



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Section 18 - Specific Exemption Request for the Postharvest Use of Fenhexamid on Pears to Control Gray Mold (*Botrytis cinerea*) in California (99-CA-42)
-- ACTION MEMORANDUM --

FROM: James J. Jones, Director
Registration Division

TO: Susan B. Hazen, Acting Deputy Director
Office of Pesticide Programs

I. APPLICANT REQUEST

Applicants: California Department of Pesticide Regulation (CDPR)

Chemical: Fenhexamid

Product: Elevate 50 WDG (containing 50% active ingredient), manufactured by Tomen Agro.

Site: Pears (post-harvest)

Pests: Gray mold (*Botrytis cinerea*)

Rate: One application may be made postharvest by packers of pears for fresh shipment; use 1.5 lbs. of product (0.75 lbs. a.i.) in sufficient water to treat 200,000 lbs. of fruit. If using dip tank, completely change tank solution after 200,000 pounds of fruit have been treated.

Acreage: A maximum of 90,000 tons of fruit in California are being requested for treatment.

Use Season: Date of issuance - October 15, 1999

7

Emergency, Economics, & Alternative Measures:

According to the Applicant, development of thiabendazole (TBZ) resistance in California *Botrytis* populations has left packing houses without an effective tool to control the disease. Registered alternatives include thiabendazole, captan, Bio-Save (*Pseudomonas syringae*), Aspire (*Candida oleophila*), chlorine, ozone and sodium o-phenylphenate (SOPP). Testing for thiabendazole resistance was conducted both in laboratory experiments and in the field in 1998. Laboratory tests showed 100% TBZ-resistance on petri dishes and 63% resistance on fruit tested. Due to the wide spread field use of the related compounds benomyl and thiophanate-methyl, resistance is progressive in California and 75-85% resistance in California packing houses is predicted in the 1999 season. Captan is not considered a viable alternative because Taiwan (and several other foreign countries) has banned the import of captan-treated fruit. While treated pears are not banned in Taiwan, there is concern if captan were used on pears, other fruit might become adulterated with captan residues from the sorting equipment in packing houses or in transit. The Applicant claims that the unpredictable efficacy and results of biological controls have kept the pear industry from adopting this technology. Both ozone and chlorine are claimed to damage the pears. It is additionally claimed that cooler than normal weather will result in higher *Botrytis* pressure in the orchards.

II. BACKGROUND

This is the first year this postharvest use of fenhexamid on pears has been requested. Due to a state-level setback in identifying an effective fungicide candidate that had registrant support, the section 18 application was not actually received by the Agency until after the requested use season had started, which has presented a hurdle as a postharvest use requires that a time-limited tolerance be established prior to or in conjunction with authorization of the section 18. This year several states requested the section 18 use of Elevate (fenhexamid) and Switch (fludioxonil and cyprodinil) on strawberries and caneberries to control *Botrytis*. In all of these cases the Agency determined that the situation only warranted to use of a single product, and the states chose Switch. Fenhexamid was registered for use on grapes and strawberries in late May of this year.

Reregistration/Special Review Considerations:

Fenhexamid was registered after 1984, and is therefore not subject to reregistration. Fenhexamid is not the subject of a Special Review.

Progress Toward Registration:

This is the first year this use has been requested; Tomen Agro has indicated support of this section 18 use and has indicated their intent to pursue a section 3 registration. Fenhexamid was registered for use on strawberries and grapes in May of this year.

III. EPA EVALUATION

Biological & Economic Analysis:

The Biological and Economic Analysis Division (BEAD) reviewed this year's request and concludes that the use of fenhexamid on pears to control postharvest gray mold has not been documented to be urgent or non-routine and that an emergency exemption is not justified. According to BEAD, the state does not provide documentation to support their claim that registered alternatives (alone or in combination) are ineffective at controlling the disease under packing house environment. BEAD concludes that the projected statewide losses of 20% using registered alternatives are excessively high and highly unlikely even under the worst possible scenario. The data submitted by the state only support losses of 8-10%, and these are based on only a single packing house. Finally, BEAD concludes that significant economic losses are not expected using currently available alternative controls. In reaching these conclusions, BEAD relied on the data submitted with the application, additional information submitted by fruit packing houses separate from the application, and testimony from the qualified experts listed in the application as well as from several additional contacts (both within and outside California) suggested by the grower group pursuing the section 18 emergency exemption.

