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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301205; FRL–6817–9]

RIN 2070–AB78

Imazamox; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of imazamox in or on the raw agricultural commodities: alfalfa forage, seed and hay, canola seed, vegetable, legume, group wheat forage, grain, bran, germ, shorts, hay and straw. BASF Corporation, formerly American Cyanamid Company, 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 27, 2001. Objections and requests for hearings, identified by docket control number OPP–301205, 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–301205 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Jim Tompkins, 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	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/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_180/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301205. 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 March 29, 2000 (65 FR 16594) (FRL–6498–5), 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 American Cyanamid Company, P.O. Box 400, Princeton, NJ 08543–0400. This notice included a summary of the petition prepared by American Cyanamid Company, the registrant. There were no comments received in response to the notice of filing. The petition was subsequently transferred to BASF Corporation, P.O. Box 400, Princeton, NJ 08543–0400.

The petition requested that 40 CFR 180.508 be amended by establishing a tolerance for residues of the herbicide imazamox, (±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(methoxymethyl)-3-pyridinecarboxylic acid, in or on the raw agricultural commodities: vegetable, legume, group at 0.05 ppm; canola, seed at 0.05 ppm. Tolerances are established for the combined residues of the herbicide imazamox, and its metabolite, AC263284 (±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(hydroxymethyl)-3-pyridinecarboxylic acid in or on the following raw agricultural commodities wheat, grain, forage and hay at 0.3 ppm, wheat, straw at 0.2 ppm, wheat, bran at 1.0 ppm, wheat, shorts at 0.8 ppm, and wheat, germ at 0.6 ppm. Tolerances are established for the combined residues of the herbicide imazamox, and its metabolite, AC263284 (free and conjugated), and AC312622, (±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-3,5-pyridinecarboxylic acid in or on the following raw agricultural commodities: alfalfa, seed at 0.4 ppm, alfalfa, forage at 2.0 ppm and alfalfa, hay at 4.0 ppm respectively.

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 tolerances for residues of the herbicide imazamox, (±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(methoxymethyl)-3-pyridinecarboxylic acid, in or on the raw agricultural commodities: vegetable, legume, group at 0.05 ppm; canola, seed at 0.05 ppm. Tolerances are established for the combined residues of the herbicide imazamox, and its metabolite, AC263284 (±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(hydroxymethyl)-3-pyridinecarboxylic acid in or on the following raw agricultural commodities wheat, grain, forage and hay at 0.3 ppm, wheat, straw at 0.2 ppm, wheat, bran at 1.0 ppm, wheat, shorts at 0.8 ppm, and wheat, germ at 0.6 ppm. Tolerances are established for the combined residues of the herbicide imazamox, and its metabolite, AC263284 (free and conjugated), and AC312622, (±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-3,5-pyridinecarboxylic acid in or on the following raw agricultural commodities: alfalfa, seed at 0.4 ppm, alfalfa, forage at 2.0 ppm and alfalfa, hay at 4.0 ppm respectively. 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 imazamox are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL). There was no lowest observed adverse effect level (LOAEL) in any of the subchronic or chronic toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.1100	Acute Oral	LD_{50} > 5,000 mg/kg (limit dose), toxicity category IV
870.1200	Acute Dermal	LD_{50} > 4,000 mg/kg (twice the limit dose), toxicity category III
870.1300	Acute Inhalation	LC_{50} > 6.3 mg/L, toxicity category IV
870.2400	Primary Eye Irritation	moderately irritating, toxicity category III
870.2500	Primary Skin Irritation	Non-irritating, toxicity category IV
870.2600	Dermal Sensitization	Non sensitizer
870.3100	90–Day oral toxicity rodents	NOAEL = 1,661 mg/kg/day, Highest Dose Tested (HDT)
870.3150	90–Day oral toxicity in nonrodents	NOAEL = 1,333 mg/kg/day, HDT
870.3200	21/28–Day dermal toxicity	NOAEL = 1,000 mg/kg/day, HDT
870.3700	Prenatal developmental in rodents	Maternal and Developmental NOAEL = 1,000 mg/kg/day, HDT
870.3700	Prenatal developmental in nonrodents	Maternal and Developmental NOAEL = 900 mg/kg/day, HDT
870.3800	Reproduction and fertility effects	Parental/Systemic, Reproductive and Offspring NOAEL = 1469 mg/kg/day, HDT
870.4100 870.4200	Chronic toxicity and Carcinogenicity rodents.	NOAEL = 1,068 mg/kg/day, HDT; no evidence of carcinogenicity
870.4100	Chronic toxicity dogs	NOAEL = 1,165 mg/kg/day, HDT
870.4300	Carcinogenicity mice	NOAEL = 1,053 mg/kg/day, HDT; no evidence of carcinogenicity
870.5100	Gene Mutation	Negative
870.5375	Cytogenetics	Negative
870.5385	Other Effects	Negative

