ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300758; FRL–6045–3]

RIN 2070–AB78

Imidacloprid; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent in or on field corn forage at 0.1 parts per million (ppm), field corn stover (fodder) at 0.2 ppm, and field corn grain at 0.05 ppm. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on field corn. This regulation establishes maximum permissible levels for residues of imidacloprid in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and are revoked on May 1, 2000.

DATES: This regulation is effective December 2, 1998. Objections and requests for hearings must be received by EPA on or before February 1, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300758], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300758], 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 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300758]. 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: Andrew Ertman, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9367, e-mail: ertman.andrew@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to sections 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for the combined residues of the insecticide imidacloprid, in or on field corn forage at 0.1 ppm, field corn stover (fodder) at 0.2 ppm, and field corn grain at 0.05 ppm. These tolerances will expire and are revoked on May 1, 2000. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq*., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq* . The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996)(FRL–5572–9).

New 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. . . .''

Section 18 of 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 FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

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.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Imidacloprid on Field Corn and FFDCA Tolerances

The states of Illinois and Iowa requested the use of imidacloprid on field corn to control the flea beetle because the flea beetle has been shown to be a vector of a bacteria that causes Stewart's Wilt in corn. Stewart's wilt can cause serious yield loss when infection occurs early in the growing

season. Also, many countries require seed fields to be inspected for Stewart's wilt infected plants, and will not allow seed from these fields to be sent to their country. The United States is a major producter of seed corn for the world. EPA has authorized under FIFRA section 18 the use of imidacloprid on field corn for control of corn flea beetles (a vector of Stewart's wilt) in Illinois and Iowa. After having reviewed the submission, EPA concurs that emergency conditions exist for these states.

As part of its assessment of these emergency exemptions, EPA assessed the potential risks presented by residues of imidacloprid in or on field corn. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) 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 under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on May 1, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on field corn 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 these tolerances are being approved under emergency conditions EPA has not made any decisions about whether imidacloprid meets EPA's registration requirements for use on field corn or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of imidacloprid by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any States other than Illinois and Iowa to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing 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 above.

III. 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 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) .

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 time-limited tolerances for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent on field corn forage at 0.1 ppm, field corn stover (fodder) at 0.2 ppm, and field corn grain at 0.05 ppm. 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*. Acute Reference dose (RfD): 0.42 milligrams per kilogram of bodyweight per day (mg/kg bwt/day). The endpoint selected for assessment of acute dietary risk is 42 mg/kg bwt/day (Lowest Observed Effect Level (LOEL)) from an acute neurotoxicity study in rats. A NOAEL was not established in this study. The uncertainty factors (UF) are 10X for inter-, 10X for intra-species variations, and 3X for FQPA.

2. *Short- and intermediate-term toxicity*. Dermal and inhalation short- and intermediate-term risk assessments are not required for imidacloprid as dermal and inhalation exposure endpoints were not identified due to the demonstrated absence of toxicity. A short-term aggregate risk assessment (oral exposure) is required for hand-to-mouth residential exposure. The Agency utilized the acute toxicological endpoint for this risk assessment. The acute dietary endpoint is based upon dose-related decreases in motor activity in female rats from an acute neurotoxicity study.

3. *Chronic toxicity*. EPA has established the RfD for imidacloprid at 0.057 milligrams/kilogram/day (mg/kg/day). This RfD is based on decreased body weight gains in female rats and increased number of thyroid lesions in male rats from a combined chronic toxicity/carcinogenicity study at 16.9 mg/kg bwt/day LOEL. The No Observed Adverse Effect Level (NOAEL) in this study was established at 5.7 mg/kg bwt/day. An uncertainty factor of 100 is required for all population subgroups (10X for inter-species variation and 10X for intra-species variation). For chronic dietary risk assessment, the Agency determined that the FQPA safety factor could be reduced to 3X and should be applied to all population subgroups.

