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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

May 31, 2002

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its tolerance reassessment decision for Fenbutatin-Oxide. This letter, signed on May 31, 2002, and the attached "Overview" document serve as EPA's "Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for Fenbutatin-oxide." A Notice of Availability soliciting public comment for a 30-day period will be published in the *Federal Register* (FR) shortly.

FFDCA, as amended, requires EPA to reassess all the tolerances that were in effect for registered chemicals on or before the date of the enactment of FQPA in August of 1996 against the new safety standard adopted in the FQPA. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. The tolerances are considered reassessed once the safety finding has been made or a modification or revocation occurs. A reregistration eligibility decision (RED) for fenbutatin-oxide was completed in September 1994 prior to FQPA enactment. Therefore, it needed to be updated to reassess the tolerances under the FQPA standard.

The Agency has evaluated the dietary risks associated with fenbutatin-oxide and has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to fenbutatin-oxide when considering dietary exposure and all other non-occupational sources of pesticide exposure for which there is reliable information. Therefore, no mitigation measures are needed, and the tolerances established for residues of fenbutatin-oxide are now considered reassessed as safe under section 408(q) of the FFDCA.

FQPA requires that EPA consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect, as would a higher level of exposure to any of the other substances individually. EPA did not perform a cumulative risk assessment as part of this review of fenbutatin-oxide because the Agency has not determined that there are any other chemical substances that have a mechanism of toxicity in common with fenbutatin-oxide. If EPA identifies other substances that share a common mechanism, then a cumulative risk assessment will be conducted that includes fenbutatin-oxide once EPA's final framework for conducting cumulative risk assessments is available. Further, EPA is in the process of developing criteria for characterizing and testing endocrine disrupting chemicals and plans to implement an Endocrine Disruptor Screening Program. Fenbutatin-oxide will be reevaluated at that time and additional studies may be required.

The Agency's human health findings for the pesticide fenbutatin-oxide were discussed in a closure conference call on May 30, 2002, and are summarized in the attached, "Overview of Fenbutatin-Oxide Risk Assessment." The risk assessment and other documents pertaining to the fenbutatin-oxide tolerance reassessment decision are listed at the end of this document and are available on the Internet at http://www.epa.gov/pesticides/reregistration/status.htm and in the public docket for viewing.

Tolerances are established for residues of fenbutatin-oxide in/on raw agricultural commodities as defined in 40 CFR 180.180.362. Based on the available residue data and to better harmonize with CODEX, EPA has concluded that the tolerance expression for plants should include the parent compound only, and for meat, milk, poultry and eggs the tolerance expression should include the parent compound and its organotin metabolites dihydroxybis(2-methyl-2-phenylpropyl)stannane (SD-31723) and 2-methyl-2-phenylpropylstannoic acid (SD-33608). Adequate enforcement methods are available for the determination of these residues. No additional residue data are required at this time.

EPA will propose to reassign individual tolerances for almonds, pecans, and walnuts and replace with a tolerance for "tree nuts group"; combine tolerances for "cherries, sour" and "cherries, sweet" into a single tolerance for "cherries"; and reassign the tolerance for "prunes" to "plums (fresh prunes)". EPA also will propose to establish a new tolerance for "apples, wet pomace". Several commodity definitions will also be corrected. The following table summarizes EPA's tolerance reassessment decision.

