

US EPA ARCHIVE DOCUMENT



Nitrogen TRED

April 2004



United States
Environmental Protection

Prevention, Pesticides
and Toxic Substances

April 7, 2004

Agency

(7508C)

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



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 Nitrogen," which was approved on April 7, 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 pesticide chemical residue tolerances or tolerance exemptions 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 nitrogen must be reassessed in accordance with FFDCA, as amended by FQPA.

The Agency has evaluated all currently registered uses of nitrogen and has determined that there is a reasonable certainty that no harm to any population subgroup will result from exposure to nitrogen 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 tolerance exemption at 40 CFR 180.1050 for nitrogen when used after harvest in modified atmospheres for stored product insect control on all food commodities is now considered reassessed under section 408(q) of the FFDCA.

Nitrogen is used as a fumigant to control insects in enclosed indoor areas where grain or other food and feed crops are stored. Taking into consideration the available information on nitrogen, including its designation by the US Food and Drug Administration as generally recognized as safe (GRAS), its expected use pattern, its safe history of use as a food additive and its essential role in the human body, there is a reasonable certainty of no harm from exposure to nitrogen through its use in pesticides. As a result, the Agency, using a qualitative approach to assessing human health risks from exposure to nitrogen, has made a safety finding that nitrogen 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.

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 for nitrogen, nor does nitrogen appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, EPA has not assumed that nitrogen 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/>.

The current tolerance exemption for nitrogen at 40 CFR 180.1050, when used after harvest in modified atmospheres for stored product insect control on all food commodities is now considered reassessed under section 408(q) of the FFDCFA. This document summarizes the Agency's decision on the tolerance reassessment for nitrogen. Please contact Mark Perry of my staff with any questions regarding this decision. He may be reached by phone at (703)308-8024 or by e-mail at perry.mark@epa.gov.

Sincerely,

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

Enclosures: *Lower Risk Pesticide Chemical Focus Group's Assessment for Nitrogen Tolerance
Reassessment* (4/1/2004, OPP Lower Risk Pesticide Chemical Focus Group)