the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information 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.

VI. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300632] (including any comments and data submitted electronically). 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 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall 1B2, 1921 Jefferson Davis Hwy., Arlington, VA.

Electronic comments may 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 any copies of objections and hearing requests 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 Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

This final rule establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: March 12, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is 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. Section 180.1195 is added to read as follows:

§ 180.1195 Titanium dioxide; exemption from the requirement of a tolerance.

Titanium dioxide is exempted from the requirement of a tolerance for residues in or on growing crops, when used as an inert ingredient (UV protectant) in microencapsulated formulations of the insecticide lambda-cyhalothrin at no more than 3.0% by weight of the formulation.

[FR Doc. 98–7492 Filed 3–24–98; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300625; FRL–5776–5]

RIN 2070–AB78

Imidacloprid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of the insecticide 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine and its metabolites in or on pecans. The Bayer Corporation submitted a petition to EPA

under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104-170) requesting this tolerance.

DATES: This regulation is effective March 25, 1998. Objections and requests for hearings must be received by EPA on or before May 26, 1998.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [OPP–300625], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the document control number, [OPP–300625], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the document control number [OPP–300625]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Elizabeth T. Haeberer, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–2891, e-mail: haeberer.elizabeth@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 17, 1997 (62 FR 66077)(FRL–5758–3), EPA, issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP 5F4480) by the Bayer Corporation, 8400 Hawthorn Road, P.O. Box 4913, Kansas City, MO 64120-0013, to establish tolerances for the residues of the insecticide 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidiinimine in or on pecan, nut at 0.05 parts per million (ppm). This notice included a summary of the petition prepared by the Bayer Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.472(a) be amended by establishing a tolerance for the insecticide, 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidiinimine, in or on pecans at 0.05 ppm.

I. Risk Assessment and Statutory Findings

EPA establishes maximum legal levels (tolerances) for pesticide residues on food under section 408 of the FFDCA. EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of Section 408 and a complete description of the risk assessment process, see the Final Rule on Bifenthrin Pesticide Tolerances in the **Federal Register** of November 26, 1997, (62 FR 62961–62970)(FRL–5754–7).

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine and its metabolites containing the 6-chloropyridinyl moiety, all calculated as imidacloprid, and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine and its metabolites containing the 6-chloropyridinyl moiety, all calculated as imidacloprid, on pecans at 0.05 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine and its metabolites containing the 6-chloropyridinyl moiety are discussed below.

1. A battery of acute toxicity studies placing technical imidacloprid in Toxicity Category II for oral LD_{50}, Category IV for dermal LD_{50}, inhalation LC_{50}, eye iritation and dermal irritation. Imidacloprid is a non-sensitizer.

2. In an acute neurotoxicity study, groups of Sprague-Dawley rats (18/sex/dose) were given a single oral administration of imidacloprid (97.6%) in 0.5% methylcellulose with 0.4% Tween 80 in deionized water at 0, 42, 151 or 307 mg/kg. Parameters evaluated included: clinical pathology (6/sex/dose); Functional Observation Battery (FOB) measurements (12/sex/dose); and neuropathology (6/sex/dose). FOB measurements were made approximately 90 minutes post dosing, and on days 7 and 14. Motor activity measurements were made at approximately 2.5 hours post dosing.

At 307 mg/kg/day, 4/18 males and 10/18 females died and both sexes of rats at this dose exhibited decreased numbers of rears, grip strength (forelimb and hindlimb) and response to stimuli (auditory, touch, or tail pinch) as well as increased gait abnormalities, righting reflex impairments and body temperatures. These symptoms regressed by day 5. At 151 milligram/kilograms/day (mg/kg/day), cage side FOB assessments revealed tremors in one male and one female and red nasal staining in one male. On the day of dosing, a dose-related decrease in total session motor activity was observed in males at 151 mg/kg/day (25% decrease) and 307 mg/kg/day (73%) and in females at all dose levels with the decreases (25, 48, and 81%, respectively at 42, 151 and 307 mg/kg/day) reaching statistical significance ($p < 0.05$) at 151 and 307 mg/kg/day dose levels. Decreases in motor activity were seen at all time intervals. Total session locomotor activity was also decreased to about the same percentage difference but statistical significance was not reported. On days 7 and 14, decreases (not statistically significant) were still observed in motor and locomotor activity in surviving high-dose males. The lowest-observed-effect level (LOEL) was 42 mg/kg based on the decrease in

motor and locomotor activities observed in females; a no-observed-effect level (NOEL) was not established.

