

sewage or discharge outside of the designated zones.

#### List of Subjects in 40 CFR Part 140

Environmental protection; Sewage disposal, Vessels.

Dated: June 21, 1995.

**William J. Muszynski,**

*Acting Regional Administrator.*

For the reasons set out in the preamble, 40 CFR part 140 is proposed to be amended as follows:

#### PART 140—[AMENDED]

1. The authority citation for part 140 continues to read as follows:

**Authority:** Sec. 312, as added Oct. 18, 1972, Pub. L. 92-500, sec. 2, 86 Stat. 871. Interpret or apply sec. 312(b)(1), 33 U.S.C. 1322(b)(1).

2. In § 140.4 paragraph (b)(1) is amended by designating the undesignated text after the colon as paragraph (b)(1)(i) and by adding paragraph (b)(1)(ii) to read as follows:

#### § 140.4 Complete prohibition.

\* \* \* \* \*

(b)\*\*\*

(1)\*\*\*

(ii) Two portions of the Hudson River in New York State, the first of which is bounded by the Mohawk River on the south and Lock 2 on the north, as described in item 1 of 6 New York Code of Rules and Regulations (NYCRR) Part 941.6, and the second of which is bounded on the north by the southern end of Houghtaling Island and on the south by a line between the Village of Roseton on the western shore and Low Point on the eastern shore, as described in Items 2 and 3 of 6 NYCRR Part 858.4.

[FR Doc. 95-16418 Filed 7-3-95; 8:45 am]

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#### 40 CFR Part 180

[PP 5E4425/P619; FRL-4962-5]

RIN 2070-AC18

#### Imidacloprid; Pesticide Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA proposes to establish a tolerance for residues of the insecticide (1-[6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine (referred to in this document as imidacloprid) and its metabolites in or on the raw agricultural commodity dried hops. The Interregional Research Project No. 4 (IR-4) requested pursuant to the Federal

Food, Drug and Cosmetic Act (FFDCA) the proposed regulation to establish a maximum permissible level for residues of the insecticide.

**DATES:** Comments identified by the document control number, [PP 5E4425/P619], must be received on or before August 4, 1995..

**ADDRESSES:** By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information". CBI should not be submitted through e-mail. Information marked as CBI 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 4:30 p.m., Monday through Friday, excluding legal holidays.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PP 5E4425/P619]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in the "SUPPLEMENTARY INFORMATION" section of this document.

**FOR FURTHER INFORMATION CONTACT:** By mail: Hoyt L. Jamerson, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA 22202, (703)-308-8783; e-mail: jamerson.hoyt@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** The Interregional Research Project No. 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903, has submitted pesticide petition (PP) 5E4425 to EPA on behalf of the Agricultural Experiment Stations of Oregon and Washington. This petition requests that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), amend 40 CFR 180.472 by establishing a tolerance for residues of the insecticide imidacloprid (1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, all expressed as 1-[(6-chloro-3-pyridinyl)-methyl]-N-nitro-2-imidazolidinimine, in or on the raw agricultural commodity dried hops at 6 parts per million (ppm).

In the **Federal Register** of June 28, 1994 (59 FR 33204), EPA established a time-limited tolerance for residues of imidacloprid on dried hops at 3.0 ppm. The imidacloprid tolerance for dried hops was established to expire on June 28, 1995, to allow IR-4 sufficient time to conduct additional residue field trials in support of a permanent tolerance for this use. Subsequently, IR-4 submitted the data from the residue field trials and petition 5E4425 in support of a permanent tolerance, but EPA extended the time-limited tolerance to expire on June 28, 1996 (60 FR 24784, May 10, 1995), when it became apparent that the IR-4 proposed tolerance could not be established prior to the June 28, 1995 expiration date. The IR-4 residue data have been reviewed and determined to be adequate to support a permanent tolerance for imidacloprid on dried hops at 6 ppm.