4. *Carcinogenicity*. Imidacloprid has been classified by the Agency as a Group E chemical, no evidence of carcinogenicity for humans, thus, a cancer risk assessment is not required.

B. Exposures and Risks

1. *From food and feed uses*. Tolerances, some time-limited, are currently established (40 CFR 180.472) for the combined residues of the insecticide imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent, in or on a variety of raw agricultural and animal commodities at levels ranging from 0.02 ppm in eggs to 15 ppm in raisins, waste. 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 1–day or single exposure. Application of the 3X safety factor 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

This acute dietary (food) risk assessment used the Theoretical Maximum Residue Contribution (TMRC) which assumes tolerance level residues and 100% crop-treated. The Novigen DEEM (Dietary Exposure Evaluation Model) system was used for this acute dietary exposure analysis. The analysis evaluates individual food consumption as reported by respondents in the USDA Continuing

Surveys of Food Intake by Individuals conducted in 1989 through 1992. The model accumulates exposure to the chemical for each commodity and expresses risk as a function of dietary exposure. Resulting exposure values (at the 99th percentile) and percentage of the Acute RfD utilized are shown in the following Table 1.

TABLE 1.—ACUTE DIETARY (FOOD ONLY) EXPOSURE ANALYSIS BY DEEM FOR IMIDACLOPRID

Population Subgroup	Exposure @ 99th Percentile (mg/kg bwt/day)	Percent Acute RfD[1]
U.S. Population (48 states)	0.051	12
All infants (< 1 yr)	0.067	16
Nursing infants (< 1 yr)	0.096	23
Non-nursing infants (< 1 yr)	0.059	14
Children (1–6 yrs)	0.086	20
Children (7–12 yr)	0.058	14

[1] Percentage reference dose (% Acute RfD) = Exposure/Acute RfD X 100%

The subgroups listed above are: (1) the U.S. population (48 states) and (2) those for infants and children. There are no other subgroups for which the percentage of the Acute RfD occupied is greater than that occupied by the subgroup U.S. Population (48 states).

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. This RfD (RfD = NOAEL/UF) is based on the NOAEL of 5.7 mg/kg bwt/day in male rats from the chronic toxicity/carcinogenicity study in rats, and an uncertainty factor (UF) of 100. The FQPA Safety Factor for enhanced sensitivity of infants and children was reduced to 3X. For this risk assessment, the FQPA factor applies to all population subgroups. Application of the 3X safety factor 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.

In conducting this chronic dietary (food only) risk assessment, EPA used: (1) tolerance level residues for field corn and all other commodities with published, pending, permanent or time-limited, imidacloprid tolerances; and, (2) percent crop-treated (%CT) information for some of these crops. Thus, this risk assessment should be viewed as partially refined. Further refinement using anticipated residue values and additional %CT information would result in a lower estimate of chronic dietary exposure. The Novigen DEEM (Dietary Exposure Evaluation Model) system was used for this chronic dietary exposure analysis. The analysis evaluates individual food consumption as reported by respondents in the USDA Continuing Surveys of Food Intake by Individuals conducted in 1989 through 1992. The model accumulates exposure to the chemical for each commodity and expresses risk as a function of dietary exposure.

The existing imidacloprid tolerances (published, pending, and including the necessary section 18 tolerance(s)) result in a TMRC that is equivalent to the percentages of the Chronic RfD in the following Table 2:

TABLE 2.—CHRONIC EXPOSURE ANALYSIS BY THE DEEM SYSTEM FOR IMIDACLOPRID

Population Subgroup	Exposure (mg/kg/day)	Percent Reference Dose[1] (%Chronic RfD)
U.S. Population (48 States)	0.0032	5.6
All Infants (<1 year old)	0.0039	6.9
Nursing Infants (<1 year old)	0.0014	2.4
Non-Nursing Infants (<1 year old)	0.0050	8.7
Children (1–6 years old)	0.0074	13
Children (7–12 years old)	0.0046	8.2
U.S. Population (Autumn Season)	0.0032	5.7
Northeast Region	0.0032	5.7
Western Region	0.0033	5.7
Non-hispanic (Other Than Black or White)	0.0036	6.2

[1] Percentage reference dose (% Chronic RfD) = Exposure/Chronic RfD X 100%

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

2. *From drinking water.* There is no established Maximum Contaminant Level for residues of imidacloprid in drinking water. No health advisory levels for imidacloprid in drinking water have been established.