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

Guideline No.	Study Type	Results
870.7485	Metabolism and pharmacokinetics	Rapidly excreted primarily in the urine following intravenous administration, and in the urine and feces following oral administration, mainly as unchanged parent.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.508) for the residues of imazamox, in or on the raw agricultural commodity soybeans. Due to low toxicity, it was determined that a dietary risk assessment of imazamox in food is not needed and, therefore, none was conducted.

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 one day or single exposure. No appropriate endpoint attributable to a single exposure (dose) was identified in the imazamox toxicity database including oral developmental toxicity studies in rats and rabbits.

ii. *Chronic exposure.* There were no observed adverse effects at the highest dose tested (1,000 mg/kg/day or higher) in any of the subchronic or chronic toxicity tests conducted and the August 1998 OPPTS Series 870 Harmonized Test Guidelines for health effects recommend for subchronic and chronic testing the highest dose tested should not exceed 1,000 mg/kg/day using the procedures described for these studies, unless potential human exposure data indicate the need for higher doses. When imazamox was tested up to or above the limit dose, no significant adverse effects were observed. Therefore, it was determined that a chronic dietary risk assessment of imazamox in food is not needed and, therefore, none was conducted.

2. *Dietary exposure from drinking water.* 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 concentration in ground water (SCI-GROW) model is used to predict pesticide concentrations in shallow groundwater. 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.

Based on the FIRST and SCI-GROW models the estimated environmental concentrations (EECs) of imazamox for acute exposures are estimated to be 32 parts per billion (ppb) for surface water and 0.62 ppb for ground water. The EECs for chronic exposures are estimated to be 3.4 ppb for surface water and 0.62 ppb for ground water. These concentrations were compared to the lowest high dose tested in the toxicity studies (900 mg/kg) divided by an uncertainty factor of 100, i.e., 9 mg/kg. For chronic exposure in surface water, the EEC of 3.4 ppb is 5/10,000% of 9 mg/kg. For acute exposure in surface water, the EEC of 32 ppb is 4/1,000% of 9 mg/kg. For chronic and acute exposure in ground water, the EEC of 0.62 ppb is 7/10,000% of 9 mg/kg. Because the concentration of imazamox in drinking water are much smaller than 9 mg/kg, the contribution of consumption of imazamox via drinking water to total dietary consumption of imazamox (food plus water) is not significant.

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). Imazamox 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 imazamox 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, imazamox 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 imazamox 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 database on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children.

2. *Prenatal and postnatal sensitivity.* No significant toxicity or pre- or post-natal toxicity was seen in any of the studies conducted with imazamox.

3. *Conclusion.* Due to its low toxicity a risk assessment using a safety factor approach was not conducted for imazamox. For similar reasons, it would not be appropriate to use an additional 10x safety factor to protect infants and children.

E. Aggregate Risks and Determination of Safety

1. *Acute risk.* Since the acute toxicity is low (toxicity categories III and IV) for all tests conducted, the occurrence of an effect of concern as a result of a one day or single exposure is highly unlikely. It

was determined that contribution of additional dietary risk due to drinking water consumption is insignificant as described in section C. 2. above.

