provided, however, that ASCAP and BMI shall be entitled to receive music use reports covering not less than ninety (90) PBS Stations in any given calendar year. Subject to the limitations set forth above, PBS Stations shall be obligated to furnish to ASCAP and BMI such music use reports for each station for a period of no more than seven days in each calendar year.

(3) Non-PBS Stations shall furnish to ASCAP and BMI, upon request and designation of ASCAP and BMI, music use reports listing all musical compositions broadcast by such Non-PBS Stations showing the title, author and publisher of each composition, to the extent such information is reasonably obtainable. Non-PBS Stations will make a good faith effort to obtain the information to be listed on such music use reports. In each calendar year, ASCAP and BMI shall each be limited to requesting music use reports from no more than fifty (50) percent of Non-PBS Stations. Subject to the limitations set forth above, Non-PBS Stations shall be obligated to furnish to ASCAP and BMI such music use reports for each station for a period of no more than seven days in each calendar year.

(4) NPR Stations which have six (6) or more full-time employees shall furnish to ASCAP and BMI, upon request and designation of ASCAP and BMI, music use reports listing all musical compositions broadcast by such NPR Station showing the title, author or and publisher of each composition, to the extent such information is reasonably obtainable; provided, however, that NPR Stations shall not be responsible for providing cue sheets for programs for which cue sheets have already been provided by NPR to ASCAP and BMI. NPR Stations will make a good faith effort to obtain the information to be listed on such music use reports. In each calendar year, ASCAP and BMI shall each be limited to requesting music use reports from no more than fifty (50) percent of NPR Stations which have six (6) or more full-time employees. Notwithstanding the foregoing, if the number of NPR Stations with six (6) or more employees (from which ASCAP and BMI shall initially designate and request reports) falls below twenty-five (25) percent of the total number of all NPR Stations, then ASCAP and BMI may each request reports from additional NPR Stations, regardless of the number of employees, so that ASCAP and BMI shall each be entitled to receive music use reports from not less than twenty-five (25) percent of all NPR Stations. NPR Stations shall be obligated to furnish music use reports for each station for a period of up to one week in each calendar year to ASCAP and BMI.

(5) Non-NPR Stations which have six (6) or more full-time employees shall furnish to ASCAP and BMI, upon request and designation of ASCAP and BMI, music use reports listing all musical compositions broadcast by such Non-NPR Station showing the title, author and publisher of each composition, to the extent such information is reasonably obtainable. Non-NPR Stations will make a good faith effort to obtain the information to be listed on such music use reports. In each calendar year, ASCAP and BMI shall each be limited to requesting music use reports from no more than fifty (50) percent of the Non-NPR Stations which have six (6) or more full-time employees. Notwithstanding the foregoing, if the number of Non-NPR Stations with six (6) or more employees (from which ASCAP and BMI shall initially designate and request reports) falls below twenty-five (25) percent of the total number of all Non-NPR Stations, then ASCAP and BMI may each request reports from additional Non-NPR Stations, regardless of the number of employees, so that ASCAP and BMI shall each be entitled to receive music use reports from not less than twenty-five (25) percent of all Non-NPR Stations. Non-NPR Stations shall be obligated to furnish music use reports for each station for a period of up to one week in each calendar year to ASCAP and BMI.

So Ordered.

James H. Billington,

The Librarian of Congress.

Dated: September 17, 1998.

So Recommended.

Marybeth Peters,

Register of Copyrights.

[FR Doc. 98–24986 Filed 9–17–98; 8:45 am]

BILLING CODE 1410–33–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300717; FRL–6027–1]

RIN 2070–AB78

Imidacloprid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety in or on sugar beets (tops, roots, molasses), barley (grain, straw, hay), wheat (grain, forage, straw, hay), as requested by Gustafson, Incorporated (PP 5F4584 and PP 4F4337); and cereal grains crop group (grain, forage, straw, hay, stover), sweet corn, safflower (seed, meal), legume vegetables crop group (seed, foliage), soybean meal, as requested by Bayer Corporation (PP 6F4765). Gustafson, Incorporated, and Bayer Corporation requested these tolerances under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective September 18, 1998. Objections and requests for hearings must be received by EPA on or before November 17, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, OPP–300717, 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), PO Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, OPP–300717, 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, Crystal Mall #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 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number OPP–300717. 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: Peg Perreault, 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, 703–305–5417, e-mail: Perreault.Peg@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Registers** of June 25, 1997 (62 FR 34261) (FRL–5719–6) and February 26, 1997 (62 FR 8731) (FRL–5589–2), EPA issued notices pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of pesticide petitions (PP 5F4584, PP 4F4337, Gustafson; and PP 6F4765, Bayer) for tolerances by Gustafson, Incorporated, PO Box 660065, Dallas, Texas 75255-0065; and Bayer Corporation, 8400 Hawthorn Road, PO Box 4913, Kansas City, MO 64120-0013. These notices included summaries of the petitions prepared by Gustafson, Incorporated, and Bayer Corporation, the registrants. There were no comments received in response to the notices of filing. The petitions requested that 40 CFR 180.472(a) and (d) be amended by establishing tolerances for combined residues of the insecticide imidacloprid (1-[(6-chloro-3-pyridinyl) methyl]-N-nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, all expressed as (1-[(6-chloro-3-pyridinyl) methyl]-N-nitro-2-imidazolidinimine), in or on sugar beets (tops) at 0.5, roots at 0.05, molasses at 0.3 parts per million (ppm), barley (grain) at 0.05, straw at 0.5, hay at 0.5 ppm, wheat (grain) at 0.05, forage at 7.0, straw at 0.5, hay at 0.5 ppm 40 CFR 180.472(a); and cereal grains crop group - grain at 0.05, forage at 2.0, straw at 3.0, hay at 6.0, stover at 0.3 ppm, sweet corn (kernel plus cob with husk removed) at 0.05, safflower - seed at 0.05, meal at 0.5, legume vegetable crop group - seed at 0.3, foliage at 2.5, soybean meal at 0.5 ppm (inadvertent or indirect residues, 40 CFR 180.472(d)).

I. Risk Assessment and Statutory Findings

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

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 (62 FR 62961, November 26, 1997) (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 imidacloprid and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety in or on sugar beets (tops) at 0.5, roots at 0.05, molasses at 0.3 parts per million (ppm), barley (grain) at 0.05, straw at 0.5, hay at 0.5 ppm, wheat grain at 0.05, forage at 7.0, straw at 0.5, hay at 0.5 ppm (40 CFR 180.472(a); and cereal grains crop group - grain at 0.05, forage at 2.0, straw at 3.0, hay at 6.0, stover at 0.3 ppm, sweet corn (kernel plus cob with husk removed) at 0.05, safflower - seed at 0.05, meal at 0.5, legume vegetable crop group - seed at 0.3, foliage at 2.5, soybean meal at 0.5 ppm (40 CFR.180.472(d)). EPA's assessment of the dietary exposures and risks associated with establishing the tolerances 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 imidacloprid are discussed below.

1. *Acute toxicity*. The following table contains a summary of the acute toxicity data for technical imidacloprid.

Guideline Number	Study Type	MRIDs Nos.	Results	Toxicity Category
81-1	Acute Oral	42055331	LD_{50} = 424 mg/kg (M) > 450 mg/kg (F)	II
81-2	Acute Dermal	42055332	LD_{50} >5,000 mg/kg	IV
81-3	Acute Inhalation	42256317	LC_{50} > 5.33 mg/L	IV
81-4	Primary Eye Irritation	42055334	Non-irritant	IV
81-5	Primary Skin Irritation	42055335	Non-irritant	IV
81-6	Dermal Sensitization	42055336	Non-sensitizer	NA
81-8	Acute Neurotoxicity	41317301 43285801	NOAEL = Not established LOEL = 42 mg/kg bwt/day	NA

The following table contains a summary of the acute toxicity of the end-use product (40.7% formulation) for imidacloprid (Gaucho 480F, EPA Reg. No. 7501-155).

