Dated: July 3, 1999.

John P. DeVillars,

Regional Administrator, Region 1.

40 CFR Part 62 of the Code of Federal Regulations is amended as follows:

PART 62—[AMENDED]

1. The authority citation for Part 62 continues to read as follows:

Authority: 42 U.S.C. 7401–7642.

Subpart W—Massachusetts

2. Part 62 is amended by adding a new § 62.5340 and a new undesignated center heading to Subpart W to read as follows:

Plan for the Control of Designated Pollutants From Existing Facilities (Section 111(d) Plan)

§ 62.5340 Identification of Plan.

(a) Identification of Plan. Massachusetts Plan for the Control of Designated Pollutants from Existing Plants (Section 111(d) Plan).

(b) The plan was officially submitted as follows:

(1) Control of metals, acid gases, organic compounds and nitrogen oxide emissions from existing municipal waste combustors, submitted on January 11, 1999. The Plan does not include: the site assignment provisions of 310 CMR 7.08(2)(a); the definition of ''materials separation plan'' at 310 CMR 7.08(2)(c); and the materials separation plan provisions at 310 CMR 7.08(2)(f)(7).

(c) Designated facilities. The plan applies to existing sources in the following categories of sources:

(1) Municipal waste combustors.

3. Part 62 is amended by adding a new § 62.5425 and a new undesignated center heading to Subpart W to read as follows:

Metals, Acid Gases, Organic Compounds and Nitrogen Oxide Emissions From Existing Municipal Waste Combustors With the Capacity to Combust Greater Than 250 Tons Per Day of Municipal Solid Waste

§ 62.5425 Identification of sources.

(a) The plan applies to the following existing municipal waste combustor facilities:

(1) Fall River Municipal Incinerator in Fall River.

(2) Ogden Martin-Haverhill MWC in Haverhill.

(3) SEMASS RRF in Rochester.

(4) Wheelabrator Millbury Inc. in Millbury.

(5) Saugus RESCO in Saugus.

(6) NESWC MWC in North Andover.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300879; FRL–6086–5]

RIN 2070–AB78

Imazamox; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of imazamox, [2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-methoxymethyl-3-pyridine-carboxylic acid, applied as the free acid or ammonium salt in or on canola and dry beans. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on canola and dry beans. This regulation establishes a maximum permissible level for residues of imazamox in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and are revoked on July 15, 2001.

DATES: This regulation is effective July 14, 1999. Objections and requests for hearings must be received by EPA on or before September 13, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300879], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300879], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300879]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Barbara Madden, 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. 284, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–6463, madden.barbara@epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for residues of the herbicide imazamox, in or on canola and dry beans at 0.05 part per million (ppm). These tolerances will expire and are revoked on July 15, 2001. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Findings

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

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

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

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

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

II. Emergency Exemptions for Imazamox on Canola and Dry Beans and FFDCA Tolerances

Minnesota and North Dakota requested use of imazamox on canola for control of wild mustard. According to the States, there are several factors that have caused an increase in the wild mustard population causing an emergency condition. First, there was above normal rainfall in 4 of 5 years during 1993-1997 and very high rainfall in 1998. Second, there has been an increase in the adoption of reduced-tillage practices to conserve soil moisture and prevent soil erosion. Third, there has been an increase in rotation to crops with limited or no control options. Wild mustard emerges early in the spring and is very competitive with canola. A canola crop containing 5% or more mustard seed will likely be rejected. Weed control is essential for successful oil seed crop production.

Currently there are no herbicides registered for use on canola that control wild mustard. The Agency has issued emergency exemptions for use of glufosinate-ammonium and glyphosate, which will also control wild mustard; however, the States claim the total amount of product available under those exemptions is not enough to control wild mustard infestations in all the canola acreage. In-crop cultivation is not a viable alternative for weed control since canola is commonly seeded in narrow rows.

Colorado, Idaho, Minnesota, Montana, North Dakota and Wyoming requested use of imazamox on dry beans for control of nightshade. Nightshades and velvetleaf have become a severe problem in dry bean production in parts of the Northwest and West Central United States. Hairy and black nightshade germinate throughout the growing season and can successfully tolerate shading. These characteristics allow plants to survive most current control strategies and contaminate fields at harvest. A single plant growing with crop competition can produce up to 1,600 berries per plant. The high moisture content of foliage and berries results in significant reductions in harvest efficiency; berries are poisonous and the purple-black juice from the berries stains the beans and reduces quality. A zero tolerance is established for dry beans grown for seed; one nightshade berry in a 300 pound sample will result in the rejection of an entire field.

