

5. Section 63.347 is amended by revising the introductory text in paragraph (e)(2) and paragraph (f)(1) to read as follows:

§ 63.347 Reporting requirements.

* * * * *

(e) * * *

(2) If the State in which the source is located has not been delegated the authority to implement the rule, each time a notification of compliance status is required under this part, the owner or operator of an affected source shall submit to the Administrator a

notification of compliance status, signed by the responsible official (as defined in § 63.2) who shall certify its accuracy, attesting to whether the affected source has complied with this subpart. If the State has been delegated the authority, the notification of compliance status shall be submitted to the appropriate authority. The notification shall list for each affected source:

* * * * *

(f) * * *

(1) If the State in which the source is located has not been delegated the

authority to implement the rule, the owner or operator of an affected source shall report to the Administrator the results of any performance test conducted as required by § 63.7 or § 63.343(b). If the State has been delegated the authority, the owner or operator of an affected source should report performance test results to the appropriate authority.

* * * * *

6. Table 1 to subpart N of Part 63 is amended by revising the entry for "63.5(a)" to read as follows:

TABLE 1 TO SUBPART N OF PART 63—GENERAL PROVISIONS APPLICABILITY TO SUBPART N

General provisions reference	Applies to subpart N	Comment
63.5(a)	Yes	Except replace the term "source" and "stationary source" in § 63.5(a) (1) and (2) of subpart A with "affected sources."

Subpart O—[Amended]

7. Section 63.360 is amended by revising paragraph (f) to read as follows:

§ 63.360 Applicability.

* * * * *

(f) The owner or operator of a source, subject to the provisions of the title 40, chapter I, part 63 subpart O, using 1 ton (see definition) is subject to title V permitting requirements. These affected sources, if not major or located at major sources as defined under 40 CFR 70.2, may be deferred by the applicable title V permitting authority from title V permitting requirements for 5 years after the date on which the EPA first approves a part 70 program (i.e., until December 9, 1999). All sources receiving deferrals shall submit title V permit applications within 12 months of such date (by December 9, 2000). All sources receiving deferrals still must meet compliance schedule as stated in this § 63.360.

* * * * *

Subpart M—[Amended]

8. Section 63.320 is amended by adding paragraph (k) to read as follows:

§ 63.320 Applicability.

* * * * *

(k) The owner or operator of any source subject to the provisions of this subpart M is subject to title V permitting requirements. These affected sources, if not major or located at major sources as defined under 40 CFR 70.2, may be deferred by the applicable title V

permitting authority from title V permitting requirements for 5 years after the date on which the EPA first approves a part 70 program (i.e., until December 9, 1999). All sources receiving deferrals shall submit title V permit applications within 12 months of such date (by December 9, 2000). All sources receiving deferrals still must meet compliance schedule as stated in this § 63.320.

Subpart X—[Amended]

9. Section 63.541 is amended by adding paragraph (c) to read as follows:

§ 63.541 Applicability.

* * * * *

(c) The owner or operator of any source subject to the provisions of the title 40, chapter I, part 63 subpart X is required to obtain a title V permit from the applicable permitting authority in which the affected source is located.

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BILLING CODE 6560-50-P

40 CFR Part 180

[PP 5E4598/P638; FRL-4990-5]

RIN 2070-AC18

Imidacloprid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish a time-limited tolerance for indirect or

inadvertent combined residues of the insecticide (1-[6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine (referred to in this document as imidacloprid) and its metabolites resulting from crop rotational practices in or on the raw agricultural commodities in the cucurbit vegetables crop group. The proposed regulation to establish a maximum permissible level for residues of the insecticide was requested in a petition submitted by the Interregional Research Project No. 4 (IR-4) pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA). The time-limited tolerance would expire on December 31, 1996.

DATES: Comments, identified by the document control number [PP 5E4598/P638], must be received on or before January 12, 1996.

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 Hwy., Arlington, VA 22202. 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/P638]. 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.

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.

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) 5E4598 to EPA on behalf of the Agricultural Experiment Stations of California, Florida, Georgia, South Carolina, and Texas. The 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 indirect or inadvertent, combined residues of the insecticide imidacloprid (1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine) and its metabolites containing the 6-metabolopyridinyl moiety, all expressed as 1-[(6-chloro-3-pyridinyl)-methyl]-N-nitro-2-imidazolidinimine, resulting from crop rotational practices in or on the raw agricultural commodities in the cucurbit vegetables crop group at 0.2 part per million (ppm).

