compliance costs on Indian tribal governments.

Takings Implication Assessment (Executive Order 12630)

According to Executive Order 12630, the rule does not have significant Takings Implications. A Takings Implication Assessment is not required. The rulemaking is not a governmental action capable of interfering with constitutionally protected property rights.

Civil Justice Reform (Executive Order 12988)

According to Executive Order 12988, the Office of the Solicitor has determined that this rule does not unduly burden the judicial system and does meet the requirements of sections 3(a) and 3(b)(2) of the Order.

National Environmental Policy Act

The final rulemaking does not introduce requirements that would cause lessees or operators to perform or change any activities on the OCS which would result in environmental impacts beyond those addressed in the National Environmental Policy Act documents associated with the OCS plans.

Unfunded Mandates Reform Act (UMRA) of 1995 (Executive Order 12866)

This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The rule does not have any Federal mandates, nor does the rule have a significant or unique effect on State, local, or tribal governments or the private sector. A statement containing the information required by the UMRA (2 U.S.C. 1531 *et seq.*) is not required.

List of Subjects in 30 CFR Part 250

Continental shelf, Environmental impact statements, Environmental protection, Government contracts, Investigations, Mineral royalties, Oil and gas development and production, Oil and gas exploration, Oil and gas reserves, Penalties, Pipelines, Public lands—mineral resources. Public lands—rights-of-way, Reporting and recordkeeping requirements, Sulphur development and production, Sulphur exploration, Surety bonds.

Dated: October 20, 2003.

Rebecca W. Watson,

Assistant Secretary—Land and Minerals Management.

■ For the reasons stated in the preamble, MMS amends 30 CFR Part 250 as follows:

PART 250—OIL AND GAS AND SULPHUR OPERATIONS IN THE OUTER CONTINENTAL SHELF

■ 1. Authority citation for Part 250 continues to read as follows:

Authority: 43 U.S.C. 1334.

■ 2. Section 250.1403 is revised to read as follows:

§ 250.1403 What is the maximum civil penalty?

The maximum civil penalty is $30,000 per day per violation.

[FR Doc. 03–27280 Filed 10–28–03; 8:45 am]

BILLING CODE 4310–MR–P

POSTAL SERVICE

39 CFR Part 111

Price of Semipostal Stamp

AGENCY: Postal Service.

ACTION: Final rule; correction.

SUMMARY: The effective date for the pricing and issuance of *Stop Family Violence* Semipostal Stamp published in the **Federal Register** on August 18, 2003 (Vol. 68, No. 159, pages 49362–49363) is changed from October 11, 2003 to October 8, 2003.

DATES: This notice is effective October 29, 2003.

SUPPLEMENTARY INFORMATION: On October 8, 2003, President George Bush announced the nationwide sale of the *Stop Family Violence* Semipostal Stamp at a White House ceremony recognizing October as Domestic Violence Awareness Month.

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 03–27185 Filed 10–28–03; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0327; FRL–7330–4]

Imidacloprid; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance 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 parent in or on soybean seed. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide as a seed treatment on soybean seed. This regulation establishes a maximum permissible level for residues of imidacloprid in this food commodity. The tolerance will expire and is revoked on December 31, 2006.

DATES: This regulation is effective October 29, 2003. Objections and requests for hearings, identified by docket (ID) number OPP–2003–0327, must be received on or before December 29, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; e-mail address: *Sec-18-Mailbox@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are a Federal or State government agency involved in administration of environmental quality programs (e.g., Departments of Agriculture, Environment). Potentially affected entities may include, but are not limited to:

- Federal or State Government Entity (NAICS 9241).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action

under docket (ID) number OPP–2003–0327. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/ Title_40/40cfr180_00.html*, a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408 (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance 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 parent in or on soybean seed at 1.0 parts per million (ppm). This tolerance will expire and is revoked on December 31, 2006. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 of the FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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) of the FFDCA 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) of the FFDCA 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. . . .''

