(1) *Promote health.* Care is deemed to promote health if the care will enhance the quality of life or daily functional level of the veteran, identify a predisposition for development of a condition or early onset of disease which can be partly or totally ameliorated by monitoring or early diagnosis and treatment, and prevent future disease.

(2) *Preserve health.* Care is deemed to preserve health if the care will maintain the current quality of life or daily functional level of the veteran, prevent the progression of disease, cure disease, or extend life span.

(3) *Restoring health.* Care is deemed to restore health if the care will restore the quality of life or daily functional level that has been lost due to illness or injury.

(c) In addition to the care specifically excluded from the ''medical benefits package'' under paragraphs (a) and (b) of this section, the ''medical benefits package'' does not include the following:

(1) Abortions and abortion counseling.

(2) In vitro fertilization.

(3) Drugs, biologicals, and medical devices not approved by the Food and Drug Administration unless the treating medical facility is conducting formal clinical trials under an Investigational Device Exemption (IDE) or an Investigational New Drug (IND) application, or the drugs, biologicals, or medical devices are prescribed under a compassionate use exemption.

(4) Gender alterations.

(5) Hospital and outpatient care for a veteran who is either a patient or inmate in an institution of another government agency if that agency has a duty to give the care or services.

(6) Membership in spas and health clubs.

Authority: 38 U.S.C. 101, 501, 1701, 1705, 1710, 1721, 1722.

§ 17.43 [Amended]

6. In § 17.43, paragraph (a) is removed and paragraphs (b) through (e) are redesignated as paragraphs (a) through (d), respectively.

§ 17.47 [Amended]

7. In § 17.47, paragraph (h) is removed; paragraphs (i) through (l) are redesignated as paragraphs (h) through (k), respectively; and newly redesignated paragraph (h) is amended by removing ''hospital or'' and by removing ''or hospital care in a Federal hospital under agreement,''.

§ 17.93 [Amended]

8. In § 17.93, paragraph (a)(2) is amended by removing ''Medical services'' and adding, in its place, ''Subject to the provisions of §§ 17.36 through 17.38, medical services''.

§ 17.99 [Removed]

9. Section 17.99 is removed.

§ 17.100 [Amended]

10. In § 17.100, the third sentence is amended by removing ''a new application is filed, and''.

[FR Doc. 99–25871 Filed 10–5–99; 8:45 am]
BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300927; FRL–6382–3]

RIN 2070–AB78

Imazapic-Ammonium; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of imazapic-ammonium, (+)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2- yl]-5-methyl-3-pyridinecarboxylic acid, applied as its ammonium salt and its metabolite (+)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-hydromethyl-3- pyridinecarboxylic acid both free and conjugated in or on grass forage at 30 ppm; grass hay at 15 ppm; milk, fat, meat, meat byproducts (except kidney) of cattle, goats, hogs, horses, and sheep at 0.10 ppm; kidney of cattle, goats, hogs, horses, and sheep at 1 ppm. 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 pasture/rangeland and land in the Conservation Reserve Program. This regulation establishes a maximum permissible level for residues of imazapic-ammonium and its metabolite in these food commodities. The tolerances will expire and are revoked on December 31, 2001.

DATES: This regulation is effective October 6, 1999. Objections and requests for hearings, identified by docket control number OPP–300927, must be received by EPA on or before December 6, 1999.

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'' section. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300927 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Libby Pemberton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: 703 308–9364; and e-mail address: pemberton.libby@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	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the ''FOR FURTHER INFORMATION CONTACT'' section.