Guideline Number	Study Type	MRIDs Nos.	Results	Toxicity Category
81-1	Acute Oral/Rat	42857703	LD_{50} = 4687 mg/kg (M) 4067 mg/kg (F)	III
81-2	Acute Dermal/Rat	42857703	LD_{50} >5,050 mg/kg	IV
81-3	Acute Inhalation/Rat	42256326	LC_{50} = 2.11 mg/L (M&F)	IV
81-4	Primary Eye Irritation/Rabbit	42857705	Irritation score: 0.7 (1 hr.); 0.1 (24 hr.) 0.0 (48 hr.); 0.0 (72 hr.)	IV
81-5	Primary Dermal Irritation/ Rabbit	42256328	PIS: 0.0 (non-irritating)	IV
81-6	Dermal Sensitization/ Guinea Pig	42857707	Not a sensitizer	NA

2. *Subchronic toxicity*. In a dermal toxicity study, groups of 5 male and 5 female New Zealand White rabbits received repeated dermal applications of imidacloprid (95%) at 1,000 milligrams/kilograms (mg/kg) body weight/day (bwt/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 no observable adverse effect level (NOAEL) was >1,000 mg/kg bwt/day; a lowest observable effect level (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 bwt/day in males and 0, 10.5, 69.3 or 213 mg/kg bwt/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 NOAEL was 150 ppm (9.3 and 10.5 mg/kg bwt/day in males and females, respectively) and the LOEL was 1,000 ppm (63.3 and 69.3 mg/kg bwt/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/week for 4 weeks), the NOAEL for imidacloprid was 5.5 mg/m^3 (MRID No. 422730-01).

3. *Chronic toxicity*. In a chronic 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 bwt/day, respectively) for 52 weeks. The 1,250 ppm dose was increased to 2,500 ppm from week 17 onwards. The threshold NOAEL was 1,250 ppm (41 mg/kg bwt/day). The LOEL was 2,500 ppm (72 mg/kg bwt/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 LOEL 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 NOAEL and 2,500 ppm the threshold LOEL (MRID No. 42273002).

4. *Carcinogenicity*. 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 bwt/day in males and 0, 7.6, 24.9, or 73 mg/kg bwt/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 bwt/day in males and females, respectively) for 104 weeks. For chronic toxicity, the NOAEL was 100 ppm (5.7 mg/kg bwt/day) and the LOEL was 300 ppm (16.9 mg/kg bwt/day) based on decreased body weight gains in females and increased thyroid lesions in males. There was no evidence of carcinogenicity in either sex (MRID No. 42256331 and 42256332).

In 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 bwt/day in males and 0, 30, 104 or 274 mg/kg bwt/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 bwt/day in males and females, respectively) for the same time period. For chronic toxicity, the NOAEL was 1,000 ppm (208 mg/kg bwt/day). The LOEL was 2,000 ppm (414 mg/kg bwt/day) based on decreased body weight gain, food consumption, and water consumption. There was no evidence of carcinogenicity in either sex (MRID No. 42256335 and 42256336).

5. *Developmental toxicity*. 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 bwt/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 bwt/day. No treatment-related effects were seen in any of the reproductive parameters (i.e., Cesarean section evaluation). At 100 mg/kg bwt/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 bwt/day (LDT) based on decreased body weight gain; a NOAEL was not established. For developmental toxicity, the NOAEL was 30 mg/kg bwt/day and the LOEL was 100 mg/kg bwt/day based on increased wavy ribs (MRID No. 42256338).

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 bwt/day during gestation days 6 through 18. For maternal toxicity, the NOAEL was 24 mg/kg bwt/day and the LOEL was 72 mg/kg bwt/day based on mortality, decreased body weight gain, increased resorptions, and increased abortions. For developmental toxicity, the NOAEL was 24 mg/kg bwt/day and the LOEL was 72 mg/kg bwt/day based on decreased fetal body weight, increased resorptions, and increased skeletal abnormalities (MRID No. 42256339).

6. *Reproductive toxicity*. 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 bwt/day for males and 0, 8.0, 20.5, or 57.4 mg/kg bwt/day for females) (MRID No. 42256340, Doc. No. 010537). For parental/systemic/reproductive toxicity, the NOAEL was 250 ppm (18.3 mg/kg bwt/day) and the LOEL was 750 ppm (52 mg/kg bwt/day), based on decreases in body weight in both sexes in both generations. Based on these factors, the EPA/OPP/HED Hazard Identification Assessment Review Committee (HIARC) recommended that the Data Evaluation Record should be revised to indicate the parental/systemic/reproductive NOAEL and LOEL to be 250 and 700 ppm, respectively, based upon the body weight decrements observed in both sexes in both generations.

7. *Mutagenicity*. As shown below, mutagenicity studies have demonstrated that imidacloprid is non-mutagenic both *in vivo* and *in vitro*.

Assay	MRIDs Nos.	Results
Ames-Salmonella	42256363	Negative up to 5,500 μg/plate
Recombination assay - yeast	42256353	Negative for crossing-over in yeast up to 10,000 g
Chromosomal aberration - *in vivo*	42256344	Negative for chromosome breakage up to 2,000 μg/mL
Chromosomal aberration - *in vitro*	42256345	Positive at 500 μg/mL -S9 and 1,300 μg/mL +S9, both toxic doses
Sister Chromatid assay - *in vivo*	42256346	Negative up to 2,000 μg/mL
Cytogenetics -CHO cells - *in vitro*	42256342	Negative for inducing forward mutation in CHO (mammalian) cells treated up to 1,222 μg/mL
Micronucleus - mouse	42256366	Negative up to (toxic) 50 mg/kg (ip)
DNA repair test	42256353	Negative for crossing-over in yeast up to 10,000 g
HGPRT assay - CHO	42256365	Negative up to 2,000 μg/mL

8. *Dermal absorption*. No dermal absorption studies are available. However, this is not a concern since occupational and residential risk assessments are not required for dermal exposure due to the lack of dermal or systemic toxicity (following single or repeated dermal application of imidacloprid to laboratory animals).

9. *Neurotoxicity*. 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% methyl cellulose 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 bwt/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 mg/kg bwt/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 bwt/day (25% decrease) and 307 mg/kg bwt/day (73%) and in females at all dose levels with the decreases (25, 48, and 81%, respectively at 42, 151, and 307 mg/kg bwt/day) reaching statistical significance ($p < 0.05$) at 151 and 307 mg/kg bwt/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 LOEL was 42 mg/kg based on the decrease in motor and locomotor activities observed in females; a NOAEL was not established (MRID No. 41317031 and 43285801).

10. *Other-toxicological considerations*. EPA is requiring a developmental neurotoxicity study (Guideline No. 83-6) for imidacloprid. The following information was considered in the weight-of-evidence evaluation:

i. Imidacloprid is a neurotoxic chemical. Evidence of functional neurotoxicity was seen in the acute neurotoxicity study where a single oral dose caused a dose-related decrease in motor activity in all dosed females, including a 25% decrease at the lowest dose tested (42 mg/kg bwt/day).

ii. Imidacloprid is a nicotine analog and is expected to act as a nicotinic agonist.

iii. With this class of chemical, there is no readily available biomarker (e.g., cholinesterase inhibition) for assessment of subtle neurotoxic effects.

iv. In the 1993 2-year chronic study in rats, significant alterations of brain weight were noted in males and females at 900 ppm (51.3 and 73 mg/kg bwt/day in males and females, respectively).

v. There has been no assessment of the delayed neurotoxicity study in the hen.

vi. A review of the literature suggests that nicotine causes developmental toxicity, including functional deficits, in animals and/or humans exposed *in utero*.

