United States Environmental Protection Agency
Prevention, Pesticides and Toxic Substances (7508C)
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Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for Trifluralin

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 Trifluralin," which was approved on August 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. Additionally, the Agency will be proposing to establish a tolerance for trifluralin in mint oil.

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

The Agency has completed the human health risk assessment for trifluralin and has determined that there is a reasonable certainty that no harm to any population subgroup will result from exposure to trifluralin 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 180.207 for residues of trifluralin are now considered reassessed under section 408(q) of the FFDCA. Accordingly, the Agency will be proposing to establish a permanent tolerance at 2.0 ppm for mint oil.

Trifluralin is used as a pre-emergence herbicide to control annual grasses and broadleaf weeds on a variety of food crops as well as for non-food uses, including residential use sites. Taking into consideration available information on trifluralin and its expected use pattern, there is reasonable certainty of no harm from exposure to trifluralin through its use in pesticides. Available data show that residues of trifluralin in foods prepared with mint oil will not exceed the existing raw agricultural commodity tolerance. As a result, the Agency, using a qualitative approach to assessing human health risks from exposure to trifluralin, has made a safety finding that trifluralin is safe as currently used in pesticide products.

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.

The Agency has not yet determined whether the chemical class which includes trifluralin exhibits a common mechanism of toxicity. Therefore, the Agency defers any cumulative risk assessment to a later date. For the purposes of tolerance reassessment of trifluralin, EPA is assuming no common mechanism with other compounds. Therefore, a cumulative assessment was not conducted for this TRED.

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

Trifluralin is classified as a skin sensitizer. However, EPA has no method of quantifying risk due to skin sensitization and remains concerned about *dermal sensitization* reactions to adults and children who are exposed to trifluralin in residential settings. Therefore, it is recommended that all products containing trifluralin be labeled as "SENSITIZER" and state that "skin contact should be avoided".

Currently, there is no tolerance for trifluralin in or on raw agricultural commodities for mint oil. Therefore, a permanent tolerance of 2.0 ppm for mint oil will be proposed for trifluralin at 40 CFR 180.207 and is now considered reassessed under section 408(q) of the FFDCA.

This document summarizes the Agency's decision on the tolerance reassessment for trifluralin and the establishment of a permanent tolerance for mint oil. Please contact John W. Pates, Jr. of my staff with any questions regarding this decision. He may be reached by phone at (703-308-8195) or via e-mail at Pates.john@epa.gov.

Sincerely,

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

Enclosures: *Trifluralin Risk Assessment Overview*