mutually acceptable amendments to the terms described in the direct final rule.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301198; FRL–6816–2]

RIN 2070–AB78

Imazapic; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of imazapic, (±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-methyl-3-pyridinecarboxylic acid and its metabolite (±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-hydroxymethyl-3-pyridinecarboxylic acid, both free CL 263284 and conjugated CL 189215) in or on grass, forage and grass, hay and the combined residues of imazapic and its metabolite CL 263284 in or on milk; fat, meat, and meat byproducts (except kidney) of cattle, goats, horses, and sheep; and kidney of cattle, goats, horses, and sheep. BASF requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective December 26, 2001. Objections and requests for hearings, identified by docket control number OPP–301198, must be received by EPA on or before February 25, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301198 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Tompkins, Product Manager (PM) 25, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 305–5697; and e-mail address: tompkins.jim@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to 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. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301198. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of August 24, 2000 (65 FR 51608) (FRL–6598–6), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP 9F5092) for tolerance by American Cyanamid Company, P.O. Box 400, Princeton, NJ 08543–0400. This notice included a summary of the petition prepared by American Cyanamid, the registrant at the time of filing. The current registrant for the chemical is BASF, at the same address. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.490(a) be amended by establishing a tolerance for combined residues of the herbicide imazapic and its hydroxymethyl metabolite, both free (CL 263284) and conjugated (CL 189215) in or on the raw agricultural commodities grass, forage at 35 ppm, and grass, hay at 15 parts per million (ppm). Tolerances were also proposed for the combined residues of imazapic and its free hydroxymethyl metabolite in or on milk at 0.1 ppm; fat, meat, and meat byproducts (except kidney) of cattle, goats, horses, and sheep at 0.1 ppm; and kidney of cattle, goats, horses, and sheep at 2.0 ppm.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from

aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for combined residues of imazapic and its metabolite, both free CL 263284 and conjugated CL 189215, in or on grass, forage at 30 ppm, and grass, hay at 15 ppm; and for the combined residues of imazapic and its free hydroxymethyl metabolite in milk at 0.1 ppm; fat, meat, and meat byproducts (except kidney) of cattle, goats, horses, and sheep at 0.1 ppm; and kidney of cattle, goats, horses, and sheep at 1.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by imazapic are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—IMAZAPIC TECHNICAL SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type (All Studies Acceptable)	Results
870.3100	90-Day oral toxicity rodents-rat	NOAEL = 1,552 mg/kg/day in males, 1,728 mg/kg/day in females (HDT) LOAEL = not established
870.3200	21-Day dermal toxicity-rabbit	NOAEL = 1,000 mg/kg/day (males and females) LOAEL = not established
870.3700	Prenatal developmental in rodents-rat	Maternal NOAEL = 1,000 mg/kg/day (HDT) LOAEL = not established Developmental NOAEL = 1,000 mg/kg/day LOAEL = not established
870.3700	Prenatal developmental in nonrodents-rabbit	Maternal NOAEL = 350 mg/kg/day LOAEL = 500 mg/kg/day based on decreased body weight gain and food consumption. At 700 mg/kg/day (HDT), there was excessive mortality resulting in a total of only 7 surviving litters Developmental NOAEL = 500 mg/kg/day LOAEL = not established. Due to excessive mortality at 700 mg/kg/day, only 47 fetuses were available for examination which precluded a meaningful evaluation of developmental findings at this dose level
870.3800	Reproduction and fertility effects-rat	Parental/Systemic NOAEL = 1,205 mg/kg/day in males, 1,484 mg/kg/day in females (HDT) LOAEL = not established Reproductive NOAEL = 1,205 mg/kg/day in males, 1,484 mg/kg/day in females LOAEL = not established Offspring NOAEL = 1,205 mg/kg/day in males, 1,484 mg/kg/day in females LOAEL = not established

