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.

IV. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a ''significant regulatory action'' as an action that is likely to result in 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 referred to 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 entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; 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, it has been determined that this rule is not a ''significant regulatory action,'' because it does not meet any of the regulatory-significance criteria listed above.

B. Regulatory Flexibility Act

This proposed rule has been reviewed under the Regulatory Flexibility Act of 1980 (Pub. L. 96–354; 94 Stat. 1164, 5 U.S.C. 601 et seq.), and EPA has determined that it will not have a significant economic impact on a substantial number of small businesses, small governments, or small organizations.

Accordingly, I certify that this proposed rule does not require a separate regulatory flexibility analysis under the Regulatory Flexibility Act.

C. Paperwork Reduction Act

This proposed regulatory action does not contain any information collection requirements subject to review by OMB under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq.

D. Unfunded Mandates

This proposed rule contains no Federal mandates under Title II of the Unfunded Mandates Reform Act of 1995. Pub. L. 104–4 for State, local, or tribal governments or the private sector because it would not impose enforceable duties on them.

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.

Jack E. Housenger,

Chief, Special Review Branch, Special Review and Reregistration 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 § 180.390, by amending the table therein by revising the entries for grass, hay and grass, rangeland, forage to read as follows:

§ 180.390 Tebuthiuron; tolerances for residues.

* * * * *

Commodity	Parts per million
* * * * *	
Grass, hay	10.0
Grass, forage	10.0
* * * * *	

[FR Doc. 95–29735 Filed 12–5–95; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Parts 180 and 186

[PP 3F4169 and FAP 3H5655/P628; FRL–4971–7]

RIN 2070–AC18

Imidacloprid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish permanent tolerances for residues of the insecticide (1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine) (also known as imidacloprid) and it metabolites in or on cottonseed and cotton gin byproducts, to revoke the existing feed additive tolerance for imidacloprid on cotton meal, and to establish a maximum residue limit for imidacloprid on cottonseed meal. Bayer Corp. (formerly Miles, Inc.) submitted petitions pursuant to the Federal Food, Drug Cosmetic Act (FFDCA) requesting these regulations to establish certain maximum permissible levels for residues of the insecticide.

DATES: Comments, identified by the document control number, [PP 3F4169 and FAP 3H5655/P628], must be received on or before January 5, 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. 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). Information so marked will not be disclosed except in accordance with procedures set fourth 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 addressed 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 format. All comments and data in electronic form must be identified by the docket number [PP 3F4169 and FAP 3H5655/P628]. 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: Dennis H. Edwards, Jr., Product Manager (PM) 19, Registration Division (7505C), Office of Pesticide Programs, 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; e-mail: edwards.dennis@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

Pursuant to petitions from Miles, Inc., EPA issued final rules establishing pesticide tolerances under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a, for residues of the insecticide (1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine, in or on the raw agricultural commodities apples at 0.5 part per million (ppm), potatoes at 0.3 ppm, and cottonseed at 6.0 ppm. Based on a feed additive petition (FAP) 3H5655 from Miles, Inc., EPA established food or feed additive regulations under FFDCA section 409, 21 U.S.C. 348, for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as imidacloprid, on apple pomace (wet or dried) at 3 ppm, on potato chips at 0.4 ppm, on potato waste at 0.9 ppm, and on cottonseed meal at 9.0 ppm. The tolerances for cottonseed and cottonseed meal were established as time-limited tolerances and are due to expire on November 30, 1996 (see the Federal Register of November 30, 1994 (59 FR 61278)).

The reason the cottonseed and cottonseed meal tolerances were established as 2-year time-limited tolerances was to enable Bayer to complete additional cotton residue trials and present a final report. On June 2, 1994, the Agency issued a guidance document on crop residue trials. Among other things, this document provided guidance on the number and location of domestic crop field trials for establishment of pesticide residue trials. Based on this guidance document, the Agency determined that additional residue trials were needed and residue data on gin trash were required to fully support the cotton tolerances.

On March 31, 1995, Bayer submitted the additional residue studies. A request was also submitted to establish a tolerance for cotton gin byproducts. These data have been reviewed and determined to be adequate to support both the proposed cotton gin byproducts tolerance and the removal of the expiration date for the cottonseed and cottonseed meal tolerances.