11. *Metabolism*. The metabolism of NTN 33893 (imidacloprid) in rats was reported in seven studies (85-1), and found to be Core Minimum. They are:

i. Methylene-[^{14}C] Imidacloprid: Metabolism Part of the General

Metabolism Study in the Rat (MRID No. 42256354).

ii. [^{14}C]-NTN 33893: Biokinetic Part of the General Metabolism Study in the Rat (MRID No. 42256356).

iii. [Imidazolidine-4,5-^{14}C] Imidacloprid: Investigation of the Biokinetic Behavior and Metabolism in the Rat (MRID No. 42256357).

iv. Imidacloprid - WAK 3839: Comparison of the Biokinetic Behavior and Metabolism in the Rat Following Single Oral Dosage and Investigation of the Metabolism after Chronic Feeding of Imidacloprid to Rats and Mice (MRID No. 42256373).

v. A Liquid Chromatographic Method for the Determination of NTN 33893 in Aqueous Dose Mixtures (MRID No. 42256359).

vi. A Liquid Chromatographic Method for the Determination of NTN 33893 in Inhalation Chamber Atmospheres (MRID No. 42256358).

vii. [^{14}C]-NTN 33893: Investigations on the Distribution of Total Radioactivity in the Rat by Whole-Body Autoradiography (MRID No. 42256355).

These data show that imidacloprid was rapidly absorbed and eliminated in the excreta (90% of the dose within 24 hours), demonstrating no biologically significant differences between sexes, dose levels, or route of administration. Elimination was mainly renal (70-80% of the dose) and fecal (17-25%). The major part of the fecal activity originated in the bile. Total body accumulation after 48 hours consisted of 0.5% of the radioactivity with the liver, kidney, lung, skin and plasma being the major sites of accumulation. Therefore, bioaccumulation of imidacloprid is low in rats. Maximum plasma concentration was reached between 1.1 and 2.5 hours. Two major routes of biotransformation were proposed for imidacloprid. The first route included an oxidative cleavage of the parent compound rendering 6-chloronicotinic acid and its glycine conjugate. Dechlorination of this metabolite formed the 6-hydroxynicotinic acid and its mercapturic acid derivative. The second route included the hydroxylation followed by elimination of water of the parent compound rendering NTN 35884. A comparison between [methylene-^{14}C]-imidacloprid and [imidazolidine-4,5-^{14}C]-imidacloprid showed that while the rate of excretion was similar, the renal portion was higher with the imidazolidine-labeled compound. In addition, accumulation in tissues was generally higher with the imidazolidine-labeled compound.

A comparison between imidacloprid and one of its metabolites, WAK 3839, showed that the total elimination was the same for both compounds. The proposed metabolic pathways for these two compounds were different. WAK 3839 was formed following pretreatment (repeated dosing) of imidacloprid.

B. Toxicological Endpoints

1. *Acute toxicity*. The endpoint selected for acute dietary risk assessment is based on neurotoxicity characterized by decreases in motor or locomotor activity in female rats at 42 mg/kg bwt/day (LOEL) in an acute neurotoxicity study (MRID No. 41370301 and 43285801). A NOAEL was not established in this study.

Although developmental toxicity studies showed no increases in sensitivity in fetuses as compared to maternal animals following *in utero* exposures in rats and rabbits, and no increased sensitivity in pups as compared to adults and offspring in the two generation reproductive toxicity study in rats, and the toxicology data base is complete with respect to core requirements, the Agency determined that an acceptable acute dietary exposure (food plus water) of 33.3% or less of the acute reference dose (RfD) for all population subgroups is required based on the following weight-of-the-evidence considerations:

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.

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 Agency determined that the 3x factor used for FQPA (as discussed under section II.E. of this unit), is adequate to cover the use of the LOEL as well because of the low confidence in the endpoint based on the minimal nature of the effect (decreased motor activity only in females), the fact that this effect was seen in adult rats, and because the same effect was not seen in the subchronic toxicity study following repeated doses.

2. *Short - and intermediate-term toxicity*. No dermal or systemic toxicity was seen in a 21–day dermal toxicity study in rabbits following repeated dermal applications of imidacloprid at 1,000 mg/kg bwt/day (limit-dose) for 3 weeks. In addition, an inhalation endpoint has not been established for imidacloprid. In a 28–day rat inhalation study in which rats were exposed 6 hours/day, 5 days/week, the NOAEL was 5.5 mg/m^3. Imidacloprid also has a relatively low vapor pressure (6.9 x 10^{-9} torr). Since available data show no potential for dermal or inhalation toxicity from short- and intermediate-term exposure to imidacloprid, a risk assessment is not required.

3. *Chronic toxicity*. EPA has established the RfD for imidacloprid at 0.057 mg/kg/day. This RfD is based on the results of a combined chronic toxicity/ carcinogenicity study, in which 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 bwt/day in males and 0, 7.6, 24.9, or 73 mg/kg bwt/day in females, respectively) for 104 weeks. For chronic toxicity, the NOAEL was 100 ppm (5.7 mg/kg bwt/day in males and 7.6 mg/kg bwt/day in females) and the LOEL was 300 ppm (16.9 mg/kg bwt/day in males and 24.9 mg/kg bwt/day in females) based on decreased body weight gains in females and increased thyroid lesions in males. Organ weight changes were observed in both sexes of rats at a dose of 900 ppm. There was no evidence of carcinogenicity in either sex. Dose/endpoint for establishing the RfD: NOAEL = 5.7 mg/kg bwt/day based on decreased body weight gains in females and increased number of thyroid lesions in males at 16.9 mg/kg bwt/day (LOEL). This is the endpoint selected for chronic dietary risk assessment.

Uncertainty Factor (UF): 10x for inter-species variation plus 10x for intra-species variation

Chronic RfD: The RfD is calculated as follows: Chronic RfD = NOAEL UF = 5.7 mg/kg bwt/day 100 = 0.057 mg/kg bwt/day

The Agency determined that the additional uncertainty factor (UF) for FQPA (reduced to 3x as discussed under Units II.B.1. and II.E. of this preamble) applies to all population subgroups and also applies to both acute and chronic risk. Application of the additional 3x safety factor for enhanced susceptibility of infants and children to the Chronic RfD results in an acceptable chronic dietary exposure (food plus water) of 33.3% or less of the Chronic RfD for all population subgroups.

4. *Carcinogenicity*. Imidacloprid has been classified as a Group E chemical,

no evidence of carcinogenicity in humans. A cancer risk assesment is not required.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.472) for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety in or on a variety of raw agricultural commodities and meat at 0.3 ppm, milk 0.1 ppm, poultry 0.05 ppm, and egg 0.02 ppm. 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. As previously stated, the endpoint selected for assessment of acute dietary risk is 42 mg/kg bwt/day (LOEL). The UFs are 10x for inter-, 10x for intra-species variations and 3x for FQPA. Application of the 3X safety factor for enhanced susceptibility of infants and children to the acute RfD results in an acceptable acute dietary exposure (food plus water) of 33.3% or less of the acute RfD for all population subgroups. An acute dietary risk assessment is required for all population subgroups.