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'' and then look up the entry for this document under the ''Federal Register- -Environmental Documents.'' You can also go directly to

the Federal Register listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–300927. 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

EPA, on its own initiative, in accordance with sections 408 (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for combined residues of the [herbicide] imazapic-ammonium and its metabolite both free and conjugated, in or on grass forage at 30 part per million (ppm); grass hay at 15 ppm; milk, fat, meat, meat byproducts (except kidney) of cattle, goats, hogs, horses, and sheep at 0.10 ppm; kidney of cattle, goats, hogs, horses, and sheep at 1 ppm. These tolerances will expire and are revoked on December 31, 2001. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

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.EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

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 the Federal Insecticide, Fungicide, and Rodenticide Act (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 Food Quality Protection Act (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemptions for Imazapic-Ammonium on Pasture/Rangeland and Land in the Conservation Reserve Program and FFDCA Tolerances

The Applicant has stated that picloram can not be used in areas with sensitive desirable plants such as trees nor in areas with a shallow depth to groundwater; and high rates of 2,4-D have proven ineffective in controlling leafy spurge. Economic loss from the infestation of leafy spurge is measured in loss of livestock carrying capacity. It is estimated the potential economic loss will continue to average $5.5 million per year in Nebraska without the use of imazapic. EPA has authorized under FIFRA section 18 the use of imazapic-ammonium on pasture/rangeland and land in the Conservation Reserve Program for control of leafy spurge in Nebraska. After having reviewed the submission, EPA concurs that emergency conditions exist for this state.

As part of its assessment of these emergency exemptions, EPA assessed the potential risks presented by residues of (+)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*- imidazol-2-yl]-5-methyl-3-pyridinecarboxylic acid applied as its ammonium salt and its metabolite (+)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5- hydromethyl-3-pyridinecarboxylic acid both free and conjugated in or on grass forage; grass hay; milk, fat, meat, meat byproducts (except kidney) of cattle, goats, hogs, horses, and sheep; and kidney of cattle, goats, hogs, horses, and sheep. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6). Although these tolerances will expire and are revoked on December 31, 2001, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on grass forage; grass hay; milk, fat, meat, meat byproducts (except kidney) of cattle, goats, hogs, horses, and sheep; and kidney of cattle, goats, hogs, horses, and sheep 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 these tolerances at the time of that application. EPA will take action to revoke these tolerances 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 imazapic-ammonium meets EPA's registration requirements for use on pasture/rangeland and land in the Conservation Reserve Program 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 imazapic-ammonium by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Nebraska 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 the emergency exemptions for imazapic-ammonium, contact the Agency's Registration

Division at the address provided under the ''ADDRESSES'' section.

IV. 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 imazapic-ammonium and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for combined residues of imazapic-ammonium and its metabolite both free and conjugated on grass forage at 30 ppm; grass hay at 15 ppm; milk, fat, meat, meat byproducts (except kidney) of cattle, goats, hogs, horses, and sheep at 0.10 ppm; and kidney of cattle, goats, hogs, horses, and sheep at 1 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by imazapic-ammonium are discussed in this unit.

B. Toxicological Endpoint

1. *Acute toxicity*. For acute dietary risk assessment, the no-observed adverse effect level (NOAEL) of 175 milligrams/kilogram/day (mg/kg/day), based on developmental effects increased incidence of fetuses with rudimentary ribs at the lowest observed adverse effect level (LOAEL) of 350 mg/kg/day, from the developmental study in rabbits was used. Pregnant females 13+, is the population subgroup of concern. The acute dietary population adjusted dose (aPAD) is defined as the Reference Dose (RfD)/FQPA safety factor. The acute RfD of 1.75 mg/kg day is based on the developmental NOAEL of 175 mg/kg/day and the usual 100x uncertainty factor for intra- and inter-species differences and variations. The acute dietary aPAD is 0.175 mg/kg/day, based on the RfD of 1.75 mg/kg/day, and an additional uncertainty factor of 10x to account for potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children (based on the determination of developmental effects below the level of maternal toxicity in the rabbit developmental study). There is no acute dietary aPAD for other population subgroups, including infants and children.