EPA, however, has determined a section 409 feed additive tolerance is no longer necessary to prevent cottonseed meal from being deemed adulterated, and, therfore, EPA is preparing to revoke the cottonseed meal tolerance. Addtionally, EPA is proposing to establish a maximum residue limit for imidacloprid residues in cottonseed meal to simipifly enforcement.

II. Statutory Background

The FFDCA, 21 U.S.C. 301 et seq., authorizes the establishment by regulation of maximum permissible levels of pesticides in foods. Such regulations are commonly referred to as ''tolerances.'' Without such a tolerance or an exemption from the requirement of a tolerance, a food containing a pesticide residue is ''adulterated'' under section 402 of the FFDCA and may not be legally moved in interstate commerce. 21 U.S.C. 331, 342. EPA was authorized to establish pesticide tolerances under Reorganization Plan No. 3 of 1970. 5 U.S.C. App. at 1343 (1988). Monitoring and enforcement of pesticide tolerances are carried out by the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA).

The FFDCA has separate provisions for tolerances for pesticide residues on raw agricultural commodities and for residues on processed food. For pesticide residues in or on raw commodities, EPA establishes tolerances, or exemptions from tolerances when appropriate, under section 408 of the act. 21 U.S.C. 346a. EPA regulates pesticide residues in processed foods under section 409 which pertains to ''food additives.'' 21 U.S.C. 348. Maximum residue regulations established under section 409 are commonly referred to as food additive tolerances. Section 409 food additive tolerances are needed, however, only for certain pesticide residues in processed food. Under section 402(a)(2) of the FFDCA, a pesticide residue in processed food will not render the food adulterated if the residue results from application of the pesticide to a raw commodity consistent with a section 408 tolerance and the residue in the processed food when ''ready to eat'' has been removed to the extent possible by good manufacturing processes and is below the tolerance set under section 408. This exemption in section 402(a)(2) is commonly referred to as the ''flow-through'' provision because it allows the section 408 raw food tolerance to flow through to the processed food form.

III. Proposed Removal of Expiration Date from Cottonseed Tolerance and Establishment of Cotton Gin Byproduct Tolerance

The scientific data submitted in the petition and other relevant material have been evaluated regarding the Miles' request to remove the expiration date from the cottonseed tolerance and to establish a tolerance for cotton gin byproducts. The toxicological data considered in support of the tolerance include:

1. A three-generation rat reproduction study with a no-observed-effect level (NOEL) of 100 ppm (8 mg/kg/bwt); rat and rabbit teratology studies were negative at doses up to 30 mg/kg/ bwt and 24 mg/kg/bwt, respectively.

2. A 2-year rat feeding/carcinogenicity study that was negative for carcinogenic effects under the conditions of the study and had a NOEL of 100 ppm (5.7 mg/kg/bwt in male and 7.6 mg/kg/bwt female) for noncarcinogenic effects that included decreased body weight gain in females at 300 ppm and increased thyroid lesions in males at 300 ppm and females at 900 ppm.

3. A 1-year dog feeding study with a NOEL of 1,250 ppm (41/mg/kg/bwt).

4. A 2-year mouse carcinogenicity study that was negative for carcinogenic effects under conditions of the study and that had a NOEL of 1,000 ppm (208/mg/kg/day).

There is no cancer risk associated with exposure to this chemical. Imidacloprid has been classified under ''Group E'' (no evidence of carcinogenicity for humans) under EPA's cancer Assessment Guidelines by the Office of Pesticide Programs (OPP) Reference Dose (RFD) Committee.

The reference dose (RfD), based on the 2-year rat feeding/ carcinogenic study with a NOEL of 5.7 mg/kg/bwt and 100-fold uncertainty factor, is calculated to be 0.057 mg/kg/bwt. The theoretical maximum residue contribution (TMRC) from published uses is 0.008088 mg/kg/day. This represents 14% of the RfD for the overall U.S. population. For exposure of the most highly exposured subgroup in the population, children

(ages 1 to 6 years), the TMRC is 0.016735 mg/kg/day. This is equal to 30% of RfD. The proposed cotton gin byproduct tolerance will not increase the TMRC. Dietary exposure from the existing uses and proposed uses will not exceed the reference dose for any subpopulation (including infants and children) based on the information available from EPA's Dietary Risk Evaluation System.

