



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



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 for Flumetsulam," which was approved on September 16, 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.

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 flumetsulam must be reassessed in accordance with FFDCA, as amended by FQPA.

The Agency has evaluated all current registered uses of flumetsulam and has determined that there is a reasonable certainty that no harm to any population subgroup will result from exposure to flumetsulam 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 current tolerances at 40 CFR 180.468 for flumetsulam used on field corn (forage, stover, and grain) and soybean are now considered reassessed under section 408(q) of the FFDCA. The tolerances for the four commodities has been determined to remain at 0.05 ppm.

Flumetsulam is a herbicide registered for use on soybeans and field corn and belongs to the triazolopyrimidine chemical class. Flumetsulam can be applied pre-plant, pre-emergence, or post-emergence to control broadleaf weeds and may be applied alone or in formulation with other active ingredients. The maximum application rate for flumetsulam is 0.07 lb a.i./acre with a minimum pre-harvest interval range of 70 to 85 days. The highest usage of flumetsulam is on corn and approximately 12,000 pounds are used annually. An additional new use petition for dry beans has been submitted to the Agency. This use has been included in the risk assessment and is awaiting further action by the Registration Division.

Flumetsulam is in Toxicity Category III or IV for acute oral, dermal, and inhalation exposure and for dermal and ocular irritation, and is not a dermal sensitizer. There was no indication of reproductive, neurotoxicant, or carcinogenic effects from flumetsulam in the reviewed studies.

There are no studies that identify an acute hazard based on toxic effects observed following a single oral dose. No effects in the developmental toxicity studies in the rabbit or rat were attributed from a single oral exposure during gestation. Therefore, a dose and endpoint are not proposed for the general population including infants and children or females 13-49 years of age.

The chronic feeding study conducted with dogs supports the toxicity endpoint for chronic dietary exposure. The No Observed Adverse Effect Level (NOAEL) is 100/500 mg/kg/day and the Lowest Observed Adverse Effect Level (LOAEL) is 500/not identified mg/kg/day. An uncertainty factor of 100 (10X for interspecies extrapolation and 10X for intraspecies variability) was applied to the chronic toxicity endpoint. The chronic reference dose for flumetsulam is 1.0 mg/kg/day. Dietary risk assessments incorporate both exposure and toxicity of a given pesticide. For chronic assessments, the risk is expressed as a percentage of a maximum acceptable dose. This dose is referred to as the population-adjusted dose (PAD). The PAD is equivalent to the reference dose divided by the special Food Quality Protection Act (FQPA) Safety Factor. The toxicology database for flumetsulam is adequate for FQPA considerations. Based on the hazard data, the Agency recommended that the special FQPA Safety Factor be reduced to 1X because there are low concerns, and no residential uncertainties with regard to pre and/or post-natal toxicity.

A conservative dietary (food and water) risk assessment concluded that for all supported commodities (including proposed use on dry bean), the chronic dietary exposure estimates are below the Agency's level of concern for all population subgroups at less than 1% of the chronic PAD. The Agency is, therefore, not concerned with any risk resulting from exposure to flumetsulam.

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 Agency considers other substances because 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.

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 as to flumetsulam and any other substances and flumetsulam does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that flumetsulam 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 Office of Pesticide Programs 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/pesticides/cumulative/>.

Based on currently available data, flumetsulam 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, flumetsulam may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

This document summarizes the Agency's decision on the tolerance reassessment for flumetsulam. Please contact Mika J. Hunter of my staff with any questions regarding this decision. She may be reached by phone at (703)308-0041 or by e-mail at hunter.mika@epa.gov.

Sincerely,

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

cc: Lois Rossi, Registration Division

Enclosures: *Flumetsulam: HED Risk Assessment for the Tolerance Reassessment Eligibility Document (TRED)*, dated August 31, 2004, *Flumetsulam. Chronic Dietary Exposure Assessment for the Tolerance Reassessment Eligibility Document*, dated August 31, 2004, *Flumetsulam. Summary of Analytical Chemistry and Residue Data for the Tolerance Reassessment Eligibility Decision*, dated August 31, 2004, *Drinking Water Assessment for Flumetsulam for Uses on Field Corn and Soybeans*, dated May 19, 2004.

