.0	1/9 uses exceed Pear RQ = 1.2
Freshwater invertebrates	9/9 uses exceed RQ range: 4.2 – 70	5/9 uses exceed RQ range: 1.0 – 5.0
Estuarine/marine Fish	1/9 uses exceed Pear RQ = 0.8	1/9 exceeds Pear RQ = 1.5
Estuarine/marine invertebrates	9/9 uses exceed RQ range: 5.3 – 88	9/9 uses exceed RQ range: 1.1 – 10
Birds	9/9 uses exceed	9/9 uses exceed

	RQ range: 0.04 – 2.4	RQ range: 0.15 – 20
Small mammals (feeding on short grass)	9/9 uses exceed RQ range: 0.01 – 4.6	9/9 uses exceed RQ range 0.5 – 60

Since azinphos-methyl is an alternative for phosmet on several of the subject crops, EPA has compared the risk to non-target species of these two chemicals. For example, while phosmet RQ values exceed acute risk LOCs across all of the uses evaluated for freshwater invertebrates, RQ values only exceed the acute risk LOC for fish for a single use, pears, at the maximum application rate. In contrast for AZM, RQ values exceed acute risk LOCs across all uses for freshwater fish (range: 12 – 54). For freshwater invertebrates, RQ values for AZM ranged from 26 – 121; this range is wider than that of phosmet. Unlike AZM, phosmet has no reported fish-kill incidents associated with normal use.

Only one phosmet use (pears) exceeded the chronic risk LOC for freshwater fish. RQ values for freshwater invertebrates exceed the chronic risk LOC for five out of the nine uses evaluated by factors as high as 4.9X. However, for AZM all of the uses evaluated exceed the chronic risk LOC for fish and invertebrates by factors ranging between 5 – 24X and 13 – 61X, respectively.

RQ values however, are dimensionless numbers and their magnitude cannot be legitimately compared across chemicals and taxa unless it can be demonstrated that the dose-response curves are similar. However, analyses conducted on AZM indicate that for freshwater organisms, the dose response curves have relatively steep slopes and that minor increases in AZM concentrations will result in marked increases in toxicity and therefore, risk. Phosmet exhibits a more gradual dose response.

Currently, EPA does not assess risk to non-target insects; however, the results of a honey bee acute toxicity (LD_{50}) study indicated that phosmet is very highly toxic to bees. In addition, six reported incidents of bee mortality in Washington, California and North Carolina have been attributed to phosmet use, primarily in orchards (1993-1998). Based on phosmet's acute toxicity to non-target insects and the bee-kill incidents attributed to phosmet, a precautionary bee statement is on current labeling.

Other than the bee-kill incidents, the only other reported ecological incident involved the accidental misuse of phosmet in a North Carolina orchard in 1994 (the species and number of organisms affected were not reported).

Crop Specific Considerations

APPLES

Current use parameters

Current label rates: The maximum rate per application is 4 lbs ai/A, with a seasonal maximum of 21 lbs ai/A.

Average rate: Nationally, the average application rate is 1.56 lbs ai/A per application, with an average of 1-3 applications per season.

Current REI: 3 days (for thinning, the short-term (ST) MOE = 13, and the intermediate-term (IT) MOE = 10)[1]. In the June 2006 decision document, EPA proposed extending this REI to 7 days (for thinning, ST MOE = 17, IT MOE = 13).

Current PHI: 7 days (for hand harvesting, ST MOE = 34, IT MOE = 25)

Post-application prohibition period for "pick your own" harvesting: 14 days (MOE>100).

Worker risks

For post-application workers thinning apples that have had phosmet applied at the maximum rate of 4 lbs ai/A, the short-term MOE is 13 at the current labeled REI of 3 days. Over a 4-6 week thinning season, the intermediate-term MOE is 10 at the maximum application rate. At this application rate, it would take 39 days to reach an MOE > 100. However, it is unlikely that workers would be exposed to the maximum rate every day for 30 days or more, suggesting that the intermediate-term exposure MOE likely overestimates risk.

Risks from "pick-your-own" operations

Risks to youths and adults conducting "pick-your-own" (PYO) harvesting activities were calculated using phosmet-specific exposure data. Based on this assessment, risks to members of the general public participating in PYO harvesting are below EPA's level of concern (MOE>100) at 14 days after application.

Risks to bystanders in the vicinity of apple orchards

Based on EPA's analysis of drift from airblast applications, risks to bystanders (children) are below EPA's level of concern (MOE>100) at 25 feet from the application site for all but the "sparse" foliage scenario. For this scenario, risks are below the Agency's level of concern at 50 feet. For aerial application to apples at 50 feet from the application site, an MOE >100 was calculated for "coarse" droplet size spray applications, and MOE of 66 for "medium" droplet size spray, and an MOE of 33 for "fine" droplet size spray.

Ecological risks

[1] Short-term exposure is defined as 1-30 days of exposure; intermediate-term exposure is defined as 1-6 months of exposure.

Although phosmet applications in apples orchards have the potential to result in some acute and chronic risks to aquatic invertebrates (freshwater and estuarine/marine), birds, and mammals, these risks are generally lower than those of most pyrethroid and OP alternatives. In particular, phosmet has substantially lower ecological risks than azinphos-methyl, a primary alternative to phosmet in apples.

Alternatives and grower impacts

Washington State is the largest producer of U.S. apples, accounting for 59% of total US production, followed by New York, (10.5%), Michigan (7.9%), Pennsylvania (5.2%) and California (3.6%).

In 2005, an estimated 33% of the U.S. apple acreage was treated with phosmet (57% of the eastern U.S. apple crop, and 17% of the western U.S. apple crop). Average application rates in the west (an average of 2 to 3 pounds of active ingredient per acre per application) are typically higher than average application rates in the east (an average of 1 to 1.5 pounds of active ingredient per acre per application). More than 90% of the area treated with phosmet in the west is at a rate of 3.5 pounds of active ingredient per acre or less, while in the east, 90% of the area treated with phosmet is at a rate of 2.5 pounds of active ingredient per acre or less.

Extending the REIs for phosmet could severely limit the amount of time a labor crew has to complete necessary orchard activities such as hand thinning, tree training, limb propping, summer pruning for fire blight. This could impact growers by not allowing them not to achieve the desired results from these activities resulting in reduced tree health, fruit size, and quality. Furthermore, extending the REIs beyond the maximum feasible length of 7 days, would likely force growers to abandon phosmet use in favor of another OP (AZM, diazinon, dimethoate) or pyrethroids such as fenpropathrin, esfenvalerate or lambda cyhalothrin which also have either worker or ecological concerns.

Pyrethroids are not a desirable alternative as they tend to be less compatible with integrated pest management and mating disruption programs than is phosmet. An additional concern with pyrethroids is that use of these pesticides tends to precipitate secondary pest outbreaks, such as spider mites, necessitating the use of a miticide at an additional cost of about $50 per acre.

Some new chemistries are available, such as neonicitinoids. However, two applications of neonicitinoids and two applications of insect growth regulators would likely be required to achieve the results of the typical three applications of phosmet. The cost of these applications would be double the cost of the three applications of phosmet.

No yield or quality losses are likely if growers switch to a combination of alternative insecticides. However, increases in chemical control costs using the alternatives to phosmet may result in decreases in per acre net revenues for growers currently using phosmet. Per acre net revenues could decrease as much as 18% for apple

growers currently using phosmet in the eastern U.S., and 3% for apple growers currently using phosmet in the western U.S.

Final regulatory decision and mitigation

- For apples east of the Rockies:
  - extend the REI to 4 days,
  - prohibit harvesting for 7 days, and
  - prohibit dormant season applications

After a review of growers' and extension agents' comments submitted during the post-decision comment period, and a reevaluation of the risks and benefits, EPA is requiring that the REI for apples east of the Rockies be 4 days (for thinning, ST MOE = 14, IT MOE = 10), rather than the June-proposed 7 days. Apple growers in eastern production regions commonly apply pesticides using an alternate middle row application technique, which results in substantially less pesticide being applied per acre, per application. Under this spraying regime, an REI of seven days would interfere with critical orchard tasks (such as thinning). An REI of 4 days would allow growers to continue performing alternate middle row applications. Because of the lower application rates used with alternate row middle spraying, risks to post-application workers would be lower than those calculated (for example, at 2 lbs ai/A, MOEs would be twice as high as those calculated).

A harvesting prohibition of 7 days is consistent with the existing PHI for apples. Phosmet is not applied to apple orchards during the dormant season.

- For apples west of the Rockies, and crabapples (CA only):
  - extend the REI to 7 days
  - prohibit dormant season applications

In the western U.S., alternate middle row spraying is not used. In addition, most orchards are chemically thinned, although some orchards may require additional hand-thinning. Extending the REI from 3 to 7 days will still allow growers to conduct the remaining necessary field activities such as hand thinning, pruning, mowing, irrigating, and scouting. At an REI of 7 days, the short-term MOE for workers hand thinning apples would be 17 (<30 days exposure), and the intermediate term MOE would be 13 (>30 days exposure). Although the thinning season lasts for 4-6 weeks, it is unlikely that workers would be exposed to phosmet applied at the maximum rate on every day for that entire period, suggesting that the intermediate-term exposure MOE likely overestimates risk.