The nature of the residue in plants and livestock is adequately understood. The residues of concern are imidacloprid and its metabolites that contain the 6-chloropyridinyl moiety, all calculated as imidacloprid. The analytical methods are common moiety methods for imidacloprid and its metabolites containing the 6-chloropyridinyl moiety using permanganate oxidation, silyl derivatization, and capillary GC-MS selective ion monitoring. Adequate geographically representative magnitude of the residue crop field trial data for imidacloprid on cotton indicate that residues of total imidacloprid will not exceed the proposed tolerances when the formulation is used as directed. Based on the results of the imidacloprid bovine and poultry feeding studies, finite imidacloprid residues will occur in meat, milk, poultry, and eggs from feeding of imidacloprid-treated feed items, or their processed feed items, when the formulations are used as directed. Appropriate secondary tolerances are established.

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

This pesticide is considered useful for the purposes for which the tolerances are sought. Based on the information and data considered, the Agency has determined that the tolerances established by amending 40 CFR part 180 would protect the public health. Therefore, it is proposed that the tolerances be established as set forth below.

IV. Proposed Revocation of the Feed Additive Tolerance for Cottonseed Meal

In June 1995 (60 FR 31300, June 14, 1995), EPA issued a revised policy concerning when section 409 food and feed additive tolerances were needed to prevent the adulteration of foods and animal feeds. Under EPA's revised policy, a section 409 tolerance is necessary for pesticide residues in processed food when it is likely that the level of some residues of the pesticide will exceed the section 408 tolerance level in ''ready to eat'' processed food. Of particular relevance to the imidacloprid feed additive tolerance is EPA's decision to interpret the term ''ready to eat'' processed food as food ready for consumption ''as is'' without further preparation. For foods that are found to be not ''ready to eat,'' EPA takes into account the dilution of residues that occurs in preparing a ''ready to eat'' food.

EPA has determined that cottonseed meal is not a ''ready to eat'' animal feed. EPA has found no evidence that cottonseed meal is fed to livestock as a stand-alone feedstock. Rather, cottonseed meal is used as an ingredient in animal feeds. As such, cottonseed meal can constitute up to 50 percent of an animal feed.

The section 408 tolerance for imadicloprid on cottonseed is 6 parts per million (ppm). The highest residue found in crop field trials for imidacloprid on cotton was 5.2 ppm. A processing study showed that in producing cottonseed meal residues concentrated 50 percent (a concentration factor of 1.5X). Thus, given this information, it is likely that imadicloprid residues of 7.8 ppm (1.5 X 5.2) could occur in cottonseed meal. However, to project what residues are likely in ''ready to eat'' animal feed containing cottonseed meal the 7.8 ppm level must be divided by 2 to allow for dilution occurring when cottonseed meal is added to other ingredients in the preparation of animal feed. Once this dilution is taken into account, the likely residue of imidacloprid in animal feed would not be expected to exceed 3.9 ppm. Since this is below the section 408 tolerance level, animal feed containing such residue levels would not be adulterated, and no section 409 tolerance is needed. Accordingly, EPA proposes to revoke the section 409 feed additive tolerance for imidacloprid in cottonseed meal.

V. Proposed Establishment of a Maximum Residue Level of Imidacloprid Residues in Cottonseed Meal

In the June 1995 policy announcement, EPA noted that it generally would establish maximum residue levels (MRLs) under FFDCA section 701 for not-ready-to-eat foods where such foods could contain residues exceeding the section 408 tolerance. EPA's rationale was that such MRLs are important to the efficient enforcement of the FFDCA. It is far less resource intensive for FDA and USDA, which are the Federal agencies which regulate pesticide residue levels in foods, to monitor residue levels in the bulk commodities used in preparing ready-to-eat foods than in the myriad of ready-to-eat foods manufactured from such commodities.