This acute dietary (food) risk assessment used the Theoretical Maximum Residue Contribution (TMRC) which assumes tolerance level residues and 100% crop-treated. The DRES System was used for this acute dietary exposure analysis. The analysis evaluates individual food consumption as reported by respondents in the USDA 1977-78 Nationwide Food Consumption Survey (NFCS) and accumulates exposure to the chemical for each commodity. Resulting exposure values and percent of the acute RfD utilized are shown below.

Acute Dietary (Food Only) Exposure and Risk for Imidacloprid		
Population Subgroup	Exposure @ 99th Percentile (mg/kg bwt/day)	Percent Acute RfD
U.S. Population (48 states)	0.050	12%
Infants (< 1 yr)	0.10	24%
Children (1-6 yrs)	0.10	24%
Females (13+ yrs)	0.040	9.5%
Males (13+ yrs)	0.050	12%

Values for the 99th percentile are considered to be conservative as EPA policy dictates exposure estimates from as low as the 95th percentile may be utilized for risk estimates from acute DRES runs not using Monte Carlo Analysis. Thus, 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 of acute dietary exposure.

ii. *Chronic exposure and risk.* The chronic dietary exposure analysis from food sources was conducted using the reference dose (Chronic RfD) of 0.057 mg/kg bwt/day. The FQPA Safety Factor for enhanced sensitivity of infants and children was reduced to 3x. The FQPA factor was applied in the risk assessment for all population subgroups. Application of the 3x safety factor for enhanced susceptibility of infants and children to the Chronic RfD results in an acceptable chronic dietary exposure (food plus water) of 33.3% or less of the Chronic RfD for all population subgroups.

A tolerance is established for residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent, in or on canola seed at 0.05 ppm. Canola seed per se is not a human food item. Canola seed is processed into canola oil which is consumed by humans. Because canola is not listed as a commodity in DRES, EPA has estimated the dietary exposure from imidacloprid treated canola seed in the following manner: Consumption (g/kg/day) x Residue (mg/kg) = Exposure (mg/kg bwt/day)

The consumption value for canola was taken as the U.S. production volume (877 million lbs or 3.98×10^{11} g) divided by the U.S. population in the 1977-1978 USDA Food Consumption Survey (240 million) to get grams of canola consumed per year. Further division was done to estimate consumption per day for an average person (body weight 58.9 kg) to get consumption per person per day. Tolerance level residues and 100% crop treated were assumed. The estimated exposure resulting from the established imidacloprid tolerance on canola (0.05 ppm) is 3.86×10^{-6} mg/kg bwt/day. This exposure represents <1.0% of the RfD. EPA concludes the dietary exposure from the imidacloprid tolerance on canola is not significant.

This approach to estimating the exposure due to consumption of imidacloprid treated canola results in a conservative exposure assessment. EPA notes that the consumption of corn oil by the general US population in the 1977-1978 USDA Food Consumption Survey was only 0.022 g/kg bwt/day. The consumption estimate for canola is approximately 3.5 times this value.

In conducting this chronic dietary (food) risk assessment, EPA used: (1) tolerance level residues for the proposed tolerances of these petitions and all other commodities with published, pending, permanent or time-limited, imidacloprid tolerances; and (2) percent crop-treated information on some of these crops. Thus, this risk assessment should be viewed as partially refined. Further refinement using anticipated residue values and additional percent crop treated information would result in a lower estimate of chronic dietary exposure. The DRES System was used for this chronic dietary exposure analysis. The analysis evaluates individual food consumption as reported by respondents in the USDA 1977-1978 Nationwide Food Consumption Survey (NFCS) and accumulates exposure to the chemical for each commodity.

The RACs (Raw Agricultural Commodities) and tolerances, used in the dietary risk assessment, were derived from 40 CFR 180.472 and EPA's Tolerance Index System.

The following table summarizes the estimated dietary exposures for the U.S. population, those population subgroups that include infants and children, and

all population subgroups with risk estimates above that of the U.S. Population.

Chronic Dietary Exposure (Food Only) and Risk for Imidacloprid		
Subgroup	Exposure (mg/kg bwt/day)	Percent Chronic RfD
U.S. Population (48 States)	0.0039	6.8%
Nursing Infants (< 1 year old)	0.0032	5.6%
Non-nursing Infants (<1 year old)	0.011	19%
Children (1 to 6 years old)	0.0081	14%
Children (7 to 12 years old)	0.0057	10%
U.S. Population - Fall Season	0.0040	7.0%
U.S. Population Winter Season	0.0040	7.0%
Northeast Region	0.0040	7.0%
Western Region	0.0041	7.2%
Hispanics	0.0043	7.5%
Non-Hispanic Others	0.0042	7.4%

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 to show what percentage of the food derived from such crop is likely to contain such pesticide residue; (2) that the exposure estimate does not underestimate exposure for any significant subpopulation group; and (3) if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate 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 finding (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 findings (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.* There are no Maximum Contaminant Levels (MCL) or Health Advisory (HA) levels established for residues of imidacloprid in drinking water. This information was furnished by the EPA Safe Drinking Water Hotline (1-800-426-4791) on June 16, 1998.

Information in EPA's Pesticide Environmental Fate One Line Summary data base (last update May 6, 1997) suggests that imidacloprid is persistent and mobile.

EPA's ''Pesticides in Ground Water Database'' (EPA 734-12-92-001, 9/92) has no entry for imidacloprid.

i. *Acute exposure and risk*—a. *Acute exposure.* Estimated maximum concentrations of imidacloprid in surface and ground water are 50.9 and 0.605 ppb, respectively.

EPA used PRZM1 (Pesticide Root Zone Model - simulates the transport of a pesticide off the agricultural field) and EXAMS (Exposure Analysis Modeling System - simulates fate and transport of a pesticide in surface water) models to estimate concentrations of imidacloprid residues in surface water. It should be noted that PRZM1/EXAMS models were designed for use in ecological risk assessment. They are not ideal tools for use in drinking water risk assessment. PRZM1/EXAMS could overestimate actual drinking water concentrations. Thus, these models should be considered a screening tool.

EPA used the SCI-GROW (Screening Concentration In Ground Water) model to estimate the concentration of imidacloprid residues in ground water. SCI-GROW is a prototype model for estimating ''worst case'' ground water concentrations of pesticides. SCI-GROW is biased in that studies where the pesticide is not detected in ground water are not included in the data set. Thus, it is not expected that SCI-GROW estimates would be exceeded.

b. *Acute risk.* EPA has calculated drinking water levels of concern (DWLOC's) for acute exposure to imidacloprid in surface and ground

water for various population subgroups. The DWLOC's for acute exposure to imidacloprid are summarized below.