- For all apples: decrease the maximum seasonal application rate from 21 lbs ai/A to 15.5 lbs ai/A

A seasonal maximum of 15.5 lbs ai/A reflects current national use patterns on apples. While this limitation does not change EPA's calculated MOEs for individual

worker risk, it will serve to reduce actual human and environmental exposure in those circumstances where phosmet is currently used in amounts greater than 15.5 lbs ai/A per season.

- For all apples: prohibit "pick-your-own" activities for 14 days after application

"Pick-your-own" harvesting is an important component of apple operations. Orchards are opened to the public as the first fruit ripens. Later, the remaining fruit is harvested for commercial sale. The PYO portion may be quite significant to the operations revenues, since growers receive a premium for the fruit.

In the June 2006 proposal, EPA proposed that PYO be prohibited. After reviewing submitted comments, and conducting a PYO risk assessment using a phosmet-specific exposure study, the Agency has determined that PYO may be retained for apples, but that phosmet labels must prohibit entry for PYO for at least 14 days. This restriction will be protective of potential risks to members of the general public (youths and adults) participating in PYO harvesting in apple orchards.

- For all apples: require a buffer zone between the application site and houses or other occupied structures, as follows:
    - 25 feet for ground applications during the growing season,
    - 50 feet for aerial applications during the growing season,
    - Require "medium" or coarser spray for aerial applications, and
    - Prohibit application during the dormant season

Based on the spray drift assessment for airblast application, risks to bystanders are below the Agency's level of concern at 25 feet from the application site for all but the "sparse" foliage scenario (dormant applications are an example of a "sparse" foliage scenario). Growing season applications do not begin until after petal fall, when trees have foliage.

In the June 2006 proposal, EPA proposed that aerial application to apple orchards be prohibited. Although aerial application of phosmet to orchard crops is rare, growers commented that aerial application is necessary when fields are too wet to enter with a ground rig. At 50 feet from the application site, the calculated bystander short-term MOE for aerial application to apples is 66, for "medium" spray applications. However, since aerial application is infrequent, actual exposure to bystanders would be of an acute rather than a short-term (up to 30 days) duration. Assuming acute exposure, the MOE would be >100 at 50 feet, using "medium" or coarser spray.

Risk-Benefit Rationale

EPA believes that, with the mitigation measures described above, the benefits of phosmet use on apples outweigh the risks in the short term, for the following reasons:

1) The Agency believes that the apple REIs outlined in this document will allow for

the performance of necessary field activities and will not drive additional use of AZM;
2) Where AZM is still an alternative, the use of phosmet will present fewer risks;
3) While some risk to workers and the environment remain after imposition of the mitigation in this decision, EPA is not aware of any information that suggests that numerous adverse incidents are likely to result from the use of phosmet;
4) Some alternatives would have to be applied more often, increasing the environmental loading of some chemicals with similar or greater ecological risks;
5) Some alternatives tend to create secondary pest control concerns. These require additional pesticides to control, resulting in higher environmental loading of pesticide chemicals;
6) It is likely that production costs will increase, because the alternatives that can be used in conjunction with certain critical cropping activities are more costly. Were the Agency to increase the REIs beyond the time frames set forth above, rather than impose the mitigation outlined in this decision, these impacts could be considerable, especially in the near term, given the time involved in developing alternative control practices.

As outlined in the beginning of this document, however, the Agency remains concerned that the calculated margins of exposure to phosmet are low, and therefore indicative of some measure of worker risk from exposure to phosmet. As previously noted, the phosmet human health database supporting this decision is not as refined as that for some other compounds. In the Agency's experience, additional refinement of the human health database (e.g., development of worker biomonitoring data) has generally served to demonstrate that risks are lower than estimated using only laboratory data. This is not uniformly true, however, and the Agency is therefore not prepared to make an open-ended determination that the benefits of phosmet outweigh the risks based on the current risk assessment, especially in light of the fact that new alternatives may become available.

The Agency believes that with additional data to be completed in 2008, as set forth in this decision, there will be greater clarity on the extent of the risks workers face from phosmet. The Agency therefore intends to revisit this decision in 2008 upon the submission of such data and consider, in light of those data (and any new information regarding the benefits of phosmet) whether the mitigation outlined above for apples should be retained, strengthened, or reduced.

PEARS

Current use parameters

Current label rates: The maximum rate per application is 4 lbs ai/A, with a seasonal maximum of 11.2 lbs ai/A.

Typical rate: The average application rate is 3.5 lbs ai/A per application, with an average of 1.8 applications per season.

Current REI: 3 days (for thinning, ST MOE = 13, IT MOE = 10). In the June 2006 decision document, EPA proposed extending this REI to 7 days (for thinning, ST MOE = 17, IT MOE = 13).

Current PHI: 7 days (for hand harvesting, ST MOE = 28, IT MOE = 20).

Post-application prohibition period for "pick your own" harvesting: 14 days.

Worker risks

For post-application workers thinning apples that have had phosmet applied at the maximum rate of 4 lbs ai/A, the short-term MOE is 13 at the current labeled REI of 3 days. Over a 4-6 week thinning season, the intermediate-term MOE is 10 at the maximum application rate. At this application rate, it would take 39 days to reach an MOE > 100. However, it is unlikely that workers would be exposed to the maximum rate every day for 30 days or more, suggesting that the intermediate-term exposure MOE likely overestimates risk.

Risks from "pick your own" operations

Risks to youths and adults conducting "pick-your-own" (PYO) harvesting activities were calculated using phosmet-specific exposure data. Based on this assessment, risks to members of the general public participating in PYO harvesting are below EPA's level of concern (MOE>100) at 14 days after application.

Risks to bystanders in the vicinity of pear orchards

Based on EPA's analysis of drift from airblast applications, risks to bystanders (children) are below EPA's level of concern (MOE>100) at 25 feet from the application site for all but the "sparse" foliage scenario. For this scenario, risks are below the Agency's level of concern at 50 feet. For aerial application to apples at 50 feet from the application site, an MOE >100 was calculated for "coarse" droplet size spray applications, and MOE of 66 for "medium" droplet size spray, and an MOE of 33 for "fine" droplet size spray.

Ecological risks

Although phosmet applications in pear orchards have the potential to result in some acute and chronic risks to aquatic invertebrates (freshwater and estuarine/marine), birds, and mammals, these risks are generally lower than those of most pyrethroid and OP alternatives. In particular, phosmet has substantially lower ecological risks than azinphos-methyl, a primary alternative to phosmet in pears.

Alternatives and grower impacts

Over 94% of U.S. pear acreage is in the western states of California (26%), Oregon (27%), and Washington (41%). Colorado, Connecticut, Michigan, New York, Pennsylvania and Utah grow the remaining 6%.

Phosmet is applied to about 21% of the U.S. pear acreage. Usage is quite variable from state to state and from year to year. For example, only 10% of California pear was treated with phosmet in 2003, but in 2004, the acreage treated rose to 23%. The usage and importance of phosmet is likely to increase as AZM becomes less available, since phosmet is a likely replacement.

The current REI for pears is 3 days. An REI greater than 7 days would interfere with irrigation, mowing, scouting and hand harvesting activities and an REI greater than 14 days would interfere with fire blight removal activities. If a longer REI were imposed, growers would replace phosmet with one or more of several available but costlier alternatives.

No yield or quality losses are likely if growers had to switch to alternative insecticides. However, insecticide costs would likely increase by 270% (a net cost increase of $230 per acre), because the available alternatives, such as acetamiprid and methoxyfenozide, are more costly and have to be applied more often. The concomitant loss of AZM would force a more dramatic shift to costlier alternatives, increasing total operating production costs by 8.8%, and decreasing net revenues by 10.5%.

Final regulatory decision and mitigation

- Extend the REI to 7 days

Most orchards are chemically thinned, although some orchards may require additional hand-thinning. Extending the REI from 3 to 7 days will still allow growers to conduct the remaining necessary field activities such as hand thinning, pruning, mowing, irrigating, and scouting. At an REI of 7 days, the short-term MOE for workers hand thinning pears would be 17 (<30 days exposure), and the intermediate term MOE would be 13 (>30 days exposure). Although the thinning season lasts for 4-6 weeks, it is unlikely that workers would be exposed to phosmet applied at the maximum rate on every day for that entire period, suggesting that the intermediate-term exposure MOE likely overestimates risk.

- Prohibit “pick-your-own” activities for 14 days after application

“Pick-your-own” harvesting is an important component of pear operations. Orchards are opened to the public as the first fruit ripens. Later, the remaining fruit is harvested for commercial sale. The PYO portion may be quite significant to the operations revenues, since growers receive a premium for the fruit.

In the June 2006 proposal, EPA proposed that PYO be prohibited. After reviewing submitted comments, and conducting a PYO risk assessment using a phosmet-specific exposure study, the Agency has determined that PYO may be retained for pears, but that phosmet labels must prohibit entry for PYO for at least 14 days. This restriction will be protective of potential risks to members of the general public (youths and adults) participating in PYO harvesting in pear orchards.