2. *Short- and intermediate-term toxicity*. For short-term margin of exposure (MOE) calculations, the developmental NOAEL of 175 mg/kg/day from the developmental study in rabbits was used. At the LOAEL of 350 mg/kg/day, there were increased rudimentary ribs below a level of maternal toxicity. The short term NOAEL can be used for both dermal and inhalation. An MOE of 100 is required for both dermal and inhalation exposure. For intermediate-term dermal exposures, the LOAEL of 137 mg/kg/day lowest dose tested (LDT) from the one year feeding study in dogs was used. At the LOAEL of 137 mg/kg/day, there was skeletal muscle degeneration in both sexes. The intermediate term LOAEL can be used for both dermal and inhalation exposures. An MOE of 300 is required for both dermal and inhalation exposure and is based on the usual 100x safety factor for intra- and inter-species differences and an addtional 3x safety factor for the absence of a NOAEL in the critical study.

3. *Chronic toxicity*. EPA has established the RfD for imazapic-ammonium at 0.5 mg/kg/day. This RfD is based on a one year feeding study in dogs with a LOAEL of 137 mg/kg/day (LDT) based on skeletal muscle degeneration. A NOAEL was not established in the study. An uncertainty factor of 3000x was recommended and was based on 10x for interspecies differences, 10x for intraspecies variations, 10x for infants and children, and 3x for absence of a NOAEL.

4. *Carcinogenicity*. Imazapic has been classified as a Group ''E'' (evidence of non- carcinogenicity for humans) chemical.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.490) for the combined residues of imazapic-ammonium and its metabolite both free and conjugated, in or on peanut nutmeat at 0.1 ppm. Risk assessments were conducted by EPA to assess dietary exposures and risks from imazapic-ammonium 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. The acute dietary (food only) risk assessment used the TMRC (theoretical maximum residue contribution). At the 95th percentile of exposure for user- days and per-capita days, the Tier 1 acute DEEM analysis predicts an exposure level of 0.000494 mg/kg/day for the females (13+, pregnant, not nursing) population subgroup, which is equivalent to 0.3% of the aPAD. This should be viewed as a conservative risk estimate; refinement using anticipated residue values and percent crop-treated data in conjunction with Monte Carlo analysis would result in a lower acute dietary exposure estimate.

ii. *Chronic exposure and risk*. In conducting the chronic dietary risk assessment, conservative assumptions — 100% of all commodities having imazapic tolerances will contain imazapic residues and those residues would be at the level of the tolerance — were used, which results in an overestimation of human dietary exposure. The existing imazapic tolerances (published and pending result in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to the following percentages of the RfD:

Subgroup	Percentage
U.S. Population (48 States).	0.5
Nursing Infants (<1 year old).	0.3
Non-Nursing Infants (<1 year old).	1.3
Children (1-6 years old)	1.4
Children (7-12 years old) ..	0.9
Hispanics	0.6
Males 13-19 yrs	0.6

The subgroups listed above are: (a) The U.S. population (48 states); (b) those for infants and children; and, (c) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 states).

2. *From drinking water.* Acute and chronic (56-day) DWECs (drinking water estimated concentration) for surface water were calculated by GENEEC (GENeric Expected Environmental Concentration) screening model to be 7.57 and 4.16 ppb, respectively. According to HED drinking water guidance (HED SOP 98.4) the 56-day GENEEC value may be divided by 3 to

obtain a value for chronic risk assessment calculations. Therefore, the Tier 1 chronic surface water value is 1.39 ppb. A ground water estimate was made using the SCI-GROW (Screening Concentration In GROund Water) screening model based on actual ground water monitoring data collected from small-scale prospective ground water monitoring studies for the registration of a number of pesticides that serve as benchmarks for the model. The DWEC for imazapic in ground water was calculated at 5.95 ppb. This concentration may be used for both the acute and chronic scenarios.