Section 18 of the FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Imidacloprid on Soybean Seed and FFDCA Tolerances

The States of Iowa and Wisconsin requested the use of imidacloprid as a seed treatement on soybean seed to control the bean leaf beetle, a vector of bean pod mottle virus. Due to abnormal weather pattens, the incidence of bean pod mottle virus was expected to be highter than normal in 2003. EPA has authorized under FIFRA section 18 the use of imidacloprid on soybean seed for control of bean leaf beetle in Iowa and Wisconsin. After having reviewed the submissions, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of imidacloprid in or on soybean seed. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although this tolerance will expire and is revoked on December 31, 2006, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on soybean seed after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether imidacloprid meets EPA's registration requirements for use on soybean seed or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of imidacloprid by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Iowa and Wisconsin to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for imidacloprid, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

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 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances November 26, 1997 (62 FR 62961) (FRL–5754–7).

Consistent with section 408(b)(2)(D) of the FFDCA, 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) of the FFDCA, for a time-limited tolerance for combined residues of imidacloprid in or on soybean seed at 1.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for imidacloprid used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR IMIDACLOPRID FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (all populations including infants and children)	NOAEL = not determined LOAEL = 42 milligrams/kilogram/day (mg/kg/day) UF = 300 Acute RfD = 0.14 mg/kg/day	FQPA SF = 1 aPAD = acute RfD FQPA SF = 0.14 mg/kg/day	Acute neurotoxicity - rats LOAEL = 42 mg/kg/day based on decreased motor activity in female rats
Chronic dietary (all populations)	NOAEL = 5.7 mg/kg/day UF = 100 Chronic RfD = 0.057 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD FQPA SF = 0.057 mg/kg/day	Combined chronic toxic/carcinogenicity - rat LOAEL = 16.9 mg/kg/day, based upon increased incidence of mineralized particles in thyroid colloid in males
Short-term oral (1–30 days)	Oral study NOAEL = 10 mg/kg/day	LOC for MOE = 100 (residential, includes the FQPA SF)	Developmental toxicity - rat Maternal LOAEL = 30 mg/kg/day, based upon decreased body weight gain and corrected body weight gain
Intermediate-term oral (1–6 months)	Oral study NOAEL = 9.3 mg/kg/day	LOC for MOE = 100 (residential, includes the FQPA SF)	Subchronic neurotoxicity - rat LOAEL = 63.3 mg/kg/day, based upon decreased body weight gain
Short-term dermal (1–30 days)	Oral study NOAEL = 10 mg/kg/day (dermal absorption rate = (7.2%)	LOC for MOE = 100 (occupational) LOC for MOE = 100 (residential, includes the FQPA SF)	Developmental toxicity - rat Maternal LOAEL = 30 mg/kg/day, based upon decreased body weight gain and corrected body weight gain

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR IMIDACLOPRID FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Intermediate-term dermal (1–6 months)	Oral study NOAEL = 9.3 mg/kg/day (dermal absorption rate = 7.2%)	LOC for MOE = 100 (occupational) LOC for MOE = 100 (residential, includes the FQPA SF)	Subchronic neurotoxicity - rat LOAEL = 63.3 mg/kg/day, based upon decreased body weight gain
Long-term dermal (6 months)	Oral study NOAEL = 5.7 mg/kg/day (dermal absorption rate = 7.2%)	LOC for MOE = 100 (occupational) LOC for MOE = 100 (residential, includes the FQPA SF)	Combined chronic toxic/carcinogenicity - rat LOAEL = 16.9 mg/kg/day, based upon increased incidence of mineralized particles in thyroid colloid in males
Short-term inhalation (1–30 days)	Oral study NOAEL = 10 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (occupational) LOC for MOE = 100 (residential, includes the FQPA SF)	Developmental toxicity - rat Maternal LOAEL = 30 mg/kg/day, based upon decreased body weight gain and corrected body weight gain
Intermediate-term inhalation (1–6 months)	Oral study NOAEL = 9.3 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (occupational) LOC for MOE = 100 (residential, includes the FQPA SF)	Subchronic neurotoxicity - rat LOAEL = 63.3 mg/kg/day, based upon decreased body weight gain
Long-term inhalation (> 6 months)	Oral study NOAEL = 5.7 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (occupational) LOC for MOE = 100 (residential, includes the FQPA SF)	Combined chronic toxic/carcinogenicity - rat LOAEL = 16.9 mg/kg/day, based upon increased incidence of mineralized particles in thyroid colloid in males
Cancer (oral, dermal, inhalation)	No evidence of carcinogenicity for humans	Not applicable	No evidence of carcinogenicity in rats and mice