Drinking Water Levels of Concern for Acute Exposure to Imidacloprid					
Population Subgroup	Dietary Exposure[1] (mg/kg bwt/day)	Max. Exposure from Water (mg/kg bwt/day)	Bodyweight (kg)	Daily Water Consumption (Liters)	DWLOC (μg/L)
U.S. Population (48 States)	0.050	0.090	70	2	3,200
Females (13+ years)	0.040	0.10	60	2	3,000
Children (1 - 6 years)	0.010	0.13	10	1	1,300

[1]99th percentile

To calculate the DWLOC relative to an acute toxicity endpoint, the acute dietary food exposure (from DRES) was subtracted from one-third the Acute RfD to obtain the acceptable acute exposure to imidacloprid in drinking water. The value of one-third the Acute RfD was utilized to account for the FQPA Safety Factor of 3x. DWLOCs were then calculated using default body weights and drinking water consumption figures.

ii. *Short-term exposure and risk*—a. *Short-term exposure*. Estimated maximum concentrations of imidacloprid in surface and ground water are 50.9 and 0.605 μg/mL, respectively. EPA utilized PRZM1 and EXAMS to generate these estimates. Descriptions of these models are above.

b. *Short-term risk*. EPA has calculated a drinking water level of concern (DWLOC) for short-term exposure to imidacloprid in surface and ground water for the population subgroup children, 1 to 6 years old. This DWLOC is for short-term exposure to imidacloprid from home garden and turf uses. A DWLOC for short-term exposure from imidacloprid pet uses was not determined as the exposure level from the home garden and turf uses is higher than that of the pet uses. Thus, the DWLOC for the imidacloprid pet uses will be higher than that of the home garden and turf uses. The DWLOC for short-term exposure to imidacloprid is summarized below.

Drinking Water Levels of Concern for Short-Term Exposure to Imidacloprid					
Population Subgroup	Total Exposure[1] (mg/kg bwt/day)	Max. Exposure from Water (mg/kg bwt/day)	Bodyweight (kg)	Daily Water Consumption (Liters)	DWLOC (μg/L)
Children (1 - 6 years)	0.080	0.060	10	1	600

[1]Total Exposure = sum of exposures from chronic food plus home turf and garden uses.

The DWLOC for short-term exposure to imidacloprid was calculated relative to the acute RfD which was utilized for estimating risk for short-term oral exposure to imidacloprid. To calculate the DWLOC for short-term exposure relative to an acute toxicity endpoint, the sum of chronic dietary food exposure (from DRES) plus the oral exposure from imidacloprid home garden and turf uses was subtracted from one-third the Acute RfD to obtain the acceptable short-term exposure to imidacloprid in drinking water. The value of one-third the Acute RfD was utilized to account for the FQPA Safety Factor of 3x. DWLOCs were then calculated using default body weights and drinking water consumption figures.

iii. *Chronic exposure and risk*—a. *Chronic exposure*. The estimated average concentration of imidacloprid in surface water (for chronic exposure) is 19.1 μg/mL. An estimated average concentration of imidacloprid in ground water was not provided. EPA used PRZM1 and EXAMS models to estimate chronic environmental concentrations of imidacloprid residues in surface water.

b. *Chronic risk*. EPA has calculated DWLOCs for chronic (non-cancer) exposure to imidacloprid in surface and ground water for various population subgroups. The DWLOC's for chronic exposure to imidacloprid are summarized below.

Drinking Water Levels of Concern for Chronic Exposure to Imidacloprid					
Population Subgroup	Dietary Exposure (mg/kg bwt/day)	Max. Exposure from Water (mg/kg bwt/day)	Bodyweight (kg)	Daily Water Consumption (Liters)	DWLOC (μg/L)
U.S. Population (48 States)	0.0039	0.015	70	2	530
Females (13+ yrs., pregnant)	0.0036	0.015	60	2	460

Drinking Water Levels of Concern for Chronic Exposure to Imidacloprid					
Population Subgroup	Dietary Exposure (mg/kg bwt/day)	Max. Exposure from Water (mg/kg bwt/day)	Bodyweight (kg)	Daily Water Consumption (Liters)	DWLOC (μg/L)
Non-nursing Infants	0.011	0.0080	10	1	80

To calculate the DWLOC for chronic (non-cancer) exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from DRES) was subtracted from one-third the chronic RfD to obtain the acceptable chronic (non-cancer) exposure to imidacloprid in drinking water. The value of one-third of the RfD was utilized to account for the FQPA Safety Factor of 3x. DWLOCs were then calculated using default body weights and drinking water consumption figures.

A DWLOC for chronic (cancer) exposure was not calculated as imidacloprid has been classified as a Group E chemical (no evidence of carcinogenicity).

3. *From 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, household or domestic dwellings (indoor/outdoor), and cats/dogs. Available data do not demonstrate that imidacloprid has either dermal or inhalation toxicity potential, therefore, non-dietary dermal and inhalation exposure assessments are not required. Since available 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. However, there is the potential for residential exposure via incidental non-dietary ingestion from treated lawns and gardens and incidental non-dietary ingestion by toddlers of pesticide residues on pets from hand-to-mouth transfer. Therefore, an increase in aggregate risk is anticipated from residential exposure via incidental non-dietary ingestion and residential exposure and risk assessments are required for the use of imidacloprid in/on lawns and gardens and on pets.

The product Premise, a termiticide, is also registered for residential use. It may be applied only by Pest Control Operators (PCOs) and only to inaccessible areas of homes or other buildings; therefore, oral exposure to children is not expected. There is potential for inhalation exposure; however, an inhalation endpoint has not been established and imidacloprid has a low vapor pressure (6.9×10^{-9} torr). Since oral exposure to children is not expected and the Agency feels there is no contribution to toxicity from the inhalation route of exposure, no increase in aggregate risk is anticipated and a residential exposure assessment based upon the imidacloprid termiticide use is not required.

i. *Exposure and risk from incidental non-dietary ingestion from treated lawns and gardens.* A summary of post-application exposure estimates and risk assessments are summarized in the table below. The post-application exposure scenarios for toddlers examined include:

- Incidental non-dietary ingestion of residues on lawns from hand-to-mouth transfer.
- Ingestion of pesticide-treated turfgrass.
- Incidental ingestion of soil from treated gardens.

The calculations and assumptions utilized to determine these exposures are as per the Draft Standard Operating Procedures for Residential Exposure Assessments (December 18, 1997).

Post Application Exposure Estimates and Risk Assessments								
Scenario	Receptor	AR[a] (lb ai/A)	DFRt[b] (μg/cm^2)	GRt[c] (μg/cm^2)	SRt[d] (μg/g)	ADD[e] (mg/kg bwt/day)	NOAEL (mg/kg/day)	MOE[f]
Hand-to-mouth for treated lawns	Toddler	0.4	0.9	—	—	0.07	42	640
Turf-grass	Toddler	0.4	—	0.9	—	0.0015	42	28,000
Incidental Soil Ingestion	Toddler	0.4	—	—	3	0.000020	42	2,100,000

[a]AR,Application Rate
[b]DFRt, Dislodgeable foliar residue (μg/cm^2)
[c]GRt, Grass residue (μg/cm^2)
[d]SRt, Soil residue (μg/g)
[e]ADD, Average daily dose (mg/kg bwt/day) .
[f]MOE = NOAEL/ ADD (No NOAEL established, LOEL of 42 mg/kg bwt/day used)

ii. *Exposure and risk to toddlers from incidental non-dietary ingestion of pesticide residues on pets from hand-to-mouth transfer.* Advantage 110 Flea Adulticide (EPA Reg. No. 011556-121) is a 5.0 mL vial that is applied to two locations on the dog (2.5 mL per 1 in 2). The method for assessing hand-to-mouth transfer in the Draft Standard Operating Procedures for Residential Exposure Assessments (December 18, 1997) is intended for a complete body dip of the treated animal. Therefore, a modified approach was applied to estimate oral exposures. Assumptions and calculations used are as follows:

Assumptions:

- On the day of application it may be assumed that 20% (0.20) of the application rate is retained on the pets as dislodgeable residue. This value is

based on the professional judgement and experience of the EPA staff from the review of company-submitted data and is believed to be an upper-percentile assumption.