TOLERANCE REASSESSMENT SUMMARY

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 180.362(a)			
Almonds Pecans Walnuts	0.5 0.5 0.5	Reassign at 0.5 ppm	*Tree nuts group*
Almonds, hulls	80	80	
Apples Apples, wet pomace	15 --	15 100	
Cherries, sour Cherries, sweet	6.0 6.0	Combine into one tolerance at 6 ppm	*Cherries*
Citrus fruits Citrus oil Citrus pulp, dried	20 140 100	20 140 100	
Cucumbers	4.0	4.0	
Eggplant	6.0	6.0	
Grapes Raisin	5.0 20	5.0 20	
Papayas	2.0	2.0	
Peaches	10	10	
Pears	15	15	
Plums	4.0	4.0	*Plums (fresh prunes)*
Prunes	4.0	Reassign	Covered under *"Plums (fresh prunes)"*
Prunes, dried	20	20	
Strawberries	10	10	
Tolerances listed under 180.362(b)			
Cattle, fat	0.5	0.5	
Cattle, mbyp	0.5	0.5	
Cattle, meat	0.5	0.5	
Eggs	0.1	0.1	
Goats, fat	0.5	0.5	
Goats, mbyp	0.5	0.5	
Goats, meat	0.5	0.5	
Hogs, fat	0.5	0.5	
Hogs, mbyp	0.5	0.5	
Hogs, meat	0.5	0.5	
Horses, fat	0.5	0.5	
Horses, mbyp	0.5	0.5	
Horses, meat	0.5	0.5	
Milk fat	0.1	0.1	*Milk, fat*
Poultry, fat	0.1	0.1	

Tolerance Summary Table *(Continued)*.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Poultry, mbyp	0.1	0.1	
Poultry, meat	0.1	0.1	
Sheep, fat	0.5	0.5	
Sheep, mbyp	0.5	0.5	
Sheep, meat	0.5	0.5	
Tolerances listed under 180.362(c)			
Raspberries	10	10	

This document also contains a generic Data Call-In (DCI) that outlines further data requirements for this chemical. Note that registrants of fenbutatin-oxide must respond to DCIs issued by the Agency within 90 days of receipt of this letter.

If you have questions on this document, please contact the Chemical Review Manager, *Lorilyn Montford*, at *(703) 308-8170*.

Sincerely,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments: List of Supporting Documents
Overview of Fenbutatin-Oxide Risk Assessment
Generic Data Call-In (DCI)

List of Documents Supporting the Fenbutatin-Oxide Tolerance Reassessment Decision

The Tolerance Reassessment Decision for fenbutatin-oxide is based on the revised human health risk findings, disciplinary chapters, and other supporting documentation as follows:

Fenbutatin-oxide. Revised Preliminary Human Health Risk Assessment. HED Chapter for the Tolerance Reassessment Eligibility Decision (TRED). Chemical No. 104601. Paula Deschamp (May 3, 2002; D282791)

Revised Tier 3 Chronic Dietary Exposure Assessment. Sheila Piper (May, 2002; D282678)

Revised Residential Exposure Assessment for Recommendations for the Tolerance Reassessment Evaluation Decision (TRED) Document for Fenbutatin-Oxide. Shanna Recore (May, 2002; D282677)

Fenbutatin-Oxide - Fourth Report of the Hazard Identification Assessment Review Committee. David G. Anderson (April 30, 2002; TXR.0050696).

Fenbutatin Oxide - Reassessment Report of the FQPA Safety Factor Committee. Brenda Tarplee (May 2, 2002)

Revised (1st) Toxicology Chapter for the TRED for Fenbutatin-oxide. David G. Anderson (14-January-2002; D272900, TXR#0050393)

The Outcome of the HED Metabolism Assessment Review Committee to Discuss degradates in Drinking Water. Sheila Piper (10-May-2001)

Residue Chemistry Chapter for the Tolerance Reassessment Eligibility Decision (TRED) Document. (1-November-2001; D272901)

Product Chemistry Chapter for the Tolerance Reassessment Eligibility Decision (TRED) Document. K. Dockter (4-September-2001; D274437)

Quantitative Usage Analysis for Fenbutatin-Oxide. Jihad Alsadek (20-September-2001)

Review of Fenbutatin-Oxide Incident Reports. Jerome Blondell (17-May-2001; D275020)

Drinking Water Assessment to Support TRED for Fenbutatin Oxide. Lucy Shanaman (31-July-2001; D275465)

Generic Data Call-In

[place holder -- to be generated]