* The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

In its objections to a separate imidacloprid tolerance action, NRDC claims that EPA erred by regulating on the basis of a LOAEL for acute and chronic toxicity. As can be seen from the above table, NRDC is mistaken with regard to use of a LOAEL for estimating the RfD for chronic risk. The acute toxicity endpoint was based upon a LOAEL of 42 mg/kg/day from an acute neurotoxicity study in rats. This value was adjusted with a safety factor of 3X to approximate the value of a NOAEL. EPA has high confidence that this value of 3X is sufficient for several reasons. The effect seen at the LOAEL in the acute neurotoxicity study (decreased motor activity), occurred only in one sex of the rat (females), was characterized as minimal, and may have been a result of the use of the gavage dosing in the study. The decreased motor activity was not replicated following repeated dietary administration (non-gavage) at lower and higher doses (10, 70 or 200 mg/kg/day) in the subchronic neurotoxicity study in the same species (rats). Further, using a safety factor of 3X produces a regulatory endpoint lower than the acute effect levels in other standard studies for determining an acute endpoint, developmental toxicity studies in two species, and in another study that is on occasion used for such a purpose, the developmental neurotoxicity study in rats. Also in these objections, NRDC claims that EPA failed to calculate residential risks for some scenarios, based on low toxicity (no endpoints were chosen). On October 8, 2002, the Health Effects Division (HED), Hazard Identification Assessment Review Committee (HIARC) reviewed the hazard data base for imidacloprid and established additional endpoints. Endpoints were chosen for each of the following exposure scenarios: Acute dietary, chronic dietary, short-term oral, intermediate-term oral, short-term dermal, intermediate-term dermal, long-term dermal, short-term inhalation, intermediate-term inhalation, and long-term inhalation. In the current risk assessment (Unit II.E. of this document), EPA calculated short-term residential risks (oral, dermal, and inhalation) for both adults and children for a wide-range of representative scenarios, including applications to lawns, ornamental plantings, indoor and outdoor potted plants, and dogs and cats. Based on current residential use patterns for imidacloprid, EPA expects the duration of exposure to be short-term (1–30 days), and would not result in intermediate-term or long-term exposure. EPA also conducted human health aggregate risk assessments for the following exposure scenarios: Acute aggregate (food + drinking water), short-term aggregate exposure (food + drinking water + residential), and chronic aggregate exposure (food + drinking water).

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.472) for the combined residues of imidacloprid, in or on a variety of raw agricultural commodities. Meat, milk, poultry, and egg tolerances have also been established for the combined residues of imidacloprid. In conducting dietary exposure assessments, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM™-FCID) which

incorporates food consumption data as reported by respondents in the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The 1994–96 and 1998 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Consumption data are averaged for the entire U.S. population and within population subgroups for chronic exposure assessment, but are retained as individual consumption events for acute exposure assessment. Risk assessments were conducted by EPA to assess dietary exposures from imidacloprid in food as follows:

i. *Acute exposure*. 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 1 day or single exposure. DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996/1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: A Tier 1, deterministic acute dietary exposure assessment was conducted using tolerance-level residues, 100 PCT information for registered and proposed commodities; and modified DEEM™ (vision 7.76) processing factors for some commodities based on guideline processing studies. EPA estimated exposure based on the 95th percentile value from this deterministic exposure assessment.

