

II. EPA Action

Based on the proposed full approval set forth in today's **Federal Register**, EPA believes that the District has corrected the original disapproval deficiencies that started the sanction clock and, therefore, EPA is taking this interim final action finding that the District has corrected the disapproval deficiencies, effective on publication. This action does not stop the sanction clock that started under section 179 for this area on March 24, 1995. However, this action will stay the application of the offset sanction and will defer the application of the highway sanction. See 40 CFR 52.31. Publication of final approval by EPA will stop the sanction clock and will permanently lift any applied, stayed or deferred sanctions.

Today EPA is also providing the public with an opportunity to comment on this interim final action. If, based on any comments on this action and any comments on EPA's proposed full approval of the State's submittal, EPA determines that the State's submittal is not fully approvable and this final action was inappropriate, EPA will take further action to disapprove the State's submittal and to find that the State has not corrected the original disapproval deficiency. As appropriate, EPA will also issue an interim final determination or a final determination that the deficiency has not been corrected. In addition, the sanctions consequences described in the sanctions rule will also apply. See 40 CFR 52.31.

III. Administrative Requirements

Because EPA has preliminarily determined that the District has an approvable plan, relief from sanctions should be provided as quickly as possible. Therefore, EPA is invoking the good cause exception under the Administrative Procedure Act (APA) in not providing an opportunity for comment before this action takes effect.¹ 5 U.S.C. 553(b)(B). The EPA believes that notice-and-comment rulemaking before the effective date of this action is impracticable and contrary to the public interest. The EPA has reviewed the District's submittal and, through its proposed action, is indicating that the District has corrected the deficiency that started the sanctions clock. Therefore, it is not in the public interest to initially apply sanctions or to keep applied sanctions in place when the State has

most likely done all that it can to correct the deficiency that triggered the sanctions clock. Moreover, it would be impracticable to go through notice-and-comment rulemaking on a finding that the State has corrected the deficiency prior to the rulemaking approving the State's submittal. Therefore, EPA believes that it is necessary to use the interim final rulemaking process to temporarily stay or defer sanctions while EPA completes its rulemaking process on the approvability of the District's submittal. In addition, EPA is invoking the good cause exception to the 30-day notice requirement of the APA because the purpose of this notice is to relieve a restriction. See 5 U.S.C. 553(d)(1).

The Office of Management and Budget has exempted this action from review under Executive Order 12866.

Under the Regulatory Flexibility Act, 5 U.S.C. § 600 *et. seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. §§ 603 and 604. Alternatively, EPA may certify that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

This action, pertaining to the interim final approval of corrections to the District of Columbia's New Source Review regulation, temporarily relieves sources of an additional burden potentially placed on them by the sanction provisions of the Act. Therefore, I certify that it does not have an impact on any small entities.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental regulations, Reporting and recordkeeping, Ozone, Volatile organic compounds, and nitrogen oxides.

Authority: 42 U.S.C. §§ 7401-7671q.

Dated: May 21, 1997.

William T. Wisniewski,

Acting Regional Administrator.

[FR Doc. 97-14304 Filed 5-30-97; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300502; FRL-5721-1]

RIN 2070-AB78

Imazamox; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This document establishes tolerances for the 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] (PC Code No. 129171, CAS No. 114311-32-9), applied as the free acid or ammonium salt, in or on soybean seed. American Cyanamid submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act as amended by the Food Quality Protection Act of 1996 requesting the tolerances.

DATE: This rule becomes effective June 2, 1997. Objections and requests for hearings must be received by EPA on or before August 1, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP-300502], may 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 should be identified by the docket control number [OPP-300502] must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, 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:

¹ As previously noted, however, by this action EPA is providing the public with a chance to comment on EPA's determination after the effective date and EPA will consider any comments received in determining whether to reverse such action.