The proposed tolerance will not support registration for imidacloprid on cucurbit vegetables. EPA will not

consider applications for section 3 or section 24(c) registration of imidacloprid on cucurbit vegetables based the proposed time-limited tolerance. The tolerance would allow growers to produce cucurbit vegetables in rotation with crops that are treated in accordance with registered uses of imidacloprid. Imidacloprid registrations prohibit growers from planting crops which lack an imidacloprid tolerance on ground treated with the insecticide within a 12-month period. In some areas, however, it is a common practice for growers to plant back cucurbit vegetables (melons, squash, and cucumbers) in fields that have been used to produce tomatoes and peppers. Imidacloprid is registered and tolerances are established for the fruiting vegetables crop group (including tomatoes and peppers). There are no established imidacloprid tolerances, however, for the cucurbit vegetables. Crop rotational studies reviewed by EPA indicate that plant-back crops grown in fields treated with imidacloprid may contain measurable amounts of the pesticide residue, if the rotational crop is planted within 12 months of application of the pesticide.

Currently, growers who plan to double crop with cucurbit vegetables must not use imidacloprid, or they must not plant back cucurbit vegetables in fields treated within 12 months of application with imidacloprid. According to the University of Florida Cooperative Extension Service, the inability to double crop because of the imidacloprid plant-back restriction will have a serious financial impact on the South Florida vegetable industry. Approximately 12,000 acres in South Florida are double cropped with cucurbit vegetables. Much of this acreage has been treated with imidacloprid to control sweet potato whitefly (silverleaf whitefly) on tomatoes. Prior to registration of imidacloprid on tomatoes, EPA approved emergency exemptions under Section 18 of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for its use in California, Florida, South Carolina, and Texas to avert significant economic loss from sweet potato white fly damage.

The proposed tolerance, which would expire on December 31, 1996, should allow IR-4 sufficient time to submit a permanent tolerance for imidacloprid on cucurbit vegetables. IR-4 is developing field residue data in support of a permanent tolerance and registration for use of imidacloprid on cucurbit vegetables. The permanent tolerance will be proposed by IR-4 to cover residues in cucurbit vegetables

from application to the growing crop, as well as crop rotational practices.

EPA's policy is to consider tolerance petitions, when requested by the registrants or any interested parties, for pesticide residues on replacement or rotational crops when residues result from pesticide carryover in soil from treatment of previous crops. Such tolerances will be set at levels determined to be appropriate based on evaluations of toxicity and residue data submitted to the Agency by the petitioner. Guidance on how to conduct residue studies on rotation crops can be found in the EPA publication "Pesticide Reregistration Reject Rate Analysis Residue Chemistry/Environmental Fate Follow Up Guidance for Conducting Rotational Crop Studies," February 1993. The procedures for filing a petition, as described in 40 CFR 180.7, should be followed, and each petition must be accompanied by the appropriate fee, as specified in 40 CFR 180.33.

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 no-observed-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 was negative for mutagenic effects in all but two of 23 mutagenic 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 cucurbit vegetables. A cancer risk assessment is not appropriate for imidacloprid since the pesticide is assigned to "Group E" (no evidence of carcinogenicity) 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.

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 utilizes less than 15 percent of the RfD for the general population and less than 30 percent of the RfD for nonnursing infants less than 1 year in age. The proposed tolerance for cucurbit vegetables would utilize less than 1 percent of the RfD for the general population and all population subgroups.

There is no reasonable expectation that secondary residues will occur in milk and eggs, or meat, fat, and meat byproducts of livestock or poultry; there are no livestock feed items associated with the cucurbit vegetables.

The metabolism of imidacloprid in plants and livestock is adequately

understood. The residues of concern are combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all calculated as imidacloprid. The analytical method is a common moiety method for imidacloprid and its metabolites containing the 6-chloropyridinyl moiety using a permanganate oxidation, silyl derivatization, and capillary GC-MS selective ion monitoring.

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 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 FFDCA.

A record has been established for this rulemaking under docket number [PP 5E4598/P638] (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 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 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: November 30, 1995.