In its objections to a separate imidacloprid tolerance action, NRDC asserts that EPA erred by relying on the exposure value for the 95th percentile of the population in estimating exposure. NRDC claims that this approach leaves 5% of the population unprotected. These comments by NRDC represent a misunderstanding of EPA's exposure assessments. Although EPA estimated exposure using the 95th percentile, EPA most definitely was not, however, acting in a manner designed to protect only 95% of the population. To the contrary, EPA's exposure estimates were designed to reasonably capture the full range of exposures in each population subgroup. As explained in its science policy paper on this subject, EPA, in estimating exposure for population subgroups, generally considers various population percentiles of exposure between 95 and 99.99, depending on the extent of overestimation in the residue data used in the assessment. In each exposure assessment EPA is attempting to reasonably estimate the full range of exposures in a subgroup. Accordingly, as EPA noted in its policy paper, just as when EPA uses the 95th percentile with non-probabilistic exposure assessments EPA is not suggesting that EPA is leaving 5% of the population unprotected, EPA is not by choosing the 99.9th percentile for probabilistic exposure assessments concluding that only 99.9% of the population deserves protection. Rather, it is EPA's view that, with probabilistic assessments, the use of the 99.9th percentile generally produces a reasonable high-end exposure such that if that exposure does not exceed the safe level, EPA can conclude there is a reasonable certainty of no harm to the general population and all significant population groups. (Office of Pesticide Programs, EPA, Choosing a Percentile of Acute Dietary Exposure as a Threshold of Regulatory Concern 31 (March 22, 2000)). Importantly, EPA generally uses a population percentile of 95 when EPA relies on worst-case residue values - i.e., all crops covered by the tolerance contain residues at the tolerance value. Even at the 95th percentile of estimated exposure, actual exposure, when based on this assumption tends to be significantly overstated. For example, EPA has found that when it uses realistic residue information (e.g., data from monitoring of the food supply), that exposure estimates are generally substantially lower even at the 99.99th percentile.

As noted above, EPA did use the worst-case assumption that all food covered by imidacloprid tolerances would bear residues at the tolerance level. Hence, EPA believes its exposure estimate is unlikely to understate exposure; rather, in all likelihood, the estimate probably substantially overstates exposure.

ii. *Chronic exposure*. The following assumptions were made for the chronic exposure assessments: The chronic dietary exposure assessment was performed using published and proposed tolerance levels, DEEM™ default processing factors, and percent crop treated (PCT) information on some commodities.

iii. *Cancer*. A quantitative cancer aggregate risk assessment was not performed because imidacloprid is not carcinogenic.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(F) of the FFDCA 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: Condition 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; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 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 PCT as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows: For the acute assessment, 100 PCT was assumed for all registered and proposed commodities. For the chronic assessment, average weighted PCT information was used for the following commodities: Apple 34%; Brussels sprouts 56%; broccoli 35%; cabbage 14%; cantaloupe 31%; cauliflower 52%; collards 10%; corn, field 1%; cotton 3%; cucumber 2%; eggplant 36%; grapefruit 3%; grape 32%; mustard greens 16%; honeydew 26%; kale 30%; lemon 1%; lettuce, head 49%; lime 5%; orange 1%; pear 16%; pepper 62%; pumpkin 7%; spinach 15%; squash 7%; sugarbeet 1%; tangerine 9%; tomato 9%; watermelon 6%; wheat 1%. A default value of 1% was used for all commodities which were reported as having >1% CT.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to

underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 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 the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which imidacloprid may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for imidacloprid in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of imidacloprid.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will generally use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a percent reference dose (%RfD) or percent population adjusted dose (%PAD). Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to imidacloprid, they are further discussed in the aggregate risk sections below.

Analysis of monitoring data for degradates (ground water only) shows that imidacloprid parent is the dominant residue with imidacloprid urea the most likely degradate. Based on the available information, modeling of total residue results in only modest increases over the exposure estimates with parent alone. Based on the FIRST and SCI-GROW models the estimated environmental concentrations (EECs) of imidacloprid (total residue) for acute exposures are estimated to be 36.04 parts per billion (ppb) for surface water and 2.09 ppb for ground water. The EECs for imidacloprid (parent only) for acute exposures are estimated to be 35.89 ppb for surface water and 1.43 ppb for ground water. The EECs for imidacloprid (total residue) for chronic exposures are estimated to be 17.24 ppb for surface water and 2.09 ppb for ground water. The EECs for imidacloprid (parent only) for chronic exposures are estimated to be 16.52 ppb for surface water and 1.43 ppb for ground water.