Overview of Fenbutatin-Oxide Risk Assessment

May, 2002

Introduction

The Agency has completed its review and announces the tolerance reassessment decision for fenbutatin oxide. This decision also releases to the public the human health assessment, as presented fully in the document entitled "**Fenbutatin-oxide.** Revised Preliminary Human Health Risk Assessment. HED Chapter for the Tolerance Reassessment Eligibility Decision (TRED)" dated May 3, 2002, and related documents supporting this decision. The purpose of this overview is to assist the reader by identifying the key features and findings of the risk assessment in order to enhance understanding of the conclusions reached in the tolerance reassessment decision. The Agency's reassessment of dietary risk, including public exposure through food and drinking water, is required by the Federal Food, Drug, and Cosmetic Act (FFDCA). The Agency must review tolerances and tolerance exemptions that were in effect when the Food Quality and Protection Act (FQPA) was enacted in August 1996 to ensure that these existing pesticide residue limits for food and feed commodities meet the safety standard of the new law.

FFDCA requires the Agency to review all the tolerances for registered chemicals in effect on or before the date of the enactment of FQPA. In reviewing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. The tolerances are considered reassessed once the safety finding has been made or a tolerance revocation occurs. A RED for fenbutatin-oxide was completed September 1994, prior to FQPA enactment; therefore it needed to be updated to consider the provisions of the Act.

FQPA requires that the Agency, when considering whether to establish, modify, or revoke a tolerance, consider "available information" concerning the cumulative effects of the particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency does not, at this time, have sufficient reliable information available to determine whether fenbutatin-oxide has a common mechanism of toxicity with other substances. Therefore, for the purposes of this risk assessment, the Agency has not assumed that fenbutatin-oxide has a common mechanism of toxicity with other substances. If EPA identifies other substances that share a common mechanism of toxicity with fenbutatin-oxide, a cumulative risk assessment for those substances will be performed.

The risk assessment and documents pertaining to the Agency's report on FQPA tolerance reassessment progress and decision for fenbutatin-oxide are available on the Internet at http://www.epa.gov/pesticides/reregistration/status.htm and in the public docket. Because the risks posed by the use of fenbutatin-oxide are low and not of concern to the Agency, the normal process of meeting stakeholders (i.e., growers, extension offices, environmental and commodity

groups, and other government offices) to discuss risks of concern and solicit input on risk mitigation strategies was not necessary for this chemical. Rather, the Agency's report on FQPA tolerance reassessment progress and interim risk management decision for fenbutatin-oxide will be announced in the Federal Register. Since there are no risk concerns for fenbutatin-oxide alone, no further actions are warranted at this time pending a determination of whether a cumulative risk assessment for fenbutatin-oxide may be needed and is completed.

Use Profile

- **Acaricide:** Fenbutatin-oxide, trade name Vendex, is an organotin acaricide registered for use against mies on almonds, apples, cherries, citrus fruits, cucumbers, eggplant, grapes, papayas, peaches, pears, pecans, plums, raspberries, strawberries, and walnuts, greenhouse crops, and ornamentals. Fenbutatin-oxide is primarily used in agriculture with key markets in Florida and California. Fenbutatin-oxide residential products are used on ornamentals and are typically applied using hand-held equipment such as low pressure handwands, backpack sprayers, or hose-end sprayers.

- **Formulation:** Fenbutatin-oxide products include wettable powders in water-soluble packets, 50% active ingredient (ai), and emulsifiable concentrates, 0.5% - 0.75% ai.

- **Methods of Application:** Fenbutatin-oxide is applied aerially and with airblast, groundboom, and hand-held equipment.

- **Use Rates:** Single application rate ranges from 0.1 lbs ai/acre to 2.8 lbs ai/acre.

- **Annual Usage:** Based on available pesticide survey use data from 1990 through 2000, annual fenbutatin-oxide total domestic usage averaged approximately 390,000 pounds ai for 503,000 acres treated. In terms of the total pounds active ingredient used, fenbutatin-oxide has its largest markets in oranges, grapefruit, almonds, peaches, berries and strawberries, tangerines, apples, and grapes. Most use is in California, Florida, Michigan, Georgia, New Jersey, Massachusetts, Nebraska, Minnesota, and Pennsylvania.