TABLE 1.—IMAZAPIC TECHNICAL SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type (All Studies Acceptable)	Results
870.4100	Chronic toxicity dogs	NOAEL = not established LOAEL = 137 mg/kg/day in males, 180 mg/kg/day in females based on increased incidence of minimal degeneration and/or necrosis and lymphocyte and/or macrophage infiltration in skeletal muscle in both males and females and slightly decreased blood creatinine levels in females (LDT)
870.4100/870.4200	Chronic/carcinogenicity rats	NOAEL = 1,029 mg/kg/day in males, 1,237 mg/kg/day in females (HDT) LOAEL = not established No evidence of carcinogenicity
870.4300	Carcinogenicity mice	NOAEL = 1,134 mg/kg/day in males, 1,422 mg/kg/day in females (HDT) LOAEL = not established No evidence of carcinogenicity
870.5265	Gene mutation	Non-mutagenic when tested up to 5,000 μg/plate, in presence and absence of activation, in *S. typhimurium* strains TA98, TA100, TA1535 and TA1537 and *E.coli* strain WP2uvra.
870.5300	Gene mutation	Non-mutagenic at the HGPRT locus in Chinese hamster ovary (CHO) cells tested up to cytotoxic concentrations or limit of solubility, in presence and absence of activation.
870.5375	Chromosome aberration	Did not induce structural chromosome aberration in CHO cell cultures in the presence and absence of activation.
870.5385	Chromosomal aberration	Non-mutagenic in rat bone marrow chromosomal aberrations assay up to 5,000 mg/kg.
870.7485	Metabolism and pharmacokinetics - rat	Total recovery of the administered dose was 98–106% at 7 days. Urinary excretion was the major route of elimination (94–102% of the dose), with only unchanged parent detected. There was no evidence of bioaccumulation in the tissues. There were no sex- or dose-related differences following oral or intravenous administration.

B. 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 level of concern (LOC). 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. Because a developmental neurotoxicity study is not needed, there are currently no residential uses, dietary exposure assessments will not underestimate the potential exposures for infants and children, and the toxicology database is complete, no additional FQPA Safety Factor (FQPA SF) is required.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) 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 Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the 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 x 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 imazapic used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR IMAZAPIC 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 (general population and females 13-50 years old)	None	An acute dietary endpoint was not selected based on the absence of an appropriate endpoint attributed to a single dose	None
Chronic dietary (all populations)	LOAEL= 137 mg/kg/day UF = 300 Chronic RfD = 0.5 mg/kg/day	FQPA SF = 1X cPAD = cRfD/FQPA SF = 0.5 mg/kg/day	LOAEL = 137 mg/kg/day based on increased incidence of minimal degeneration and/or necrosis of skeletal muscle in 1 year dog feeding study
Incidental oral, short-term (1-7 days)	Oral NOAEL = 350 mg/kg/day	LOC = 100	LOAEL = 500 mg/kg/day based on decreased body weight and food consumption during the dosing period in rabbit developmental study
Incidental oral, intermediate-term (7 days-several months)	Oral NOAEL = 350 mg/kg/day	LOC = 100	LOAEL = 500 mg/kg/day based on decreased body weight and food consumption during the dosing period in rabbit developmental study
Short- and intermediate-term dermal (1-7 days and 1 week-several months) (Occupational)	None	No systemic toxicity was seen following repeated dermal application at 1,000 mg/kg/day over a 3-week period. Since no hazard was identified, quantification is not required.	None
Long-term dermal (several months-lifetime) (Occupational)	Oral LOAEL = 137 mg/kg/day (dermal absorption rate = 50%)	LOC for MOE = 300	LOAEL = 137 mg/kg/day based on increased incidence of minimal degeneration and/or necrosis of skeletal muscle in 1 year dog feeding study
Short- and intermediate-term inhalation (1-7 days and 1 week-several months) (Occupational)	Oral study NOAEL= 350 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100	LOAEL = 500 mg/kg/day based on decreased body weight and food consumption during dosing in rabbit developmental study
Long-term inhalation (several months-lifetime) (Occupational)	Oral study LOAEL= 137 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 300	LOAEL = 137 mg/kg/day based on increased incidence of minimal degeneration and/or necrosis of skeletal muscle in 1 year dog feeding study
Cancer (oral, dermal, inhalation)	Cancer classification (''Group E'')	Risk assessment not required	No evidence of carcinogenicity