3. In a subchronic oral toxicity study, groups of Fischer 344 rats (12/sex/dose) were fed diets containing imidacloprid (98.8%) at 0, 150, 1,000, or 3,000 ppm (0, 9.3, 63.3, or 196 mg/kg/day in males and 0, 10.5, 69.3 or 213 mg/kg/day in females, respectively) for 90 days. No treatment-related effects were seen at 150 ppm. Treatment-related effects included decreases in body weight gain during the first 4 weeks of the study at 1,000 ppm (22% in males and 18% in females) and 3,000 ppm (50% in males and 25% in females) with an associated decrease in forelimb grip strength especially in males. The NOEL was 150 ppm (9.3 and 10.5 mg/kg/day in males and females, respectively) and the LOEL was 1,000 ppm (63.3 and 69.3 mg/kg/day in males and females, respectively).

4. In a subchronic dermal toxicity study, groups of five male and five female New Zealand White rabbits received repeated dermal applications of imidacloprid (95%) at 1,000 mg/kg/day (Limit Dose), 6 hours/day, 5 days/week for 3 weeks. No dermal or systemic toxicity was seen. For systemic and dermal toxicity, the NOEL was > 1,000 mg/kg/day; a LOEL was not established.

5. In a rat inhalation study (28-day study in which rats were exposed 6 hours/day, 5 days a week for 4 weeks), the no observable effect concentration (NOEC) for imidacloprid was 5.5 mg/m^3.

6. In a chronic oral toxicity study, groups of beagle dogs (4/sex/dose) were fed diets containing imidacloprid (94.9%) at 0, 200 or 1,250/2,500 ppm (0, 6.1, 15 or 41/72 mg/kg/day, respectively) for 52 weeks. The 1,250 ppm dose was increased to 2,500 ppm from week 17 onwards. The threshold NOEL was 1,250 ppm (41 mg/kg/day). The LOEL was 2,500 ppm (72 mg/kg/day) based on increased cytochrome-P-450 levels in both sexes and was considered to be a threshold dose. Due to the lack of toxicity at 1,250 ppm, a NOEL was not established in this study; following the dose increase to the 2,500 ppm level, toxicity was observed, thus making 1,250 ppm the threshold NOEL and 2,500 ppm the threshold LOEL.

7. In a combined chronic toxicity/carcinogenicity study, groups of Bor WISW rats (50/sex/dose) received imidacloprid (95.3%) at 0, 100, 300 or 900 ppm (0, 5.7, 16.9 or 51.3 mg/kg/day in males and 0, 7.6, 24.9, or 73 mg/kg/day in females, respectively) for 104 weeks. In another study, rats of the same strain (50/sex) received imidacloprid at 0 or 1,800 ppm (0, 102.6 and 143.7 mg/kg/day in males and females, respectively) for 104 weeks. For chronic toxicity, the NOEL was 100 ppm (5.7 mg/kg/day) and the LOEL was 300 ppm (16.9 mg/kg/day) based on decreased body weight gains in females and increased thyroid lesions in males. There was no evidence of carcinogenicity in either sex.

8. In a carcinogenicity study groups of B6C3F1 mice (50/sex/dose) were fed diets containing imidacloprid (95%) at 0, 100, 330 or 1,000 ppm (0, 20, 66 or 208 mg/kg/day in males and 0, 30, 104 or 274 mg/kg/day in females, respectively) for 2 years. In a supplementary study conducted to evaluate the adequacy of the high dose tested in the main study, the same strain of mice (50/sex) received 0 or 2,000 ppm (414 and 424 mg/kg/day in males and females, respectively) for the same time period. For chronic toxicity, the NOEL was 1,000 ppm (208 mg/kg/day). The LOEL was 2,000 ppm (414 mg/kg/day) based on decreased body weight gain, food consumption and water consumption. There was no evidence of carcinogenicity in either sex.