- **Classification:** General and Restricted Use Non-Systemic Organotin Acaricide Pesticide.

- **Technical Registrant:** Griffin LLC.

Hazard

Fenbutatin-oxide has low acute toxicity by the oral and dermal routes (Category III) and is more acutely toxic by the inhalation route (Category II). It is a severe eye irritant (Category I), but not an acute primary skin irritant (Category IV). A 21-day rabbit dermal study showed no systemic toxicity, but showed mild to severe skin reactions.

A major characteristic of the hazard profile for fenbutatin-oxide is that it is highly irritating and appears to be unpalatable. Subchronic and chronic studies in rats did not provide clear evidence of any specific target organ or toxic effect. Studies in the rat, mouse, and dog showed body weight and food consumption decreases in the absence of any treatment related histological findings. There was increased susceptibility in the rat reproduction study, but not in rat and rabbit developmental studies. Fenbutatin-oxide is not a carcinogen and has been placed in Group E; no evidence of carcinogenicity in the rat or mouse and is negative for mutagenicity.

Human Health Risk Assessment

Risks from dietary exposure (food and water) and residential exposure have been evaluated for fenbutatin-oxide. Table 1 below summarizes the toxicological endpoints and doses that were used to assess the human health risks associated with uses of fenbutatin-oxide.

Table 1. Summary of Toxicological Dose and Endpoints for Fenbutatin-oxide Assessment

Exposure Scenario	**Dose Used in Risk Assessment and Uncertainty Factors**	**Special FQPA SF[1] for Risk Assessment**	**Study and Toxicological Effects**
Acute Dietary All Populations	**Acute RfD** = None selected	N/A	An appropriate endpoint attributable to a single dose was not identified in any study including the rat and rabbit developmental toxicity studies.
All other scenarios including - Chronic Dietary - Oral, Dermal, and Inhalation (all time frames) All Populations	NOAEL[2]= 5.1 mg/kg/day UF[3] = 300 **LOC for MOE[4]** = 300 **Chronic RfD** = 0.017 mg/kg/day Dermal absorption 10% Inhalation abs. 100%	Special FQPA SF = 1	Two-generation study of reproduction LOAEL[5] = 16.6 mg/kg/day based on decreased pup body weight gain during lactation.
Cancer	Classification group E, not likely to be a human carcinogen.	N/A	No neoplastic lesions in rats or mice.

[1] **Special FQPA SF** = Special FQPA Safety Factor based on hazard and exposure. For fenbutatin-oxide no additional factor was applied since there is a low degree of concern for increased susceptibility and no residual uncertainties.
[2] NOAEL = no observed adverse effect level.
[3] UF = uncertainty factor, 10x for interspecies extrapolation, 10x for intraspecies variations, and 3x FQPA database uncertainty safety factor due to a data gap.
[4] LOC = level of concern; MOE = margin of exposure.
[5] LOAEL = lowest observed adverse effect level.

All the toxicity endpoints selected for risk assessment were based on decreased offspring body weight gain observed during lactation in the 2-generation rat reproduction study. The dose level of 5.1 mg/kg/day was selected for chronic dietary and short- and intermediate-term dermal and inhalation risk assessments. Risk calculations incorporated 10% dermal absorption and 100% inhalation absorption factors for estimates of dermal and inhalation exposure, respectively. An uncertainty factor (UF) of 100 was applied to all doses selected for risk assessment purposes to account for interspecies extrapolation (10x) and intraspecies variability (10x). The Agency has reevaluated the hazard and exposure data for fenbutatin-oxide and concluded that an additional 3X FQPA uncertainty safety factor is appropriate for all population subgroups and risk assessments to address the lack of a subchronic neurotoxicity study. EPA has also concluded that no additional Special FQPA Safety Factor for hazard and exposure is necessary to protect infants and children since there is a low degree of concern for increased susceptibility and there are no residual uncertainties.