The toxicological data considered in support of the proposed tolerance include:

1. A 1-year chronic feeding study in dogs fed diets containing 0, 200, 500, or 1,250/2,500 ppm (average intake was 0, 6.1, 15, or 41/72 milligrams (mg)/kilogram (kg)/day) with a noobserved-effect level of 1,250 ppm based on increased plasma cholesterol and liver cytochrome P-450 levels in dogs at the 2,500-ppm dose level. The high dose was increased to 2,500 ppm (72 mg/kg/day) from week 17 onward due to lack of toxicity at the 1,250-dose level.

2. A 2-year feeding/carcinogenicity study in rats fed diets containing 0, 100, 300, 900, or 1,800 ppm with a NOEL for chronic effects at 100 ppm (5.7 mg/kg/day in males, 7.6 mg/kg/day in females) that included decreased body weight gain in females at 300 ppm (24.9 mg/kg/day) and above; and increased thyroid

lesions in males at 300 ppm (16.9 mg/kg/day) and above, and in females at 900 ppm (73 mg/kg/day) and above. There were no apparent carcinogenic effects under the conditions of the study.

3. A 2-year carcinogenicity study in mice fed diets containing 0, 100, 330, 1,000, or 2,000 ppm with a NOEL of 1,000 ppm (208 mg/kg/day in males, 274 mg/kg/day in females) based on decreased food consumption and decreased water intake at the 2,000-ppm dose level. There were no apparent carcinogenic effects observed under the conditions of this study.

4. A three-generation reproduction study with rats fed diets containing 0, 100, 250, or 700 ppm with a reproductive no-observed-effect level (NOEL) of 100 ppm (equivalent to 8 mg/kg/day based on decreased pup body weight observed at the 250-ppm dose level).

5. A developmental toxicity study in rat given gavage doses at 0, 10, 30, or 100 mg/kg/day during gestation days 6 to 16 with a NOEL for developmental toxicity at 30 mg/kg/day based on increased wavy ribs observed at the 100 mg/kg/day dose level.

6. A developmental toxicity study in rabbits given gavage doses at 0, 8, 24, or 72 mg/kg/day during gestation days 6 through 19 with a NOEL for developmental toxicity at 24 mg/kg/day based on decreased body weight and increased skeletal abnormalities observed at the 72 mg/kg/day dose level.

7. Imidacloprid, which was tested in a battery of 23 mutagenic assays, was negative for mutagenic effects in all but two of the assays. Imidacloprid tested positive for chromosome aberrations in an *in vitro* cytogenetic study with human lymphocytes for the detection of induced clastogenic effects, and for genotoxicity in an *in vitro* cytogenetic assay measuring sister chromatid exchange in Chinese hamster ovary cells.

Dietary risk assessments for imidacloprid indicate that there is minimal risk from established tolerances and the proposed tolerance for dried hops. A cancer risk assessment is not appropriate for imidacloprid since the pesticide is assigned to "Group E" (evidence of noncarcinogenicity for humans) of EPA's cancer classification system. Dietary risk assessments for the pesticide were conducted using the Reference Dose (RfD) to assess chronic exposure and risk and the Margin of Exposure (MOE) for acute toxicity.

The RfD is calculated at 0.057 mg/kg/day of body weight/day based on a NOEL of 5.7 mg/kg/day from the 2-year rat feeding/carcinogenicity study and 100-

fold uncertainty factor. The theoretical maximum residue contribution (TMRC) from existing tolerances and the proposed tolerance for dried hops utilizes less than 5 percent of the RfD for the general population and 26 percent of the RfD for nonnursing infants less than one year in age.

The MOE is a measure of how closely the high end acute dietary exposure comes to the no-observed-effect level from the toxicity endpoint of concern. For imidacloprid the MOE was calculated as a ratio of the NOEL (24 mg/kg/day) from the rabbit developmental toxicity study to dietary exposure, as estimated for the population subgroup at greatest risk (females of childbearing age). The MOE for this subgroup is estimated at 2500 for high-end exposure. Acute dietary margins of exposure of less than 100 are generally of concern to EPA. A MOE of 2,500 poses minimal risk.

