

List of Subjects in 40 CFR Parts 152, 174, and 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Biotechnology pesticides, Pesticides and pests, Plants, Plant-pesticides, Reporting and recordkeeping requirements.

Dated: January 12, 1995.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

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40 CFR Part 180

[PP 4E4349/P599; FRL-4932-9]

RIN 2070-AC18

Pesticide Tolerance for Amitraz

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish a tolerance for residues of the insecticide/miticide amitraz and its metabolites in or on imported dried hops at 60 parts per million (ppm). AgrEvo (formerly Nor Am) Chemical Co. requested this regulation to establish the maximum permissible level of residues of the insecticide/miticide in or on the commodity.

DATE: Comments, identified by the document control number [PP 4E4349/P599], must be received on or before February 21, 1995.

ADDRESSES: Comments may be submitted to: Public Docket and Freedom of Information Section, Field Operations Division (7506C), Office of Pesticide Programs, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Dennis H. Edwards, Jr., Product Manager (PM) 19, Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 207, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6386.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the Federal Register of December 13, 1991 (56 FR 65080), which announced that Nor-Am Chemical Co., Little Falls Centre One, 2711 Centerville Rd., Wilmington, DE 19808, had submitted a food additive petition (FAP 2H5618) to EPA requesting that the Administrator, pursuant to sections 408(d) and 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d) and 348, establish a tolerance for the insecticide/miticide amitraz (*N*-[2,4-dimethylphenyl]-*N*-[(2,4-dimethylphenyl)imino]methyl]-*N*-methylmethanimidamide) and its metabolites *N*-(2,4-dimethylphenyl)-*N*-methyl formamide and *N*-(2,4-dimethylphenyl)-*N*-methylmethanimidamide (both calculated as the parent compound) in or on imported dried hops at 75 parts per million. There were no comments received in response to the initial notice of filing.

In the Federal Register of May 17, 1994 (59 FR 25586), the Agency issued a proposal to establish the amitraz hops tolerance at 75 ppm. No comments were received in response to this proposal; however, a concern was raised regarding the potential acute dietary risk of amitraz posed by its registered uses during reregistration under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 et seq., and therefore the final rule was not published. To address this concern, the company provided a voluntary human study and additional residue data and proposed a lower tolerance of 50 ppm for hops. An Agency review of the data concluded that a tolerance of 60 ppm is needed given the existing application rates.

EPA had not proposed to establish a tolerance for amitraz on hops in the past because dried hops have been considered a processed food requiring a section 409 tolerance and EPA was concerned that a section 409 tolerance for amitraz might be prohibited by the section 409 Delaney anti-cancer clause. Recently, EPA reclassified dried hops as a raw agricultural commodity (see proposed rule at 59 FR 25586; May 17, 1994).

The data submitted in the petition and all other relevant material have

been evaluated. The toxicology data considered in support of the tolerance was described in the May 17, 1994 proposed rule. In June 1994, a voluntary human study was submitted. This study indicated changes in systolic blood pressure, body temperature, ECG rate, and psychomotor performance observed from a single oral dose at the 0.125 mg/kg (the NOEL) level to be minimal and transient.

As directed by FIFRA section 4(g)(2)(A), the database for amitraz has undergone a reevaluation and reassessment as part of the reregistration process. It was determined that a combined developmental, neurological, and reproduction toxicity study in rats is needed to provide confirmatory data. The amitraz Reregistration Eligibility Document (RED), which is expected to be released shortly, will require this study.

The nature of the residue in plants and livestock is adequately understood. The residues of concern are amitraz and its metabolites containing the 2,4-dimethylaniline moiety. The residue analytical method is a common moiety method which converts amitraz and its two metabolites to 2,4-dimethylaniline with determination of the residues by gas chromatography using ⁶³Ni electron detection. The method has been published in FDA's PAM II. Magnitude of the residue data show that total amitraz residues on dried hops are not expected to exceed the proposed tolerance when amitraz is used as directed. There are currently no actions pending against continued registration of this chemical.

The Agency has prepared a dietary risk assessment for the amitraz RED, which is expected to be released shortly. Amitraz is a possible human carcinogen based on a 2-year mouse carcinogenicity study. The current dietary risk determined during preparation of the RED was calculated to be 1.4×10^{-6} (for the cottonseed/eggs/poultry use, plus pears, cattle, swine, and honey/beeswax). The addition of the use on hops will add 1.2×10^{-6} to this risk, assuming exposure over a lifetime of 70 years for a total lifetime dietary cancer risk from exposure to amitraz residues of 2.6×10^{-6} . The use of amitraz on imported hops is expected to still keep the overall lifetime dietary cancer risk within the negligible range.

The anticipated residue contribution (ARC) for this chemical from published tolerances utilizes 1 percent of the reference dose (RfD). The proposed tolerance will contribute 0.000025 mg/kg/bwt/day utilizing an additional 1 percent of the RfD. This results in a total utilization of 2 percent of the RfD.