Nightshade and velvetleaf have become severe problems due to a combination of reasons. Widespread use of trifluralin and pendimethalin have effectively controlled many grass weed species but have caused an increased prominence of nightshade. Frequent and thorough cultivations have been effective nightshade tools but are unavailable in conservation tillage. Only imazethapyr effectively controls nightshade in dry beans. Imazethapyr is not registered for use on dry beans in Idaho and Montana. Registrations are in place in Colorado, Minnesota, North Dakota, and Wyoming.

Historically, the Agency has determined that crop rotation restrictions are not a basis for an emergency when acceptable alternatives exist. However, imazethapyr has plantback intervals for sugar beets and canola of 40 months plus a successful field bioassy. Dry beans are an important rotational crop of sugar beets because sugar beets cannot be planted continuously due to nematode problems. The States have argued and the Agency agrees that a 40-month plantback restriction into an important cash crop for the region is equivalent to not having a viable alternative.

EPA has authorized under FIFRA section 18 the use of imazamox on canola for control of wild mustard in Minnesota and North Dakota, and use of imazamox on dry beans for control of nightshade in Colorado, Idaho, Minnesota, Montana, North Dakota, and Wyoming. After having reviewed these submissions, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of imazamox in or on canola and dry beans. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on July 15, 2001, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on canola and dry beans after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether imazamox meets EPA's registration requirements for use on canola and dry beans or whether

permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of imazamox by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Colorado, Idaho, Minnesota, Montana, North Dakota, and Wyoming to use this pesticide on these crops under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding these emergency exemptions for imazamox, contact the Agency's Registration Division at the address provided under the ''ADDRESSES'' section.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of imazamox and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for residues of imazamox on canola and dry beans at 0.05 ppm. EPA's assessment of the dietary 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 this unit.

B. Toxicological Endpoint

1. *Acute toxicity.* An acute reference dose (RfD) was not identified for imazamox. No toxicity was seen at doses exceeding the highest dose tested (HDT) in long-term studies in mice [no observed adverse effect level (NOAEL) = 1,053 milligrams/kilograms/day (mg/kg/day)], rats (NOAEL = 1,068 mg/kg/day) and dogs (NOAEL = 1156 mg/kg/day). No developmental toxicity was seen at 1,000 mg/kg/day in rats and 900 mg/kg/day in rabbits.

2. *Short- and intermediate-term toxicity.* Neither dermal nor systemic toxicity was seen at the HDT of 1,000 mg/kg/day in a 28-day dermal toxicity study in rats. Therefore, an endpoint was not identified for short- and intermediate-term dermal or inhalation exposure.

3. *Chronic toxicity.* EPA has established the RfD for imazamox at 3 mg/kg/day. This RfD is based on a NOAEL of 300 mg/kg/day from a developmental toxicity study in rabbits. Effects seen at the lowest observed adverse effect level (LOAEL), 600 mg/kg/day, were decreased food consumption during the treatment period; at 900 mg/kg/day, body weight gains were also reduced. An uncertainty factor of 100 (10X for inter-species extrapolation and 10X for intra-species variability) was applied to the NOAEL of 300 mg/kg/day to calculate the RfD of 3 mg/kg/day. EPA has determined that the 10X factor to account for enhanced susceptibility of infants and children, as required by FFDCA section 408(b)(2)(C), can be removed.

4. *Carcinogenicity*. Imazamox has been classified as a ''Not Likely'' carcinogen.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.508) for the residues of imazamox in or on soybeans. Risk assessments were conducted by EPA to assess dietary exposures and risks from imazamox as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No toxicity was seen at doses exceeding the HDT in long-term studies in mice, rats and dogs. No developmental toxicity was seen at 1,000 mg/kg/day in rats and 900 mg/kg/day in rabbits. Therefore, an acute RfD was not identified for imazamox and acute dietary risk assessments were not conducted.

ii. *Chronic exposure and risk.* In conducting this chronic dietary risk assessment, the following conservative assumptions have been made: (1) all of the crops having imazamox tolerances will contain imazamox residues, and (2) those residues will be at the level of the tolerance. This results in an overestimation of human dietary exposure. Thus, in making safety determinations for the canola and dry bean tolerances, the Agency is taking into account this conservative exposure assessment.

The combined imazamox tolerances (currently published and the section 18 tolerances established by this action) result in a Theoretical Maximum Residue Contribution (TMRC) that is less than 0.1% of the RfD for the U.S. population and all population subgroups.