9. In a developmental toxicity study with Sprague-Dawley rats, groups of pregnant animals (25/group) received oral administration of imidacloprid (94.2%) at 0, 10, 30, or 100 mg/kg/day during gestation days 6 through 16. Maternal toxicity was manifested as decreased body weight gain at all dose levels and reduced food consumption at 100 mg/kg/day. No treatment-related effects were seen in any of the reproductive parameters (i.e., cesarean section evaluation). At 100 mg/kg/day, developmental toxicity manifested as wavy ribs (fetus =7/149 in treated vs. 2/158 in controls and litters, 4/25 vs. 1/25). For maternal toxicity, the LOEL was 10 mg/kg/day lowest dose tested (LDT) based on decreased body weight gain; a NOEL was not established. For developmental toxicity, the NOEL was 30 mg/kg/day and the LOEL was 100 mg/kg/day based on increased wavy ribs.

10. In a developmental toxicity study with Chinchilla rabbits, groups of 16 pregnant does were given oral doses of imidacloprid (94.2%) at 0, 8, 24 or 72 mg/kg/day during gestation days 6 through 18. For maternal toxicity, the NOEL was 24 mg/kg/day and the LOEL was 72 mg/kg/day based on mortality, decreased body weight gain, increased resorptions, and increased abortions. For developmental toxicity, the NOEL was 24 mg/kg/day and the LOEL was 72 mg/kg/day based on decreased fetal body weight, increased resorptions, and increased skeletal abnormalities.

11. In a 2-generation reproductive toxicity study, imidacloprid (95.3%) was administered to Wistar/Han rats at dietary levels of 0, 100, 250, or 700 ppm (0, 7.3, 18.3, or 52.0 mg/kg/day for males and 0, 8.0, 20.5, or 57.4 mg/kg/day for females). For parental/systemic/reproductive toxicity, the NOEL was 250 ppm (18.3 mg/kg/day) and the LOEL was 750 ppm (52 mg/kg/day), based on decreases in body weight in both sexes in both generations. Based on these factors,the Data Evaluation Record should be revised to indicate the parental/systemic/reproductive NOEL and LOEL to be 250 and 700 ppm, respectively, based upon the body weight decrements observed in both sexes in both generations.

12. Studies on gene mutation and other genotoxic effects: an Ames *Salmonella* Assay which was negative up to 5,500 µg/plate concentration; recombination assay-yeast, negative for cross-over in yeast up to 10,000 µg; *In Vivo* Chromasomal Aberration, negative for chromosome breakage up to 2,000 µg/ml; *In Vitro* Chromasomal Aberrations, positive at 500 µg/ml -S9 and 1,300 µg/ml +S9, both toxic doses (acceptable study); *In Vivo* Sister Chromatid assay, negative up to 2,000 µg/ml; *In Vitro* Cytogenetics-CHO cells, negative for producing forward mutation in CHO (mammalian) cells treated up to 1,222 µg/ml; Micronucleus - mouse, negative up to (toxic) 50 µg/ml (ip); DNA repair test, negative for cross-over in yeast up to 10,000 µg; HGPRT assay-CHO, negative up to 2,000 µg/ml. Mutagenicity studies have demonstrated that imidacloprid is non-mutagenic both *in vivo* and *in vitro*.

B. Toxicological Endpoints

1. *Special sensitivity to infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of imidacloprid, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. These studies are described in unit II A. of this document. The developmental toxicity data demonstrated no increased sensitivity of rats or rabbits to in utero exposure to imidacloprid. In addition, the multi-generation reproductive toxicity study data did not identify any increased sensitivity of rats to in utero or postnatal exposure. Parental NOELs were lower or equivalent to developmental or offspring NOELs. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the

reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intra-species variability)) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

Although developmental toxicity studies showed no increased sensitivity in fetuses as compared to maternal animals following in utero exposures in rats and rabbits, no increased sensitivity in pups as compared to adults was seen in the two generation reproduction toxicity study in rats, and the toxicology data base is complete as to core requirements, the Agency determined that the additional safety factor for the protection of infants and children will be retained but reduced to 3x based on the following weight-of-the-evidence considerations relating to potential sensitivity and completeness of the data:

(i) There is concern for structure activity relationship. Imidacloprid, a chloronicotinyl compound, is an analog to nicotine and studies in the published literature suggests that nicotine, when administered causes developmental toxicity, including functional deficits, in animals and/or humans that are exposed *in utero*.