- Require a buffer zone between the application site and houses or other occupied structures, as follows:
    - 25 feet for ground applications during the growing season,
    - 50 feet for ground applications during the dormant season,
    - 50 feet for aerial applications during the growing season,
    - Require "medium" or coarser spray for aerial applications, and
    - Prohibit aerial application during the dormant season

Based on the spray drift assessment for airblast application, risks to bystanders are below the Agency's level of concern at 25 feet from the application site for all but the "sparse" foliage scenario, for which risks are below the Agency's level of concern at 50 feet from the application site (dormant applications are an example of a "sparse" foliage scenario).

In the June 2006 proposal, EPA proposed that aerial application to pear orchards be prohibited. Although aerial application of phosmet to orchard crops is rare, growers commented that aerial application is necessary when fields are too wet to enter with a ground rig. At 50 feet from the application site, the calculated bystander short-term MOE for aerial application to pears is 66, for "medium" spray applications. However, since aerial application is infrequent, actual exposure to bystanders would be of an acute rather than a short-term (up to 30 days) duration. Assuming acute exposure, the MOE would be >100 at 50 feet, using "medium" or coarser spray.

Risk-Benefit Rationale

EPA believes that, with the mitigation measures described above, the benefits of phosmet use on pears outweigh the risks in the short term, for the following reasons:

1) The Agency believes that the pear REI outlined in this document will allow for the performance of necessary field activities and will not drive additional use of AZM;
2) Where AZM is still an alternative, the use of phosmet will present fewer risks;
3) While some risk to workers and the environment remain after imposition of the mitigation in this decision, EPA is not aware of information that suggests that numerous adverse incidents are likely to result from the use of phosmet;
4) Some alternatives would have to be applied more often, increasing the environmental loading of some chemicals with similar or greater ecological risks;
5) Some alternatives tend to create secondary pest control concerns. These require additional pesticides to control, resulting in higher environmental loading of

pesticide chemicals;

6) If EPA were to increase the REIs beyond 7 days, it is likely that production costs would increase considerably, because the alternatives that can be used in conjunction with certain critical cropping activities are more costly. These impacts would likely be felt most acutely in the near term, given the time involved in developing alternative control practices.

As outlined in the beginning of this document, however, the Agency remains concerned that the calculated margins of exposure to phosmet are low, and therefore indicative of some measure of worker risk from exposure to phosmet. As previously noted, the phosmet human health database supporting this decision is not as refined as that for some other compounds. In the Agency's experience, additional refinement of the human health database (e.g., development of worker biomonitoring data) has generally served to demonstrate that risks are lower than estimated using only laboratory data. This is not uniformly true, however, and the Agency is therefore not prepared to make an open-ended determination that the benefits of phosmet outweigh the risks based on the current risk assessment, especially in light of the fact that new alternatives may become available.

The Agency believes that with additional data to be completed in 2008, as set forth in this decision, there will be greater clarity on the extent of the risks workers face from phosmet. The Agency therefore intends to revisit this decision in 2008 upon the submission of such data and consider, in light of those data (and any new information regarding the benefits of phosmet) whether the mitigation outlined above for apples should be retained, strengthened, or reduced.

PEACHES AND NECTARINES

Peaches and nectarines are varieties of the same fruit and the trees themselves are indistinguishable. The same pests attack the fruit and growers have essentially the same chemical and non-chemical control means. Therefore, the Agency's decision and mitigation measures are the same for both crops.

Current use parameters

Current label rates: The maximum application rate is 3.0 lbs ai/A per application, with a maximum of 11.9 lbs ai/A per season for peaches and 9.1 lbs ai/A per season for nectarines.

Average rate: For peaches, the average application rate is 1.43 lbs ai/A per application, with 1-4 applications made per season. California producers typically apply phosmet less frequently and at a higher rate than do producers in the East. For nectarines, the average application rate is 1.94 lbs ai/A per application, with 1-2 applications per season, but this represents only California usage. Use appears to be driven by location, with phosmet used in areas with high potential for mite outbreaks.

Current REI: 3 days (for thinning, ST MOE = 18, IT MOE = 13). In the June 2006 decision document, EPA proposed extending this REI to 7 days (for thinning, ST MOE = 23, IT MOE = 17).

Current PHI: 14 days (for hand harvesting, ST MOE = 73, IT MOE = 54).

Post-application prohibition period for "pick your own" harvesting: 14 days.

Worker risks

For post-application workers thinning peaches that have had phosmet applied at the maximum rate of 3 lbs ai/A, the short-term MOE is 18 at the current labeled REI of 3 days. Over a 4-6 week thinning season, the intermediate-term MOE is 13 at the maximum application rate. At this application rate, it would take 34 days to reach an MOE > 100. However, it is unlikely that workers would be exposed to the maximum rate every day for 30 days or more, suggesting that the intermediate-term exposure MOE likely overestimates risk.

Risks from "pick your own" operations

Risks to youths and adults conducting pick-your-own harvesting activities were calculated using phosmet-specific exposure data. Based on this assessment, risks to members of the general public participating in "pick-your-own" harvesting are below EPA's level of concern (MOE>100) at 10 days after application.

Risks to bystanders in the vicinity of peach and nectarine orchards

Based on EPA's analysis of drift from airblast applications, risks to bystanders (children) are below EPA's level of concern (MOE>100) at 25 feet from the application site for all but the "sparse" foliage scenario. For this scenario, risks are below the Agency's level of concern at 50 feet. For aerial application to peaches and nectarines at 50 feet from the application site, an MOE >100 was calculated for "coarse" droplet size spray applications, and MOE of 88 for "medium" droplet size spray, and an MOE of 44 for "fine" droplet size spray.

Ecological risks

Although phosmet applications in peach and nectarine orchards have the potential to result in some acute and chronic risks to aquatic invertebrates (freshwater and estuarine/marine), birds, and mammals, these risks are generally lower than those of most pyrethroid and OP alternatives.

Alternatives and grower impacts

California accounts for almost half of the peach acreage and about three-fourths

of production. South Carolina and Georgia are the other main peach producers, with about five percent of production each. Most nectarines are grown in California.

Phosmet use is highest in southern states (NC, SC, GA), with 66% of the acreage treated (1999-2003). Frequency of application is higher in the South as well, with Georgia and South Carolina producers averaging five or six applications per year. Approximately 36% of peach acreage was treated in the northeast (MI, NJ, NY, PA). Less than 4% of the acreage in Texas and Washington was treated with phosmet.

In California, phosmet use on peaches has remained fairly steady between 1999 and 2003, at just over 20% of the crop treated. Use on nectarines is higher, at about 40% over the same period. Phosmet usage is driven, in part, by location and associated variation in pest problems. In particular, phosmet appears to be used in areas prone to mite outbreaks as it is somewhat less toxic to beneficial insects than alternatives such as the carbamates and synthetic pyrethroids.

There is typically a single application of phosmet per year in California, but there may be as many as three. Phosmet is most commonly used as a 'rescue' treatment late in the season if prior control weakens or fails. Phosmet is also occasionally used during the dormant season as a replacement for other organophosphate pesticides that present higher risks associated with runoff to surface water.

In June 2006, EPA qualitatively assessed the impacts of extending the REI following an application of phosmet on peaches and nectarines. This assessment concluded that peach growers would be able to continue to use phosmet in conjunction with important cropping practices with an REI of seven days.

Based on grower comments received during the June-August comment period, EPA has revised its earlier assessment. U.S. eastern peach growers typically apply phosmet at weekly intervals during the post-bloom period. The practice is to apply phosmet to alternate rows in the orchard, effectively halving the amount of chemical used in each application. During this same period, however, the fruit must be thinned in order to achieve marketable sizes. Given these spraying practices, an REI greater than 4 days would interfere with thinning operations, and growers would have to replace phosmet with one or more of several available alternatives, which would likely result in significantly increased production costs. It is likely that the alternatives would have to be applied more often to achieve similar control of primary pests, and additional pesticides might have to be applied to control secondary pests, such as mites.

EPA conducted a partial budget analysis to estimate the impacts to growers of shifting to synthetic pyrethroids and a miticide for the states of Georgia and Pennsylvania, representing southern and north-eastern peach producing states, respectively. EPA estimates that shifting to alternative chemistries would represent an increase of $45/acre and a net cash returns loss of over 11% for Georgia, and an increase of $50/acre and net cash loss of about 2% for Pennsylvania, although the budget for Pennsylvania does not include many marketing costs typically borne by the grower. The

resulting increase in production costs implies national losses of almost $1.5 million per year.

EPA also examined more closely the impact to California producers of an REI greater than seven days. Within the season, seven days is the maximum REI that would not interfere with critical orchard activities such as thinning. If the REI were extended beyond seven days, growers would likely switch to a carbamate, such as carbaryl, and would also have to apply a miticide. EPA proprietary data indicates that miticide treatments cost between $4 to $60/acre and average about $27/acre. Taking the average, the cost of switching to the alternative regime would be about $26/acre, which is about 7% of net operating revenue. Because this analysis does not include fixed costs, the percentage change in grower income could be larger.