2. *From drinking water.* The Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water exposure analysis and risk assessment for imazamox. Because the Agency does not have comprehensive and reliable monitoring data, drinking water concentration estimates must be made by reliance on some sort of simulation or modeling. To date, there are no validated modeling approaches for reliably predicting pesticide levels in drinking water. The Agency is currently relying on Generic Expected Environmental Concentration (GENEEC) and PRZM/EXAMS for surface water, which are used to produce estimates of pesticide concentrations in a farm pond and Screening Concentration in Ground Water (SCI-GROW), which predicts pesticide concentrations in ground water. None of these models include consideration of the impact processing 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. For the proposed uses, based on the GENEEC and SCI-GROW models, the chronic drinking water concentration values are estimated to be 2 parts per billion (ppb) for surface water and 3.4 pbb for ground water.

In the absence of monitoring data for pesticides, 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, drinking water, and residential uses. A DWLOC will vary depending on the toxic endpoint, with drinking water consumption, and body weights. Different populations will have different DWLOCs. DWLOCs are used in the risk assessment process as a surrogate measure of potential exposure associated with pesticide

exposure through drinking water. DWLOC values are not regulatory standards for drinking water. Since DWLOCs address total aggregate exposure to imazamox, they are further discussed in the aggregate risk sections below.

3. *From non-dietary exposure.* Imazamox is not registered on any use sites which would result in non-dietary, non-occupational exposure. Therefore, EPA expects only dietary and occupational exposure from the use of imazamox.

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 more information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Acute risk.* An acute RfD was not identified for imazamox; therefore, acute dietary risk assessments were not conducted.

2. *Chronic risk.* Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to imazamox from food will utilize less than 0.1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants less than 1 year old (discussed below). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to imazamox in drinking water, after calculating a DWLOC (90,000 ppb) for the U.S. population and comparing it to conservative model estimates of concentrations of imazamox in surface and ground water (2 ppb and 3.4 pbb, respectively), EPA does not expect the aggregate exposure to exceed 100% of the RfD.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus other indoor and outdoor non-occupational exposure. Since there are no non-dietary, non-occupational exposures expected from the use of this chemical, no short- and intermediate-term risk assessments were conducted.

4. *Aggregate cancer risk for U.S. population.* Imazamox has been classified as a ''Not Likely'' carcinogen; therefore, a cancer risk assessment was not conducted.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to imazamox residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*— i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of imazamox, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* In the developmental study in rats, the maternal (systemic) NOAEL was 500 mg/kg/day, based on minimal decreases in maternal body weight gains during the treatment period at the LOAEL of 1,000 mg/kg/day. The developmental (fetal) NOAEL was ≧ 1,000 mg/kg/day, the highest dose level tested. In the developmental toxicity study in rabbits, the maternal (systemic) NOAEL was 300 mg/kg/day, based on decreased food consumption at the LOAEL of 600 mg/kg/day. The developmental (pup) NOAEL was ≧ 900 mg/kg/day, the highest dose level tested.

iii. *Reproductive toxicity study.* In the 2-generation reproductive toxicity study in rats, the systemic and reproductive NOAEL was ≧ 1,705/1,469 mg/kg/day for M/F, the highest dose level tested. The developmental (pup) NOAEL was 1,469 mg/kg/day, the highest dose level tested.

iv. *Pre- and postnatal sensitivity.* The toxicological data base for evaluating pre- and postnatal toxicity for imazamox is complete with respect to current data requirements. There are no pre- or postnatal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies and the 2-generation rat reproductive toxicity study.

v. *Conclusion.* There is a complete toxicity data base for imazamox and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The Agency concludes that reliable data support use of a 100-fold margin of exposure/uncertainty factor, rather than the standard 1,000-fold margin/factor, to protect infants and children.

2. *Acute risk.* An acute RfD was not identified for imazamox; therefore, acute dietary risk assessments were not conducted.

3. *Chronic risk.* Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to imazamox from food will utilize less than 0.1% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to imazamox in drinking

water, after calculating a DWLOC (30,000 ppb) for non-nursing infants less than 1 year old, the major identifiable subgroup with the highest aggregate exposure and comparing it to conservative model estimates of concentrations of imazamox in surface and ground water (2 ppb and 3.4 pbb, respectively), EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk.* There are no non-dietary, non-occupational exposures expected from the use of imazamox; therefore, no short- and intermediate-term risk assessments were conducted.

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

IV. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in soybeans data were reviewed in conjunction with a registration for use of imazamox on soybeans under FIFRA section 3. The soybean metabolism data were adequate to determine that the residue of concern is imazamox on soybeans. For these section 18's on canola and dry beans, the regulated residue is imazamox *per se*.

The nature of the residue in animals (poultry and ruminants) data were also reviewed in conjunction with the petition for soybeans. It was determined that no detectable imazamox residues would be expected in any animal commodities; therefore, no tolerances for any animal commodities were needed. Use of canola or dry beans as a feed item is expected to result in a similar or lower dietary burden as soybeans. Therefore, no tolerances are required for any animal commodities to support these commodities.