(ii) There is evidence that imidacloprid administration causes neurotoxicity following a single oral dose in the acute study and alterations in brain weight in rats in the 2-year carcinogenicity study.

(iii) The concern for structure activity relationship along with the evidence of neurotoxicity dictates the need of a developmental neurotoxicity study for assessment of potential alterations on functional development.

Because a developmental neurotoxicity study potentially relates to both acute and chronic effects in both the mother and the fetus, the additional UF for FQPA is being applied for all population subgroups, and both acute and chronic risk.

2. *Acute toxicity*. Acute dietary risk assessment is required for all population subgroups. LOEL=42 mg/kg/day based on decreased motor activity in female rats; MOE=300, as discussed above. Conventionally, when a LOEL from the critical study is used for risk assessment, an additional UF will be applied. For acute risk assessment with imidacloprid, however, the Committee determined that an additional uncertainty factor is not necessary because: (i) of the low confidence in the endpoint based on the minimal nature of the effect (decreased motor activity only in females);(ii) this effect was seen in adult rats; and (iii) the same effect was not seen in the subchronic toxicity study following repeated doses.

3. *Short - and intermediate - term toxicity*. In a dermal toxicity study, groups of five male and five female New Zealand White rabbits received repeated dermal applications of imidacloprid (95%) at 1,000 mg/kg/day (Limit Dose), 6 hours/day, 5 days/week for three weeks. No dermal or systemic toxicity was seen. For systemic and dermal toxicity, the NOEL was > 1,000 mg/kg/day; a LOEL was not established (MRID No. 42256329).

In an oral toxicity study, groups of Fischer 344 rats (12/sex/dose) were fed diets containing imidacloprid (98.8%) at 0, 150, 1,000, or 3,000 ppm (0, 9.3, 63.3, or 196 mg/kg/day in males and 0, 10.5, 69.3 or 213 mg/kg/day in females, respectively) for 90 days. No treatment-related effects were seen at 150 ppm. Treatment-related effects included decreases in body weight gain during the first 4 weeks of the study at 1,000 ppm (22% in males and 18% in females) and 3,000 ppm (50% in males and 25% in females) with an associated decrease in forelimb grip strength especially in males. The NOEL was 150 ppm (9.3 and 10.5 mg/kg/day in males and females, respectively) and the LOEL was 1,000 ppm (63.3 and 69.3 mg/kg/day in males and females, respectively) (MRID No. 43286401).

In a rat inhalation study (28-day study in which rats were exposed 6 hours/day, 5 days a week for 4 weeks), the no observable effect concentration (NOEC) for imidacloprid was 5.5 mg/m3 (MRID No. 422730-01).

4. *Chronic toxicity*. EPA has established the RfD for 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine at 0.019 mg/kg/day. This RfD is based upon increased number of thyroid lesions in male and decreased body weight gains in female Bor WISW rats, with a NOEL of 5.7 mg/kg/day, and LOEL of 16.9/24.9 mg/kg/day (males and females respectively); UF=300, as discussed above.

5. *Carcinogenicity*. This chemical has been classified as a Group E - no evidence of carcinogenicity for humans. A cancer risk assessment is not required.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established 40 CFR 180.472(a) for the combined residues of 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine and its metabolites, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures and risks from imidacloprid as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. An acute dietary risk assessment is required for all population subgroups.

This acute dietary (food) risk assessment used the Theoretical Maximum Residue Contribution (TMRC). Resulting exposure values and Margins of Exposure (MOEs; MOE = Acute Endpoint ÷ Exposure) are shown below.

Population Subgroup	High-End[1] Exposure (mg/kg/day)	MOE[2]	Exposure @ 99th Percentile (mg/kg/day)	MOE
U.S. population (48 states)	0.10	420	0.05[3]	840
Infants (< 1 yr)	0.15	280	0.10	420
Children (1-6 yrs)	0.15	280	0.10	420
Females (13+ yrs)	0.05	840	0.04	1050

Population Subgroup	High-End[1] Exposure (mg/kg/day)	MOE[2]	Exposure @ 99th Percentile (mg/kg/day)	MOE
Males (13+ yrs)	0.10	420	0.05	840

[1] > 99.5th Percentile.
[2] MOE = Margin of Exposure.
[3] @ 98th Percentile (U.S. Pop. only).