Final regulatory decision and mitigation

- For peaches east of the Rockies:
  - extend the REI to 4 days,
  - prohibit harvesting for 14 days, and
  - prohibit dormant season applications

After a review of growers' and extension agents' comments submitted during the post-decision comment period, and a reevaluation of the risks and benefits, EPA is requiring that the REI for peaches and nectarines east of the Rockies be 4 days (ST MOE = 19, IT MOE = 14) rather than the June-proposed 7 days. Peach growers in eastern production regions commonly apply pesticides using an alternate row application technique, which results in less pesticide being applied per acre, per application. Under this spraying regime, an REI of seven days would interfere with critical orchard tasks (such as thinning). An REI of 4 days would allow growers to continue performing alternate row applications. Because of the lower application rates used with alternate row middle spraying, risks to post-application workers would be lower than those calculated (for example, at 1.5 lbs ai/A, MOEs would be twice as high as those calculated).

A harvesting prohibition of 14 days is consistent with the existing PHI for peaches and nectarines. Phosmet is not applied to eastern peach orchards during the dormant season.

- For peaches west of the Rockies:
  - extend the REI to 7 days
  - prohibit harvesting for 14 days,
  - prohibit application until after thinning activities have been completed for the season, and
  - prohibit dormant season applications until after pruning and all other hand activities have been completed

By prohibiting application until after thinning activities have been completed, and prohibiting harvesting for 14 days, consistent with the existing PHI, the short-term MOE

for hand harvesting would be 73, and the intermediate-term MOE would be 54. Although harvesting can be carried out for 4-6 weeks (intermediate-term exposure), it is unlikely that workers would be exposed to phosmet applied at the maximum rate on every day for that entire period. As a result, the calculated intermediate-term MOE of 54 is likely to overestimate risks to harvesters.

Other than harvesting, the only remaining activities would be low exposure ones, such as irrigation and scouting. At 7 days after application, the MOE for workers conducting low exposure activities would be at least 69 for short-term exposure (intermediate-term exposure would not be expected for these activities).

- For all peaches and nectarines: prohibit "pick-your-own" activities for 14 days after application

"Pick-your-own" (PYO) harvesting is an important component of peach and nectarine operations. Orchards are opened to the public as the first fruit ripens. Later, the remaining fruit is harvested for commercial sale. The PYO portion may be quite significant to the operations revenues, since growers receive a premium for the fruit.

In the June 2006 proposal, EPA proposed that PYO be prohibited. After reviewing submitted comments, and conducting a PYO risk assessment using a phosmet-specific exposure study, the Agency has determined that PYO may be retained for peaches and nectarines, but that phosmet labels must prohibit entry for PYO for at least 14 days. Although risks are below EPA's level of concern at 10 days after application, the Agency believes it is appropriate to maintain the current prohibition of 14 days, in order to be consistent with the PHI.

- For all peaches and nectarines: require a buffer zone between the application site and houses or other occupied structures, as follows:

  East of the Rockies:
  - 25 feet for ground applications during the growing season,
  - 50 feet for aerial applications during the growing season,
  - Require "medium" or coarser spray for aerial applications, and
  - Prohibit application during the dormant season

  West of the Rockies:
  - 25 feet for ground applications during the growing season,
  - 50 feet for ground applications during the dormant season,
  - 50 feet for aerial applications during the growing season,
  - Require "medium" or coarser spray for aerial applications, and
  - Prohibit aerial application during the dormant season

Based on the spray drift assessment for airblast application, risks to bystanders are below the Agency's level of concern at 25 feet from the application site for all but the

"sparse" foliage scenario, for which risks are below the Agency's level of concern at 50 feet from the application site (dormant applications are an example of a "sparse" foliage scenario).

In the June 2006 proposal, EPA proposed that aerial application to peach and nectarine orchards be prohibited. Although aerial application of phosmet to orchard crops is rare, growers commented that aerial application is necessary when fields are too wet to enter with a ground rig. At 50 feet from the application site, the calculated bystander short-term MOE for aerial application to peaches and nectarines is 88, for "medium" spray applications. However, since aerial application is infrequent, actual exposure to bystanders would be of an acute rather than a short-term (up to 30 days) duration. Assuming acute exposure, the MOE would be >100 at 50 feet, using "medium" or coarser spray.

Risk-Benefit Rationale

EPA believes that, with the mitigation measures described above, the benefits of phosmet use on peaches and nectarines outweigh the risks in the short term, for the following reasons:

1) While some risk to workers and the environment remain after imposition of the mitigation in this decision, EPA is not aware of any information that suggests that numerous adverse incidents are likely to result from the use of phosmet;
2) Some alternatives would have to be applied more often, increasing the environmental loading of some chemicals with similar or greater ecological risks;
3) Some alternatives tend to create secondary pest control concerns. These require additional pesticides to control, resulting in higher environmental loading of pesticide chemicals;
4) If EPA were to increase the REI beyond 4 days in the eastern U.S., or 7 days in the western U.S., it is likely that production costs would increase because the alternatives that can be used in conjunction with certain critical cropping activities are more costly. These impacts would likely be felt most acutely in the near term, given the time involved in developing alternative control practices.

As outlined in the beginning of this document, however, the Agency remains concerned that the calculated margins of exposure to phosmet are low, and therefore indicative of some measure of worker risk from exposure to phosmet. As previously noted, the phosmet human health database supporting this decision is not as refined as that for some other compounds. In the Agency's experience, additional refinement of the human health database (e.g., development of worker biomonitoring data) has generally served to demonstrate that risks are lower than estimated using only laboratory data. This is not uniformly true, however, and the Agency is therefore not prepared to make an open-ended determination that the benefits of phosmet outweigh the risks based on the current risk assessment, especially in light of the fact that new alternatives may become available.

The Agency believes that with additional data to be completed in 2008, as set forth in this decision, there will be greater clarity on the extent of the risks workers face from phosmet. The Agency therefore intends to revisit this decision in 2008 upon the submission of such data and consider, in light of those data (and any new information regarding the benefits of phosmet) whether the mitigation outlined above for peaches and nectarines should be retained, strengthened, or reduced.

APRICOTS

Current Use Parameters

Current label rates: The maximum rate per application is 3.0 lbs ai/A, with a seasonal maximum of 9.1 lbs ai/A.

Average rate: The average application rate is 2.42 lbs ai/A per application, with 1.1 applications per season, on average.

Current REI: 3 days (for thinning, ST MOE = 18, IT MOE = 13). In the June 2006 decision document, EPA proposed extending this REI to 7 days (for thinning, ST MOE = 23, IT MOE = 17).

Current PHI: 14 days (for hand harvesting, ST MOE = 73, IT MOE = 54).

Post-application prohibition period for "pick your own" harvesting: 14 days.

Worker Risks

For post-application workers thinning apricots that have had phosmet applied at the maximum rate of 3 lbs ai/A, the short-term MOE is 18 at the current labeled REI of 3 days. Over a 4-6 week thinning season, the intermediate-term MOE is 13 at the maximum application rate. At this application rate, it would take 34 days to reach an MOE > 100. However, it is unlikely that workers would be exposed to the maximum rate every day for 30 days or more (intermediate-term exposure).

Risks from "pick your own" operations

Risks to youths and adults conducting pick-your-own harvesting activities were calculated using phosmet-specific exposure data. Based on this assessment, risks to members of the general public participating in "pick-your-own" harvesting are below EPA's level of concern (MOE>100) at 10 days after application.

Risks to bystanders in the vicinity of apricot orchards

Based on EPA's analysis of drift from airblast applications, risks to bystanders (children) are below EPA's level of concern (MOE>100) at 25 feet from the application

site for all but the "sparse" foliage scenario. For this scenario, risks are below the Agency's level of concern at 50 feet. For aerial application to apricots at 50 feet from the application site, an MOE >100 was calculated for "coarse" droplet size spray applications, and MOE of 88 for "medium" droplet size spray, and an MOE of 44 for "fine" droplet size spray.

Ecological risks

Although phosmet applications in apples orchards have the potential to result in some acute and chronic risks to aquatic invertebrates (freshwater and estuarine/marine), birds, and mammals, these risks are generally lower than those of most pyrethroid and OP alternatives.

Alternatives and Grower Impacts

More than 90% of U.S. apricot acreage is in California. According to data from the California Pesticide Use Reports, phosmet use on apricots declined rapidly between 1999 and 2002, from over 18% to about 5% of the crop treated. Use has remained at about 5% for the past several years. There is typically a single application per year, but there may be as many as three.

In California, phosmet is frequently used only late in the season as a "rescue" treatment in stone fruit such as apricots. Through most of the growing season, producers often rely on applications of *Bt* or spinosad to control several lepidopterous pests. In addition, mating disruption can be used to supplement insecticide applications to manage the peach twig borer. It is only if pest pressure increases near harvest that growers turn to phosmet. Apricots generally ripen in June, before the build-up of pest populations, which also helps to explain low usage in the crop.

Within the California growing season, the maximum REI that would not interfere with orchard activities is approximately seven days. Apricots must often be propped to prevent limb breakage through the growing season as fruit size increases. Extension of the phosmet REI beyond seven days would interfere with this practice, possibly resulting in limb breakage, tree injury, and fruit loss.