MRLs will enforce the statutory requirements that, where no food additive tolerance has been established, pesticide residues in processed food resulting from application of the pesticide to the precursor raw commodity render the food adulterated unless the pesticide was used in conformity with the applicable section 408 tolerance and the pesticide residue has been removed to the extent possible in good manufacturing practice. 21 U.S.C. 342(a)(2)(C). Thus, MRLs will reflect the maximum residue in processed food consistent with a legal level of residues being present on the precursor raw commodity and the use of good manufacturing practices. Processed foods not in compliance with an applicable MRL will be deemed adulterated under section 402 of the act.

EPA will compute the MRL by multiplying the maximum residue found in the raw commodity in field trials by the concentration factor determined in processing studies using good manufacturing practices. As noted, the maximum residue from the imidacloprid field trials is 5.2 ppm and the concentration factor for processing is 1.5X. Multiplying 5.2 ppm by 1.5 yields a product of 7.8 ppm. EPA believes it is appropriate to round 7.8 ppm up to 8 ppm and proposes 8 ppm as the MRL for imidacloprid residues in cottonseed meal. For purposes of enforcement of the MRL, the same analytical method used for enforcement of the section 408 tolerances should be used.

EPA is proposing to place this MRL in existing part 186 of title 40 of the Code of Federal Regulations rather than creating a new part of title 40. Currently, 40 CFR part 186 contains section 409 feed additive tolerances organized by pesticide. EPA believes it will be clearer to the regulated community and to enforcement personnel if all regulations pertaining to residue levels of a pesticide in animal feeds are located in the same part of the Code of Federal Regulations. Because EPA is proposing to expand the type of regulation that would be included in part 186, EPA proposes modifying the title of part 186 to ''Pesticides in Animal Feeds'' to reflect that change.

VI. Public Participation

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 document in the Federal Register that the portion of this rulemaking proposal concerning establishment, amendment, or revocation of tolerances under section 408 be referred to an Advisory Committee in accordance with section 408(e) of FFDCA.

Interested persons are invited to submit written comments on the proposed regulations. Comments must bear a notation indicating the document control number, [PP 3F4169 and FAP 35655/P628]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address given above from 8 a.m. to 4:30 p.m., Monday through Friday, except legal holidays.

VII. Administrative Matters

Under Executive Order 12866 (58 FR 51735, October 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). EPA has treated regulations simular to the establishment of tolerances as also not having a significant economic impact on substantial number of small entities. Therefore, the proposed MRL is not expected to have such impact.

List of Subjects in 40 CFR Parts 180 and 186

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

Dated: November 9, 1995.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR parts 180 and 186 be amended as follows:

PART 180—[AMENDED]

1. In part 180:

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

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

b. In § 180.472, by amending paragraph (a) by adding and alphabetically inserting the following new entries and by removing paragraph (b) and designating it as reserved, to read as follows:

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

(a) * * *

Commodity	Parts per million
* * * * *	
Cotton, gin byproducts	4
Cottonseed	6
* * * * *	

(b) [Reserved]

* * * * *

PART 186—[AMENDED]

2. In part 186:

a. By revising the title of part 186 to read as follows:

Part 186—Pesticides in Animal Feed

b. The authority citation for part 186 is revised to read as follows:

Authority: 21 U.S.C. 342, 348, and 701.

c. In § 186.900, by revising paragraph (b), to read as follows:

§ 186.900 1-[(6-Chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolinimine.

* * * * *

(b) A maximum residue level regulation is established for residues of the insecticide 1-[(6-choro-3-pryidinyl)methyl]-*N*-nitro-2-imidazolidinimine in or on the following feed resulting from application of the insecticide to cotton:

Food	Parts per million
Cottonseed meal	8

This regulation reflects the maximum level of residues in cottonseed meal consistent with use of 1-[(6-chloro-3-pyridinyl) methyl]-*N*-nitro-2-imidazolidinimine on cotton in conformity with § 180.472 of this chapter and with the use of good manufacturing practices.

* * * * *

[FR Doc. 95–29250 Filed 12–5–95; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 67

[Docket No. FEMA–7163]

Proposed Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Proposed rule.

SUMMARY: Technical information or comments are requested on the proposed base (1% annual chance) flood elevations and proposed base flood elevation modifications for the communities listed below. The base flood elevations and modified base flood elevations are the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: The comment period is ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in each community.

ADDRESSES: The proposed base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the following table.

FOR FURTHER INFORMATION CONTACT: Michael K. Buckley, P.E., Chief, Hazard