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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

July 5, 2002

CERTIFIED MAIL

Dear Registrant:

This is to inform you that on July 5, 2002, the Environmental Protection Agency (hereafter referred to as EPA or the Agency) completed its "Report of FQPA Tolerance Reassessment Progress and Interim Risk Management Decision (TRED) for ***Tebuthiuron***". A Notice of Availability, soliciting public comment for a 30 day period, will be published in the *Federal Register* (FR) Notice shortly.

FFDCA, as amended, requires EPA to reassess all the tolerances for registered chemicals in effect on or before the date of the enactment of the Food Quality Protection Act (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 Tebuthiuron, was completed in April 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 risk associated with Tebuthiuron and has determined that there is a reasonable certainty that no harm to any population subgroup will result from exposure to Tebuthiuron 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 Tebuthiuron 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 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 reregistration review of Tebuthiuron, because the Agency has not determined if there

are any other chemical substances that have a mechanism of toxicity common with that of Tebuthiuron. If EPA identifies other substances that share a common mechanism of toxicity with Tebuthiuron, then a cumulative risk assessment will be conducted that includes Tebuthiuron once the final framework EPA will use for conducting cumulative risk assessments is available.

The Agency's human health findings for the pesticide Tebuthiuron, were discussed in a closure conference call, and are summarized in the attached chemical overview of the risk assessments. These risk assessments and other documents pertaining to the Tebuthiuron 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 the public docket for viewing.

Tolerances for residues of tebuthiuron are related to the consumption of secondary residues in meat and milk from livestock fed tebuthiuron-treated grass forage and hay. The registered uses of tebuthiuron are classified in 40 CFR§180.390.

The 40 CFR tolerance expression under 40 CFR§180.390 must be modified as follows:

CFR§180.390 Tebuthiuron; tolerances for residues

(a) Tolerances are established for the combined residues of the herbicide tebuthiuron (*N*-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl-*N*,*N'*-dimethylurea) and its metabolites *N*-[5-(2-hydroxy-1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-*N*,*N'*-dimethylurea, –[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-*N*-methylurea, and *N*-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-*N'*-hydroxymethyl-*N*-methylurea in or on the following agricultural commodities:

Grass, hay
Grass, forage

(b) Tolerances are established for the combined residues of the herbicide tebuthiuron (*N*-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl-*N*,*N'*-dimethylurea) and its metabolites *N*-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-*N*-methylurea, –[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]urea, 2-dimethylethyl-5-amino-1,3,4-thiadiazole, and *N*-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-*N'*-hydroxymethyl-*N*-methylurea in or on the following raw agricultural commodities:

Cattle, fat
Cattle, mbyp
Cattle, meat
Goats, fat
Goats, mbyp
Goats, fat
Horses, fat

Horses, mbyp
Horses, meat
Sheep, fat
Sheep, mbyp
Sheep, meat

(c) A tolerance is established for the combined residues of the herbicide tebuthiuron (*N*-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl-*N*,*N'*-dimethylurea) and its metabolites *N*-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-*N*-methylurea, *N*-[5-(2-hydroxy-1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-*N*-methylurea, *N*-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]urea, *N*-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-*N'*-hydroxymethyl-*N*-dimethylurea, and *N*-[5-(2-hydroxy-1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-*N'*-hydroxymethyl-*N*-methylurea in or on the following raw agricultural commodity:

Milk

The Codex Commission has established that there are no maximum residue limits (MRLs) for residues of tebuthiuron in/on various raw agricultural and processed commodities. Therefore, issues of compatibility with respect to U.S. tolerances and Codex MRLs do not exist.

Tebuthiuron Tolerances

Commodity	Current Tolerance (ppm)	Reassessed Tolerance (ppm)	Tolerance Reassessment
Cattle, Fat	2	1	Lowered
Cattle, MBYP	2	5	Raised
Cattle, Meat	2	1	Lowered
Goats, Fat	2	1	Lowered
Goats, MBYP	2	5	Raised
Goats, Meat	2	1	Lowered
Grasses, Forage	20	10	Lowered
Grasses, Hay	20	10	Lowered
Horses, Fat	2	1	Lowered
Horses, MBYP	2	5	Raised
Horses, Meat	2	1	Lowered
Milk	0.3	0.8	Raised
Sheep, Fat	2	1	Lowered

Sheep, MBYP	2	5	Raised
Sheep, Meat	2	1	Lowered

A generic Data Call-In (DCI) that outlines further data requirements for this chemical will be prepared and mailed to you in the near future.

If you have questions on this document, please contact the Chemical Review Manager, Wilhelmena Livingston, at (703) 308-8025.

Lois A. Rossi, Director
Special Review and
Reregistration

Attachments:

TRED for Tebuthiuron
Addendum to TRED Drinking Water Assessment for Tebuthiuron
Product Chemistry Chapter for the TRED
Residue Chemistry Chapter for the TRED
Acute and Chronic Dietary Exposure Assessment for the TRED
Toxicology Chapter for the TRED
Third Report of the HIARC Committee
Report of the FQPA Safety Factor Committee
The Outcome of the HED MARC Meeting