Established tolerances for meat, milk, poultry, and eggs are adequate to cover secondary residues resulting from the feeding of spent hops to livestock.

The metabolism of imidacloprid in plants and animals is adequately understood. An adequate analytical method is available for enforcement purposes. The enforcement method has been submitted to the Food and Drug Administration for publication in the Pesticide Analytical Manual, Volume II (PAM II). Because of the long lead time for publication of the method in PAM II, the analytical method is being made available in the interim to any one interested in pesticide enforcement when requested from: Calvin Furlow, Public Response and Program Resources Branch, Field Operations Divisions (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1130A, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-5937.

There are currently no actions pending against the continued registration of this chemical.

Based on the information and data considered, the Agency has determined that 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 the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this notice in the Federal

Register that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDCFA.

A record has been established for this rulemaking under docket number [PP 5E4425/P619] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

opp-Docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines "significant" as those actions likely to lead to a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal

mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

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**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 23, 1995.

**Peter Caulkins,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

**PART 180—[AMENDED]**

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

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

2. In § 180.472, paragraph (a) is amended in the table therein by adding and alphabetically inserting dried hops, and paragraph (d) is removed, as follows:

**§ 180.472 1-[(6-Chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
* * * *	*
Hops, dried .....	6
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[FR Doc. 95-16429 Filed 7-3-95; 8:45 am]

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**40 CFR Part 180**

[PP 4E4374/P617; FRL-4961-9]

Rin 2070-AC18

**Dimethoate; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** This document proposes that a tolerance be established for residues of the insecticide dimethoate in or on the raw agricultural commodity asparagus. The Interregional Research Project No. 4 (IR-4) requested this proposed regulation to establish a maximum permissible level for residues of the insecticide in or on the commodity in a petition submitted pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA).

**DATE:** Comments, identified by the document control number [PP 4E4374/P617], must be received on or before August 4, 1995.

**ADDRESSES:** By mail, submit written comments to EPA's Office of Pesticide Programs (OPP) at: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 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 as "Confidential Business Information." CBI should not be submitted through e-mail. Information marked as CBI 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 4:30 p.m., Monday through Friday, excluding legal holidays.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form

must be identified by the docket number [PP 4E4374/P617]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

**FOR FURTHER INFORMATION CONTACT:** By mail: Hoyt L. Jamerson, Emergency Response and Minor Use Section (7505W), Registration Division, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA 22202, (703)-308-8783; e-mail: Jamerson.Hoyt@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** The Interregional Research Project No. 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903, has submitted pesticide petition 4E4374 to EPA on behalf of the Agricultural Experiment Stations of North Carolina and Oklahoma. The petition requested that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(e)), amend 40 CFR 180.204 to establish a tolerance for residues of the pesticide dimethoate (*O,O*-dimethyl *S*-(*N*-methylcarbamoylmethyl) phosphorodithioate) including its oxygen analog (*O,O*-dimethyl *S*-(*N*-methylcarbamoylmethyl) phosphorothioate) in or on the raw agricultural commodity asparagus at 0.15 part per million (ppm). The petitioner proposed that use of dimethoate on asparagus be geographically limited to exclude California and Arizona based on the geographical representation of the residue data submitted. Additional residue data will be required to expand the area of usage. Persons seeking geographically broader registration should contact the Agency's Registration Division at the address provided above.

The data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the proposed tolerance include:

1. A 3-month feeding study in rats fed diets containing 0, 2, 8, 32, 50, and 400 ppm with a no-observed-effect level (NOEL) for plasma, red blood cell and brain cholinesterase inhibition of 32 ppm (equivalent to 1.6 milligrams (mg)/kilogram (kg) kg/day) and a systemic NOEL of 50 ppm (equivalent to 2.5 mg/kg/day) based on depressed growth and