2. *Chronic risk.* There were no observed adverse effects at the highest dose tested (1,000 mg/kg/day or higher) in any of the subchronic or chronic toxicity tests conducted and the August 1998 OPPTS Series 870 Harmonized Test Guidelines for health effects recommend for subchronic and chronic testing the highest dose tested should not exceed 1000 mg/kg/day using the procedures described for these studies, unless potential human exposure data indicate the need for higher doses. When imazamox was tested up to or above the limit dose, no significant adverse effects were observed. Therefore, it was determined that a chronic dietary risk assessment of imazamox in food is not needed and, therefore, none was conducted.

3. *Determination of safety*. Based on the low toxicity of imazamox and the rationales described above, 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 imazamox residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The method may be requested from Francis Griffith, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Road, Fort George G. Mead, Maryland, 20755–5350; telephone number: (410) 305–2905; e-mail address: griffith.francis@epa.gov.

B. International Residue Limits

There are no established or proposed Codex Maximum Residue Limits (MRLs) for imazamox.

V. Conclusion

Therefore, tolerances are established for residues of the herbicide imazamox, (±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(methoxymethyl)-3-pyridinecarboxylic acid, in or on the raw agricultural commodities: vegetable, legume, group at 0.05 ppm; canola, seed at 0.05 ppm. Tolerances are established for the combined residues of the herbicide imazamox, and its metabolite, AC263284 (±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(hydroxymethyl)-3-pyridinecarboxylic acid in or on the following raw agricultural commodities wheat, grain, forage and hay at 0.3 ppm, wheat, straw at 0.2 ppm, wheat, bran at 1.0 ppm, wheat, shorts at 0.8 ppm, and wheat, germ at 0.6 ppm. Tolerances are established for the combined residues of the herbicide imazamox, and its metabolite, AC263284 (free and conjugated), and AC312622, (±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-3,5-pyridinecarboxylic acid in or on the following raw agricultural commodities: alfalfa, seed at 0.4 ppm, alfalfa, forage at 2.0 ppm and alfalfa, hay at 4.0 ppm respectively

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–301205 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–301205, 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 18, 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 180.508 is amended by revising paragraph (a) to read as follows:

§ 180.508 Imazamox; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide imazamox, (±)2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(methoxymethyl)-3-pyridinecarboxylic acid in or on the raw agricultural commodities:

Commodity	Parts per million
Canola, seed	0.05
Vegetable, legume, group	0.05

(2) Tolerances are established for the combined residues of the herbicide imazamox, and its metabolite AC263284 [(±)2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(hydroxymethyl)-3-pyridinecarboxylic acid in or on the raw agricultural commodities:

Commodity	Parts per million
Wheat, grain	0.30
Wheat, forage	0.30
Wheat, hay	0.30
Wheat, straw	0.20
Wheat, bran	1.0
Wheat, shorts	0.80
Wheat, germ	0.60

(3) Tolerances are established for the combined residues of the herbicide imazamox, and its metabolite AC263284 (free and conjugated), and AC312622, [(±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-3,5-pyridinecarboxylic acid in or on the raw agricultural commodities:

Commodity	Parts per million
Alfalfa, seed	0.40
Alfalfa, forage	2.0
Alfalfa, hay	4.0

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[FR Doc. 01–31799 Filed 12–26–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301197; FRL–6816–1]

RIN 2070–AB78

Halosulfuron-methyl; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of Halosulfuron-methyl in or on asparagus. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on asparagus. This regulation establishes a maximum permissible level for residues of halosulfuron-methyl in this food commodity. The tolerance will expire and is revoked on December 31, 2003.

DATES: This regulation is effective December 27, 2001. Objections and requests for hearings, identified by docket control number OPP–301197, 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 VII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301197 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Meredith Laws, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9366; and e-mail address: laws.meredith@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are 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	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/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_180/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301197. 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, 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

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for residues of the herbicide halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl) amino]carbonylaminosulfonyl-3-chloro-1-methyl-1H-pyrazole-4-carboxylate, in or on asparagus at 2.0 parts per million (ppm). This tolerance will expire and is revoked on 12/31/03. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations (CFR).