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 in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [OPP-300502]. 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, Product Manager (PM)25, 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: Rm. 241, CM 2, 1921 Jefferson Davis Hwy., Arlington, VA (703) 305-6027; e-mail: tompkins.jim@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 26, 1996 (61 FR 68036) EPA issued a notice announcing that American Cyanamid, P.O. Box 400, Princeton, NJ 08543 had submitted pesticide petition 6F4649 to EPA which requested that the Administrator, pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), and the Food Quality Protection Act (FQPA) of 1996, amend 40 CFR part 180 to establish 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], applied as the ammonium salt, in or on soybean seed at 0.1 parts per million (ppm). This notice contained a summary of the petition prepared by the petitioner and the summary contained conclusions that the petition complied with FPQA.

There were no comments received in response to the notice of filing.

The data submitted in the petition and other relevant material have been evaluated. The toxicological data listed below were considered in support of this tolerance.

I. Toxicology Profile

1. A battery of acute toxicity studies placing technical imazamox in toxicity category III for eye irritation, and acute dermal LD₅₀ and category IV for acute oral LD₅₀, primary skin irritation, and acute inhalation LD₅₀. Imazamox did not cause any dermal sensitization.

2. A 90-day rat feeding study at doses of 0, 1,000, 10,000, or 20,000 ppm (0, 81, 833, or 1,661 milligrams per kilogram per day (mg/kg/day)) showed no signs of mortality, abnormal clinical signs or ophthalmological findings. The NOEL was 20,000 ppm (1,661 mg/kg/day), the highest dose tested (HDT).

3. A 90-day subchronic dog feeding study at doses of 0, 1,000, 10,000 or 40,000 ppm (males = 0, 34, 329, or 1,333; females = 0, 36, 381, or 1,403 mg/kg/day) showed no clinical or ophthalmological effects up to 40,000 ppm. The NOEL was set at 40,000 ppm (1.3 mg/kg/day for males and 1.4 mg/kg/day for females) HDT.

4. A 28-day repeated dose dermal toxicity study in rats at doses of 0, 250, 500, or 1,000 mg/kg/day showed no clinical signs of toxicity, nor differences in ophthalmology, hematology parameters, clinical blood chemistry, organ weights, or macroscopic or microscopic organ morphology. The NOEL was determined to be 1,000 mg/kg/day (HDT).

5. A 1-year dog chronic toxicity study at doses of 0, 1,000, 10,000, or 40,000 ppm (0, 29.5, 282.5, or 1,165 mg/kg/day) HDT showed no clinical signs of toxicity, nor differences in ophthalmology, hematology parameters, clinical blood chemistry, organ weights, or macroscopic or microscopic organ pathology. The NOEL was determined to be 40,000 ppm (1,165 mg/kg/day) HDT.

6. A 2-year rat chronic/carcinogenicity study at doses of 0, 1,000, 10,000, or 20,000 ppm (males= 0, 52, 528, or 1,068 mg/kg/day; females = 0, 63, 626, or 1,284 mg/kg/day) showed no clinical or ophthalmological effects other than increased kidney weights. However, this was not dose-related and no corroborative macroscopic or histopathological changes were detected in the kidneys. The NOEL was determined to be 20,000 ppm (1,068 mg/kg/day in males and 1,284 in females) HDT.

7. A rat developmental toxicity study at doses of 0, 100, 500, or 1,000 mg/kg/day. At 1,000 mg/kg/day, the only clinical sign of toxicity was mean body weight gain. However, the differences were comparable between treated and control groups during the later and post dosage periods. The NOEL for maternal toxicity is 500 mg/kg/day based on body weight effects. The LOEL is 1,000 mg/kg/day. There were no treatment related developmental effects, therefore the developmental toxicity NOEL is > 1,000 mg/kg/day (limit dose); a LOEL was not established.

8. A rabbit developmental toxicity study at doses of 0, 300, 600, or 900 mg/

kg/day with a maternal NOEL of 300 mg/kg/day based on reduced body weights and reduced food consumption and developmental NOEL of 900 mg/kg/day (HDT).

9. A rat 2-generation reproduction study at dietary concentrations of 0, 1,000, 10,000, or 20,000 ppm (males= 0, 73 748 or 1,469 mg/kg/day; females = 0, 88, 892, or 1,826 mg/kg/day) with a NOEL of 20,000 ppm (HDT).