These results should be viewed as a very conservative risk estimate; refinement using anticipated residue values and percent crop-treated information in conjunction with Monte Carlo analysis would result in a lower estimate (i.e., higher MOE) of acute dietary exposure.

ii. *Chronic exposure and risk.* The endpoint selected for chronic risk assessment is decreased body weight gains in females and increased thyroid lesions observed at 7.6 mg/kg/day in male rats in a combined chronic toxicity/carcinogenicity study. The NOEL was 5.7 mg/kg/day. A UF of 300 is required as discussed above. In conducting this chronic dietary (food) risk assessment, EPA used: (1) tolerance level residues for pecans, grain sorghum, and all other commodities with published, permanent or time-limited imidacloprid tolerances, the pending proposed tolerance for the citrus crop group; and, (2) percent crop-treated (%CT) information on some of these crops. Thus, this risk assessment should be viewed as partially refined. Further refinement using anticipated residue values and additional %CT information would result in a lower estimate of chronic dietary exposure. The results are summarized below.

Population Subgroup	Exposure(mg/kg/day)	%RfD
Nursing Infants (<1 year old)	0.002824	15
Non-Nursing Infants (<1 year old)	0.009983	53
Children (1-6 years old)	0.007514	40
Children (7-12 years old)	0.005305	28
U.S. Population - Fall Season	0.003716	20
Northeast Region	0.003771	20
Western Region	0.003842	20
Hispanics	0.003879	20
Non-Hispanic Others	0.003906	21

The subgroups listed above are: (1) the U.S. population (48 states); (2) those for infants and children; and, (3) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 states).

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: (1) that the data used are reliable and provide a valid basis for showing the percentage of food derived from a crop that is likely to contain residues; (2) that the exposure estimate does not underestimate the exposure for any significant subpopulation and; (3) where data on regional pesticide use and food consumption are available, that the exposure estimate does not understate exposure for any regional population. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of these estimates of percent crop treated as required by the section 408(b)(2)(F), EPA may require registrants to submit data on percent crop treated.

The Agency used percent crop treated (PCT) information as follows. A routine chronic dietary exposure analysis for imidacloprid was based on likely maximum percent of crop treated as follows: 6% grapefruits, 3% oranges, 13% other citrus, 19% apples, 2% pears, 11% grapes, 30% eggplants/peppers, 32% head lettuce, 21% cole crops, 15% melons, 10% tomatoes, 6% cotton.

The Agency believes that the three conditions listed above have been met. With respect to (1), EPA finds that the PCT information described above for imidacloprid is reliable and has a valid basis. The Agency has utilized the latest statistical data from RFF (Resources For The Future), DOANE, and USDA, the best available sources for such information. Concerning (2) and (3), regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than data available through national food consumption surveys, EPA does not have available information on the consumption of food bearing imidacloprid in a particular area.

2. *From drinking water.* EPA used the estimated environmental concentration (EEC) data to calculate acute and chronic exposure estimates for imidacloprid in surface water using the following formulas:

Adult Male: Exposure (mg/kg/day) = (chemical concentration in g/L in consumed water) * (10^{-3} mg/µg) ÷ (70 kg body weight) * (2 L water consumed/day)

Adult Female: Exposure (mg/kg/day) = (chemical concentration in g/L in consumed water) * (10^{-3} mg/µg) ÷ (60 kg body weight) * (2 L water consumed/day)

Child (1-6 years): Exposure (mg/kg/day) = (chemical concentration in g/L in consumed water) * (10^{-3} mg/µg) ÷ (10 kg body weight) * (1 L water consumed/day)

Acute MOE: Acute Endpoint (42 mg/kg/day) ÷ Exposure (mg/kg/day)

Chronic Risk (%RfD): Exposure (mg/kg/day) ÷ RfD (0.019 mg/kg/day) * 100

The 2 liters (L) of drinking water consumed/day by adults and the 1 L per day consumed by children are default assumptions used by the Office of Water. The Agency's default body weights for males is 70 kg and for females, 60 kg. HED's default body weight for children is 10 kg.