B. Analytical Enforcement Methodology

Adequate enforcement methodology (residue analytical methods M2248.01 and M2333 using HPLC/UV and HPLC/MS, respectively, have been validated by EPA's Analytical Chemistry Branch and is available to enforce the tolerance expression for soybeans. For canola and dry beans, the registrant proposes a capillary electrophoresis method (M-3076) that has the same LOQ as the previously validated UV and MS methods (0.05 ppm). This method is considered acceptable for the current section 18 registration.

C. Magnitude of Residues

Residues of imazamox are not expected to exceed 0.05 ppm in/on canola or dry beans as a result of these section 18 uses. Based on metabolism studies on goats and hens, the Agency concludes that for these section 18 uses there are no reasonable expectation of finite residues of imazamox *per se* in meat, milk, poultry and eggs; therefore, tolerances for these commodities are not required at this time.

D. International Residue Limits

Imazamox is registered for use in canola in Canada. There are no Codex MRLs and no Mexican uses, as of 1998.

E. Rotational Crop Restrictions

Data that examined the potential for accumulation of [6-pyridine-^{14}C]imazamox in rotational crops indicate that ^{14}C-residues of imazamox did not accumulate (<0.01 ppm) in/on wheat commodities planted 100 days after sandy loam soil treatment at the 1.6X rate with [6-pyridine-^{14}C]imazamox. At the 268-day rotation, radioactive residues were less than 0.01 ppm in/on radish, lettuce, and corn commodities. Tolerances on rotational crops need not be established. Available data support a 3-month plantback interval for wheat, 4-month plantback interval for barley and rye, and the 9-month plantback interval for alfalfa, beans, corn, cotton, oats, peas, peanuts, potatoes, rice, sorghum (grain) and tobacco. Based on the residue data, the plantback intervals for all other crops could be 9 months, however, due to phytotoxicity concerns, some plantback restrictions are longer than 9 months.

V. Conclusion

Therefore, tolerances are established for residues of imazamox in canola and dry bean at 0.05 ppm.

VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by September 13, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (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). 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 tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record.

Information not marked confidential may be disclosed publicly by EPA without prior notice.

VII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300879] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:
opp-docket@epa.gov

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit 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 record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). 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 as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(l)(6), 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. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 28, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180–[AMENDED]

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

Authority: 21 U.S.C. 346a, 321q and 371.

2. In § 180.508, by adding paragraph (b) to read as follows:

§ 180.508 Imazamox; tolerances for residues.

(a) * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of imazamox, [2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-methoxymethyl-3-pyridine-carboxylic acid, applied as the free acid or ammonium salt in connection with use of the herbicide under section 18 emergency exemptions granted by EPA. Tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/ revocation date
Beans, dry	0.05	7/15/01
Canola	0.05	7/15/01

* * * * *

[FR Doc. 99–17352 Filed 7–13–99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300883; FRL 6087–5]

RIN 2070–AB78

Bentazon; Extension of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends a time-limited tolerance for residues of the herbicide bentazon and its metabolites in or on succulent peas at 3.0 parts per million (ppm) for an additional 1 1/2 year period. This tolerance will expire and is revoked on December 31, 2000. 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 succulent peas. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18.

DATES: This regulation becomes effective July 14, 1999. Objections and requests for hearings must be received by EPA, on or before September 13, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300883], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300883], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300883]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Andrea Beard, 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. 271, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703–308–9356; e-mail: beard.andrea@epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a final rule, published in the **Federal Register** of June 20, 1997 (62 FR 33563) (FRL–5720–4), which announced that on its own initiative under 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) it established a time-limited tolerance for the residues of bentazon and its metabolites in or on succulent peas at 3.0 ppm, with an expiration date of June 30, 1998. EPA established the tolerance because section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment. On May 11, 1998 (63 FR 25775) (FRL–5787–4), EPA published a document extending this tolerance to June 30, 1999.

EPA received a request to extend the use of bentazon on succulent peas for this year's growing season due to infestation with the weed, Canada thistle. Since there are still no effective registered alternatives, this situation continues to be an emergency. After having reviewed the submission, EPA concurs that emergency conditions exist. EPA has authorized under FIFRA section 18 the use of bentazon on succulent peas for control of Canada thistle in succulent peas.

EPA assessed the potential risks presented by residues of bentazon in or on succulent peas. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. The data and other relevant material have been evaluated and discussed in the final rule of June 20, 1997 (62 FR 33563). Based on the data and information considered, the Agency reaffirms that extension of the time-limited tolerance will continue to meet the requirements of section 408(l)(6). Therefore, the time-limited tolerance is extended for an additional