Extending REIs beyond what is feasible for crop production would result in growers shifting to one of several available alternatives for control of lepidopterous pests targeted by phosmet. These pests include the fruit tree leafroller, green fruitworm, and peach twig borer. However, phosmet is a broad-spectrum insecticide and may also be controlling a number of secondary insects. Use of alternatives that have a more narrow range of activity may result in populations of these pests increasing to damaging levels. For instance, katydids, which in the past were minor pests of stone fruit, are now causing considerable damage to nectarines and peaches in California. Two of the more effective insecticides currently available for katydid control on stone fruit orchards are phosmet and carbaryl. If phosmet were no longer available, growers would likely turn to carbaryl as the preferred alternative, which also poses risks to workers.

In California, several alternatives are used to control most or all of the pests controlled by phosmet. However, these alternatives may not be as efficacious as phosmet and could require more than one application to achieve the same level of control. Most phosmet applications take place during the fruit-development period of April through May. During this period, likely alternatives to phosmet are diazinon, esfenvalerate, spinosad, and *Bt*. Except for *Bt*, any one of these insecticides can replace phosmet on a one-to-one basis. Two well-timed applications of *Bt* would be required to replace a single phosmet application. Of the remaining alternatives, esfenvalerate is considered to be highly disruptive to beneficial arthropods due to its high toxicity rating for these organisms, whereas spinosad has a relatively low toxicity rating for beneficial species. However, instances of pest resistance have been reported for spinosad.

Of the alternatives, diazinon and esfenvalerate are less expensive and spinosad more expensive than phosmet. Sample spray programs appear to indicate that pyrethroids are used in rotation with phosmet. Thus, an additional pyrethroid application may lead to resistance problems or further mite outbreaks. Diazinon is more commonly used in the dormant season. As a replacement for phosmet, a higher-than-average application rate may be required. If growers were to switch to spinosad to replace phosmet, it appears that costs would increase about $5.00/acre, or approximately 2% of net operating revenue.

Impacts for apricot acreage outside of California cannot be quantified due to limited data on the small number of acres in production. Because apricots and peaches are closely related, both being stone fruit in the genus *Prunus*, they face similar pests and share similar control alternatives. EPA therefore assumes that impacts would be similar in cost per acre as estimated for peaches ($45-$50/acre).

Final regulatory decision and mitigation

- For apricots east of the Rockies:
  - extend the REI to 7 days,
  - prohibit harvesting for 14 days, and
  - prohibit dormant season applications

An REI greater than 7 days would interfere with crop production practices, such as propping. At 7 days, the short-term MOE for thinning is 23, and the intermediate-term MOE is 17. A harvesting prohibition of 14 days is consistent with the existing PHI for apricots (for hand harvesting, ST MOE = 73, IT MOE = 54). Although thinning and harvesting activities are carried out over a period of 4-6 weeks, it is unlikely that workers would be exposed to phosmet applied at the maximum rate on every day for that entire period (intermediate-term exposure).

Phosmet is not applied to eastern apricot orchards during the dormant season.

- For apricots west of the Rockies:
  - extend the REI to 7 days
  - prohibit harvesting for 14 days,

- prohibit application until after thinning activities have been completed for the season, and
- prohibit dormant season applications until after pruning and all other hand activities have been completed

In California, phosmet is frequently used only late in the season as a "rescue" treatment in stone fruit. In addition, apricots generally ripen in June, before the build-up of pest populations.

By prohibiting application until after thinning activities have been completed, and prohibiting harvesting for 14 days, consistent with the existing PHI, the short-term MOE for hand harvesting would be 73, and the intermediate-term MOE would be 54. Although harvesting can be carried out for 4-6 weeks (intermediate-term exposure), it is unlikely that workers would be exposed to phosmet applied at the maximum rate on every day for that entire period. As a result, the calculated intermediate-term MOE of 54 is likely to overestimate risks to harvesters.

Other than harvesting, the only remaining activities would be low exposure ones, such as irrigation and scouting. At 7 days after application, the MOE for workers conducting low exposure activities would be at least 69 for short-term exposure (intermediate-term exposure would not be expected for these activities).

- For all apricots: prohibit "pick-your-own" activities for 14 days after application

"Pick-your-own" (PYO) harvesting is an important component of apricot operations. Orchards are opened to the public as the first fruit ripens. Later, the remaining fruit is harvested for commercial sale. The PYO portion may be quite significant to the operations revenues, since growers receive a premium for the fruit.

In the June 2006 proposal, EPA proposed that PYO be prohibited. After reviewing submitted comments, and conducting a PYO risk assessment using a phosmet-specific exposure study, the Agency has determined that PYO may be retained for apricots, but that phosmet labels must prohibit entry for PYO for at least 14 days. Although risks are below EPA's level of concern at 10 days after application, the Agency believes it is appropriate to maintain the current prohibition of 14 days, in order to be consistent with the PHI.

- For all apricots: require a buffer zone between the application site and houses or other occupied structures, as follows:

  East of the Rockies:
  - 25 feet for ground applications during the growing season,
  - 50 feet for aerial applications during the growing season,
  - Require "medium" or coarser spray for aerial applications, and
  - Prohibit application during the dormant season

West of the Rockies:

- 25 feet for ground applications during the growing season,
- 50 feet for ground applications during the dormant season,
- 50 feet for aerial applications during the growing season,
- Require "medium" or coarser spray for aerial applications, and
- Prohibit aerial application during the dormant season

Based on the spray drift assessment for airblast application, risks to bystanders are below the Agency's level of concern at 25 feet from the application site for all but the "sparse" foliage scenario, for which risks are below the Agency's level of concern at 50 feet from the application site (dormant applications are an example of a "sparse" foliage scenario).

In the June 2006 proposal, EPA proposed that aerial application to apricot orchards be prohibited. Although aerial application of phosmet to orchard crops is rare, growers commented that aerial application is necessary when fields are too wet to enter with a ground rig. At 50 feet from the application site, the calculated bystander short-term MOE for aerial application to apricots is 88, for "medium" spray applications. However, since aerial application is infrequent, actual exposure to bystanders would be of an acute rather than a short-term (up to 30 days) duration. Assuming acute exposure, the MOE would be >100 at 50 feet, using "medium" or coarser spray.

Risk-Benefit Rationale

EPA believes that, with the mitigation measures described above, the benefits of phosmet use on apricots outweigh the risks in the short term, for the following reasons:

1) While some risk to workers and the environment remain after imposition of the mitigation in this decision, EPA is not aware of any information that suggests that numerous adverse incidents are likely to result from the use of phosmet;
2) It is likely that with the exception of carbaryl, a compound with similar worker risk concerns as phosmet, the alternatives will not be as efficacious as phosmet for rescue treatments of several key pests, and will therefore require a greater number of applications, at greater cost.

As outlined in the beginning of this document, however, the Agency remains concerned that the calculated margins of exposure to phosmet are low, and therefore indicative of some measure of worker risk from exposure to phosmet. As previously noted, the phosmet human health database supporting this decision is not as refined as that for some other compounds. In the Agency's experience, additional refinement of the human health database (e.g., development of worker biomonitoring data) has generally served to demonstrate that risks are lower than estimated using only laboratory data. This is not uniformly true, however, and the Agency is therefore not prepared to make an open-ended determination that the benefits of phosmet outweigh the risks based on the current risk assessment, especially in light of the fact that new alternatives may become available.

The Agency believes that with additional data to be completed in 2008, as set forth in this decision, there will be greater clarity on the extent of the risks workers face from phosmet. The Agency therefore intends to revisit this decision in 2008 upon the submission of such data and consider, in light of those data (and any new information regarding the benefits of phosmet) whether the mitigation outlined above for apricots should be retained, strengthened, or reduced.

PLUMS AND PRUNES

Plums and plums grown for prunes are different varieties with some differences in production practices, although the trees themselves are quite similar and suffer from similar pests. Furthermore, some varieties produce fruit that may be sold either fresh (i.e., as plums) or dried (i.e., as prunes). Therefore, the Agency's assessment and decisions are the same for these crops.

Current Use Parameters

Current label rates: The maximum rate per application is 3.0 lbs ai/A, with a seasonal maximum of 9.1 lbs ai/A.

Average rate: The average application rate is 2.80 lbs ai/A per application, with 1-2 applications per season. Phosmet is almost never used on prune varieties.

Current REI: 3 days (for thinning, ST MOE = 18, IT MOE = 13). In the June 2006 decision document, EPA proposed extending this REI to 7 days (for thinning, ST MOE = 23, IT MOE = 17).

Current PHI: 7 days (for hand harvesting, ST MOE = 46, IT MOE = 34).

Post-application prohibition period for "pick your own" harvesting: 14 days.

Worker Risks

For post-application workers thinning plums that have had phosmet applied at the maximum rate of 3 lbs ai/A, the short-term MOE is 18 at the current labeled REI of 3 days. Over a 4-6 week thinning season, the intermediate-term MOE is 13 at the maximum application rate. At this application rate, it would take 34 days to reach an MOE > 100. However, it is unlikely that workers would be exposed to the maximum rate every day for 30 days or more (intermediate-term exposure).