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.490(a) for the combined residues of imazapic and its metabolites CL 263284 and CL 189215, in or on peanut, nutmeat at 0.1 ppm. Time-limited tolerances set to expire December 31, 2001 are established under (40 CFR 180.490(b) in connection with section 18 emergency exemptions (99NE0009) for residues of imazapic and its metabolites CL 263284 and CL 189215 for grass, forage at 30 ppm; grass, hay at 15 ppm; milk at 0.10 ppm; fat, meat, and meat byproducts (except kidney) of cattle, goats, hogs, horses, and sheep at 0.10 ppm; and kidney of cattle, goats, hogs, horses, and sheep at 1.0 ppm. The present analyses included the published peanut values together with re-evaluated tolerance levels for livestock-derived commodities, based on the new grass use proposed. Risk assessments were conducted by EPA to assess dietary exposures from imazapic 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. An acute exposure assessment is not applicable based on the absence of an appropriate effect of concern.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™ version 7.73) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Residues present at tolerance levels, 100% of each crop is treated, and the use of default processing concentration factors (Tier 1 analysis).

iii. *Cancer*. A cancer risk assessment was not conducted, since imazapic has been classified as a ''Group E'' chemical (evidence of non-carcinogenicity for humans) based upon lack of evidence of carcinogenicity in two adequate studies (rats and mice).

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for imazapic 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 imazapic.

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 Screening Concentrations in Ground Water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will 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 %RfD or %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 imazapic they are further discussed in the aggregate risk sections below.

Based on the FIRST and SCI-GROW models, the EECs of imazapic for acute exposures are estimated to be 17 parts per billion (ppb) for surface water and 14 ppb for ground water. The EECs for chronic exposures are estimated to be 1.5 ppb for surface water and 14 ppb for ground water.

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).

Imazapic is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a 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 imazapic 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, imazapic 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 imazapic has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general*. 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 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 exposure (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*. Based on the available data, no evidence of increased susceptibility was seen in the rat and rabbit prenatal toxicity studies or following prenatal/postnatal exposure in the 2-generation reproduction study.

3. *Conclusion*. There is a complete toxicity data base for imazapic and exposure data are complete or are estimated based on data that reasonably account for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be removed. The FQPA factor is removed because: A developmental neurotoxicity study is not needed; there are currently no residential uses; and dietary exposure assessments will not underestimate the potential exposures for infants and children.

E. 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 + residential 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 the USEPA Office of Water are used to calculate DWLOCs: 2L/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, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP 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, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Imazapic is not expected to pose an acute risk because no acute endpoint of concern was identified in the toxicity test.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to imazapic from food will utilize 0.1% of the cPADs for the U.S. population, all infants, and children 1-6 years old. There are no residential uses for imazapic that result in chronic residential exposure to imazapic. In addition, there is potential for chronic dietary exposure to imazapic in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

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

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.5	0.000269	1.5	14	17,000
All infants (< 1 year old)	0.5	0.000505	1.5	14	5,000
Children (1-6 years old)	0.5	0.000684	1.5	14	5,000

3. *Short- or intermediate-term risk*. Since there are no registered uses for imazapic which would result in non-dietary, non-occupational exposure, contributions to the aggregate risk from both short- and intermediate-term non-dietary exposures are not expected.

4. *Aggregate cancer risk for U.S. population*. Imazapic has been classified as a ''Group E'' chemical (evidence of non-carcinogenicity for humans); therefore imazapic is not expected to pose a cancer risk.

5. *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 imazapic residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate independent method validation (ILV) studies have been submitted in support of all methods. A method which is similar to the peanut enforcement method has been submitted for the determination of residues of imazapic and its metabolites CL 263284 and CL 189215 in/on grass forage and hay, and methods for the enforcement of tolerances of imazapic and CL 263284 in milk and livestock tissues and an HPLC/MS method for the enforcement of tolerances in fat have been submitted.

B. International Residue Limits

There are no CODEX, Canadian, or Mexican maximum residue limits (MRLs) for imazapic residues.