- It is assumed that 1% (0.01) of the available residues are transferred to the individuals who have contact with the treated animals. This is considered to be a conservative assumption in light of the very low percentage of the pet's total skin surface being treated. It should be noted that 10% (0.10) is recommended for complete pet dips in the Draft Standard Operating Procedures for Residential Exposure Assessments (December 18, 1997). This is the only deviation from the standard operating procedures.
- It was assumed that 100% of the residue on the hands of toddlers is ingested. This is considered to be a conservative assumption.
- Post application activities assessed on the same day that the pesticide is applied since it is assumed that toddlers could handle/touch pets immediately after application. This is considered a short-term oral exposure.
- Toddlers (age 3 years), used to represent the 1 to 6 year old age group, are assumed to weigh 15 kg.
- 5.0 mL of product was used per application (EPA Reg. No. 011556-121). Product contains 9.1% ai. Density of formulation is not given on label. Density of water was assumed for converting volume in mL to lb active ingredient (ai).
- This product represents high-end exposure among similar products containing imidacloprid given that it involves the highest volume of the active ingredient.

Calculations:

The average daily dose (ADD = 0.058 mg/kg bwt/day) was calculated by multiplying the following: application rate (AR = 436 mg ai/day) x fraction of ai available on pet (F = 0.2) x fraction of residue transferred to the skin (T = 0.01), and dividing by bwt (15 kg).

A margin of exposure (MOE) of 720 was calculated by dividing the NOAEL (42 mg/kg bwt/day) by the ADD (0.058 mg/kg). (NOAEL was not established, therefore acute dietary LOEL of 42 mg/kg bwt/day was used).

The estimated MOE is 720 which is greater than the minimum required MOE of 300. Therefore, exposure via incidental non-dietary ingestion of imidacloprid residues on pets from hand-to-mouth transfer would not exceed EPA's level of concern. However, it should be noted that the 20% used for the fraction of active ingredient available on pet (F) and the 1% used for the fraction of residue transferred to the skin (T) are estimates made by EPA given a lack of available data. The actual values may differ. It is recommended that the registrant submit a study to quantify dislodgeable residues on toddler's hands from pets treated with these types of products.

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.''

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. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the Final Rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Acute risk*—i. *Food*. The acute dietary (food) risk assessment used the TMRC. Resulting exposure values and percent of the acute RfD utilized are shown below.

Acute Dietary (Food Only) Exposure and Risk for Imidacloprid		
Population Subgroup	Exposure @ 99th Percentile (mg/kg bwt/day)	Percent Acute RfD
U.S. Population (48 states)	0.050	12%
Infants (< 1 yr)	0.10	24%
Children (1-6 yrs)	0.10	24%
Females (13+ yrs)	0.040	9.5%
Males (13+ yrs)	0.050	12%

For imidacloprid, it was determined that an acceptable acute dietary exposure (food plus water) of 33.3% or less of the acute RfD for all population subgroups is needed to protect the safety of all population subgroups. The estimated exposures for all population subgroups at the 99th percentile utilize less than 33.3% of the acute RfD.

ii. *Water*. The estimated maximum concentrations of imidacloprid in surface and ground water (50.9 and 0.605 µg/mL, respectively) are less than EPA's levels of concern for imidacloprid in drinking water (1,300, 3,000 and 3,200 µg/mL) as a contribution to acute exposure. Therefore, taking into account the present uses and uses proposed in this action, EPA concludes with reasonable certainty that residues of imidacloprid in drinking water (when considered along with other sources of acute exposure for which EPA has reliable data) would not result in unacceptable levels of acute aggregate human health risk estimates at this time.

EPA bases this determination on a comparison of estimated maximum concentrations of imidacloprid in surface water to back-calculated ''levels of concern'' for imidacloprid in drinking water. These levels of concern in drinking water were determined after EPA has considered all other non-occupational/non-residential human exposures for which it has reliable data, including all current uses, and uses considered in this action. The estimates of imidacloprid in surface water are

derived from water quality models that use conservative assumptions (health-protective) regarding the pesticide transport from the point of application to surface and ground water. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of concern in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of imidacloprid in drinking water as a part of the acute aggregate risk assessment process.

Despite the potential for imidacloprid exposure from drinking water, EPA concludes that there is a reasonable certainty that no harm will result to infants, children, or adults from acute aggregate exposure to imidacloprid residues.

2. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water exposure (considered to be a background exposure level) plus indoor and outdoor residential exposure. Since dermal and inhalation exposure endpoints (short-term) were not identified due to the demonstrated absence of toxicity, no increase in aggregate risk is anticipated from dermal and inhalation exposure. Therefore, dermal and inhalation short-term risk assessments are not required for imidacloprid.

In addition to its food uses, imidacloprid is registered for use on turf, home gardens and pets. EPA has identified potential short-term oral exposures to toddlers for these uses. These exposures include the following scenarios:

- Incidental non-dietary ingestion of residues on lawns from hand-to-mouth transfer.
- Ingestion of pesticide-treated turfgrass.
- Incidental ingestion of soil from treated gardens.
- Incidental ingestion of pesticide residues on pets from hand-to-mouth transfer.

According to current EPA policy, these exposures are considered to be short-term oral exposures. EPA does not expect incidental ingestion of pesticide residues on pets from hand-to-mouth transfer to occur during the same period as the exposures from the turf and home garden uses. Thus, we will consider these exposures in separate estimates of risk. The tables below summarize the short-term aggregate exposures for imidacloprid from turf and garden uses and from the pet use.

A short-term oral endpoint was not identified for imidacloprid. According to current EPA policy, if an oral endpoint is needed for short-term risk assessment (for incorporation of food, water, or oral hand-to-mouth type exposures into an aggregate risk assessment), the acute oral endpoint (acute RfD = 0.42 mg/kg bwt/day) will be used to incorporate the oral component into aggregate risk. Short-term aggregate exposure is defined by EPA to be average food and water exposure (chronic exposure) plus residential exposure. The short-term risk estimates for the population subgroup Children, 1 to 6 years old, is summarized below. This population subgroup was chosen because it has the highest chronic food exposure and because toddlers have the highest exposure from the residential uses.

Short-Term Aggregate Exposure and Risk (Includes Turf and Garden Uses of Imidacloprid)				
Population Subgroup	Chronic Food Exposure (mg/kg bwt/day)	Residential Exposure[1] (mg/kg bwt/day)	Total Exposure[2] (mg/kg bwt/day)	Percent Acute RfD[3]
Children (1 to 6 years old)	0.0081	0.072	0.080	19%

[1]Residential Exposure = Total of imidacloprid exposure from incidental ingestion of residues on lawns from hand-to-mouth transfer plus ingestion of pesticide-treated grass plus ingestion of soil from treated gardens.
[2]Total Exposure = Chronic Food Exposure plus Residential Exposure.
[3]Percent Acute RfD = Acute RfD (0.42 mg/kg bwt/day)/Total Exposure (mg/kg bwt/day) x 100%.

Short-Term Aggregate Exposure and Risk (Includes the Pet Use of Imidacloprid)				
Population Subgroup	Chronic Food Exposure (mg/kg bwt/day)	Residential Exposure[1] (mg/kg bwt/day)	Total Exposure[2] (mg/kg bwt/day)	Percent Acute RfD[3]
Children (1 to 6 years old)	0.0081	0.058	0.066	16%

[1]Residential Exposure = Total of imidacloprid exposure from incidental ingestion of residues on pets from hand-to-mouth transfer.
[2]Total Exposure = Chronic Food Exposure plus Residential Exposure.
[3]Percent Acute RfD = Acute RfD (0.42 mg/kg bwt/day)/Total Exposure (mg/kg bwt/day) x 100%.

