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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

August 1, 2002

CERTIFIED MAIL

Cindy Baker
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Dear Ms. Baker:

This is the Environmental Protection Agency's (hereafter referred to as EPA or the Agency) "Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for Fenarimol", which was approved on August 1, 2002. A Notice of Availability of this tolerance reassessment decision will be published in the *Federal Register* (FR).

The Federal Food, Drug and Cosmetic Act (FFDCA), as amended by FQPA, requires EPA to reassess all the tolerances for registered chemicals in effect on or before the date of the enactment of the FQPA, which was in August of 1996. 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. Once a safety finding has been made that aggregate risks are not of concern, the tolerances are considered reassessed. Fenarimol was registered prior to FQPA enactment. Therefore, the tolerances need to be reassessed to meet the FQPA standard.

The Agency has evaluated the dietary risk associated with fenarimol and has determined that there is a reasonable certainty, with appropriate mitigation, that no harm to any population subgroup will result from aggregate exposure to fenarimol when considering dietary exposure and all other non-occupational sources of pesticide exposure for which there is reliable information.

Residential postapplication exposure was of concern for children and infants from incidental ingestion of fenarimol product applied in residential settings. To mitigate this risk the registrant has agreed to remove the residential uses from their labels until they conduct a special developmental toxicity study that will assess for possible effects of fenarimol on the adult and juvenile rat hormonal systems. Once these data are submitted and reviewed, the Agency will make a determination regarding the acceptability of the residential uses.

For chronic drinking water risk from surface water, potential (average) Estimated Environmental Concentrations (EECs) of fenarimol (84 ppb) exceeds the chronic Drinking Water Level of Comparison (DWLOC) for all populations. The 84 ppb value includes all residential uses and the golf course use of fenarimol. However, with the residential uses removed from the label a correction factor of .31 can be applied to the 84 ppb surface water number to account for the use of fenarimol only on tees, greens, and fairways on golf courses. This would reduce the chronic EEC to 26 ppb. Infants and children, the most sensitive population subgroups would still exceed the chronic DWLOC of 20. However, the chronic EECs were estimated using Tier I modeling and only slightly exceed the DWLOC. Additional data are being required that will provide important information on the mobility of fenarimol and its degradates. These studies will help to refine the chronic surface and ground water drinking water risk assessments.

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 considering other substances is because of 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 fenarimol, because the Agency has not determined that there are any other chemical substances that have a mechanism of toxicity common with that of fenarimol. If EPA identifies other substances that share a common mechanism of toxicity with fenarimol, then a cumulative risk assessment will be conducted that includes fenarimol once the final framework EPA will use 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. Fenarimol will be reevaluated at that time and additional studies may be requested.

The Agency's human health findings for the pesticide fenarimol, are summarized in the enclosed *Fenarimol Overview* and *Fenarimol Summary* of the risk assessments. The risk assessments and other documents pertaining to the fenarimol tolerance reassessment decision are available on the Internet at http://www.epa.gov/pesticides/reregistration/status.htm and are in the public docket for viewing.

The Agency has reassessed all 42 tolerances for fenarimol and can make a FQPA safety determination. In addition, available residue chemistry data support the establishment of a 0.02 ppm permanent tolerance for fenarimol residues in filberts under 40 CFR 180.421 (a). The Agency has sufficient residue data for reassessing the tolerances for fenarimol. The chronic dietary exposure assessment for fenarimol is highly refined using anticipated residues based on 1996-1999 Food and Drug Administration (FDA) monitoring data for apples, bananas, cherries, grapes and pears. Field trial residue data were used for pecans and filberts. Percent crop treated (%CT) information and processing factors, where available, were used in the assessment. There were no PDP monitoring data available for fenarimol. Residues of fenarimol *per se* were nondetectable (below the method limit of detection, or LOD) in all 1996-1999 FDA monitoring samples of apples, bananas, grapes, and pears (a total of more than 3,000 samples). Out of 214 cherry samples, three had detectable residues. Residues of fenarimol *per se* were nondetectable (<LOD) in/on all but one pecan nut meat sample from seven trials. There were no detectable residues in filbert samples from four field trials. Chronic dietary risks from exposure do not exceed the Agency's level of concern.

