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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

August 1, 2002

CERTIFIED MAIL

Tom Stommel
Dupont
Stine-Haskell Research Center
PO Box 30
Newark, DE 19714

Dear Mr. Stommel:

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 Hexazinone," which was approved on August 1, 2002. A Notice of Availability of this tolerance reassessment decision will be published in the *Federal Register* (FR) shortly.

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 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. A Reregistration Eligibility Decision (RED) for hexazinone was completed in September, 1994, 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 hexazinone and has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to hexazinone when considering dietary, drinking water, and residential exposure and all other non-occupational sources of pesticide exposure for which there is reliable information. There are no registered residential uses for hexazinone.

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 hexazinone,

because the Agency has not determined that there are any other chemical substances that have a mechanism of toxicity common with that of hexazinone. If EPA identifies other substances that share a common mechanism of toxicity with hexazinone, then a cumulative risk assessment will be conducted that includes hexazinone 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. Hexazinone will be reevaluated at that time and additional studies may be required.

The Agency's human health findings for the pesticide hexazinone, were discussed in a closure conference call, and are summarized in the enclosed *Hexazinone Overview* and *Hexazinone Summary* of the risk assessments. The risk assessments and other documents pertaining to the hexazinone 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 25 tolerances for hexazinone and can make a FQPA safety determination. Anticipated residues for commodities included in the dietary risk assessment are equal to the tolerance levels and it was assumed that 100% of each crop was treated. Acute and chronic dietary risks from exposure to hexazinone does not exceed the Agency's level of concern. Tolerances for residues of hexazinone in/on plant, livestock, and processed commodities are currently expressed in terms of the combined residues of hexazinone and its metabolites (calculated as hexazinone).

Because existing data were inadequate to calculate residue estimates for pasture and rangeland grass and grass hay, EPA constructed the maximum theoretical dietary burden (MTDB) of hexazinone to livestock using protective assumptions for the contributions of other hexazinone-treated feed items. Thus, tolerances for meats and milk can be reassessed. Additional field trial data for grass forage and grass hay, as well as rotational crop studies for corn and wheat are required. Because of the relatively low volume of use on pasture and rangeland, data from these confirmatory studies are not expected to significantly change current dietary risk estimates. Final tolerances are being proposed as part of this Tolerance Reassessment Decision (TRED). Some revisions to these tolerance values may be needed once the field trial data and rotational crop studies have been submitted to and reviewed by the Agency.

Tolerance Reassessment Summary for Hexazinone.

Commodity	Current Tolerance (ppm) [a]	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances presently listed under 40 CFR §180.396(a):			
Alfalfa green forage	2.0	2.0	*Alfalfa, forage*
Alfalfa hay	8.0	4.0	Tolerance should be reduced based on re-calculation of expected residues. *Alfalfa, hay*
Blueberries	0.2	0.6	Tolerance should be increased based on the combined LOQ (0.55 ppm) of the enforcement method. *Blueberry*

Commodity	Current Tolerance (ppm) [a]	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Cattle, fat	0.1	Revoke [b]	
Cattle, mbyp	0.1	0.1	
Cattle, meat	0.1	0.1	
Goat, fat	0.1	Revoke [b]	
Goat, mbyp	0.1	0.1	
Goats, meat	0.1	0.1	
Grasses, pasture	10	TBD [c]	*Grass, forage*
Grasses, rangeland	10	TBD [c]	Grass, *hay*
Hog, fat	0.1	Revoke [b]	
Hog, mbyp	0.1	Revoke [b]	
Hog, meat	0.1	Revoke [b]	
Horses, fat	0.1	Revoke [b]	
Horses, mbyp	0.1	0.1	
Horses, meat	0.1	0.1	
Milk	0.5	0.2	Tolerance should be reduced based on re-calculation of expected residues.
Pineapple	0.5	0.6	Tolerance should be increased based on the combined LOQ (0.55 ppm) of the enforcement method.
Sheep, fat	0.1	Revoke [b]	
Sheep, mbyp	0.1	0.1	
Sheep, meat	0.1	0.1	
Tolerances needed under 40 CFR §180.396(a):			
Alfalfa, seed		2.0	
Tolerances presently listed under 40 CFR §180.396(c):			
Sugarcane	0.2	0.6	Tolerance should be increased based on the combined LOQ (0.55 ppm) of the enforcement method.
Sugarcane molasses	5.0	4.0	Tolerance should be reduced based on re-calculation of expected residues.

Commodity	Current Tolerance (ppm) [a]	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Sugarcane molasses [d]	5.0	4.0	Tolerance should be reduced based on re-calculation of expected residues.

[a] Expressed in terms of the combined residues of hexazinone and its metabolites (calculated as hexazinone).

[b] Tolerances for fat are not required (Category 3, 40 CFR §180.6).

[c] TBD: These tolerances require additional field trial data and may be revised once the data have been submitted to and reviewed by the Agency.

[d] For reassessment counting purposes, the Agency will count the sugarcane molasses tolerances as two reassessments to reflect the tolerances which existed both in 40 CFR Part 185 (185.3575) and Part 186 (186.3575) at the start of FQPA.

No maximum residue limits (MRLs) for hexazinone and its metabolites have been established or proposed by Codex for any agricultural commodity. Therefore, no compatibility questions exist with respect to U.S. tolerances.

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 or any of the attached documents, please contact the Chemical Review Manager, Dirk V. Helder, at (703) 305-4610.

Sincerely,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures: "*Hexazinone Overview*" and "*Hexazinone Summary*"