10. A metabolism study in rats indicated that imazamox was rapidly absorbed and excreted within 7 days post-dosing, with the majority of the administered ¹⁴C-label (> 73%) eliminated in the urine within 24 hours. Metabolite characterization studies showed that essentially all the test material was excreted unchanged. Three minor metabolites, CL 263284 and CL 312622, and CL 303190 were detected in the urine of treated rats; however, their total contribution combined was less than or equal to 2.0% of the administered dose. HPLC/MS Analysis of the feces identified CL 263,284 (9%), CL 312,622 (3%), and N-methyl CL 299,263 (in trace amounts).

11. Acceptable studies on gene mutation and other genotoxic effects: Ames *Salmonella* Assay; CHO/HGPRT Point Mutation Assay; *In vitro* CHO cell chromosome aberration assay; Dominant lethal assay; and Unscheduled DNA synthesis (UDS) yielded negative results.

II. Dose Response Assessment

1. *Reference dose (RfD)*. The RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The RfD is determined by using the toxicological end-point or the NOEL for the most sensitive mammalian toxicological study. To assure the adequacy of the RfD, the Agency uses an uncertainty factor in deriving it. The factor is usually 100 to account for both interspecies extrapolation and intraspecies variability represented by the toxicological data. The EPA has established an RfD of 3.00 mg/kg/day based on a NOEL of 300 mg/kg/day from the rabbit developmental toxicity study.

2. *Carcinogenicity classification*. Using the Guidelines for Carcinogenic Risk Assessment published September 24, 1986 (51 FR 33992), the EPA has classified imazamox as Group "E", not a likely human carcinogen.

3. *Developmental toxicant determination*. The acceptable developmental studies (two-generation reproduction study in rats and prenatal developmental toxicity studies in rats and rabbits) provided no indication of

increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to imazamox.

III. Non-dietary (Residential and Occupational) Exposure Assessment

As part of the hazard assessment process, the Agency reviews the available toxicological database to determine if there are toxicological endpoints of concern. For imazamox, the Agency does not have a concern for short-term, intermediate-term, or chronic-term occupational or residential exposure since the available toxicology data indicates minimal toxicity only at a very high dose, such as the limit dose by the dermal or inhalation routes. Therefore, occupational or residential risk assessments are not required.

IV. Dietary Exposure Assessment

Use of an agricultural pesticide may result, directly or indirectly, in pesticide residues in food. Primary residues or indirect/inadvertent residues in food commodities are determined by chemical analysis. To account for the diversity of growing conditions, cultural practices, soil types, climates, crop varieties and methods of application of the pesticide, data from studies that represent the commodities are collected and evaluated to determine an appropriate level of residue that would not be exceeded if the pesticide is used as represented in the studies.

1. *Plant/animal metabolism and magnitude of the residue.* The nature (metabolism) of imazamox in plants and animals is adequately understood for the purposes of these tolerances. There are no Codex maximum residue levels established for residues of imazamox on soybeans or the rotational crops. In all the plant and animal (poultry and ruminants) metabolism studies submitted, the residue of concern was the parent *per se*, imazamox.

2. *Residue analytical methods.* The analytical method proposed as an enforcement method for soybean commodities is GS/MS Method M 2248.01. The method is suitable for detecting residues of the parent compound, imazamox, in soybean seeds. Tolerances for meat, milk, poultry, and eggs, are not required for this petition, therefore, an analytical method for the enforcement of animal tolerances is not needed.

V. Aggregate Exposure Assessment

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from pesticide residue in food, including water, and all other nonoccupational exposures. The aggregate sources of

exposure the Agency looks at includes food, drinking water or groundwater, and exposure from pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Acute dietary.* As part of the hazard assessment process, the Agency reviews the available toxicology database to determine the endpoints of concern. For imazamox, the Agency does not have a concern for an acute dietary risk since the available data do not indicate any evidence of significant toxicity from a 1 day or single event exposure by the oral route. Therefore, an acute dietary risk assessment was not required.

