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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

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 Primisulfuron-methyl," which was approved on July 23, 2002. Although a closure conference call was not held for this action, all stakeholders were notified by phone on or before July 22, 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 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. EPA recently reviewed a petition for a new use of primisulfuron-methyl on Kentucky bluegrass grown for seed and a proposal for establishment of tolerances for Kentucky bluegrass hay and forage. To evaluate the tolerance petition and determine if new tolerances should be established, EPA considered all of the criteria described above to ensure that the FQPA standard was met. In so doing, the Agency has also done the work necessary to reassess the existing tolerances for primisulfuron-methyl. EPA's findings are described in this document.

The Agency has evaluated the dietary risk associated with all current and proposed uses of primisulfuron-methyl and has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to primisulfuron-methyl 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 twenty-four (24) tolerances established for residues of primisulfuron-methyl in/on raw agricultural commodities 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 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.

The Agency has not yet determined whether primisulfuron-methyl and the other sulfonyl urea herbicides exhibit a common mechanism of toxicity. Therefore, the Agency defers any cumulative risk assessment to a later date. For the purposes of tolerance reassessment for primisulfuron-methyl, EPA is assuming no common mechanism. Therefore, a cumulative assessment is not necessary to determine whether tolerances established for residues of primisulfuron-methyl in/on raw agricultural commodities will be considered reassessed as safe under section 408(q) of the FFDCA.

Based on currently available data, primisulfuron-methyl does not appear to be an endocrine disruptor. However, when the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program have been developed, primisulfuron-methyl may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

The Agency's human health findings for the pesticide primisulfuron-methyl are summarized in the enclosed chemical overview and summary of the risk assessments. The risk assessments and other documents pertaining to the primisulfuron-methyl 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 for residues of primisulfuron-methyl in or on raw agricultural commodities are for the parent compound, primisulfuron-methyl per se. No metabolites or degradates are included in the tolerance expression. Existing tolerances for primisulfuron-methyl have been reassessed. In summary, 1 tolerance is to be revoked and 23 tolerances remain unchanged. No maximum residue limits (MRLs) for primisulfuron-methyl have been established or proposed by Codex; and US tolerances are identical to those established by Canada. Therefore, there are not international compatibility issues with respect to U.S. tolerances.

The Agency has considered a petition for a new use on Kentucky Bluegrass grown for seed in the TRED, but the decision to establish new tolerances will be made at a later date as a separate action. The residue chemistry data for Kentucky Bluegrass has been reviewed and included in the dietary risk assessment for all current and proposed uses. However, the occupational risk assessment conducted on Kentucky bluegrass has not been included in the TRED because it is beyond the scope of the TRED.

A summary of the reassessed tolerances for residues of Primisulfuron-methyl are found

in Table 1. All existing tolerances have been reassessed at their current levels. However, the tolerance for *Corn, fresh* (including *sweet kernels plus cobs with husks removed*) is recommended for revocation because current labels for primisulfuron-methyl prohibit use on sweet corn.

Table 1. Tolerance Reassessment Summary for Primisulfuron-methyl

Commodity	Established Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments *[Correct Commodity Definition]*
Cattle, fat	0.1	0.1	None
Cattle, meat	0.1	0.1	None
Cattle, mbyp	0.1	0.1	None
Corn, fodder	0.1	0.1	None
Corn, forage	0.1	0.1	None
Corn, fresh (including sweet kernels plus cobs with husks removed)	0.1	N/A	Revoke. Use on sweet corn is prohibited.
Corn, grain	0.02	0.02	None
Eggs	0.1	0.1	None
Goats, fat	0.1	0.1	None
Goats, meat	0.1	0.1	None
Goats, mbyp	0.1	0.1	None
Hogs, fat	0.1	0.1	None
Hogs, meat	0.1	0.1	None
Hogs, mbyp	0.1	0.1	None
Horses, fat	0.1	0.1	None
Horses, meat	0.1	0.1	None
Horses, mbyp	0.1	0.1	None
Milk	0.02	0.02	None
Poultry, fat	0.1	0.1	None
Poultry, meat	0.1	0.1	None
Poultry, mbyp	0.1	0.1	None
Sheep, fat	0.1	0.1	None
Sheep, meat	0.1	0.1	None

Commodity	Established Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments *[Correct Commodity Definition]*
Sheep, mbyp	0.1	0.1	None

The food and feed uses subject to this TRED are listed in Table 2. The Agency has not identified any label amendments which should be implemented as a result of this TRED.