Table 1 Tolerance Reassessment Summary For Fenarimol.

Commodity	Established Tolerance (ppm)	Reassessed Tolerance (ppm)	Comment *[Correct Commodity Definition]*
Tolerance Listed Under 40 CFR §180.421(a)(1)			
Apple pomace (wet and dry)	2.0	0.3	The available data indicate that the tolerance for wet apple pomace should be reduced. Dry apple pomace is no longer considered a significant livestock feed item. [*Apple, wet pomace*]
Apples	0.1	0.1	[*Apple*]
Cattle, fat	0.1	0.01	Residue data indicate that the tolerance should be reassessed at 0.01 ppm (method limit of quantitation [LOQ]).
Cattle, meat	0.01	0.01	Residue data indicate that the tolerance should be reassessed at 0.01 ppm (method limit of quantitation [LOQ]).
Cattle, mbyp	0.01	0.05	[*Cattle, meat byproducts, except kidney*] Residue data indicate that the tolerance should be reassessed at 0.05 ppm.
Cattle, kidney	0.1	0.01	Residue data indicate that the tolerance should be reassessed at 0.01 ppm (method limit of quantitation [LOQ]).
Cattle, liver	0.1	Revoke	[included in meat byproducts]
Eggs	0.01	Revoke	There are no poultry feed items associated with presently registered uses.
Goat, fat	0.1	0.01	Residue data indicate that the tolerance should be reassessed at 0.01 ppm (method limit of quantitation [LOQ]).
Goat, meat	0.01	0.01	Residue data indicate that the tolerance should be reassessed at 0.01 ppm (method limit of quantitation [LOQ]).
Goat, mbyp	0.01	0.05	[*Goat, meat byproducts, except kidney*] Residue data indicate that the tolerance should be reassessed at 0.05 ppm.
Goat, kidney	0.1	0.01	Residue data indicate that the tolerance should be reassessed at 0.01 ppm (method limit of quantitation [LOQ]).
Goat, liver	0.1	Revoke	[included in meat byproducts]

Commodity	Established Tolerance (ppm)	Reassessed Tolerance (ppm)	Comment *[Correct Commodity Definition]*
Hog, fat	0.1	Revoke	There are no hog feed items associated with presently registered uses.
Hog, meat	0.01	Revoke	
Hog, mbyp	0.01	Revoke	
Hog, kidney	0.1	Revoke	
Hog, liver	0.1	Revoke	
Horse, fat	0.1	0.01	Residue data indicate that the tolerance should be reassessed at 0.01 ppm (method limit of quantitation [LOQ]).
Horse, meat	0.01	0.01	Residue data indicate that the tolerance should be reassessed at 0.01 ppm (method limit of quantitation [LOQ]).
Horse, mbyp	0.01	0.05	[*Horse, meat byproducts, except kidney*] Residue data indicate that the tolerance should be reassessed at 0.05 ppm.
Horse, liver	0.1	Revoke	[included in meat byproducts]
Horse, kidney	0.1	0.01	Residue data indicate that the tolerance should be reassessed at 0.01 ppm (method limit of quantitation [LOQ]).
Milk	0.003	Revoke	Category 3 of 40 CFR §180.6(a)
Pears	0.1	0.1	[*Pear*]
Pecans	0.1	0.02	[*Pecan*] Residue data have been submitted to reassess the established tolerance for pecans.
Poultry, fat	0.01	Revoke	There are no poultry feed items associated with presently registered uses.
Poultry, meat	0.01	Revoke	
Poultry, mbyp	0.01	Revoke	
Sheep, fat	0.1	0.01	Residue data indicate that the tolerance should be reassessed at 0.01 ppm (method limit of quantitation [LOQ]).
Sheep, meat	0.01	0.01	Residue data indicate that the tolerance should be reassessed at 0.01 ppm (method limit of quantitation [LOQ]).
Sheep, mbyp	0.01	0.05	[S*heep, meat byproducts, except kidney*] Residue data indicate that the tolerance should be reassessed at 0.05 ppm.