3. *From non-dietary exposure.* Imazapic-ammonium is not currently registered for sites that would result in non-dietary, non-occpational exposure. Therefore, such exposures are not expected and have not been included in this risk assessment.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Imazapic is a member of the imidazolinone class of pesticides. Other members of this class include imazapyr, imazethapyr, imazaquin, and imazamethabenz-methyl. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether imazapic-ammonium has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, imazapic-ammonium does not appear to produce a toxic metabolite produced by other substances. For the purposes of these tolerance actions, therefore, EPA has not assumed that imazapic-ammonium 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.* For the population subgroup of concern, pregnant females 13+ years, the acute aggregate exposure includes food and water. For pregnant females, 13+, 0.3% of the aPAD is occupied by dietary (food) exposure. The estimated maximum concentrations of imazapic-ammonium in surface and ground water are less than the DWLOC for imazapic-ammonium in drinking water as a contribution to acute aggregate exposure. Therefore, EPA concludes with reasonable certainty that the acute aggregate risks resulting from residues of imazapic- ammonium in food and drinking water are below EPA's level of concern.

2. *Chronic risk.* For the U.S. population, 0.5% of the cPAD is occupied by dietary (food) exposure. Other highly exposed population subgroups include children 1-6 years (1.4% cPAD), hispanics (0.6% cPAD), pregnant females 13+ (0.4% cPAD) and males 13-19 years (0.6% cPAD). EPA generally has no concern for exposures below 100 percent of the cPAD, because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The estimated average concentrations of imazapic-ammonium in surface and ground water are less than the DWLOC for imazapic- ammonium in drinking water as a contribution to chronic aggregate exposure. Therefore, EPA concludes with reasonable certainty that the chronic aggregate risks resulting from residues of imazapic-ammonium in food and drinking water are below EPA's level of concern.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor non-dietary, non-occupational exposure. Since there are no registered uses for imazapic-ammonium that would result in such exposures, both short- and intermediate term aggregate risk assessments are not required.

4. *Aggregate cancer risk for U.S. population.* A cancer risk assessment was not conducted, since imazapic has been classified as a Group ''E'' non-carcinogenicity for humans based on a negative tumorigenic potential in two acceptable animal studies.

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 imazapic- ammonium 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 imazapic-ammonium, 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 post-natal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a 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 1,000 mg/kg/day highest dose tested (HDT). The developmental (fetal) NOAEL was 1,000 mg/kg/day (HDT).

In the developmental toxicity study in rabbits, the maternal (systemic) NOAEL was 350 mg/kg/day, based on decreased body weight and food consumption at the LOAEL of 500 mg/kg/day. The developmental (fetal) NOAEL was 175 mg/kg/day, based on increased incidence of rudimentary ribs at the LOAEL of 350 mg/kg/day.

iii. *Reproductive toxicity study.* In the 2-generation reproductive toxicity study in rats, the maternal (systemic) NOAEL was 1,484 mg/kg/day (HDT). The developmental (pup) NOAEL was 1,484 mg/kg/day (HDT). The reproductive NOAEL was 1,484 mg/kg/day (HDT).

iv. *Pre- and post-natal sensitivity.* The toxicological data base for evaluating pre- and post-natal toxicity for imazapic-ammonium is complete with respect to current data requirements. There appears to be extra-sensitivity

based on the pre-natal results in the rabbit developmental study. The developmental NOAEL was 175 mg/kg/day based on the increased incidence of rudimentary ribs at the LOAEL of 350 mg/kg/day. In contrast, the maternal NOAEL was 350 mg/kg/day based on decreased body weight and food consumption at the LOAEL of 500 mg/kg/day. Therefore, pre-natal developmental toxicity occurred at a dose level 350 mg/kg/day, which did not demonstrate any maternal toxicity. Based on the above, EPA concludes that reliable data support use of a 1,000-fold MOE/uncertainty factor to protect infants and children. Based on the conclusions of the rabbit developmental study, EPA used the FQPA Tier I approach which retains the 10X safety factor.

v. *Conclusion*. There is a complete toxicity database for imazapic-ammonium and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

2. *Acute risk*. The aPAD only applies to pregnant females, 13+ and is not required for infants (<1 year), non-nursing infants, and children (1-6 years). For pregnant females, 13+, dietary exposure utilized 0.4% of the aPAD. The estimated average concentrations of imazapic- ammonium in surface and ground water are less than EPA's level of concern for imazapic- ammonium in drinking water as a contribution to acute aggregate exposure.