Dietary (Food) Risk Assessments for Fenbutatin-Oxide

An acute dietary exposure assessment was not performed because a review of all available fenbutatin-oxide toxicity data did not identify an appropriate endpoint attributable to a single oral dose. Chronic dietary risk is calculated by using the average consumption values for food and average residue values for those foods over a 70-year lifetime. A risk estimate that is less than 100% of the chronic Population Adjusted Dose (cPAD) (the dose to which an individual could be exposed over the course of a lifetime and no adverse health effect would be expected) is not of concern to the Agency.

Agency did not identify any risks of concerns from exposure to fenbutatin-oxide in food. A refined Tier 3 chronic dietary exposure analysis was conducted for fenbutatin-oxide using the Dietary Exposure Evaluation Model (DEEM^{TM}) software which incorporates consumption data from USDA's Continuing Surveys of Food Intake by Individuals (CSFII), 1989-1992. Residue values were derived from USDA's Pesticide Data Program (PDP) and field trial data.

The chronic food exposure estimate for the most highly exposed subpopulation, infants less than 1 year of age, was 1.0% of the cPAD which is well below the Agency's level of concern. Table 2 below shows risks for all populations considered.

Table 2. Chronic Dietary (food) Risk Estimates

Population	Exposure (mg/kg/day)	% Chronic PAD
U.S. Population	0.000041	<1
All Infants (<1 year)	**0.000169**	**1.0**
Children 1-6 years	0.000089	<1
Children 7-12 years	0.000045	<1
Females 13-50 years	0.000031	<1
Males 13-19 years	0.000013	<1
Males 20+ years	0.000029	<1
Seniors 55+ years	0.000051	<1

Drinking Water Dietary Risk

Drinking water exposure to pesticides can occur through surface and/or ground water contamination. The Agency did not identify any risks of concern from exposure to fenbutatin-oxide in drinking water. Fenbutatin-oxide is persistent but immobile in the environment. The available data indicate that fenbutatin-oxide strongly binds to soil. This propensity towards binding precludes the possibility of significant concentrations being present in surface water and mitigates potential for significant accumulation in ground water.

The Agency considers acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate these risks. Modeling is carried out in tiers of further refinement, and is designed to provide a high end estimate of exposure. EPA currently lacks sufficient water monitoring data to complete a quantitative drinking water risk assessment for fenbutatin-oxide. Therefore, the Agency is relying on modeling to derive estimated environmental concentrations (EECs) for fenbutatin-oxide. EPA used the Tier II (PRZM/EXAMS) surface water computer model and the Tier I (SCI-GROW) ground water model to estimate concentrations. These models take into account the use patterns and the environmental profile of a pesticide, but do not include consideration of the impact that processing raw water for distribution as drinking water would likely have on pesticides in the source water. The primary use of these models by the Agency at this stage is to provide a screen for determining whether pesticide residues (and metabolites) in water are not of concern.

Surface water modeling predicted that the 1 in 10 year peak (acute) concentration will not exceed 18.5 ppb, and the average (chronic) concentration will not exceed 6.0 ppb. Ground water modeling predicted that the concentration in ground water will not exceed 0.006 ppb. Table 4 in the aggregate risk section below compares these estimated concentrations to food and residential exposures for each population.

Non-dietary (Residential/Public) Risks

Non-occupational (residential) risks are not of concern for fenbutatin-oxide. Fenbutatin-oxide is used in commercial and residential settings for control of mites and diseases on ornamental plants including roses, flowers, shrubs, and trees. Non-occupational use of fenbutatin-oxide products may result in dermal and inhalation exposure to adult handlers.

Fenbutatin-oxide is applied to residential ornamentals at a maximum application rate of 0.0005 lbs ai/gallon using low pressure handwands, backpack sprayers, and hose-end sprayers. Homeowner products are typically applied up to six times per year with four week intervals between applications. The homeowner exposure duration is assumed to be short-term (1 to 30 days) since applications are made about once per month during a six month growing season. No specific handler exposure data were available for fenbutatin-oxide; therefore, the Agency relied on the best available surrogate data from the Outdoor Residential Exposure Task Force (ORETF) and the Pesticide Handlers Exposure Database (PHED).

