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

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 Chlorimuron Ethyl," which was approved on September 22, 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.

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 associated with chlorimuron ethyl must be reassessed in accordance with FFDCA, as amended by FQPA.

The Agency has evaluated all current registered uses of chlorimuron ethyl 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 chlorimuron ethyl when considering dietary (including both food and drinking water) exposure. In the case of chlorimuron ethyl there are no other non-occupational sources of pesticide exposure. No acute dietary endpoint was identified for chlorimuron ethyl, and the chronic dietary risk estimates for the general U.S. and all population subgroups are less than 1% of the cPAD. Therefore, no mitigation measures are needed, and the current tolerances established at 40 CFR 180.429 for residues of chlorimuron ethyl in/on raw agricultural commodities are now considered reassessed under section 408(q) of the FFDCA.

Aggregate Risk Assessment

Chlorimuron ethyl is a sulfonylurea class herbicide that inhibits acetolactate synthase, which regulates plant growth. It is registered for use on soybeans and peanuts. Chlorimuron ethyl may be applied to soybean crops at preplant, preemergence, postemergence, or postharvest stages by band treatment, broadcast, ground spray, low volume spray, or soil incorporated treatment at the current maximum application rate of 0.08025 lbs active ingredient per acre (per crop cycle). Chlorimuron ethyl may be applied to peanut crops at the foliar stage by band treatment, broadcast, or low volume spray at the current maximum application rate of 0.0078125 lbs active ingredient per acre (per crop cycle). The preharvest intervals are 60 days for soybeans and 45 days for peanuts. Chlorimuron ethyl may also be applied to non-crop land at the foliar stage by broadcast at the current maximum application rate of .03125 lbs active ingredient per acre. There are no residential uses for chlorimuron ethyl. Fifteen end-use products in water dispersible granular formulations have been identified, and one pending registration exists for a granular formulation. The percentage of active ingredient in these products ranges from 8.3 to 31.8%. Additionally, there is a technical and an intermediate product with 97.8% and 54% active ingredient, respectively.

The uncertainty factors applied in the chlorimuron ethyl risk assessment consist of a standard uncertainty factor of 100X and an FQPA Safety Factor of 1x. The uncertainty factor of 100X includes both a 10X uncertainty factor for intraspecies variability (i.e. differences among humans) and a 10X uncertainty factor for interspecies variability (i.e. differences between humans and animals). The FQPA Safety Factor is a method of accounting for any increased susceptibility of infants and children to toxic effects. The Agency concluded that, because there are low concerns, no residual uncertainties with regard to pre- and/or postnatal toxicity, and high confidence that exposure estimates have not been underestimated, the factor could be reduced to 1x from the standard 10x.

Chlorimuron ethyl is classified as Toxicity Category III for acute dermal and Toxicity Category IV for acute oral toxicity and inhalation. It is a mild eye and skin irritant and does not cause skin sensitization. There is no evidence of potential neurotoxicity, mutagenicity, or carcinogenicity for chlorimuron ethyl provided in the available studies.

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and

resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

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

There are no studies identifying an acute dietary endpoint based on toxic effects observed following a single dose, therefore no acute dietary risk assessment was performed. For chronic dietary exposure, a no observed adverse effect level (NOAEL) of 9 mg/kg/day was identified from a chronic dog study in which mild anemia was observed at the lowest observed adverse effect level (LOAEL) of 51 mg/kg/day. Because chlorimuron ethyl has no residential uses, only dietary exposure was assessed. For chlorimuron ethyl, the aggregate chronic dietary risk estimates (including food and drinking water) for the general U.S. and all population subgroups are less than 1% of the cPAD and are below the Agency's level of concern.

Chronic aggregate dietary exposure to chlorimuron ethyl was calculated using a Tier 1 approach which assumes that 100% of each crop is treated with chlorimuron ethyl, that pesticide residues exist on food at the legal tolerance levels, and that levels in drinking water are at upper-bound estimates. The Dietary Exposure Evaluation Model software was employed for the risk assessment with the Food Commodity Intake Database (DEEM-FCID^{tm}, Version 1.3) which incorporates food consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. Chronic aggregate risk was assessed by comparing chronic dietary exposure estimates to the chronic Population Adjusted Dose (cPAD), with risk expressed as a percent of the cPAD. Exposure estimates that are less than 100% of the cPAD indicate a determination of safety can be concluded. The degradates of chlorimuron ethyl are not expected to be more toxic nor exceed levels of the parent compound.

Cumulative Risk Assessment

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 chlorimuron ethyl and any other substances, and chlorimuron-ethyl 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 chlorimuron-ethyl 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/*.

Tolerance Summary

All of the existing tolerances for chlorimuron ethyl established at 40 CFR 180.429 are adequately supported and are considered reassessed. These tolerances are listed in Table 1.

Table 1. Current & Reassessed Tolerances for Chlorimuron Ethyl

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)
Peanut	0.02	0.02
Soybeans	0.05	0.05

This document summarizes the Agency's decision on the tolerance reassessment for chlorimuron ethyl. Please contact Diane Sherman of my staff with any questions regarding this decision. She may be reached by phone at (703) 308-0128 or by e-mail at *sherman.diane@epa.gov*.

Sincerely,

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

Enclosures: *Chlorimuron-Ethyl Human Health Risk Assessment*

Preliminary Tier 1 Drinking Water Assessment for Chlorimuron-ethyl Use on Soybeans, Peanuts, and Non-crop Land