Imidacloprid is persistent, water soluble, and fairly mobile. Thus, residues of imidacloprid may be transported to both surface and ground waters. As a condition of registration, the Agency is requiring the submission of the results of two prospective ground water monitoring studies. Results from these studies are not yet available. EPA used estimates for the concentration of imidacloprid in surface and ground waters.

The Agency 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.

The Agency 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.

i. *Acute exposure and risk.* Estimated concentrations of imidacloprid in surface and ground water for acute exposure analysis are 4.1 and 1.1 grams per liter (parts per million) (µg/L parts per billion (ppb)), respectively. These estimated concentrations of imidacloprid in surface and ground water are based upon an application rate of 0.5 lbs active ingredient per acre per year (ai/A/year).

For purposes of risk assessment, the estimated maximum concentration for imidacloprid in surface and ground waters (which is 4.1 µg/L) should be used for comparison to the back-calculated human health drinking water levels of concern (DWLOCs) for the acute endpoint. These DWLOCs for various population categories are summarized in the following Table 3.

TABLE 3.—DRINKING WATER LEVELS OF CONCERN FOR ACUTE EXPOSURE TO IMIDACLOPRID[1]

Population Category[2]	Acute RfD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure[3] (mg/kg/day)	DWLOC[4, 5, 6] (µg/L)
U.S. Population (48 states) (male)	0.42	0.051	0.089	3100
U.S. Population (48 states) Females	0.42	0.051	0.089	2700
Nursing Infants (<1 year old)	0.42	0.096	0.044	440

[1] Values are expressed to two significant figures.
[2] Within each of these categories, the subgroup with the highest food exposure was selected.
[3] Maximum Water Exposure (Chronic or Acute) (mg/kg/day) = Chronic or Acute RfD (mg/kg/day)/3 (to account for FQPA factor of 3X) - Food Exposure (mg/kg/day).
[4] DWLOC(µg/L) = Max. water exposure (mg/kg/day) x body wt (kg)/(10^{-3} mg/µg) * water consumed daily (L/day).
[5] EPA Default body weights are: General U.S. Population, 70 kg; Males (13+ years old), 70 kg; Females (13+ years old), 60 kg; Other Adult Populations, 70 kg; and, All Infants/Children, 10 kg.
[6] EPA Default daily drinking rates are 2 L/day for adults and 1 L/day for children.

ii. *Short-term risk*. For purposes of risk assessment, the estimated maximum concentration for imidacloprid in surface and ground waters (which is 4.1 µg/L, see above) should be used for comparison to the back-calculated human health drinking water levels of concern (DWLOCs) for the short-term endpoint.

EPA has calculated a DWLOC for short-term exposure to imidacloprid in drinking 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 in the following Table 4.

TABLE 4.—DRINKING WATER LEVELS OF CONCERN FOR SHORT-TERM EXPOSURE TO IMIDACLOPRID[1]

Population Subgroup	Total Exposure[2] (mg/kg bwt/day)	Max. Exposure from Water[3] (mg/kg bwt/day)	Body-weight (kg)	Daily Water Consumption (Liters)	DWLOC[4, 5, 6] (µg/L)
Children (1–6 years)	0.080	0.060	10	1	600

[1] Values are expressed to two significant figures.
[2] Total Exposure = sum of exposures from chronic food plus home turf and garden uses.
[3] Maximum Water Exposure (Short-term) (mg/kg/day) = Acute RfD (mg/kg/day)/3 (to account for FQPA factor of 3X) - Total Exposure (mg/kg/day).
[4] DWLOC(µg/L) = Max. water exposure (mg/kg/day) x body wt (kg)/(10^{-3} mg/µg) * water consumed daily (L/day).
[5] EPA Default body weight is: All Infants/Children, 10 kg.
[6] EPA Default daily drinking rate is 1 L/day for children.