Because there is no anticipated significant post-application exposure from spot treating ornamentals in such settings as gardens, parks and other recreational areas, no post-application scenarios were assessed.

Risks were calculated using the Margin of Exposure (MOE) approach, which is a ratio of exposure to the toxicological endpoint of concern. The MOEs derived for short-term exposure were based upon comparison of dermal and inhalation exposure estimates against a NOAEL of 5.1 mg/kg/day from an oral toxicity study in rats. The risk calculations incorporated a 10% dermal absorption factor and a 100% inhalation absorption factor for dermal and inhalation exposures, respectively. An uncertainty factor (UF) of 100 was applied to the dose selected for risk assessment to account for both interspecies extrapolation and intraspecies variability. The Agency used an additional 3X uncertainty factor to address data deficiencies which was applied to all exposure scenarios. Therefore, an MOE $ 300 does not present a risk concern for residential handlers.

Table 3 presents the risk estimates for all residential handler scenarios. Calculations of combined dermal and inhalation risk indicate that the total MOEs are much greater than 300 when fenbutatin-oxide is applied using a low-pressure handwand, a backpack sprayer, or a hose-end sprayer (the lowest MOE was 4,900).

Table 3. Residential Handler Risk Estimates

Exposure Scenario (Based on short sleeved shirt, short pants, no gloves, no respirator)	**Application Rate** (lbs ai/gal)	**Amount Used Per Day** (gallons)	**Total MOE**
(1) Mixing/loading/applying liquids with low pressure handwand	0.0005	5	22,000
(2) Mixing/loading/applying liquids with backpack sprayer	0.0005	5	230,000
(3) Mixing/loading/applying with hose-end sprayer	0.0005	32	4,900

Aggregate Risk

Aggregate risk looks at the combined risk from exposure through food, drinking water, and residential uses. For fenbutatin-oxide, the aggregate risks were evaluated for two exposure durations: short-term (residential + average food + drinking water) and chronic (food + drinking water). An appropriate endpoint attributable to a single oral dose was not identified in any fenbutatin-oxide study; therefore, the Agency did not conduct an acute aggregate dietary (food and water) risk analysis.

To determine the maximum allowable contribution from water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food and through residential uses, and then determines a “drinking water level of comparison” (DWLOC) to ascertain whether estimated environmental concentrations (EECs) exceed this level. A DWLOC is a theoretical upper limit on a pesticide’s concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through residential uses. EECs that are above the corresponding DWLOC are of concern to the Agency.

Short-term aggregate risk takes into account residential exposure plus average (chronic) exposure through food and water. Chronic aggregate risk takes into account only exposure to residues of fenbutatin-oxide in food and water since no chronic residential scenarios were identified.

Table 4 below shows the EECs for ground and surface water and the DWLOCs for each population. The EECs in ground and surace water are significantly less than the DWLOCs indicating that short-term and chronic aggregate exposure to fenbutatin-oxide does not exceed the Agency's level of concern.

Table 4. Drinking Water DWLOC and EEC Comparisons for Aggregate Risk

Population Subgroup	DWLOCs (ppb)		EECs (ppb)	
	Short-Term[a]	Chronic	Ground Water (Acute and Chronic)	Surface Water (Chronic)
U.S. Population	546	594	0.006	6.0
All Infants (<1yr)	n/a[b]	168		
Children 1-6	n/a[b]	169		
Children 7-12	n/a[b]	170		
Females (13+)	468	509		
Males 13-19 yrs	546	595		
Males 20+ yrs	546	594		
Seniors 55+ yrs	545	593		

[a] Includes residential plus average food exposure and is compared to the chronic EEC.
[b] Not applicable since children are not expected to handle or apply fenbutatin-oxide products.

Occupational and Ecological Risk

Because fenbutatin-oxide is under review for tolerance reassessment only, no occupational or ecological risk assessment was conducted for this TRED. Occupational and ecological risks were evaluated and risk management decisions were made as part of the 1994 Fenbutatin-oxide RED.

