does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. E.P.A.*, 427 U.S. 246, 256–66 (S.Ct. 1976); 42 U.S.C. 7410(a)(2).

The OMB has exempted this action from review under Executive Order 12866.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compound.

Authority: 42 U.S.C. 7401–7671q.

Dated: January 6, 1995.

Felicia Marcus,

Regional Administrator.

[FR Doc. 95–1318 Filed 1–18–95; 8:45 am]

BILLING CODE 6560–50–W

40 CFR Parts 152, 174, and 180

[OPP–300378; FRL–4932–6]

RIN 2070–AC02

Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Exemptions From the Requirement of a Tolerance for Plant-Pesticides and Nucleic Acids and Viral Coat Proteins Produced in Plants under the Federal Food, Drug, and Cosmetic Act; Proposed Rules; Extension of Comment Periods

AGENCY: Environmental Protection Agency (EPA).

ACTION: Extension of comment periods.

SUMMARY: EPA is extending the comment period for a proposed rule for plant-pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and three proposed exemptions from the requirement of a tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA). The proposed rule and proposed exemptions from tolerance requirements describe how EPA proposes to address pesticidal substances produced by plants under FIFRA and FFDCA.

DATES: Comments identified by the docket control numbers [OPP– 300367a, 300368a, 300369a, 300371a] must be received on or before February 23, 1995.

ADDRESSES: Submit written comments by mail to: Program Resources Section, Public Response and Program Resources Branch, Field Operations Division (7506C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: By mail: Bernice Slutsky, Science and Policy Staff, Office of Prevention, Pesticides and Toxic Substances (7101), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. E–627, 401 M St., SW., Washington, DC, (202–260–6900).

SUPPLEMENTARY INFORMATION: The substances plants produce to protect themselves against pests and disease are considered to be pesticides under the FIFRA definition of ''pesticide.'' These substances, along with the genetic material necessary to produce them are designated ''plant-pesticides'' by EPA. In the Federal Register of November 23, 1994, EPA published: (1) A proposed policy statement that describes EPA's regulatory approach for plant-pesticides under FIFRA and FFDCA (''Proposed Policy; Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act'') (59 FR 60496); (2) a proposed regulatory amendment that would describe categories of plant-pesticides that are subject to or exempt from regulation under FIFRA and clarifies the status of plants that produce plant-pesticides (''Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule'') (59 FR 60519); (3) a proposed exemption from the requirement of a tolerance under FFDCA for categories of plant-pesticides that do not result in significantly different dietary exposures (''Plant-Pesticides; Proposed Exemption From the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act'') (59 FR 60535); (4) a proposed exemption from the requirement of a tolerance under FFDCA for nucleic acids, including deoxyribonucleic and ribonucleic acids (''Plant-Pesticides; Proposed Exemption From the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Nucleic Acids Produced in Plants,'') (59 FR 60542); and (5) a proposed exemption from the requirement of a tolerance under FFDCA for viral coat proteins (''Plant-Pesticides; Proposed Exemption From the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Viral Coat Proteins Produced in Plants'') (59 FR 60545). In response to requests by interested parties, EPA is extending the comment period for the four proposals by 30 days. Elsewhere in this issue of the Federal Register, EPA is also extending the comment period by 30 days for the proposed statement of policy for pesticidal substances produced in plants (plant-pesticides) under FIFRA and FFDCA. Comments for all documents must now be received by February 23, 1995.

Comments must be filed with the corresponding docket numbers:

Docket Number	Document Name
OPP–300369a	Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule
OPP–300368a	Plant-Pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act
OPP–300371a	Plant-Pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Nucleic Acids Produced in Plants
OPP–300367a	Plant-Pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Viral Coat Proteins Produced in Plants

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 1.4×10^{-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.