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 DEEM) 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*. Estimated concentrations of imidacloprid in surface and ground water for chronic exposure analysis are 0.1 and 1.1 µg/L (ppb), respectively. These estimated concentrations of imidacloprid in surface and ground water are based upon an application rate of 0.5 lbs ai/A/year.

For purposes of chronic risk assessment, the estimated maximum concentration for imidacloprid in surface and ground waters (which is 1.1 µg/L) should be used for comparison to the back-calculated human health drinking water levels of concern (DWLOCs) for the chronic (non-cancer) endpoint. These DWLOCs for various population categories are summarized in the following Table 5.

TABLE 5.—DRINKING WATER LEVELS OF CONCERN FOR CHRONIC EXPOSURE TO IMIDACLOPRID[1]

Population Category[2]	Chronic RfD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure[3] (mg/kg/day)	DWLOC[4, 5, 6] (μg/L)
U.S. Population (48 states) (male)	0.057	0.0032	0.0158	550
Females U.S. Population (48 states)	0.057	0.0032	0.0158	470
Children (1–6)	0.057	0.0074	0.0116	120
Non-hispanic other than black or white	0.057	0.0036	0.0154	540

[1] Values are expressed to two significant figures.
[2] Within each of these categories, the subgroup with the highest food exposure was selected.
[3] Maximum Water Exposure (Chronic or Acute) (mg/kg/day) = Chronic or Acute RfD (mg/kg/day)/3 (to account for FQPA factor of 3X) - Food Exposure (mg/kg/day).
[4] DWLOC(μg/L) = Max. water exposure (mg/kg/day) x body wt (kg)/(10^{-3} mg/μg) * water consumed daily (L/day).
[5] EPA Default body weights are: General U.S. Population, 70 kg; Males (13+ years old), 70 kg; Females (13+ years old), 60 kg; Other Adult Populations, 70 kg; and, All Infants/Children, 10 kg.
[6] EPA Default daily drinking rates are 2 L/day for adults and 1 L/day for children.
[7] Total Exposure for Short-term Exposure = sum of exposures from chronic food plus home turf and garden uses.

iv. *Conclusions concerning residues in drinking water (all time periods).* The estimated concentrations of imidacloprid in surface and ground water are less than the Agency's levels of concern for imidacloprid in drinking water as a contribution to acute, short-term and chronic aggregate exposure. Therefore, taking into account the present uses and uses proposed in this section 18, EPA concludes with reasonable certainty that residues of imidacloprid in drinking water (when considered along with other sources of acute, short-term and chronic exposure for which EPA has reliable data) would not result in an unacceptable estimate of acute, short-term and chronic aggregate human health risk at this time.

EPA bases this determination on a comparison of estimated 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 human exposures for which it has reliable data, including all current uses, and uses considered in these actions. The estimate of imidacloprid in surface water is 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, short-term and chronic aggregate risk assessment process.

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.

i. *Acute exposure and risk.* Occupational/residential exposure risk assessments (namely, short-term dermal, intermediate-term dermal, long-term dermal, and inhalation) are not required because of the demonstrated absence of dermal and inhalation toxicity.

ii. *Chronic exposure and risk.* Occupational/residential exposure risk assessments (namely, short-term dermal, intermediate-term dermal, long-term dermal, and inhalation) are not required because of the demonstrated absence of dermal and inhalation toxicity.

iii. *Short- and intermediate-term exposure and risk.* Oral exposure due to the registered residential uses of imidacloprid may result. Thus, a residential short-term risk assessment via the oral route is required. See Unit III(D)(4) of this preamble for a full discussion of this exposure and risk.