2. *Chronic dietary.* Using the Dietary Risk Evaluation System (DRES), a chronic exposure analysis was performed using tolerance level residues and 100 percent crop treated to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. This exposure analysis showed that exposure from residues in/on soybeans in the U.S. population and all subgroups would be less than 1% of the RfD.

3. *Drinking water.* To determine the exposure from drinking water, the Agency applied modeling procedures. Using the estimated chronic drinking water values of 1 µg/L for surface water, the exposure to imazamox from drinking water was calculated to be 2×10^{-5} milligram per kilogram of body weight per day (mg/kg bw/day) for the U.S. population (Surface Water), 4×10^{-5} mg/kg bw/day for non-nursing infants (Surface Water), and 4×10^{-5} mg/kg bw/day for children (1 to 6 years old). These drinking water values were developed for use in ecorisk assessment and represent a reasonable upper-bound estimate for eco-risk assessment. It is expected that they represent an overestimate for human health risk assessments. The chronic dietary analysis is also an upper-bound estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodity assumed to be treated with imazamox. Therefore, even without refinements, EPA does not consider the combined aggregate chronic dietary/drinking water risk to exceed the level of concern.

4. *Non-dietary (residential and non-occupational) exposure.* There are no residential uses for imazamox and it is not likely to be applied in or near residential areas; therefore, non-occupational non-dietary exposure is not expected.

5. *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." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may be helpful in determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodology to resolve the scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although, at present, the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanisms issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

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, 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.

VI. Determination of Safety for the U.S. Population and Non-Nursing Infants

Using the Dietary Risks Evaluation System (DRES) a chronic dietary analysis was performed based on 100% of the crop treated and all residues at tolerance levels. Based on the dietary risk assessment, the proposed uses utilize less than 1% of the RfD for the U.S. population; less than 1% of the RfD for non-nursing infants under 1 year old; less than 1% for nursing infants under 1 year old; less than 1% for children 1 to 6 years old; and less than 1% for children 7 to 12 years old. The Agency concluded that there is a reasonable certainty that no harm will occur to non-nursing infants, or any other members of the U.S. population from aggregate exposure to imazamox.

VII. Determination of Safety for Infants and Children

Risk to infants and children was determined by the use of two developmental toxicity studies in rats and rabbits and the two-generation reproduction study in rats discussed below. The developmental toxicity studies evaluate the potential for adverse effects on the developing organism resulting from exposure during prenatal development. The reproduction study provides information relating to effects from exposure to the chemical on the reproductive capability of both (mating) parents and on systemic toxicity.

The toxicological database for evaluating pre- and post-natal toxicity for imazamox is considered to be complete at this time. In the rabbits, the maternal LOEL was 600 mg/kg/day based on reduced food consumption. The maternal NOEL of 300 mg/kg/day was established based on reduced body weight gains and reduced food consumption. The developmental toxicity NOEL was set at 900 mg/kg/day, the highest dose tested (HDT). In the rat developmental toxicity study, maternal (systemic) toxicity was 500 mg/kg/day (indicated by body weight effects). The NOEL for developmental toxicity was set at equal to or < 1,000 mg/kg/day (HDT). In the rat two-generation reproduction study, no evidence of toxicity was noted in either the adults or the offspring at dietary levels at or close to the limit dose of 20,000 ppm (1,705 mg/kg/day).

FFDCA section 408 provides that the EPA shall apply an additional safety factor of 10 in the case of threshold effects for infants and children to

account for pre- and post-natal toxicity and the completeness of the database unless EPA determines, based on reliable data, that a different safety factor would be appropriate. The Agency believes that an additional safety factor for infants and children is not warranted. A complete set of developmental and reproductive studies have been submitted and EPA has found them to be acceptable. The NOEL used to calculate the RfD for the general U.S. population is 300 mg/kg bw/day derived from the rabbit developmental study. That NOEL is lower than the developmental NOEL for the teratology study in rats (3.33x), as well as lower than the NOEL for the two-generation reproduction study in male and female rats (4.89x to 5.68x). The Agency does not believe the effects seen in the above studies are of such concern to require an additional safety factor. Accordingly, the Agency believes the RfD has an adequate margin of protection for infants and children. The percent RfD utilized by imazamox is less than 1% for nursing infants (less than 1 year old), and for non-nursing infants and children 1 to 6 years old. EPA concluded that there is reasonable certainty that no harm will occur to infants and children from aggregate exposure to imazamox.