Table 2. Food/Feed Use Patterns Subject to Tolerance Reassessment for Primisulfuron-methyl

Application Type, Application Timing, and Application Equipment	Formulation [EPA Reg. No.]	Application Rate (lb ai/A)	Max. Number of Applications per Season	Max. Seasonal Application Rate (lb ai/A)	PHI (days)	Use Directions and Limitations
Corn, field and pop-						
Broadcast, unincorporated Post-emergence Ground or aerial	7.5-75% WDG [100-705, 100-774, 100-911, &100-923]	0.036 0.018	1 2	0.036 0.036	30 (forage); 45 (silage); 60 (grain)	Do not treat sweet corn. Do not soil incorporate. Do not apply by chemigation. Apply postemergence prior to tassel emergence.

This summarizes the Agency's decision on the tolerance reassessment for primisulfuron-methyl. Please contact Christina Scheltema of my staff with any questions regarding this decision. She may be reached by phone at (703)308-2201 or by e-mail at scheltema.christina@epa.gov.

Sincerely,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures: "Primisulfuron-methyl Overview" and "Primisulfuron-methyl Summary"

Technical Support Documents
for the Primisulfuron-methyl TRED

1. William J. Hazel, Byong-Han Chin, and Susan Hanley. (USEPA/OPPTS/OPP/HED). Primisulfuron-methyl. Proposed Use and Tolerances in/on Ketnucky Bluegrass Grown for Seed. Human Health Risk Assessment and Tolerance Reassessment. June 28, 2002.

2. William J. Hazel. Primisulfuron-methyl. (USEPA/OPPTS/OPP/HED). Chronic Dietary Exposure Assessment to Permit Tolerance Reasessment, Amended Section 3 Registration of the 75% WDG (EPA Reg. No. 100-705), and Establishment of Tolerances Proposed by Syngenta Crop Protection. June 20, 2002.

3. William J. Hazel. (USEPA/OPPTS/OPP/HED). [Review of] Primisulfuron-Methyl: Magnitude of the Residues in or on Bluegrass Grown-for-Seed, Following Application of Beacon. June 20, 2002.

4. William J. Hazel. (USEPA/OPPTS/OPP/HED). Primisulfuron-methyl. PP#6F4752. Ciba Crop Protection Petition for Tolerances and Proposals for Registration of the 75% WDG (EPA Reg. No. 100-705) for Use on Kentucky Bluegrass Grrown for Seed. Residue Chemistry Summary Document. June 20, 2002.

5. Paul Chin. (USEPA/OPPTS/OPP/HED). Primisulfuron-methyl. Toxicology Chapter for RED. June 11, 2002.

6. Brenda Tarplee. (USEPA/OPPTS/OPP/HED). PRIMISULFURON-METHYL- Report of the FQPA Safety Factor Committee. May 22, 2002.

7. William J. Hazel. (USEPA/OPPTS/OPP/HED). Primisulfuron-methyl (128973): Results of the HED Metabolism Assessment Review Committee (MARC) Electronic Review. May 15, 2002.

8. Paul Chin. (USEPA/OPPTS/OPP/HED). Primisulfuron-methyl - Report of the Hazard Identification Review Committee. April 26, 2002.

9. Ibrahim Abdel-Saheb. (USEPA/OPPTS/OPP/EFED). Drinking Water Assessment for Primisulfuron-methyl to support use on Kentucky Bluegrass grown for seed. April 8, 2002.

10. Ibrahim Abdel-Saheb. (USEPA/OPPTS/OPP/EFED). Correction to Drinking Water

Assessment for Primisulfuron-methyl to support use on Kentucky Bluegrass grown for seed. April 29, 2002.