The development of TBZ-resistance in the *Botrytis* population is central to the state's argument that an emergency condition exists. However, TBZ resistance in *Botrytis* has been documented for over 10 years- this has been a routine problem for packing houses. Furthermore, it is well-documented that yearly losses caused by gray mold have remained approximately 3-5% since that time, when harvested fruit are treated with a combination of registered alternatives. BEAD surmises that this may be due to the fact that only 5-10% of the pathogen isolates have resistance against thiabendazole under field conditions. BEAD claims these losses can be further reduced up to 50% with a single preharvest application of ziram. While state-specific studies in California demonstrated 100% resistance to TBZ in the lab and 63% resistance on fruit taken from a packing house, it is BEAD's conclusion that the designs of these studies highly bias the results towards demonstrating resistance, and that these results do not accurately reflect the actual degree of TBZ resistance in *Botrytis* populations in California.

Though the request is for use statewide in packing houses, yield loss and economic data submitted were local in scope. Qualified experts which were contacted implied that the losses which were quoted are not a statewide problem, and indeed may be highly localized. Additionally, these qualified experts confirmed that losses in pears are generally in the 3% range. It was suggested that the higher losses experienced by some growers last year may have been due to heavier than normal rainfall and that losses this year may not be as high as predicted. Less stringent packing house sanitation was also raised as a possible explanation for the localized losses which were experienced last year.

It is noted that available information indicates that *Botrytis* is mainly a problem in stored fruit (getting worse to longer the fruit is stored); the request sent to CDPR indicates that approximately 35,000 tons of fruit to be stored in packing houses may require treatment. Given this, it is unclear why the application received by the Agency requests treatment of

90,000 tons of pears.

While the Agency does not disagree that fenhexamid may be more efficacious than currently registered alternatives at controlling *Botrytis* in packing houses, this alone does not qualify as an emergency condition. The purpose of an emergency exemption is not to prevent losses which growers have historically incurred. As this chemical appears to be efficacious in controlling this disease and has been classified as a reduced risk pesticide, the state is strongly encouraged to coordinate with IR-4 to seek expedited Agency review towards full section 3 registration of this use.

Aggregate Risk Assessment and Determination of Safety

HED initiated review of this year's request; review was discontinued after it was determined that the emergency condition had not been met. However, from previous reviews for this chemical seems likely that chronic and acute dietary risk from fenhexamid would not of concern.

As this is a postharvest use on pears, it would be necessary to establish a time-limited tolerance prior to an authorization of the section use, since it treated fruit would enter the channels of commerce shortly after treatment. Given that the section 18 request was submitted to the Agency after the requested starting use date, it would have been difficult to make the use available in a time-frame useful to packers even if we were able conclude that the situation meets our criteria for an emergency. At this point, and given that HED has discontinued their review, it is highly unlikely that this could be accomplished in a time-frame which would be useful to the state.

Ecological Effects/Environmental Fate Review:

EFED reviewed this request and concluded that the proposed indoor use of fenhexamid on pears is not expected to present a risk to groundwater, surface water, or to non-target organisms including endangered species.

IV. RECOMMENDATION:

I recommend that this section 18 request from the California Department of Pesticide Regulation for the use of fenhexamid on pears be denied. This recommendation is based on the following:

1. BEAD concludes that this situation is routine and not urgent, and does not qualify as being an emergency condition. The basis for the state's argument for an emergency, thiabendazole resistance, is a routine problem for pear growers and has been documented as existing for almost 10 years. Additionally, it is well-documented that packing house pear losses due to *Botrytis* are around 3% annually, with the TBZ-resistance *Botrytis* population remaining relatively constant over time. The state has not submitted data supporting the predicted yield losses or the claims that registered alternatives are ineffective. Qualified experts contacted by EPA, both those listed in the state's application as well as additional contacts suggested by the grower group,

support the Agency's conclusions.

2. Even in the event that the Agency had concluded an emergency condition existed, the emergency exemption request was not submitted to the Agency in a time-frame which would allow the Agency to establish a time-limited tolerance prior to approval of the section 18 request. As this is a post-harvest use, a tolerance must be in place prior to treatment with the product.

Susan B. Hazen, Acting Deputy Director
Office of Pesticide Programs

Date: _____

5