Commodity	Established Tolerance (ppm)	Reassessed Tolerance (ppm)	Comment *[Correct Commodity Definition]*
Sheep, kidney	0.1	0.01	Residue data indicate that the tolerance should be reassessed at 0.01 ppm (method limit of quantitation [LOQ]).
Sheep, liver	0.1	Revoke	[included in meat byproducts]
Tolerance Listed Under 40 CFR §180.421(a)(2)			
Bananas [1]	0.5 (Not more than 0.25 ppm shall be present in the pulp after peel is removed)	0.25	[*Banana*] Residue data have been submitted to reassess the established tolerance for bananas.
Cherries	1.0	1.0	[*Cherry*]
Grape juice	0.6	Revoke	Not required based on reexamination of available grape processing data.
Grape pomace (wet and dry)	2.0	Revoke	No longer considered a significant livestock feed item.
Grapes	0.2	0.1	[*Grape*] Residue data have been submitted to reassess the established tolerance for grapes.
Raisin waste	3.0	Revoke	No longer considered a significant livestock feed item.
Raisins	0.6	Revoke	Not required based on reexamination of available grape processing data.
Tolerance to be Established Under 40 CFR §180.421(a)(1)			
Filberts	not applicable	0.02	Residue chemistry data support the establishment of a 0.02 ppm tolerance for filberts.

[1] For tolerance reassessment purposes, the banana tolerance is counted as two tolerances to reflect the baseline count determined at the start of FQPA (bananas and bananas, pulp).

Codex/International Harmonization

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for residues of fenarimol in/on various raw agricultural and processed commodities. The Codex MRLs are expressed in terms of fenarimol *per se*. A numerical comparison of the Codex MRLs and the corresponding reassessed U.S. tolerances is presented in the Table below. The Table shows that except for cattle liver, cherries, and pecans, the U.S. tolerances and Codex MRLs are not in harmony with respect to numerical levels.

Table 2 Codex MRLs and applicable U.S. tolerances for fenarimol. Recommendations are based on conclusions following reassessment of U.S. tolerances.

Codex		Reassessed U.S. Tolerance, ppm	Recommendation And Comments
Commodity, As Defined	MRL [1] (mg/kg)		
Apple pomace, dry	5	wet apple pomace = 0.3	Dry apple pomace is no longer considered a significant livestock feed item.
Artichoke globe	0.1	--	
Banana	0.2	0.25	
Cattle kidney	0.02 (*)	0.01 (*)	
Cattle liver	0.05	Revoke	covered by tolerance for meat byproducts
Cattle meat	0.02 (*)	0.01 (*)	
Cherries	1	1	
Dried grapes (currants, raisins and sultanas)	0.2	Revoke	
Grapes	0.3	0.1	
Hops, dry	5	--	
Melons, except watermelon	0.05	--	
Peach	0.5	--	
Pecan	0.02 (*)	0.02 (*)	
Peppers, sweet	0.5	--	
Pome fruits	0.3	apple/pear = 0.1	
Strawberry	1	--	

[1] All MRLs are at CXL step. An asterisk (*) signifies that the MRL or US tolerance was established at or about the limit of detection.

Note that you will be sent a Section 3(c)(2)(B) Data-Call-In (DCI) letter under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) in a separate mailing. If you have questions on this document, please contact the Chemical Review Manager, Tom Myers, at (703) 308-8589.

Sincerely,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures: "*Fenarimol Overview*" and "*Fenarimol Summary*"