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 more 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).

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

1. *Acute risk.* Using the conservative TMRC exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, EPA has estimated the acute exposure to imidacloprid from food will utilize 12% of the Acute RfD for the most highly exposed population subgroup (U.S. population - all seasons). All other population subgroups which include adults have acute risk estimates (food only) below that of the population subgroup U.S. Population - all seasons. For imidacloprid, it was determined that an acceptable acute dietary exposure (food plus water) of 33.3% or less of the Acute RfD is needed to protect the safety of all population subgroups. The estimated exposures at the 99th percentile for all population subgroups that include adults utilize less than 33.3% of the Acute RfD.

Despite the potential for exposure to imidacloprid in drinking water, EPA does not expect the aggregate exposure to exceed 33.3% of the Acute RfD for adults. Under current Agency

guidelines, the registered non-dietary uses of imidacloprid do not constitute an acute exposure scenario. EPA concludes that there is a reasonable certainty that no harm will result to adults from acute aggregate exposure to imidacloprid residues.

2. *Chronic risk.* Using the partially refined exposure assumptions described in Unit III(B)(1)(ii) of this preamble, and taking into account the completeness and reliability of the toxicity data, the Agency has estimated the chronic exposure to imidacloprid from food will utilize 6.2% of the chronic RfD for the most highly exposed adult population subgroup, non-hispanic (other than black or white). All other population subgroups which include adults have chronic (non-cancer) risk estimates (food only) below that of the population subgroup non-hispanic (other than black or white). For imidacloprid, it was determined that an acceptable acute dietary exposure (food plus water) of 33.3% or less of the chronic RfD is needed to protect the safety of all population subgroups. The estimated exposures for all adult population subgroups utilize less than 33.3% of the chronic RfD.

Despite the potential for exposure to imidacloprid in drinking water, EPA does not expect the aggregate exposure to exceed 33.3% of the Chronic RfD. Under current Agency guidelines, the registered non-dietary uses of imidacloprid do not constitute a chronic exposure scenario. EPA concludes that there is a reasonable certainty that no harm will result to adults from chronic aggregate exposure to imidacloprid residues.

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

Dermal and inhalation short- and intermediate term risk assessments are not required for imidacloprid as dermal and inhalation exposure endpoints were not identified due to the demonstrated absence of toxicity. Short- and intermediate-term oral exposure are not expected for adult population subgroups. A discussion of short and intermediate term oral exposure and risk for children 1–6 years old can be found in Unit III.D.4 of this preamble.

4. *Aggregate cancer risk for U.S. population.* Imidacloprid has been classified as a Group E chemical, no evidence of carcinogenicity for humans, thus, 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 from aggregate exposure to imidacloprid residues.

D. 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 two-generation reproduction study in the rat. 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 margin of exposure (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 MOE and 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.

ii. *Developmental toxicity studies.* 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.

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.

iii. *Reproductive toxicity study.* In a two-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). 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 Agency determined that the review 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.

iv. *Pre- and post-natal sensitivity.* The developmental toxicity data demonstrated no increased sensitivity of rats or rabbits to *in utero* exposure to imidacloprid. In addition, the multi-generation reproductive toxicity study data did not identify any increased sensitivity of rats to *in utero* or postnatal exposure. Parental NOAELs were lower or equivalent to developmental or offspring NOAELs.

v. *Conclusion.* There is a need for a developmental neurotoxicity study for assessment of potential alterations of functional development. However, the Agency has determined that this data gap does not preclude the establishment/continuance of tolerances. The 10X safety factor to account for enhanced sensitivity of infants and children (as required by FQPA) was reduced to 3X and the factor applies to all population subgroups.