The results are summarized below:

Population Subgroup	Acute Scenario			Chronic Scenario		
	µg/L in Water Consumed	Exposure (mg/kg/day)	MOE	µg/L in Water Consumed	Exposure (mg/kg/day)	% RfD
Adult male	50.9	0.00145	29,000	19.1	0.00055	2.9
Adult Female	50.9	0.00170	24,700	19.1	0.00064	3.4
Child (1-6 yrs)	50.9	0.00509	8,250	19.1	0.00191	10.1

These results should be viewed as a very conservative risk estimate. Refinement by applying factors to account for the percent of acreage planted in a watershed, the percent of crop-treated, and the water flow rate would result in a lower estimate of acute and chronic exposure from consumption of surface waters containing imidacloprid residues.

3. *From non-occupational non-dietary exposure.* Imidacloprid is currently registered for use on the following residential non-food sites: ornamentals (e.g., flowering and foliage plants, ground covers, turf, lawns, et al.), tobacco, golf courses, walkways, recreational areas, bathrooms, household or domestic dwellings (indoor/outdoor), cats/dogs, and wood protection treatment to buildings. Available data do not demonstrate that imidacloprid has either dermal or inhalation toxicity potential, therefore, non-occupational non-dietary risk assessments are not required. Since data show no toxicity from short term exposure via the dermal or inhalation route, the Agency feels there is no contribution to toxicity from these routes of exposure, and no increase in aggregate risk is anticipated from this exposure. Therefore residential exposure does not aggregate with dietary exposure for any risk assessments.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and '' other substances that have a common mechanism of toxicity.'' An explanation of the current Agency approach to assessment of pesticides with a common mechanism of toxicity may be found in the Final Rule on Bifenthrin Pesticide Tolerances **Federal Register** of November 26, 1997, (62 FR 62961–62970)(FRL–5754–7).

EPA does not have, at this time, available data to determine whether imidacloprid has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, imidacloprid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that imidacloprid has a common mechanism of toxicity with other substances. Imidacloprid is the sole member to date of the new chloronicotinyl class of pesticides.

D. Aggregate Risks and Determination of Safety for U.S. Population, Infants and Children

1. *Acute risk.* Acute aggregate dietary risk (combined food and water) is estimated by adding the acute exposures to food and water (highest of ground or surface water) and comparing this exposure to the acute dietary endpoint:

Aggregate MOE_{ACUTE} = acute dietary endpoint ÷ aggregate exposure.

The results of the acute aggregate dietary (food and water) risk assessment are given below.

Population Subgroup	Exposure from Food (mg/kg/day)	Exposure from Surface Water (mg/kg/day)	Aggregate Exposure (mg/kg/day)	Aggregate Acute MOE
U.S. population (48 states)	0.101	0.0023	0.102	412
Infants (<1 yr)	0.102	0.0054	0.105	4005
Children (1-6 yrs)	0.102	0.005	0.105	4005
Females (13+ yrs)	0.051	0.002	0.052	808
Males (13+ yrs)	0.101	0.002	0.102	412

[1] High-End Exposure (>99.5th Percentile).
[2] Exposure @ 99th percentile; high-end exposure = 0.15 mg/kg/day.
[3] 3 Exposure value used was that calculated for females (13+ years) and males (13+ years).
[4] Exposure value used was that calculated for children (1-6 years).
[5] Based on exposure @ 99th percentile; MOE is 271 @ high-end exposure (>99.5th percentile).

For imidacloprid, an (aggregate) acute dietary MOE of ≥300 is needed to protect the safety of all population subgroups. The aggregate MOEs for the general population, females (13+ years), and males (13+ years) are >400 at the high-end exposure. The aggregate MOEs for infants and children are calculated to be 400 at the 99th percentile of exposure, and 271 at the high-end exposure (>99.5th percentile).

In conducting the acute dietary (food) risk assessment the Theoretical Maximum Residue Contribution (TMRC) was used. There was no refinement using anticipated residue values and percent crop-treated information in conjunction with Monte Carlo analysis which would result in a much lower estimate (i.e., higher MOE) of acute dietary exposure.

Because of the very conservative nature of the assumptions used in these calculations, and the fact that refinement would lower the risk estimates (i.e., result in higher MOE values) for both MOE_{food} and MOE_{water}, EPA concludes that there is a reasonable certainty that no harm will result to infants, children, or adults from acute agregate (food and water) exposure to imidacloprid residues.