The New York State Department of Environmental Conservation, Division of Solid and Hazardous Materials has submitted extensive water monitoring information from Nassau and Suffolk Counties of New York. Nassau and Suffolk counties have ground water that is exceptionally vulnerable to pesticide contamination and have a long history of a number of pesticides being banned from use in these counties over the years. In general, the kinds of concentrations of imidacloprid (parent only) found in the monitoring/observation and private drinking water wells are in the range expected in highly vulnerable ground water. Imidacloprid has been detected in approximately 20 (including some clusters of wells in the same immediate area) out of about 2,000 public and private water supply and monitoring wells. Imidacloprid was detected in 24 of the approximately 3,500 well samples analyzed for imidacloprid in Nassau and Suffolk Counties. Although detection of imidacloprid in about 20 of 2,000 wells in an area with highly vulnerable ground water does not demonstrate particularly widespread ground water contamination, 3 of 2,000 wells in this highly vulnerable ground water have at least one detection greater than the SCI-GROW for imidacloprid (parent only) at 1.43 ppb. The three samples that exceed the SCI-GROW ECs are reported at 2.06 ppb, 5.98 ppb, and 6.69 ppb. Since the surface water model screening levels are greater than the ground water model screening levels and the detection levels reported from the water monitoring from Nassau and Suffolk Counties, New York, the Agency will use the surface water ECs for imidacloprid total residue as a worse case estimate for drinking water in the aggregate risk assessment.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Imidacloprid is currently registered for use on the following residential non-dietary sites: Granular products for application to lawns and ornamental plants; ready-to-use spray for application to flowers, shrubs and house plants; plant spikes for application to indoor and outdoor residential potted plants; ready-to-use potting medium for indoor and outdoor plant containers; liquid concentrate for application to lawns, trees, shrubs and flowers; ready-to-use liquid for directed spot application to cats and dogs. In addition, there are numerous registered products intended for use by commercial applicators to residential sites. These include gel baits for cockroach control; products intended for commercial ornamental, lawn and turf pest control; products for ant control; and products used as preservatives for wood products, building materials, textiles and plastics.

As these products are intended for use by commercial applicators only, they are not addressed in terms of residential pesticide handlers. The risk assessment was conducted using the following residential exposure assumptions: EPA has determined that residential handlers

are likely to be exposed to imidacloprid residues via dermal and inhalation routes during handling, mixing, loading, and applying activities. Based on the current use patterns, EPA expects duration of exposure to be short-term (1–30 days). EPA does not expect imidacloprid to result in exposure durations that would result in intermediate-term or long-term exposure.

The scenarios likely to result in adult dermal and/or inhalation residential handler exposures are as follows:

- Dermal and inhalation exposure from using a granular push-type spreader.
- Dermal exposure from using potted plant spikes.
- Dermal exposure from using a plant potting medium.
- Dermal and inhalation exposure from using a garden hose-end sprayer (dermal and inhalation exposure from using a RTU trigger pump spray is expected to be negligible).
- Dermal and inhalation exposure from using a water can/bucket for soil drench applications.
- Dermal exposure from using pet spot-on.

EPA has also determined that there is potential for short-term (1 to 30 days), post-application exposure to adults and children/toddlers from the many residential uses of imidacloprid. Due to residential application practices and the half-lives observed in the turf transferable residue study, intermediate-term and long-term post-application exposures are not expected. The scenarios likely to result in dermal (adult and child/toddler) and incidental non-dietary (child/toddler) short-term post-application exposures are as follows:

- Toddler oral hand-to-mouth exposure from contacting treated turf.
- Toddler incidental oral ingestion of granules.
- Toddler incidental oral ingestion of pesticide-treated soil.
- Toddler incidental oral exposure from contacting treated pet.
- Toddler dermal exposure from contacting treated turf.
- Toddler dermal exposure from hugging treated pet/contacting treated pet.
- Adult dermal exposure from contacting treated turf.
- Adult golfer dermal exposure from contacting treated turf.
- Adolescent golfer dermal exposure from contacting treated turf.
- Adult dermal exposure from contacting treated pet