The estimated maximum concentrations of imidacloprid in surface and ground water (50.9 and 0.605 µg/mL, respectively) are less than EPA's level of concern for imidacloprid in drinking water (600 g/mL) as a contribution to short-term exposure from imidacloprid home garden, turf and pet uses. Therefore, taking into account the present uses and uses proposed in this action, EPA concludes with reasonable certainty that residues of imidacloprid in drinking water (when considered along with other sources of short-term exposure for which EPA has reliable data) would not result in unacceptable levels of short-term aggregate human health risk estimates at this time.

EPA bases this determination on a comparison of estimated maximum concentrations of imidacloprid in surface water to the back-calculated ''level of concern'' for imidacloprid in drinking water. The level of concern in drinking water was determined after EPA has considered all other non-occupational human exposures for which it has reliable data, including all current uses and uses considered in this action. The estimates of imidacloprid in surface and ground water are derived from water quality models that use conservative assumptions (health-protective) regarding the pesticide transport from the point of application to surface and ground water. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of concern in drinking water may vary as those uses change. If new

uses are added in the future, EPA will reassess the potential impacts of imidacloprid in drinking water as a part of the a short-term aggregate risk assessment process.

As noted above, potential short-term exposure from drinking water is at a level well below EPA's level of concern. EPA concludes the short-term aggregate risk to the highest exposed population subgroup from home garden, turf, and pet uses of imidacloprid does not exceed our level of concern.

3. *Chronic risk*. The chronic dietary (food only) risk assessment utilized the following exposure assumptions: (i) tolerance level residues for the proposed tolerances of these petitions and all other commodities with published or pending, permanent or time-limited, imidacloprid tolerances; and (ii) percent crop-treated information on some of these crops. Using the exposure assumptions described above, EPA has concluded that aggregate exposure to imidacloprid from food will utilize 6.8% of the Chronic RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is infants (discussed below in section E). EPA 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. Despite the potential for exposure to imidacloprid in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *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.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population from aggregate exposure to imidacloprid residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*—i. *In general*. 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 discussed under section A. of this unit. 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 did not identify any increased sensitivity of rats to *in utero* or post-natal exposure. Parental NOAELs were lower or equivalent to developmental or offspring NOAELs. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during 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 data base 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 2-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:

a. 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*.

b. 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.

c. 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, EPA has applied the additional UF for FQPA for all population subgroups, and in both acute and chronic risk assessments.

ii. *Conclusion*. The toxicology data base for imidacloprid is complete with respect to core requirements; however, a developmental neurotoxicity study (Guideline No. 83-6) is required. Exposure data is estimated based on data that reasonably accounts for potential exposures; however, a study to quantify dislodgeable residues on toddler's hands from pets treated with imidacloprid is required.

2. *Acute risk*. Aggregate acute risks for the entire U.S. population and for population subgroups, including infants and children, are discussed in section D.1. of this unit.

3. *Short- and intermediate-term risk*. Aggregate short- and intermediate-term risks for the entire U.S. population and for population subgroups, including infants and children are discussed in section D.2. of this unit.

4. *Chronic risk*. Using the exposure assumptions described above, EPA has concluded that aggregate exposure to imidacloprid from food will utilize 5.6% of the RfD for nursing infants, 19% of the RfD for non-nursing infants, 14% of the RfD for children 1 to 6 years old, and 10% of the RfD for children 7 to 12 years old. EPA 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. Despite the potential for exposure to imidacloprid in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to imidacloprid residues.

III. Other Considerations

A. Metabolism in Plants and Animals

1. *Nature of the residue in plants and livestock*. Data concerning the metabolism of imidacloprid in apples, potatoes, tomatoes, eggplant,

cottonseed, field corn, ruminants and poultry have previously been submitted. 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 (September 14, 1994, PP 4F4337 and September 23, 1997, PP 6F4765).

2. *Confined accumulation in rotational crops*. Data concerning the metabolism of imidacloprid in rotational crops was previously submitted. The nature of the residue in rotational crops is adequately understood and is nearly identical to that identified in the primary crops. The residue of concern in rotational crops is imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent (September 23, 1997, PP 6F4765).

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 PAM II (November 8, 1994 and April 13, 1995, PP 5F4415, June 17, 1996, PP 5F4480). In the interim, these methods are available from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703–305–5229).

Bayer Corporation has previously submitted adequate multiresidue method (MRM) recovery data for imidacloprid and its olefin, hydroxy, guanidine, and 6-chloronicotininc acid metabolites through FDA's Protocols A through E. Imidacloprid and its metabolites were not recoverable by these methods. These data have been forwarded to FDA and we expect them to be published in PAM, Vol. I, Appendix I in a future update. Additional MRM recovery data are not required (June 18, 1993, PP 3F4169).

C. Magnitude of Residues

1. *Crop field trials*. The results of the previously submitted wheat, barley, and sugar beet field trials support the proposed tolerances for combined residues of imidacloprid and its regulable metabolites as follows (March 6, 1998, PP 4F4337):

Crop	Commodity	Proposed Tolerance (ppm)
Beets, Sugar	tops roots molasses	0.5 0.05 0.3
Barley	grain straw hay	0.05 0.5 0.5
Wheat	grain forage straw hay	0.05 7.0 0.5 0.5

Residue data for aspirated grain fractions were not required for this seed treatment use (September 14, 1994, PP 4F4337).

2. *Field accumulation in rotational crops*. The results of the previously submitted rotational crop field trials support the proposed tolerances for inadvertent or indirect combined residues of imidacloprid and its regulable metabolites as follows (September 23, 1997, PP 6F4765):

Crop Group or Crop	Commodity	Tolerance Level (ppm)
Cereal Grains (Crop Group)	grain	0.05
Forage, Fodder and Straw of Cereal Grains Crop Group	forage straw hay stover	2.0 3.0 6.0 0.3
Sweet Corn	K+CWHR	0.05
Safflower	seed meal	0.05 0.5
Legume Vegetables (Crop Group)	seed	0.3
Foliage of Legume Vegetables (Crop Group)	foliage	2.5
Soybean	meal	0.5

K+CWHR = Kernel plus cob with husk removed.

3. *Magnitude of the residue in processed food/feed*—i. *Wheat*. The results of a previously submitted wheat processing study showed that residues of imidacloprid and its metabolites are not expected to concentrate into the processed products of wheat. The study utilized a 5x exaggerated application rate (September 14, 1994 and May 16, 1995, PP 4F4337).

ii. *Sugar beets*. The results of a previously submitted sugar beet processing study (2.7x exaggerated application rate) showed that residues of imidacloprid and its metabolites are not expected to concentrate into dehydrated pulp. However, the results did show residues are expected to concentrate into sugar beet molasses. A tolerance of 0.3 ppm is adequate for residues of imidacloprid and its metabolites in sugar beet molasses (September 14, 1994 and May 16, 1995, PP 4F4337).

iii. *Barley*. Processing data for barley were not required for this seed treatment use (September 14, 1994, PP 4F4337).

iv. *Field corn*. The results of a previously submitted field corn processing study showed that residues of imidacloprid and its metabolites are not expected to concentrate into the processed products of field corn. The study utilized exaggerated application rates of 2.5x and 4x (February 19, 1998, PP 6F4765).

v. *Safflower*. A safflower processing study has not been submitted. The petitioner has indicated that they intend to conduct a safflower processing study. This deficiency is not resolved. A safflower processing study for imidacloprid is required. EPA recommends in favor of the proposed tolerances for imidacloprid and its metabolites in/on safflower seed and meal provided the requirement for a safflower processing study is made a condition of the registration of imidacloprid on safflower. The proposed tolerances are based upon a maximum residue level of <0.05 ppm (estimated to be approximately 0.03 ppm) for total imidacloprid residues in safflower seed and a theoretical maximum concentration factor of 9.1x for safflower meal (September 23, 1997 and February 19, 1998, PP 6F4765).

vi. *Soybeans*. A soybean processing study has not been submitted. The petitioner has proposed establishing a permanent tolerance for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety in soybean meal at 0.5 ppm in lieu of providing a soybean processing study. This request is based upon a maximum residue level of 0.2 ppm for total imidacloprid residues in soybean seed and a theoretical maximum concentration factor of 2.2x for soybean meal. EPA has considered this issue and has concluded that the requirement for a soybean processing study should be made a condition of the registration of imidacloprid on soybeans. Thus, a soybean processing study is required. The proposed tolerances for imidacloprid and its metabolites for soybean seed and meal are adequate pending submission of the soybean processing study (February 19, 1998, PP 6F4765).

