United States Environmental Protection Agency | Prevention, Pesticides and Toxic Substances (7508C) | January 25, 2005

Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for Desmedipham

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This letter and the attached risk assessment constitute 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 for Desmedipham," which was approved on July 31, 2004. This document is also known as a Tolerance Reassessment Decision, or TRED. A Notice of Availability of this tolerance reassessment decision will be published shortly in the Federal Register.

Regulatory Determination

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 enactment of the FQPA on August 3, 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, the tolerances are considered reassessed. Existing tolerances and exemptions associated with the pesticide active ingredient desmedipham must be reassessed in accordance with FFDCA, as amended by FQPA.

The Agency has evaluated the aggregate risks associated with all current registered uses of the desmedipham and has determined, based on adequate data, that there is a reasonable certainty that no harm to any population subgroup will result from exposure to desmedipham 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 desmedipham in/on the raw agricultural commodities sugar beet (roots and tops) and red beet (roots and tops) are now considered reassessed under section 408(q) of the FFDCA.

The Agency has conducted a screening-level assessment for dietary exposures which create estimates that are deliberately intended to over-estimate exposure potential. Using these conservative assessments, and considering the uncertainly associated with combining such screening-level assessments, the Agency has concluded that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to residues of

desmedipham. The attached risk assessment presents the Agency's conclusions regarding the potential for adverse effects resulting from aggregate exposures to desmedipham, and forms the basis for this determination.

Cumulative Risk

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish,modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA does not have at this time available data to determine whether desmedipham has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding to desmedipham and any other substances, and desmedipham does not appear to produce a toxic metabolite that is also produced by other substances. Therefore, for the purposes of this tolerance action, the Agency has not assumed that desmedipham has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity, and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/fedrgstr/EPA-PEST/2002/January/Day-16/*.

Tolerance Summary

Desmedipham (ethyl m-hydroxy-carbanilate carbanilate) is a member of the phenylcarbamate family of herbicides. Desmedipham is currently registered by Bayer CropScience (formerly Aventis Cropsciences) for use as a selective post-emergence herbicide on sugar beets. Desmedipham is formulated only as an active ingredient in emulsifiable concentrates ~~and wettable powders~~. Bayer recently submitted use deletion requests for the two existing wettable powder formulations (Betanex 70WP and Betamix WP) in March, 2004. The use deletions became effective after August 7, 2004. Permanent tolerances are established for desmedipham residues in/on sugar beet roots and tops under 40 CFR § 180.353(a). Time-limited tolerances have been established in conjunction with a Section 18 Emergency exemption. The expiration date of 6/30/05 had been established for desmedipham residues in red beet roots and tops under 40 CFR § 180.353(b). No tolerances exist for residues of desmedipham in animal commodities, and no food/feed additive tolerances have been established. The reassessed tolerances for this chemical are presented in Tolerance Reassessment Table for Desmedipham below.

Tolerance Reassessment Table for Desmedipham		
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)
Tolerances listed under 40 CFR §180.353(a):		
Sugar beets (roots)	0.2	0.10[a]
Sugar beets (tops)	0.2	15[a]
Tolerances established under 40 CFR §180.353(b):		
Red beet roots	0.2	0.20[b]
Red beet tops	15	15[b]

[a] Additional residue data are required for roots and tops before these tolerences are characterized.
[b]New residue data is being submitted by the registrant which potentially may change these existing tolerances.

The current tolerances for desmedipham under 40 CFR §180.353(a) and 40 CFR §180.353(b) are considered reassessed under section 408(q) of the FFDCA. It should be noted however that confirmatory data is need to support the current tolerence for sugar beets (roots and tops) under 40 CFR §180.353(a).

This document summarizes the Agency's decision on the tolerance reassessment for desmedipham. You will receive a separate Data Call-In (DCI) letter in a separate mailing. Please contact Nathan Mottl with any questions regarding this decision. He may be reached by phone at (703)305-0208 or by e-mail at mottl.nathan@epa.gov.

Sincerely,

Debra Edwards, Ph.D.
Director
Special Review and Reregistration Division

Enclosures: *FQPA Risk Assessment for Tolerance Reassessment of Desmedipham* (6/29/2004, OPP Lower Toxicity Pesticide Chemical Focus Group).

Desmedipham Acute and Chronic Dietary Exposure Assessments for the Tolerance Reassessment Eligibility Decision (Memorandum from Sherrie L. Kinard to Elissa Reaves, 6/1/2004).

Desmedipham. Report of the Metabolism Assessment Review Committtee. (Memorandum from Sherrie L. Kinard to Yan Donovan, 6/22/2004).

Tier 1 Drinking Water Assessment for Desmedipham (Memorandum from William P.Eckel, Ph.D to Demson Fuller, 4/20/2004).