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCA 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

C. Safety Factor for Infants and Children

1. *In general.* Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure 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 margin of explosure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* There is no quantitative or qualitative evidence of increased susceptibility of rat and rabbit fetuses to *in utero* exposure in developmental studies. There is no quantitative or qualitative evidence of increased susceptibility of rat offspring in the multi-generation reproduction study. There is evidence of increased qualitative susceptibility in the rat developmental neurotoxicity study, but the concern is low since:

- The effects in pups are well-characterized with a clear NOAEL.
- The pup effects occur in the presence of maternal toxicity with the same NOAEL for effects in pups and dams.
- The doses and endpoints selected for regulatory purposes are protective of the pup effects noted at higher doses in the developmental neurotoxicity study.

Therefore, there are no residual uncertainties for prenatal/postnatal toxicity in this study.

3. *Conclusion.* There is a complete toxicity data base for imidacloprid and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X SF to protect infants and children should be reduced to 1X for the following reasons:

- The toxicological data base is complete for FQPA assessment.
- The acute dietary food exposure assessment utilizes existing and proposed tolerance level residues and 100 PCT information for all commodities. By using these screening-level assessments, actual exposures/risks will not be underestimated.
- The chronic dietary food exposure assessment utilizes existing and proposed tolerance level residues and PCT data verified by the Agency for several existing uses. For all proposed uses, 100 PCT is assumed. The chronic assessment is somewhat refined and based on reliable data and will not underestimate exposure/risk.

The dietary drinking water assessment utilizes water concentration values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be exceeded.

The residential handler assessment is based upon the residential standard operating procedures (SOPs) in conjunction with chemical-specific study data in some cases and the Pesticide Handlers Exposure Database (PHED) unit exposures in other cases. The majority of the residential post-application assessment is based upon chemical-specific turf transferrable residue data or other chemical-specific post-application exposure study data. The chemical-specific study data as well as the surrogate study data used are reliable and also are not expected to underestimate risk to adults as well as to children. In a few cases where chemical-specific data were not available, the SOPs were used alone. The residential SOPs are based upon reasonable worst-case assumptions and are not expected to underestimate risk.

These assessments of exposure are not likely to underestimate the resulting estimates of risk from exposure to imidacloprid.

In its objections to a separate imidacloprid tolerance action, NRDC argues that in light of the outstanding data requirement for prospective ground water monitoring studies, EPA should have retained a 10X FQPA factor for imidacloprid. EPA disagrees. Two small-scale prospective ground water monitoring studies were originally requested by the Agency in 1994. This request predates the development of the Tier 1 ground water screening model in 1997 and the FQPA. The field phase of these prospective ground water monitoring studies commenced in 1996. Results from these studies have now been received and the levels of imidacloprid observed (0.1 ppb) are below the screening concentration of 2.09 ppb calculated on the basis of the SCI-GROW, the Tier 1 ground water screening model. In any event, as noted above, since higher values are predicted for imidacloprid residues in surface water, these higher values were used in conducting the risk assessment.

D. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + chronic non-dietary, non-occupational exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to imidacloprid in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison 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 on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to imidacloprid will occupy 25% of the aPAD for the U.S. population, 17% of the aPAD for females 13 to 49 years, 54% of the aPAD for infants < 1 year old and 64% of the aPAD for children 1–2 years. In addition, despite the potential for acute dietary exposure to imidacloprid in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of imidacloprid in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO IMIDACLOPRID

Population Subgroup	aPAD (mg/kg)	%aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. population	0.14	25	36.04	2.09	3,700
Females (13–49 years)	0.14	17	36.04	2.09	3,500
Infants (< 1 year)	0.14	54	36.04	2.09	650
Children (1–2 years)	0.14	64	36.04	2.09	510

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to imidacloprid from food will utilize 11% of the cPAD for the U.S. population, 26% of the cPAD for infants < 1 year, and 35% of the cPAD for children 1–2 years. Based on the use pattern, chronic residential exposure to residues of imidacloprid is not expected. In addition, there is potential for chronic dietary exposure to imidacloprid in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO IMIDACLOPRID

