

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.

[FR Doc. 95-1319 Filed 1-18-95; 8:45 am]

BILLING CODE 6560-50-F

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 X 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 X 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 X 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.

As stated previously, the May 17, 1994 proposed rule to establish a tolerance for amitraz in/on imported hops was not finalized because the amitraz reregistration activities indicated the potential for an acute risk of concern. Using the voluntary human study submitted by the company, a revised dietary exposure analysis was performed assessing the acute risk from the proposed use of amitraz on dried hops. Acute exposure from beer was calculated by multiplying individual, single day consumption estimates taken from the USDA's 1977-1978 Nationwide Food Consumption Survey by a residue of 0.22 ppm to derive a distribution of acute exposures for the two subgroups previously identified as being most highly exposed to amitraz through beer, "Males 13 years and older" and "Females 13 years and older." Because hops are mixed as part of the brewing process, a residue value in beer reflecting the average residue in hops was deemed more appropriate than using a residue value in beer based on the tolerance on hops.

The Margin of Exposure (MOE) is a measure of how closely exposure comes to the NOEL (the highest dose at which no effects were observed in the study), and is calculated as the ratio of the NOEL to the exposure (NOEL/exposure = MOE). The Agency normally considers an MOE of 10 or greater acceptable when the NOEL is based on a human study. MOEs at the 99th percentile from amitraz in beer were 10 for "Males, 13 +" and 15 for "Females, 13 +". Only those consumers within both subgroups having consumption greater than the 99th percentile consumer would have MOEs for beer which are below 10. Additionally, the acute risk assessment assumed that 100 percent of all imported beer and 100 percent of all imported hops used in domestic beer production would contain amitraz. The Agency considers this to be extremely unlikely.

The Agency expects a brewing study providing additional residue data to be submitted which may enable further refinement and reevaluation of the risk. At this time, no residue data supporting domestic use have been submitted for the U.S., and there are no U.S. registrations for the use of amitraz on hops. The Agency will not consider any applications for registration of amitraz to be used on hops in the U.S., nor will EPA consider any Special Local Needs Registrations (FIFRA section 24(c)) until acceptable U.S. residue data are submitted and reviewed and a risk/benefit analysis is performed.

Based on the above information considered by the Agency, the tolerance

established by amending 40 CFR part 180 would protect the public health. Therefore, it is proposed that the tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide under FIFRA, as amended, which contains any of the ingredients listed herein may request within 30 days after publication of this document in the Federal Register that this rulemaking proposal be referred to an Advisory Committee in accordance with FFDCA section 408(e).

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [PP 4E4349/P599]. All written comments filed in response to this petition will be available in the Public Docket and Freedom of Information Section, at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Recording and recordkeeping requirements.

Dated: January 12, 1995.

Stephen L. Johnson,
Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that part 180 be amended as follows:

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In § 180.287, by amending the table therein by adding and alphabetically inserting the raw agricultural commodity dried hops, to read as follows:

§ 180.287 Amitraz; tolerances for residues.
* * * * *

Commodity	Parts per million
* * * * *	* * * * *
Hops, dried	60
* * * * *	* * * * *

[FR Doc. 95-1320 Filed 1-18-95; 8:45 am]
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LEGAL SERVICES CORPORATION

45 CFR Part 1611

Eligibility

AGENCY: Legal Services Corporation.

ACTION: Proposed rule.

SUMMARY: The Legal Services Corporation ("LSC" or "Corporation") proposes to amend regulations relating to eligibility for LSC-funded legal services. This regulation has been substantially revised and reordered, in part to simplify the regulation and clarify current Corporation policy and in part to revise Corporation policy, particularly with respect to access by LSC to client records.

DATES: Comments may be submitted on or before March 20, 1995.

ADDRESSES: Comments may be submitted to the Office of General Counsel, Legal Services Corporation, 750 First St., NE., 11th Floor, Washington, DC 20002-4250.

FOR FURTHER INFORMATION CONTACT: Victor Fortunato, General Counsel, (202) 336-8810.

SUPPLEMENTARY INFORMATION: The Operations and Regulations Committee of the LSC Board ("Committee") held public hearings on June 20, 1994, and September 17, 1994, in Washington, DC, to consider a draft of proposed revisions to 45 CFR part 1611, LSC's regulations on eligibility for LSC-funded legal assistance. At a meeting in Washington, DC, on October 28, 1994, the Committee approved a draft to be published in the Federal Register as a proposed rule for public comment.

Under this proposal, part 1611 has been substantially revised and reordered to make the regulation less complex and easier for recipients to apply. While there are numerous proposals for substantive change, the majority of the revisions reflect the Committee's desire to make this rule more comprehensible and less subject to confusion and misinterpretation than is the current regulation. Throughout the rule, there are slight changes in language to clarify the rule or to make it consistent with