Risks from "Pick Your Own" operations

Risks to youths and adults conducting pick-your-own harvesting activities were calculated using phosmet-specific exposure data. Based on this assessment, risks to

members of the general public participating in "pick-your-own" harvesting are below EPA's level of concern (MOE>100) at 10 days after application.

Risks to bystanders in the vicinity of plum orchards

Based on EPA's analysis of drift from airblast applications, risks to bystanders (children) are below EPA's level of concern (MOE>100) at 25 feet from the application site for all but the "sparse" foliage scenario. For this scenario, risks are below the Agency's level of concern at 50 feet. For aerial application to plums at 50 feet from the application site, an MOE >100 was calculated for "coarse" droplet size spray applications, and MOE of 88 for "medium" droplet size spray, and an MOE of 44 for "fine" droplet size spray.

Ecological risks

Although phosmet applications in plum and prune orchards have the potential to result in some acute and chronic risks to aquatic invertebrates (freshwater and estuarine/marine), birds, and mammals, these risks are generally lower than those of most pyrethroid and OP alternatives.

Alternatives and Grower Impacts

Plums and plums grown for prune are typically distinct varieties with different production practices although the trees themselves are quite similar and suffer from similar pests. Over 95% of the plum/prune acreage is in California, of which about two-thirds is in prune varieties. The Pacific Northwest and Michigan are the other main producers of plums/prunes.

In California, phosmet use reported for prunes has been negligible between 1999 and 2004, averaging less than one percent of the crop acreage treated. Use reported for plums has remained at about 25% of the crop acreage treated during the same period. There is typically a single application per year on plums, but there may be as many as three.

California has established a five-day REI for phosmet for stone fruit. An REI greater than five days would likely interfere with key mid-season crop production practices, such as propping up fruit-laden tree limbs to avoid breakage.

Phosmet use is concentrated on plum production, so any impacts to prune producers are expected to be small. If the REI were extended to the point that phosmet use were no longer feasible, California plum growers would likely face higher production costs because alternatives must be used more frequently or combined with other chemicals to treat secondary pests. Cost increases may be about $25-30 per acre. In the Pacific Northwest, plum producers appear to have fewer pest problems than those in California, and thus less need for phosmet.

Eastern plum producers, however, face a more challenging suite of pests and lack an alternative common to all pest situations. EPA does not have data on plum production costs in the eastern U.S. but believes that impacts may be similar to those estimated for peach production, such that switching from phosmet to alternative pesticides would result in for $45 to $50 higher costs per acre. In the eastern U.S. region, esfenvalerate is the most likely alternatives for plum curculio. Currently, spinosad is available for the control of the apple maggot and two neonicotinoids, imidacloprid and thiamethoxam, are available to control the plum curculio. However, imidacloprid is labeled only for 'suppression' and may have limited efficacy.

Final regulatory decision and mitigation

- For plums and prunes east of the Rockies:
  - extend the REI to 7 days,
  - prohibit harvesting for 14 days, and
  - prohibit dormant season applications

An REI greater than 7 days would interfere with crop production practices, such as propping. At 7 days, the short-term MOE for thinning is 23, and the intermediate-term MOE is 17. A harvesting prohibition of 14 days is consistent with the prohibition for other stone fruit (for hand harvesting, ST MOE = 73, IT MOE = 54). Although thinning and harvesting activities are carried out over a period of 4-6 weeks, it is unlikely that workers would be exposed to phosmet applied at the maximum rate on every day for that entire period (intermediate-term exposure).

Phosmet is not applied to eastern plum and prune orchards during the dormant season.

- For plums and prunes west of the Rockies:
  - extend the REI to 7 days
  - prohibit harvesting for 14 days,
  - prohibit application until after thinning activities have been completed for the season, and
  - prohibit dormant season applications until after pruning and all other hand activities have been completed

California produces 95% of the plum/prune acreage in the United States and has established a five-day REI for phosmet in stone fruit. If the REI were extended beyond 7 days, California plum growers would likely face some cost increases. Given the large proportion of acreage, this could affect supply on a national level.

By prohibiting application until after thinning activities have been completed, and prohibiting harvesting for 14 days, consistent with the prohibition for other stone fruit, the short-term MOE for hand harvesting would be 73, and the intermediate-term MOE would be 54. Although harvesting can be carried out for 4-6 weeks (intermediate-term

exposure), it is unlikely that workers would be exposed to phosmet applied at the maximum rate on every day for that entire period. As a result, the calculated intermediate-term MOE of 54 is likely to overestimate risks to harvesters.

Other than harvesting, the only remaining activities would be low exposure ones, such as propping, irrigation and scouting. At 7 days after application, the MOE for workers conducting low exposure activities would be at least 69 for short-term exposure (intermediate-term exposure would not be expected for these activities).

- For all plums and prunes: prohibit "pick-your-own" activities for 14 days after application

"Pick-your-own" (PYO) harvesting is an important component of plum operations. Orchards are opened to the public as the first fruit ripens. Later, the remaining fruit is harvested for commercial sale. The PYO portion may be quite significant to the operations revenues, since growers receive a premium for the fruit.

In the June 2006 proposal, EPA stated that PYO should be prohibited. After reviewing submitted comments, and conducting a PYO risk assessment using a phosmet-specific exposure study, the Agency has determined that PYO may be retained for plums and prunes, but that phosmet labels must prohibit entry for PYO for at least 14 days. Although risks are below EPA's level of concern at 10 days after application, the Agency believes it is appropriate to maintain the current prohibition of 14 days, in order to be consistent with other stone fruit.

- For all plums and prunes: require a buffer zone between the application site and houses or other occupied structures, as follows:

  East of the Rockies:
  - 25 feet for ground applications during the growing season,
  - 50 feet for aerial applications during the growing season,
  - Require "medium" or coarser spray for aerial applications, and
  - Prohibit application during the dormant season

  West of the Rockies:
  - 25 feet for ground applications during the growing season,
  - 50 feet for ground applications during the dormant season,
  - 50 feet for aerial applications during the growing season,
  - Require "medium" or coarser spray for aerial applications, and
  - Prohibit aerial application during the dormant season

Based on the spray drift assessment for airblast application, risks to bystanders are below the Agency's level of concern at 25 feet from the application site for all but the "sparse" foliage scenario, for which risks are below the Agency's level of concern at 50 feet from the application site (dormant applications are an example of a "sparse" foliage scenario).

In the June 2006 proposal, EPA proposed that aerial application to plum and prune orchards be prohibited. Although aerial application of phosmet to orchard crops is rare, growers commented that aerial application is necessary when fields are too wet to enter with a ground rig. At 50 feet from the application site, the calculated bystander short-term MOE for aerial application to plums and prunes is 88, for "medium" spray applications. However, since aerial application is infrequent, actual exposure to bystanders would be of an acute rather than a short-term (up to 30 days) duration. Assuming acute exposure, the MOE would be >100 at 50 feet, using "medium" or coarser spray.

Risk-Benefit Rationale

EPA believes that, with the mitigation measures described above, the benefits of phosmet use on plums and prunes outweigh the risks in the short term, for the following reasons:

For eastern plums and prunes:

1) While some risk to workers and the environment remain after imposition of the mitigation in this decision, EPA is not aware of any information that suggests that numerous adverse incidents are likely to result from the use of phosmet;
2) Some alternatives would have to be applied more often, increasing the environmental loading of some chemicals with similar or greater ecological risks;
3) Some alternatives tend to create secondary pest control concerns. These require additional pesticides to control, resulting in higher environmental loading of pesticide chemicals;
4) It is likely that production costs will increase, because the alternatives that can be used in conjunction with certain critical cropping activities are more costly.

For western plums and prunes:

1) While some risk to workers and the environment remain after imposition of the mitigation in this decision, EPA is not aware of any information that suggests that numerous adverse incidents are likely to result from the use of phosmet;
2) With the added prohibition that phosmet applications cannot be made until after thinning activities are completed for the season, the remaining highest exposure activity is hand harvesting. With a 14 day prohibition on hand harvesting, consistent with other stone fruit, the short-term MOE is 73 and the intermediate-term MOE is 54. Although the harvesting can last for 4-6 weeks, it is unlikely that workers would be exposed to phosmet applied at the maximum rate on every day for that entire period, suggesting that the intermediate-term exposure MOE likely overestimates risk.
3) Although benefits to western plum and prune production appear to be lower than in the east, the proportion of phosmet treated acreage and production is significant, suggesting that phosmet likely has some measure of additional

unquantified benefits to western to growers that EPA was not able to measure.

4) Phosmet is less toxic to beneficial insects than other available (but less costly) alternatives, such as esfenvalerate and diazinon, and may offer an alternative to other OPs and pyrethroids that are of concern due to aquatic toxicity.