2. *Chronic risk.* Dermal and inhalation exposure endpoints were not selected due to the demonstrated absence of toxicity, thus, there is no residential component for assessing chronic aggregate exposure and risk.

In conducting the chronic dietary (food) risk assessment, EPA used: (i) tolerance level residues for pecans, grain sorghum, and all other commodities with published, permanent or time-limited imidacloprid tolerances, the pending proposed

tolerance for the citrus crop group; and, (ii) percent crop-treated (%CT) information on some of these crops. Thus, this risk assessment should be viewed as partially refined. Further refinement using anticipated residue values and additional %CT information would result in a lower estimate of chronic dietary exposure.

Chronic aggregate dietary risk (combined food and water) will be estimated by adding the chronic exposures to food and water (highest of ground or surface water) and comparing this exposure to the RfD:

Aggregate %RfD Occupied = (aggregate exposure ÷ RfD) x 100.

The results of the chronic aggregate dietary (food and water) risk assessment are given below.

Population Subgroup	Exposure from Food (mg/kg/day)	Exposure from Surface Water (mg/kg/day)	Aggregate Exposure (mg/kg/day)	% RfD Occupied
U.S. population (48 states)	0.0036	0.00061	0.0042	22
Nursing infants (<1 yr old)	0.0028	0.00192	0.0047	25
Non-nursing infants (<1 yr old)	0.0100	0.00192	0.0119	63
Children (1-6 yrs old)	0.0075	0.0019	0.0094	49
Children (7-12 yrs old)	0.0053	0.00192	0.0072	38

[1] Used average value based on adult male (0.00055 mg/kg/day) and adult female (0.00064 mg/kg/day).
[2] Data not available; used the value for children (1-6 years).

This chronic aggregate dietary risk assessment is based on conservative exposure consumptions. Refinement of the assumptions used in estimating exposure from food and water sources would result in lower estimates of chronic aggregate dietary risk.

The calculated results indicate that the aggregate dietary exposure to imidacloprid utilizes 22% of the RfD for the U.S. general population.

For infants and children, the percentage of the RfD that is utilized by aggregate dietary exposure to imidacloprid ranges from 25% for nursing infants less than 1-year old, up to 63% for non-nursing infants less than 1-year old.

The Agency generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

EPA concludes that there is a reasonable certainty that no harm will result to infants, children, or adults from chronic aggregate (food plus water) exposure to imidacloprid residues.

3. *Short - intermediate - term risk.* Short - and intermediate - term aggregate exposure take into account chronic dietary food and water plus indoor and outdoor residential exposure. This risk assessment is not required for imidacloprid.

E. Aggregate Cancer Risk for U.S. Population

Imidacloprid has been classified as a Group E chemical, no evidence of carcinogenicity for humans, therefore, a cancer risk assessment is not required.

III. Other Considerations

A. Metabolism In Plants and Animals

The nature of imidacloprid residues in plants and animals is adequately understood. The residue of concern is imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent, as specified in 40 CFR 180.472.

B. Analytical Enforcement Methodology

Adequate enforcement methods are available for determination of the regulated imidacloprid residue in plant (Bayer GC/MS Method 00200 and Bayer HPLC-UV Confirmatory Method 00357) and animal (Bayer GC/MS Method 00191) commodities. These methods have successfully completed EPA Tolerance Method Validation, and are awaiting publication in Pesticide Analytical Manual II (PAM II). In the interim, these methods are available from Calvin Furlow, EPA, OPP, IRSD, PIRIB.

C. Magnitude of Residues

Residue data have been submitted from 13 field trials, with adequate geographical representation, and including 8 varieties of pecans. The pecan trees in 7 field trials were treated with 1 or 2 foliar applications starting at the fill stage for the first application and at or prior to shuck split for the second application for a repeat application interval of 10 + or - 2 days. Pecan trees were treated with imidacloprid at a rate of 0.17 lb ai/acre/application plus a spray adjuvant using ground airblast sprays, for a total application of 0.34 lb/ai/acre/season. Pecans were gathered at the earliest harvest which varied from 4 to 31 days after the last application. Pecan trees in 6 field trials were treated with imidacloprid in a single soil application at a rate of 0.5 lb/ai/acre. The pre-harvest interval (PHI) for pecans from the single soil application ranged from 99 to 150 days.

