United States Environmental Protection Agency | Prevention, Pesticides and Toxic Substances (7508C) | December 2004

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

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 Nicosulfuron," which was approved December 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 nicosulfuron must be reassessed in accordance with FFDCA, as amended by FQPA.

The Agency has evaluated all current registered uses of nicosulfuron and has determined that there is a reasonable certainty that no harm to any population subgroup will result from exposure to nicosulfuron 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 current tolerances at 40 CFR 180.454 for nicosulfuron are now considered reassessed under section 408(q) of the FFDCA. All tolerances were reassessed and maintained at 0.1 ppm.

Nicosulfuron is a sulfonyl urea herbicide registered for early-postemergent and postemergent use on corn. It may be used alone or in formulation with other active ingredients to control annual and perennial grasses and broadleaf weeds. Application methods include band treatment, broadcast, low volume spray (concentrate) using aircraft, or ground equipment. The maximum application rate is 0.06248 lb a.i./acre. The highest usage of nicosulfuron is on corn and approximately 200,000 pounds are used annually.

Nicosulfuron is in Toxicity Category IV for acute oral, inhalation, and dermal irritation. It is Toxicity Category III for acute dermal and acute eye irritation. Nicosulfuron is not likely to be carcinogenic based on bioassays in the rat and mouse and lack of *in vitro* and *in vivo* mutagenic effects. Nicosulfuron showed no developmental or reproductive effects in rats and developmental effects in rabbits only at high doses. There were no indications of neurotoxic effects elicited by nicosulfuron in animal tests.

For acute dietary, an endpoint of concern attributable to a single dose was not identified. Acute studies showed no affect at high doses. Therefore, a risk assessment for this exposure was not performed and a toxic endpoint derived from a chronic study was considered the most appropriate for risk assessment purposes.

For the chronic dietary risk assessment, a chronic dog feeding study with a No Observable Adverse Effect Level (NOAEL) of 125 mg/kg/day and a Lowest Observed Adverse Effect Dose (LOAEL) of 500 mg/kg/day was used. All population subgroups' Chronic Population Adjusted Dose (% cPAD) are less than 1% which is below the Agency's Level of Concern (LOC).

In addition, for chronic aggregate exposure (food + water), nicosulfuron dietary exposure and risk is below EPA's level of concern. The level of refinement of the analyses is Tier 1 or tolerance level without any percent crop treated information. EPA's LOC for the aggregate is not exceeded for all population subgroups including the general U.S. population for the chronic analyses. The population subgroup, children ages 3-5, utilizes the highest percentage of the cPAD and constitutes less than 1%.

There are no residential uses that might contribute to aggregate risks, and occupational exposure is not assessed in this TRED. There are no unfulfilled data requirements for nicosulfuron.

The nature of the residue in plants and livestock is adequately understood based on metabolism studies with corn and goats. The residue of concern for both risk assessment and tolerance enforcement purposes is nicosulfuron *per se*. Seven tolerances for corn scenarios (all set at 0.1 ppm) are established under 40 CFR §180.454 for residues of nicosulfuron [3-pyridinecarboxamide, 2-((((4,6-dimethoxypyrimidin-2-yl)aminocarbonyl)aminosulfonyl)) -N,N-dimethyl]. There are no tolerances established for nicosulfuron residues in livestock tissues, milk or eggs as the Agency has concluded that there is no reasonable expectation of finite residues (40 CFR §180.6(a)(3)) of nicosulfuron in livestock commodities based on the current registered uses in or on livestock feed commodities that might result in nicosulfuron residues. Therefore, the seven existing tolerances for nicosulfuron are considered reassessed 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 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 nicosulfuron and any other substances and nicosulfuron 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 nicosulfuron 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, nicosulfuron 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, nicosulfuron 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 nicosulfuron. Please contact Meghan French of my staff with any questions regarding this decision. She may be reached by phone at (703)308-8004 or by e-mail at french.meghan@epa.gov.

Sincerely,

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

Enclosures: Nicosulfuron Risk Assessment Document