Stephen L. Johnson,
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, by adding new paragraph (f), to read as follows:

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

* * * *

(f) Time-limited indirect or inadvertent tolerance: A time-limited tolerance, to expire on December 31, 1996, is established for indirect or inadvertent combined residues of the insecticide 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, when present therein as a result of the application of the pesticide to growing crops listed in this section and other nonfood crops as follows:

Commodity	Parts per million
Vegetables, cucurbit	0.2

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BILLING CODE 6560-50-F

40 CFR Part 721

[OPPTS-50601G; FRL-4976-3]

Ethane, 1,1,1,2,2-pentafluoro-; Revocation of a Significant New Use Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to revoke a significant new use rule (SNUR) promulgated under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for ethane, 1,1,1,2,2-pentafluoro-, based on receipt of new data. The data indicate that for purposes of TSCA section 5, the substance will not present an unreasonable risk to human health.

DATES: Written comments must be received by January 12, 1996.

ADDRESSES: All comments must be sent in triplicate to: OPPT Document Control Officer (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M Street, SW., Room G-099, East Tower, Washington, DC 20460.

Comments that are confidential must be clearly marked confidential business information (CBI). If CBI is claimed, an additional sanitized copy must also be

submitted. Nonconfidential versions of comments on this proposed rule will be placed in the rulemaking record and will be available for public inspection. Comments should include the docket control number. The docket control number for the chemical substance in this SNUR is OPPTS-50601G. Unit III of this preamble contains additional information on submitting comments containing CBI.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: nctic@epamail.epa.gov. Electronic comments must be submitted as 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 (OPPTS-50601G). No 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 in Unit IV of this document.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-543A, 401 M St., SW., Washington, DC 20460, Telephone: (202) 554-1404, TDD: (202) 554-0551; e-mail: TSCA-Hotline @epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 23, 1992 (57 FR 44064), EPA issued a SNUR (FRL-4001-2) establishing significant new uses for ethane, 1,1,1,2,2-pentafluoro-. Because of additional data EPA has received for this substance, EPA is proposing to revoke this SNUR.

I. Proposed Revocation

EPA is proposing to revoke the significant new use and recordkeeping requirements for ethane, 1,1,1,2,2-pentafluoro- under 40 CFR part 721, subpart E. In this unit, EPA provides a brief description for the substance, including its premanufacture notice (PMN) number, chemical name (generic name if the specific name is claimed as CBI), CAS number (if assigned), basis for the revocation of the section 5(e) consent order for the substance, and the CFR citation removed in the regulatory text section of this proposed rule. Further background information for the substance is contained in the rulemaking record referenced in Unit IV of this preamble.

PMN Number: P-91-1392

Chemical name: Ethane, 1,1,1,2,2-pentafluoro-.
CAS Registry Number: Not available.
Effective date of revocation of section 5(e) consent order: February 21, 1995.
Basis for revocation of section 5(e) consent order: The order was revoked based on test data submitted under the terms of the consent order. Based on the Agency's analysis of the submitted data, EPA can no longer support a finding that the manufacture, processing, distribution in commerce, use, or disposal of the PMN substance may present an unreasonable risk to human health. Accordingly, EPA has determined that further regulation under section 5(e) is not warranted at this time.

Toxicity testing results: The PMN substance P-91-1392 was tested in a cardiac sensitization study (epinephrine challenge in dogs), a 90-day inhalation toxicity study in rats, and a developmental inhalation toxicity study (rats and rabbits). The 90-day subchronic study showed that there were no observable adverse effects at concentrations up to 50,000 parts per million (ppm). There were no observed developmental toxicity effects at concentrations up to 50,000 ppm in the developmental toxicity study. There was evidence of maternal toxicity at 50,000 ppm but no maternal effects noted at 15,000 ppm. The PMN substance P-91-1392 was found to be a cardiac sensitizer when exposures occurred at a 10 percent concentration in air (100,000 ppm) for 10 minutes. Lower exposures did not elicit a sensitization response.
CFR Number: 40 CFR 721.3240

II. Background and Rationale for Proposed Revocation of the Rule

During review of the PMN submitted for the chemical substance that is the subject of this proposed revocation, EPA concluded that regulation was warranted under section 5(e) of TSCA pending the development of information sufficient to make a reasoned evaluation of the environmental effects of the substance, and that the substance is expected to be produced in substantial quantities and there may be significant or substantial human exposure. EPA identified the tests necessary to make a reasoned evaluation of the risks posed by the substance to the human health. Based on these findings, a section 5(e) consent order was negotiated with the PMN submitter and a SNUR was promulgated.

EPA reviewed testing conducted by the PMN submitter pursuant to the