C. Conditions

The registrant has committed to conduct four side-by-side grass field trials using the maximum rate WDG acid formulation. The registrant has also agreed to conduct four additional grass field trials reflecting a single postemergence application of the 2 lb acid equivalence (ae)/gal ammonium salt SC formulation at 0.1875 lb ae/A; these trials will be conducted in Regions 7 and 8. The registrant also is required to conduct a 28–day inhalation toxicity study, using the protocol for the existing 90–day inhalation toxicity study. The results of this study will provide a basis from which to determine more reliable route-specific Margins of Exposure (MOEs) for worker inhalation risks rather than the less reliable route-to-route MOE calculations currently being used.

V. Conclusion

Therefore, the tolerance is established for combined residues of the herbicide imazapic and its hydroxymethyl metabolite, both free (CL 263284) and conjugated (CL 189215) in or on the raw agricultural commodities grass, forage at 30 ppm, and grass, hay at 15 ppm. Tolerances are also established for the combined residues of imazapic and its free hydroxymethyl metabolite in or on milk at 0.1 ppm; fat, meat, and meat byproducts (except kidney) of cattle, goats, horses, and sheep at 0.1 ppm; and kidney of cattle, goats, horses, and sheep at 1.0 ppm.

VI. 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 of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the

necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409. 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 control number OPP–301198 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 February 25, 2002.

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 (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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 (202) 260–4865.

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.

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.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.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.2. Mail your copies, identified by docket control number OPP–301198, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). 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 petition under FFDCA section 408(d), 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 FFDCA section 408(n)(4). 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.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this 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: December 11, 2001.

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 180.490 is amended by revising paragraph (a) and removing and reserving the text of paragraph (b) to read as follows:

§ 180.490 Imazapic-ammonium; tolerances for residues.

(a) *General.* (1) Tolerances are established for combined residues of the herbicide imazapic, (±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-methyl-3-pyridinecarboxylic acid and its metabolite (±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-hydroxymethyl-3-pyridinecarboxylic acid, both free and conjugated, in or on the following food commodities:

Commodity	Parts per million
Grass, forage	15
Grass, hay	30
Peanut nutmeat	0.1

(2) Tolerances are also established for the combined residues of the herbicide imazapic, (±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-methyl-3-pyridinecarboxylic acid and its free metabolite (±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-hydroxymethyl-3-pyridinecarboxylic acid, in or on the following food commodities:

Commodity	Parts per million
Cattle, fat	0.10
Cattle, kidney	1.0
Cattle, mbyp (except kidney)	0.1
Cattle, meat	0.1
Goats, fat	0.1
Goats, kidney	1.0
Goats, mbyp (except kidney)	0.1
Goats, meat	0.1
Horses, fat	0.1
Horses, kidney	1.0
Horses, mbyp (except kidney)	0.1
Horses, meat	0.1
Milk	0.1

Commodity	Parts per million
Sheep, fat	0.1
Sheep, kidney	1.0
Sheep, mbyp (except kidney)	0.1
Sheep, meat	0.1

(b) *Section 18 emergency exemptions.* [Reserved]

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[FR Doc. 01–31493 Filed 12–21–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301200; FRL–6816–8]

RIN 2070–AB78

Halosulfuron-methyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of halosulfuron-methyl in or on the melon subgroup. IR-4 requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective December 26, 2001. Objections and requests for hearings, identified by docket control number OPP–301200, must be received by EPA on or before February 25, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301200 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 308–3194; and e-mail address: brothers.shaja@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'', ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301200. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of August 31, 2001 (66 FR 45993) (FRL–6796–1), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP) for tolerance by the Interregional Research Project Number 4 (IR-4), 681 U.S. Highway 1 South, North Brunswick, NJ 08902–3390. This notice included a summary of the petition prepared by Gowan Company, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.479 be amended by establishing a tolerance for residues of the herbicide halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl) aminocarbonylamino] sulfonyl-3-chloro-1-methyl-1H-pyrazole-4-carboxylate, in or on the melon subgroup-crop group 9A (includes citron melon, muskmelon, and watermelon) at 0.1 part per million (ppm).

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