As outlined in the beginning of this document, however, the Agency remains concerned that the calculated margins of exposure to phosmet are low, and therefore indicative of some measure of worker risk from exposure to phosmet. As previously noted, the phosmet human health database supporting this decision is not as refined as that for some other compounds. In the Agency's experience, additional refinement of the human health database (e.g., development of worker biomonitoring data) has generally served to demonstrate that risks are lower than estimated using only laboratory data. This is not uniformly true, however, and the Agency is therefore not prepared to make an open-ended determination that the benefits of phosmet outweigh the risks based on the current risk assessment, especially in light of the fact that new alternatives may become available.

The Agency believes that with additional data to be completed in 2008, as set forth in this decision, there will be greater clarity on the extent of the risks workers face from phosmet. The Agency therefore intends to revisit this decision in 2008 upon the submission of such data and consider, in light of those data (and any new information regarding the benefits of phosmet) whether the mitigation outlined above for plums and prunes should be retained, strengthened, or reduced.

GRAPES

Current Use Parameters

Current label rates: The maximum rate per application is 1.5 lbs ai/A, with a seasonal maximum of 4.55 lbs ai/A.

Average rate: The average application rate is 1.26 lbs ai/A per application, with 1-3 applications per season.

Current REI: 14 days (ST MOE = 13 for grape girdling, IT MOE = 20 for vine training). In the June 2006 decision document, EPA proposed maintaining the REI at 14 days.

Current PHI: 7 days (< 1.0 lbs ai/A), 14 days (>1.0 lbs ai/A). For hand harvesting at 7 days, the ST MOE = 25 and the IT MOE = 18. For hand harvesting at 14 days, the ST MOE = 27, and the IT MOE = 20.

Post-application prohibition period for "pick your own" harvesting: 14 days.

Worker Risks

Post-application workers girdling grapes would not be expected to conduct this very high exposure activity (TC = 10,000) for more than 30 days (only short-term exposure would be expected). The short-term MOE is 13 at the REI of 14 days, and would only reach 100 at 44 days after application.

Post-application workers training vines could be expected to conduct this high exposure activity (TC = 5,000) for more than 30 days (intermediate-term exposure). At the REI of 14 days, the short-term MOE is 27, and the intermediate-term MOE is 20. It would take 38 days to reach an MOE > 100. However, it is unlikely that workers would be exposed to the maximum rate every day for 30 days or more.

Risks from "Pick Your Own" operations

Risks from "pick-your-own" harvesting in grape vineyards were not calculated, but are expected to be high.

Risks to bystanders in the vicinity of grape vineyards

Based on EPA's analysis of drift from airblast applications, risks to bystanders (children) are below EPA's level of concern (MOE>100) at 25 feet from the application site for all but the "sparse" foliage scenario, for which the MOE = 83. It does not appear that phosmet is aerially applied to grapes.

Ecological risks

Although phosmet applications in grape vineyards have the potential to result in some acute and chronic risks to aquatic invertebrates (freshwater and estuarine/marine), birds, and mammals, these risks are generally lower than those of most pyrethroid and OP alternatives.

Alternatives and Grower Impacts

Grapes are produced in nearly every state in the U.S., but California comprises over 85% of the total acreage. Washington and New York are the other main producers.

According to data from the California Pesticide Use Reports, phosmet use on grapes declined between 1999 and 2004, from less than two percent crop area treated to less than one percent. The total amount of phosmet applied in California has fallen from about 26,000 lb in 1999 to about 5,700 lb in 2004. EPA proprietary data indicate that in the Pacific Northwest, less than 10% on average of crop area is treated, and use seems to be declining in recent years.

Few data are available on use in other states. It appears that growers in the northeast rely more heavily on phosmet than do western producers. Data suggest that 15-20% of the acreage is treated, although recent data are particularly sparse.

Extending REIs beyond 14 days would likely interfere with hand harvesting and other in-season crop maintenance activities. If REIs were extended beyond 14 days, growers in California and the Pacific Northwest would have a number of alternatives. These include chlorpyrifos, *Bt*, imidacloprid, and methoxyfenozide, depending on which pest is targeted. Eastern growers would likely turn to methoxyfenozide, carbaryl, methomyl, or fenpropathrin. The last three chemicals have integrated pest management concerns and methoxyfenozide is most useful for early season control. Fenpropathrin can be used to control Japanese beetle and grape berry moth. However, it should not be used more than once per year because of resistance. Both methomyl and carbaryl are highly toxic to mite predators, whereas phosmet is softer on beneficial insects.

EPA quantified the impacts to grape producers in California and the Northeast U.S. of extending the phosmet REI beyond 14 days. Impacts to growers in the Pacific Northwest were not quantified due to lack of data. Phosmet may be used for grape mealybugs or cutworms in the Pacific Northwest, but it does not appear to be a critical insecticide.

Impacts are expected to be relatively small in California, less than 2% of net operating revenue, because alternative controls are similar in price and efficacy. Impacts of about 6% of net revenue can be expected in the Northeast where alternative control regimes are more expensive and growers operate on a narrower margin. Fixed costs are not included in EPA's analysis; therefore, the impacts on grower income may be higher than those estimated.

Final regulatory decision and mitigation

- For grapes east of the Rockies:
    - retain the current REI of 14 days,
    - prohibit hand harvesting for 14 days (mechanical harvesting could occur at the 7 day PHI, for application rates of 1 lbs ai/A or less)

Approximately 15-20% of the grape acreage in the northeast is treated with phosmet (however, few recent data are available). Extending the REI beyond 14 days would likely interfere with hand harvesting and other in season crop maintenance activities.

At 14 days, the MOE for very high exposure activities such as leaf pulling and grape girdling is 13 (< 30 days exposure). For high exposure activities pruning and training, the MOE is 27 for short-term exposure (pruning and training are sporadic activities that would not be carried out for more than 30 consecutive days in a row). Hand harvesting could occur over a period of a month or more, resulting in an intermediate-term MOE of 20. However, it is unlikely that workers would be exposed to phosmet applied at the maximum rate on every day for more than 30 days. As a result, the calculated intermediate-term MOE of 20 may overestimate risks to harvesters.

- For grapes west of the Rockies:

- retain the current REI of 14 days
- prohibit any hand activities from occurring after an application of phosmet, except for scouting, hand weeding, and irrigation
- require mechanical harvesting of vineyards to which phosmet has been applied in the same growing season
- prohibit aerial application
- prohibit application during the dormant season

Of the total U.S. grape acreage, 85% is in California, but less than two percent of this acreage is treated with phosmet. By prohibiting any hand activities from occurring after an application of phosmet, except for scouting, hand weeding, and irrigation, the MOE for workers conducting these remaining low exposure activities would be >100 at 14 days after application.

- For all grapes: prohibit "pick-your-own" activities

"Pick-your-own" (PYO) harvesting can occur in grapes, but was proposed to be prohibited in the June 2006 proposal. Since exposure to PYO harvesters is likely to be high, PYO activities will be prohibited for grapes treated with phosmet.

- For all grapes: require a buffer zone between the application site and houses or other occupied structures, as follows:

  East of the Rockies:
  - 25 feet for ground applications during the growing season,
  - 50 feet for ground applications during the dormant season,
  - prohibit aerial application

  West of the Rockies:
  - 25 feet for ground applications during the growing season,
  - Prohibit aerial application
  - prohibit application during the dormant season

Based on the spray drift assessment for airblast application, risks to bystanders are below the Agency's level of concern at 25 feet from the application site for all but the "sparse" foliage scenario, for which risks are below the Agency's level of concern at 50 feet from the application site (dormant applications are an example of a "sparse" foliage scenario). Since phosmet does not appear to be aerially applied to grapes, little or no impacts are expected from prohibiting aerial application.

Risk-Benefit Rationale

For eastern grapes:

1) While some risk to workers and the environment remain after imposition of the mitigation in this decision, EPA is not aware of any information that suggests that

numerous adverse incidents are likely to result from the use of phosmet;
2) Most alternatives tend to create secondary pest control concerns. These require additional pesticides to control, resulting in higher environmental loading of pesticide chemicals;
3) It is likely that production costs will increase, decreasing revenue by as much as 6% in the Northeast, because the alternatives that can be used in conjunction with certain critical cropping activities are more costly.

For western grapes:
1) Benefits of phosmet to western grape production appear to be low. Phosmet may be used for grape mealybugs or cutworms in the Pacific Northwest, but it does not appear to be a critical insecticide. In California, impacts of extending the REI beyond 14 days are expected to be less than 2% of net operating revenue, because alternative controls are similar in price and efficacy.
2) Extending the REI for western grapes to 29 days will reduce overall seasonal use and substantially reduce risks to post-application workers, while still retaining phosmet as an available rescue treatment for growers.

As outlined in the beginning of this document, however, the Agency remains concerned that the calculated margins of exposure to phosmet are low, and therefore indicative of some measure of worker risk from exposure to phosmet. As previously noted, the phosmet human health database supporting this decision is not as refined as that for some other compounds. In the Agency's experience, additional refinement of the human health database (e.g., development of worker biomonitoring data) has generally served to demonstrate that risks are lower than estimated using only laboratory data. This is not uniformly true, however, and the Agency is therefore not prepared to make an open-ended determination that the benefits of phosmet outweigh the risks based on the current risk assessment, especially in light of the fact that new alternatives may become available.