All treated pecan samples were below the limit of quantitation (LOQ) of <0.05 ppm regardless of the PHI. Total imidacloprid residues ranged from approximately 0.001 ppm to 0.005 ppm or <1/2 the limit of detection (LD).

Crop field trial data are adequate to show that combined residues of imidacloprid and its metabolites, all calculated as imidacloprid, will not exceed the tolerance of 0.05 ppm requested and prescribed in this **Federal Register** rule for the pesticide chemical residue in the raw agricultural commodity, pecans. OPPTS Test Guidelines, Series 860, Residue Chemistry, Table 1, does not list any processed commodities for pecans, thus no imidacloprid in pecans processing study is required. Similarly , there are no bovine, porcine, or poultry feedstuffs associated with pecans; thus there is little likelihood of additional imidacloprid in meat, milk, poultry, and eggs from the feeding of pecans. The established imidacloprid secondary tolerances are adequate for any inadvertent feeding of pecans.

D. Rotational Crop Restrictions.

Field crop rotational studies with three crop groups (small grains, root crops, and leafy vegetables) support a 12-month plant-back restriction. Since pecans are not considered to be a rotated crop, this restriction does not apply to pecans.

E. International Residue Limits

There are no CODEX or Mexican maximum residue limits (MRLs) for imidacloprid on any crop. There are Canadian MRLs for combined residues of imidacloprid plus metabolites with the 6-chlorophenyl moiety, but not on pecans. International compatibility is thus not an issue.

IV. Conclusion

Therefore, the tolerance is established for residues of 1-[(6-chloro-3-

pyridinyl)methyl]-N-nitro-2-imidazolidinimine and its metabolites in or on pecans at 0.05 ppm.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by May 26, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information 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.

VI. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300625] (including any comments and data submitted electronically). 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 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may 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 any copies of objections and hearing requests 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 Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance for the residues of imidacloprid at 0.05 ppm in/on pecans under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance for the residues of imidacloprid in/on pecans at 0.05 ppm in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: March 16, 1998

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is 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. Section 180.472, paragraph (a) is amended by alphabetically adding the commodity to read as follows:

§ 180.472 Imidacloprid; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * * * *	
Pecans	0.05
* * * * * * *	

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[FR Doc. 98–7647 Filed 3–24–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300628; FRL–5778–3]

RIN 2070–AB78

Imidacloprid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the insecticide 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine and its metabolites in or on sorghum grain 0.05 parts per million (ppm), forage 0.10 ppm, and stover 0.10 ppm. Gustafson, Inc. submitted a petition to EPA under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104-170) requesting these tolerances.

DATES: This regulation is effective March 25, 1998. Objections and requests for hearings must be received by EPA on or before May 26, 1998.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [OPP–300628], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the document control number, [OPP–300628], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the document control number [OPP–300628]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Elizabeth T. Haeberer, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–2891, e-mail: haeberer.elizabeth@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 29, 1997 (62 FR 56171)(FRL–5752–2), EPA, issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP 4F4415) by Gustafson, Inc., 1400 Preston Road, Suite 400, Plano, Texas 75093, to establish tolerances for the residues of the insecticide 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidiinimine in or on sorgum grain at 0.05 parts per million (ppm), forage 0.10 ppm, and stover 0.10 ppm. This notice included a summary of the petition prepared by Gustafson, Inc., the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.472(a) be amended by establishing tolerances for the insecticide, 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidiinimine, in or on sorghum grain, forage, and stover at 0.05, 0.10, and 0.10 ppm respectively.

I. Risk Assessment and Statutory Findings

EPA establishes maximum legal levels (tolerances) for pesticide residues on food under section 408 of the FFDCA. EPA performs a number of analyses to determine the risk from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the Final Rule on Bifenthrin Pesticide Tolerances in the **Federal Register**, of November 26, 1997, (62 FR 62961–62970)(FRL–5754–7).

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine and its metabolites containing the 6-chloropyridinyl moiety, all calculated as imidacloprid, and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine and its metabolites containing the 6-chloropyridinyl