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.057	11	17.24	2.09	1,800

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO IMIDACLOPRID—Continued

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
Infants (< 1 year)	0.057	26	17.24	2.09	420
Children (1–2 years)	0.057	35	17.24	2.09	370
Females (13–49 years)	0.057	8.3	17.24	20.9	1,600

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Short-term aggregate risk assessments are needed for adults as there is potential for both dermal and inhalation handler exposure, and dermal post-application exposure from the residential uses of imidacloprid on turf and pets. In addition, short-term aggregate risk assessments are needed for children/toddlers because there is a potential for oral and dermal, post-application exposure resulting from the residential uses of imidacloprid on turf and pets. The pet-treatment scenario resulted in the lowest combined MOE for adults (MOE = 400; handler and post-application) and children (MOE = 260; post-application). The turf-treatment resulted in much lower exposures for both adults (MOE = 15,000; handler and post-application) and children (MOE = 1,500; post-application). Therefore, the pet-treatment exposure estimates were aggregated with the chronic dietary (food) to provide a worst-case estimate of short-term aggregate risk for the U.S. population and children 1–2 years old (the child population subgroup with the highest estimated chronic dietary food exposure). Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 320 for the U.S. population, and 170 for children 1–2 years. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of imidacloprid in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO IMIDACLOPRID

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-term DWLOC (ppb) U.S. population
U.S. population	320	100	17.24	2.09	2,400
Children (1–2 years old)	170	100	17.24	2.09	410

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level).

Intermediate-term and long-term aggregate risk assessments were not performed because, based on the current use patterns, the Agency does not expect exposure durations that would result in intermediate-term or long-term exposures.

5. *Aggregate cancer risk for U.S. population*. There is no evidence of carcinogenicity to humans based on carcinogenicity studies in male and female rats and mice. The Agency concludes that pesticidal uses of imidacloprid are not likely to pose a cancer risk to humans.

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

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available for determination of imidacloprid residues of concern in plant (Bayer Gas Chromatography/Mass Spectrometry (GC/MS) Method 00200) and livestock commodities (Bayer GC/MS Method 00191). These methods have undergone successful EPA petition method validations (PMVs), and the registrant has fulfilled the remaining requirements for additional raw data, method validation, independent laboratory validation (ILV), and an acceptable confirmatory method (high performance liquid chromatography/ultraviolet (HPLC/UV) Method 00357).

Adequate enforcement methodology (example—gas chromotography) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no CODEX, Canadian, or Mexican Maximum Residue Limits (MRLs) for imidacloprid on soybean seed.

VI. Conclusion

Therefore, the tolerance is 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 parent, in or on soybean seed at 1.0 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may

file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0327 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before December 29, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by the docket ID number OPP–2003–0327, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a 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(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Statutory and Executive Order Reviews

This final rule establishes a time-limited tolerance under section 408 of the FFDCA. 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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under section 408 of the FFDCA, such as the tolerance 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final 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: October 17, 2003.

Peter Caulkins,

Acting 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. 321(q), 346(a) and 371.

■ 2. Section 180.472 is amended by adding the following commodity to the table in paragraph (b) to read as follows:

§ 180.472 Imidacloprid; tolerances for residues.

(a) * * *

(b) * * *

Commodity	Parts per million	Expiration/revocation date
* * * *	*	
Soybean, seed	1.0 ppm	12/31/06
* * * *	*	

[FR Doc. 03–26926 Filed 10–28–03; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Part 303

Standards for Program Operations

CFR Correction

In Title 45 of the Code of Federal Regulations, parts 200 to 499, revised as of Oct. 1, 2002, on page 260, § 303.108, paragraph (c), is corrected by removing the phrase ''Secretary of the U.S. Treasury'' and adding in its place the word ''first''.

[FR Doc. 03–55530 Filed 10–28–03; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 021209300–3048–02; I.D. 101003F]

Fisheries off West Coast States and in the Western Pacific;Pacific Coast Groundfish Fishery; Whiting Closure for the Catcher/Processor Sector

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Fishing restrictions; request for comments.