The Agency believes that with additional data to be completed in 2008, as set forth in this decision, there will be greater clarity on the extent of the risks workers face from phosmet. The Agency therefore intends to revisit this decision in 2008 upon the submission of such data and consider, in light of those data (and any new information regarding the benefits of phosmet) whether the mitigation outlined above for grapes should be retained, strengthened, or reduced.

HIGHBUSH BLUEBERRIES[2]

Current Use Parameters

Current label rates: The maximum application rate is 1.0 lbs ai/A, with a maximum of 5 applications per season.

[2] NOTE: "Pick Your Own" restriction will also apply to lowbush blueberries.

Average rate: Nationally, the average application rate is 0.86 lbs ai/A per application, with an average of 2.1 applications per season.

Current REI: 24 hours (for irrigating, weeding, and scouting ST MOE = 75). In the June 2006 decision document, EPA proposed extending this REI to 3 days (ST MOE = 86).

Current PHI: 3 days (for hand harvesting, the ST MOE = 86, the IT MOE = 63).

Post-application prohibition period for "pick your own" harvesting: None on current labels.

Worker Risks

For post-application workers hand harvesting blueberries applied at the maximum rate of 1 lb ai/A, at the current labeled PHI of 3 days, the short-term MOE is 86, and the intermediate-term MOE is 63. Although hand harvesting could be carried out for more than 30 days (intermediate-term exposure), it is unlikely that workers would be exposed to phosmet applied at the maximum rate on every day for that entire period.

For other activities, such as scouting, irrigating, hand weeding, the short-term MOE is 75 at the current REI of 24 hours. Intermediate-term exposure would not be expected for these activities. For all activities in blueberries, with phosmet applied at the maximum rate, it would take 10 days to reach an MOE > 100.

Risks from "Pick Your Own" operations

Risks to youths and adults conducting pick-your-own harvesting activities were calculated using phosmet-specific exposure data. Based on this assessment, risks to members of the general public participating in "pick-your-own" harvesting are below EPA's level of concern (MOE>100) on the day of application.

Risks to bystanders in the vicinity of blueberry fields

Based on EPA's analysis of drift from airblast and aerial applications, risks to bystanders (children) are below EPA's level of concern (MOE>100) at 25 feet from the application site.

Ecological risks

Although phosmet applications in apples orchards have the potential to result in some acute and chronic risks to aquatic invertebrates (freshwater and estuarine/marine), birds, and mammals, these risks are generally lower than those of most pyrethroid and OP alternatives. In particular, phosmet has substantially lower ecological risks than azinphos-methyl, a primary alternative to phosmet in highbush blueberries.

Alternatives and Grower Impacts

About 40% of highbush blueberries are produced in the north central regions of Michigan and Indiana and about 15% come from the Pacific Northwest. Remaining production is spread across the eastern U.S. from New York and New Jersey to Arkansas and Alabama.

Approximately 52% of U.S. highbush blueberry acreage is treated with phosmet. The highest use occurs in Michigan (74% of acres treated) and New Jersey (47% of acres treated), where phosmet use appears to be increasing since 2001.

In highbush blueberries, phosmet is needed to control late-season pests that are present near harvest. The critical target pests for phosmet are likely to be the blueberry maggot and the Japanese beetle, although other less serious pests are probably simultaneously controlled by typical phosmet use.

In June 2006, EPA released a grower impact assessment for phosmet use in highbush blueberry production. In that assessment, EPA examined the quality and yield losses that were likely to occur if the phosmet REI were extended beyond 3 days, as a stand alone insecticide and with a simultaneous loss of another insecticide with similar target pests, AZM. EPA focused on the majority of growers who are likely to be impacted in the North Central and Eastern U.S. regions if phosmet were no longer available. The North Central region includes Michigan and Indiana. The Eastern U.S. region includes New Jersey, North Carolina, Georgia, Florida, New York, Arkansas, and Alabama.

If phosmet were no longer available to growers in the north central region, EPA estimated a quality loss range of a 5-10% transfer of harvest from fresh market to “no sale”, and a 10-15% transfer of harvest from processed market to “no-sale”. In addition, under normal pest pressure, EPA estimated that variable costs to growers would increase by about 4%, or $143 per acre (from $3,359 to $3,502 per acre) as a result of switching to phosmet alternatives. EPA’s upper bound estimate is that returns above variable costs (net operating revenues) would decrease by approximately 82%, or $656 per acre (from $802 to $147 per acre).

If phosmet were no longer available to growers in the eastern region, EPA estimated a quality loss range of a 5-7% transfer of harvest from fresh market to “no sale”, and a 10-15% transfer of harvest from processed market to “no-sale”. In addition, EPA estimated that variable costs to growers would increase by approximately 3%, or $143 per acre (from $4,089 to $4,232 per acre) as a result of switching to phosmet alternatives. In an upper bound estimate, EPA’s upper bound estimate is that returns above variable costs (net operating revenues) would decrease by approximately 30%, or $628 per acre (from $2,075 to $1,447 per acre).

Final regulatory decision and mitigation

- Retain the current REI of 24 hours, but prohibit harvesting for 3 days

In the June 2006 proposal, EPA proposed that the REI for highbush blueberries be increased from 24 hours to 3 days. Based on submitted comments, EPA has revised its decision to retain the current REI of 24 hours and prohibit hand harvesting for 3 days, consistent with the current PHI.

At 3 days, the short-term MOE for hand harvesting would be 86, and the intermediate-term MOE would be 63. Although hand harvesting could be carried out for more than 30 days (intermediate-term exposure), it is unlikely that workers would be exposed to phosmet applied at the maximum rate on every day for that entire period. No other high exposure activities are performed in highbush blueberries.

Workers performing irrigation and scouting activities would not conduct these activities for more than 30 days in a row, so only short-term exposure would occur. At the current REI of 24 hours, the short-term MOE is 75. However, irrigators and scouts would be expected to spend only a few hours in the field, so the calculated MOE of 75 may overestimate risks.

- Prohibit "pick-your-own" activities for 3 days after application

"Pick-your-own" (PYO) harvesting is an important component of blueberry operations. Fields are opened to the public as the first fruit ripens. Later, the remaining fruit is harvested for commercial sale. The PYO portion may be quite significant to the operations revenues, since growers receive a premium for the fruit.

In the June 2006 proposal, EPA proposed that PYO be prohibited. After reviewing submitted comments, and conducting a PYO risk assessment using a phosmet-specific exposure study, the Agency has determined that PYO may be retained for highbush blueberries, but that phosmet labels must prohibit entry for PYO for at least 3 days, consistent with the current PHI. This restriction will be protective of potential risks to members of the general public (youths and adults) participating in PYO harvesting in blueberry fields. [3]

- Require a buffer zone between the application site and houses or other occupied structures, as follows:
    - 25 feet for ground applications,
    - 50 feet for aerial applications, and
    - Require "medium" or coarser spray for aerial applications

Although risks are below the level of concern for bystanders at 25 feet from the application site, the Agency is requiring a buffer zone of 50 feet for aerial application, in order to be consistent with the other time-limited crops.

Risk-Benefit Rationale

[3] This 3-day prohibition on "Pick Your Own" activities will also apply to lowbush blueberries (which have the same PHI of 3 days).

EPA believes that, with the mitigation measures described above, the benefits of phosmet use on apples outweigh the risks in the short term, for the following reasons:

1) The Agency believes that the highbush blueberry REI outlined in this document will allow for the performance of necessary field activities and will not drive additional use of AZM;
2) Where AZM is still an alternative, the use of phosmet will present fewer risks;
3) The calculated post-application worker MOEs are greater than 75 for all activities, with the exception of hand harvesting blueberries for more than 30 consecutive days in a row (MOE = 63). Even for this activity, it is unlikely that workers would be exposed to maximum phosmet residues every day for more than 30 days.
4) While some risk to workers and the environment remain after imposition of the mitigation in this decision, the estimated risk approaches EPA's protective "level of concern" of an MOE of 100, and EPA is not aware of any information that suggests that numerous adverse incidents are likely to result from the use of phosmet;
5) Without phosmet, growers would experience a substantial increase in the cost of production, in addition to losses in crop quality and yield.

As outlined in the beginning of this document, however, the Agency remains concerned that the calculated margins of exposure to phosmet are low, and therefore indicative of some measure of worker risk from exposure to phosmet. As previously noted, the phosmet human health database supporting this decision is not as refined as that for some other compounds. In the Agency's experience, additional refinement of the human health database (e.g., development of worker biomonitoring data) has generally served to demonstrate that risks are lower than estimated using only laboratory data. This is not uniformly true, however, and the Agency is therefore not prepared to make an open-ended determination that the benefits of phosmet outweigh the risks based on the current risk assessment, especially in light of the fact that new alternatives may become available.

The Agency believes that with additional data to be completed in 2008, as set forth in this decision, there will be greater clarity on the extent of the risks workers face from phosmet. The Agency therefore intends to revisit this decision in 2008 upon the submission of such data and consider, in light of those data (and any new information regarding the benefits of phosmet) whether the mitigation outlined above for grapes should be retained, strengthened, or reduced.

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