2. *Acute risk.* Using the conservative TMRC exposure assumptions described

in Unit III.B.1.i of this preamble, and taking into account the completeness and reliability of the toxicity data, EPA has estimated the acute exposure to imidacloprid from food will utilize 23% of the Acute RfD for the most highly exposed population subgroup that includes children (Nursing infants, <1 year). All other population subgroups which include children have acute risk estimates (food only) below that of the population subgroup Nursing Infants (<1 year). For imidacloprid, it was determined that an acceptable acute dietary exposure (food plus water) of 33.3% or less of the Acute RfD 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.

Despite the potential for exposure to imidacloprid in drinking water, EPA does not expect the aggregate exposure to exceed 33.3% of the Acute RfD. Under current EPA guidelines, the registered non-dietary uses of imidacloprid do not constitute an acute exposure scenario. EPA concludes that there is a reasonable certainty that no harm will result to children from acute aggregate exposure to imidacloprid residues.

3. *Chronic risk.* Using the partially refined exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, EPA has estimated the chronic exposure to imidacloprid from food will utilize 13% of the Chronic RfD for the most highly exposed population subgroup that includes children (Children, 1–6 years old). All other population subgroups which include children have chronic risk estimates (food only) below that of the population subgroup Children, 1–6 years old). For imidacloprid, it was determined that an acceptable acute dietary exposure (food plus water) of 33.3% or less of the Chronic RfD for all population subgroups is needed to protect the safety of all population subgroups. The estimated exposures for all population subgroups which include children utilize less than 33.3% of the Acute RfD. Despite the potential for exposure to imidacloprid in drinking water, EPA does not expect the aggregate exposure to exceed 33.3% of the Chronic RfD. Under current EPA guidelines, the registered non-dietary uses of imidacloprid do not constitute a chronic exposure scenario. EPA concludes that there is a reasonable certainty that no harm will result to children from chronic aggregate exposure to imidacloprid residues.

4. *Short- or intermediate-term risk.* Dermal and inhalation short- and intermediate-term risk assessments are not required for imidacloprid as dermal and inhalation exposure endpoints were not identified due to the demonstrated absence of toxicity. However, a short term residential oral risk assessment is required. 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 children 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. Incidental ingestion of pesticide residues on pets from hand-to mouth transfer may occur during the same period as the exposures from the turf and home garden uses. However, children's exposures from pet and turf uses are not expected to both occur at the high-end level. Therefore, these exposures were considered in separate estimates of risk.

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 in Tables 6 and 7. This population subgroup was chosen because it has the highest chronic food exposure and because toddlers have the highest exposure from the residential uses.

TABLE 6.—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)	0.0074	0.072	0.079	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 = Total Exposure (mg/kg bwt/day) x 100% Acute RfD (0.42 mg/kg bwt/day)

TABLE 7.—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)	0.0074	0.058	0.065	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 = Total Exposure (mg/kg bwt/day) x 100% Acute RfD (0.42 mg/kg bwt/day)

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.

IV. Other Considerations

A. Metabolism in Plants and Animals

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.

B. Analytical Enforcement Methodology

Adequate enforcement methodology (example - gas chromotography) is available to enforce the tolerance expression. The method may be requested 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 22202, (703–305–5229).

C. Magnitude of Residues

A study on field corn RAC's has been submitted. This study has not been reviewed in detail. Residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent, are not expected to exceed 0.1 ppm in field corn forage, 0.2 ppm in field corn stover (fodder) and 0.05 ppm in field corn grain. Since this section 18 proposed use is a seed treatment, a tolerance for aspirated grain fractions is not required.

A study on field corn processing has been submitted. In this study, field corn grown from imidacloprid-treated (3.5-7 oz ai/A, 7X) seed were harvested at maturity and processed by wet and dry milling. All processed fractions contained residues of imidacloprid and its metabolites at levels less than the limit of quantification (<0.05ppm). Residues of imidacloprid and its metabolites did not concentrate into the field corn processed products. The Agency concludes tolerances for imidacloprid and its metabolites are not required for field corn processed commodities.