4. *Magnitude of secondary residues in meat, milk, poultry eggs*—i. *Ruminants*. A ruminant feeding study was previously submitted. EPA has estimated the maximum imidacloprid dietary burden from proposed and established imidacloprid tolerances. The total dietary burden from our worst case diet for dairy cattle is approximately 20 ppm. The total dietary burden from our worst case diet for beef cattle is approximately 12 ppm. Tolerances are established for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid, in ruminant fat, meat, and meat byproducts at 0.3 ppm and in milk at 0.1 ppm. EPA concludes the established tolerances for imidacloprid and its metabolites in ruminant commodities will not be exceeded as a result of additional dietary burden from the tolerances proposed in these petitions (September 21, 1993, PP 3F4169 and March 6, 1998, PP 4F4337).

ii. *Poultry*. A poultry feeding study was previously submitted. EPA has estimated the maximum imidacloprid dietary burden for poultry from proposed and established imidacloprid tolerances. The total dietary burden from our worst case diet for poultry is approximately 2.2 ppm. Tolerances are established for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid, in poultry fat, meat and meat byproducts at 0.05 ppm and in eggs at 0.02 ppm. EPA concludes the established tolerances for imidacloprid and its metabolites in poultry commodities will not be exceeded as a result of additional dietary burden from the tolerances proposed in these petitions (September 21, 1993, PP 3F4169 and March 6, 1997, PP 4F4337).

D. International Residue Limits

There are no established CODEX, Canadian, or Mexican residue limits for imidacloprid in/on the crop groups cereal grains, legume vegetables and the foliage of legume vegetables; and the crops sweet corn, safflower, wheat, barley and sugar beets. Thus, harmonization of the proposed tolerances with CODEX, Canada, and Mexico is not an issue for these petitions.

IV. Conclusion

Therefore, the tolerances are established for the combined residues of imidacloprid (1-[(6-chloro-3-pyridinyl) methyl]-N-nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, all expressed as (1-[(6-chloro-3-pyridinyl) methyl]-N-nitro-2-imidazolidinimine) in or on sugar beets -tops at 0.5, roots at 0.05, molasses at 0.3 parts per million (ppm), barley - grain at 0.05, straw at 0.5, hay at 0.5 ppm, wheat - grain at 0.05, forage at 7.0, straw at 0.5, hay at 0.5 ppm (40 CFR 180.472(a)); and cereal grains crop group - grain at 0.05, forage at 2.0, straw at 3.0, hay at 6.0, stover at 0.3 ppm, sweet corn (K+CWHR) at 0.05, safflower - seed at 0.05, meal at 0.5, legume vegetable crop group seed at 0.3, foliage at 2.5, soybean meal at 0.5 ppm (inadvertent or indirect residues, 40 CFR 180.472(d)).

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 November 17, 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. 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 Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the 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 Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number OPP–300717 (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 Rm. 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 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

A. Certain Acts and Executive Orders

This final rule establishes tolerances for imidacloprid 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 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 tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances for imidacloprid 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.

B. Executive Order 12875

Under Executive Order 12875, entitled ''Enhancing Intergovernmental Partnerships'' (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or Tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local and Tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and Tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local or Tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled ''Consultation and Coordination with Indian Tribal Governments'' (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the Tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected Tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that

significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

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: September 9, 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.

§ 180.472 [Amended]

2. Section 180.472 is amended by adding the commoditiy wheat (hay) to the table in paragraph (a) and revising the following entries to paragraphs (a) and (d) to read as follows:

(a) * * *

Commodity	Parts per million	Expiration/ Revocation date
* *	* *	*
Barley (grain)	0.05	None
Barley (hay)	0.5	None
Barley (straw)	0.5	None
* *	* *	*
Beets, sugar (tops)	0.5	None
Beets, sugar (roots)	0.05	None
Beets, sugar, molasses	0.3	None
* *	* *	*
Wheat (forage) ..	7.0	None
Wheat (grain)	0.05	None
Wheat (hay)	0.5	None
Wheat (straw)	0.5	None

* * * * *

(d) * * *

Commodity	Parts per million	Expiration/ Revocation date
Cereal grains crop group (grain)	0.05	None
Foliage of legume vegetables crop group (foliage)	2.5	None
Forage, fodder, and straw of cereal grains crop group (forage)	2.0	None
Forage, fodder, and straw of cereal grains crop group (hay)	6.0	None
Forage, fodder, and straw of cereal grains crop group (stover)	0.3	None
Forage, fodder, and straw of cereal grains crop group (straw)	3.0	None
Legume vegetables crop group (seed) ..	0.3	None
Safflower (meal)	0.5	None
Safflower (seed)	0.05	None
Soybean (meal)	0.5	None
Sweet corn (kernel plus cob with husk removed)	0.05	None
* *	* *	*

FR Doc. 98–25085 Filed 9–17–98; 8:45 am

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–6161–5]

Georgia: Final Authorization of State Hazardous Waste Management Program Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Immediate final rule.

SUMMARY: Georgia has applied for final authorization of revisions to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). Georgia's revisions consist of the provisions contained in the rules promulgated between July 1, 1995 and June 30, 1996, RCRA Cluster VI and requirements promulgated August 26, 1996 and February 19, 1997. These requirements are listed in section B of this document. The Environmental Protection Agency (EPA) has reviewed Georgia's application and has made a decision, subject to public review and comment, that Georgia's hazardous waste program revisions satisfy all of the requirements necessary to qualify for final authorization. Thus, EPA intends to approve Georgia's hazardous waste program revisions. Georgia's application for program revisions is available for public review and comment.

DATES: Final authorization for Georgia shall be effective without further notice, November 17, 1998 if EPA receives no adverse comment on this document by October 19, 1998. Should EPA receive such comments EPA will withdraw this rule before its effective date by publishing a notice of withdrawal in the **Federal Register**. Any comments on Georgia's program revision application must be filed by October 19, 1998.

ADDRESSES: Send comments to: Patricia Herbert, Chief, RCRA Programs Branch, Waste Management Division, EPA, 61 Forsyth Street, Atlanta, Georgia 30303. Copies of Georgia's program revision application and the materials which EPA used in evaluating the revision are available for inspection and copying during regular office hours of 9 a.m. to 5 p.m., Monday through Friday, at the following addresses:

Georgia Department of Natural Resources, Environmental Protection Division, Floyd Towers East, Room 1154, 205 Butler Street, SE, Atlanta, Georgia 30334

U.S. EPA Region 4, Library, 61 Forsyth Street, Atlanta, Georgia 30303