VIII. Other Considerations

Endocrine effects. No specific tests have been conducted with imazamox to determine whether the chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects. However, there were no significant findings in other relative toxicity studies, i.e., teratology and multi-generation reproductive studies, which would suggest that imazamox produces endocrine related effects.

IX. 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 the new section 408(e) and (1)(6) as was provided in the old section 408 and 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 August 1, 1997, file written objections to any aspect of this regulation and may also request a hearing with the Hearing Clerk, at the address given below (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 issue(s) on which a hearing is requested, the requestor's contentions on each such issue, and a summary of any evidence relied upon by the objector, 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 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 issue(s) 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 marked as CBI 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.

X. Public Docket

EPA has established a record for this rulemaking under docket number [OPP-300502] (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 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), 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 address in "ADDRESSES" at the beginning of this document.

XI. Regulatory Assessment Requirements

This final rule establishes a tolerance under section 408 of the FFDCA and is in response to a petition received by the Agency requesting the establishment of such a tolerance. 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). In addition, this final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or 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, because tolerances that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Prior to the recent

amendments to the FFDCA, however, EPA had treated such actions as subject to the RFA. The amendments to the FFDCA clarify that no proposed rule is required for such regulatory actions, which makes the RFA inapplicable to these actions. 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 (46 FR 24950, May 4, 1981). In accordance with Small Business Administration (SBA) policy, this determination will be provided to the Chief Counsel for Advocacy of the SBA upon request.

XII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted 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 General Accounting Office prior to publication of this rule in today's **Federal Register**. This 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, Food additive, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 22, 1997.

Stephen L. Johnson,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

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

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

2. By adding a new § 180.508 to subpart C to read as follows:

§ 180.508 Imazamox; tolerances for residues.

(a) *General.* Tolerances are being established for residues of the of the herbicide imazamox, [2-[4,5-dihydro-4-methyl-4-(1methylethyl)-5-oxo-1H-imidazol-2-yl]-5-methoxymethyl-3-pyridine-carboxylic acid], (CAS No. 114311-32-9) applied as the free acid or ammonium salt, in or on following food commodity:

Commodity	Parts per million
Soybeans	0.1

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

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 97-14301 Filed 5-28-97; 1:23 pm]

BILLING CODE 6560-50-F

DEPARTMENT OF TRANSPORTATION**Research and Special Programs Administration****49 CFR Part 171**

[Docket No. RSPA-97-2501 (HM-221B)]

RIN 2137-AD04

Hazardous Materials: Use of Non-Specification Open-Head Fiber Drum Packagings

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Direct final rule.

SUMMARY: RSPA is allowing the transportation of certain liquid hazardous materials in non-specification open-head fiber drums until September 30, 1999, if the fiber drums have been filled before, and are not emptied and refilled after, the expiration of the current authority for the use of these packagings.

RSPA is terminating its rulemakings relating to alternate standards for open-head fiber drums based on the recommendation of the National Academy of Sciences (NAS) that RSPA should not extend authorization for the transportation of liquid hazardous materials in open-head fiber drums that do not meet the performance-oriented packaging standards adopted in RSPA's rulemaking docket No. HM-181. This action completes the rulemakings mandated by Section 406 of the Interstate Commerce Commission Termination Act concerning alternate standards for open-head fiber drums used in the transportation of liquid hazardous materials.

DATES: This final rule is effective October 1, 1997, unless an adverse comment or notice of intent to file an adverse comment is received by August 1, 1997. RSPA will publish in the **Federal Register** a timely document confirming the effective date of this direct final rule.