D. International Residue Limits

There are no CODEX, Canadian, or Mexican maximum Residue Limits (MRL) for imidacloprid on field corn. Thus, harmonization is not an issue for this section 18.

E. Rotational Crop Restrictions

Data concerning the metabolism of imidacloprid in rotational crops were previously submitted. In conjunction with this study, EPA has concluded that a rotation interval of 12 months is appropriate for all crops except those with imidacloprid tolerances which may be rotated at anytime. In conjunction with PP 6F4765, tolerances for inadvertent residues in/on the crop groups Cereal Grains, Forage, Fodder and Straw of Cereal Grains, Legume Vegetables and the Foliage of Legume Vegetables; and the crops sweet corn, soybeans and safflower have been proposed in conjunction with a 30-day plantback interval for these crops.

EPA has recently recommended in favor of the granting of these tolerances and the 30–day plant back interval. EPA concludes the following rotation restriction is adequate for this section 18: Any crops, except those having imidacloprid tolerances, sweet corn, soybeans and safflower and the crops of the crop groups Cereal Grains and Legume Vegetables, may be planted back one year following imidacloprid applications. The crops sweet corn, soybeans, and safflower, and the crops of the crop groups Cereal Grains and Legume Vegetables may be rotated 30–days after the last imidacloprid treatment. Other crops having imidacloprid tolerances/uses may be rotated at anytime.

V. Conclusion

Therefore, the tolerance is established for combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent in field corn forage at 0.1 ppm, field corn stover (fodder) at 0.2 ppm, and field corn grain at 0.05 ppm ppm.

VI. 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 February 1, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's

contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300758] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C) Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes tolerances under FFDCA section 408 (l)(6). 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 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 under FFDCA section 408 (l)(6), such as the tolerances 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 the Intergovernmental Partnership* (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 to 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 officials 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.

IX. 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: November 16, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. In § 180.472, the table to paragraph (b) by adding alphabetically entries for field corn forage, field corn stover (fodder), and field corn grain, to read as follows:

§ 180.472 Imidacloprid; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.*
* * *

Commodity	Parts per million	Expiration/ Revocation Date
* * *	*	*
Field corn forage	0.1	5/1/00
Field corn stover (fodder)	0.2	5/1/00
Field corn grain	0.05	5/1/00
* * *	*	*

* * * * *

[FR Doc. 98–31686 Filed 12–1–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300700A; FRL–6040–4]

RIN 2070–AB78

Triasulfuron; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical amendment.

SUMMARY: EPA is issuing a technical amendment to a tolerance regulation for triasulfuron [3-(6-methoxy-4-methyl-1,3,5-triazin-2-yl)-1-(2-(2-chloroethoxy)phenylsulfonyl)urea] that published in the **Federal Register** on August 18, 1998.

DATES: This regulation is effective December 2, 1998. Objections and requests for hearings must be received by EPA on or before February 1, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300700A], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300700A], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP300700A]. 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: Jim Tompkins, 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, 703–305–5697; e-mail: tompkins.jim@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the August 18, 1998 issue of the **Federal Register** EPA issued a regulation establishing tolerances for residues of triasulfuron [3-(6-methoxy-4-methyl-1,3,5-triazin-2-yl)-1-(2-(2-chloroethoxy)phenylsulfonyl)urea] in or on cattle, kidney; goat, kidney; grass, forage; grass, hay; horse, kidney; and sheep, kidney. Novartis Crop Protection, Inc., requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170). At the time of the petition, (63FR 29401, May 29, 1998) Novartis Crop Protection, Inc., also requested that tolerances be established for residues of this herbicide in or on hog kidney. Inadvertently, hog kidney was left out of the August 18, 1998 final rule that amended 40 CFR 180.459. This document corrects the August 18, 1998 regulation by adding tolerances for residues in or on hog kidney.

I. 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 February 1, 1999, 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