Tolerance Reassessment Summary

Currently there are 42 tolerances for residues of fenbutatin-oxide in or on food/feed commodities. These tolerances are defined in *40 CFR §180.362 (a), (b), and (c)*, and expressed in terms of the combined residues of hexakis(2-methyl-2-phenylpropyl)-distannoxane and its organotin metabolites calculated as hexakis(2-methyl-2-phenylpropyl)-distannoxane. EPA has concluded that the toxic residues resulting from use of fenbutatin oxide are the parent compound and its organotin metabolites dihydroxybis(2-methyl-2-phenylpropyl)stannane (SD-31723) and 2-methyl-2-phenylpropyl-stannoic acid (SD-33608). Codex maximum residue limits (MRLs) were established on various commodities. However, the Codex MRLs and applicable U.S. tolerances are incompatible due to differences for the animal commodities. Based on the

available residue data and to better harmonize with CODEX, EPA has concluded that the tolerance expression for plants should include the parent compound only, and for meat, milk, poultry and eggs the tolerance expression should include the parent compound and its organotin metabolites dihydroxybis(2-methyl-2-phenylpropyl)stannane (SD-31723) and 2-methyl-2-phenylpropylstannoic acid (SD-33608). Adequate enforcement methods are available for the determination of these residues. Existing tolerances for fenbutatin-oxide residues range from 0.1 ppm to 0.5 ppm in livestock commodities and from 0.5 ppm (nut meats) to 140 (citrus oil) in raw agricultural commodities and processed food/feed items. Table 5 below summarizes the tolerance reassessment for fenbutatin-oxide.

Table 5. Tolerance Reassessment Summary

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 180.362(a)			
Almonds Pecans Walnuts	0.5 0.5 0.5	Reassign at 0.5 ppm	*Tree nuts group*
Almonds, hulls	80	80	
Apples Apples, wet pomace	15 --	15 100	
Cherries, sour Cherries, sweet	6.0 6.0	Combine into one tolerance at 6 ppm	*Cherries*
Citrus fruits Citrus oil Citrus pulp, dried	20 140 100	20 140 100	
Cucumbers	4.0	4.0	
Eggplant	6.0	6.0	
Grapes Raisin	5.0 20	5.0 20	
Papayas	2.0	2.0	
Peaches	10	10	
Pears	15	15	
Plums	4.0	4.0	*Plums (fresh prunes)*
Prunes	4.0	Reassign	Covered under *"Plums (fresh prunes)"*
Prunes, dried	20	20	
Strawberries	10	10	
Tolerances listed under 180.362(b)			
Cattle, fat	0.5	0.5	
Cattle, mbyp	0.5	0.5	
Cattle, meat	0.5	0.5	
Eggs	0.1	0.1	
Goats, fat	0.5	0.5	
Goats, mbyp	0.5	0.5	

TABLE 5. *(Continued)*.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Goats, meat	0.5	0.5	
Hogs, fat	0.5	0.5	
Hogs, mbyp	0.5	0.5	
Hogs, meat	0.5	0.5	
Horses, fat	0.5	0.5	
Horses, mbyp	0.5	0.5	
Horses, meat	0.5	0.5	
Milk fat	0.1	0.1	*Milk, fat*
Poultry, fat	0.1	0.1	
Poultry, mbyp	0.1	0.1	
Poultry, meat	0.1	0.1	
Sheep, fat	0.5	0.5	
Sheep, mbyp	0.5	0.5	
Sheep, meat	0.5	0.5	
Tolerances listed under 180.362(c)			
Raspberries	10	10	

Summary of Pending Data

Toxicology

- OPPTS 870.3465: 28-day inhalation toxicity study. The protocol for the existing 90-day inhalation toxicity study should be followed with the exposure (treatment) ending after 28 days, instead of 90 days. The study should be conducted with a 50% formulated product instead of the technical grade of fenbutatin-oxide.

- OPPTS 870.2000: Neurotoxicity Screening Battery.