3. *Chronic risk*. The %cPAD utilized for chronic dietary exposure were 1.3% for non- nursing infants, 1.4% for children 1-6 years, and 1.0% for all infants (<1 year). The estimated average concentrations of imazapic-ammonium in surface and ground water are less than EPA's level of concern for imazapic-ammonium in drinking water as a contribution to chronic aggregate exposure.

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

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 imazapic-ammonium residues.

V. Other Considerations

A. Metabolism in Plants and Animals

The nature of the residue in plants and livestock has been adequately defined for this time-limited tolerance. The residues of concern in grass are imazapic-ammonium and its hydroxymethyl metabolite, both free and conjugated. Based on the results of a goat metabolism study, the residues of concern in ruminants were identified as imazapic-ammonium and its hydroxymethyl metabolite. For the purposes of this time-limited tolerance only, the residues of concern in animals are imazapic and its hydroxymethyl metabolite.

B. Analytical Enforcement Methodology

An adequate analytical enforcement method is available to enforce the grass forage and hay tolerances for imazapic-ammonium and its hydroxymethyl metabolite. American Cyanamid Company submitted an Independent Laboratory Validation (ILV) of a Capillary Electrophoresis determinative method (Method M3114) for determination of residues in grass.

Adequate analytical enforcement methods are available to enforce the animal commodity tolerances for imazapic-ammonium and its hydroxymethyl metabolite. American Cyanamide Company submitted Independent Laboratory Validations (ILVs) of Capillary Electrophoresis determinative and LC/MS confirmatory methods (Methods M3118; M3222; and M3233) for determination of residues in milk; cattle muscle, kidney, and liver tissue; and bovine milk fat and tissue fat, respectively.

The methods may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305-5229; e-mail address: furlow.calvin@epa.gov.

C. Magnitude of Residues

Residues of imazapic-ammonium and its hydroxymethyl metabolite, free and conjugated, are not expected to exceed 30 and 15 ppm in/on grass forage and hay, respectively, as a result of this emergency use. Secondary residues in animal commodities are not expected to exceed 0.10 ppm in milk, meat, fat, or meat byproducts (except kidney); or 1.0 ppm in kidney as a result of this emergency use. There are no processed food/feed items resulting from this emergency use.

D. International Residue Limits

There are no CODEX, Canadian, or Mexican maximum residue limits for imazapic on pastures/rangeland.

VI. Conclusion

Therefore, the tolerances are established for [combined residues] of imazapic- ammonium, (+)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5- methyl-3-pyridinecarboxylic acid, applied as its ammonium salt and its metabolite (+)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-hydromethyl-3- pyridinecarboxylic acid both free and conjugated in grass forage at 30 ppm; grass hay at 15 ppm; milk, fat, meat, meat byproducts (except kidney) of cattle, goats, hogs, horses, and sheep at 0.10 ppm; and kidney of cattle, goats, hogs, horses, and sheep at 1 ppm.

VII. 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–300927 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 December 6, 1999.

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, 401 M St., SW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Room M3708, 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 be 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.'' (cite). 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, 401 M St., SW., 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, 401 M St., SW., 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 VII.A. of this preamble, you should also send a copy of your request to the PIRB for its inclusion in the official record that is described in Unit I.B.2. of this preamble. Mail your copies, identified by the docket number OPP–300927, 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 or by courier, bring a copy to the location of the PRIB described in Unit I.B.2. of this preamble. 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 5.1/6.1 file format 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).

VIII. Regulatory Assessment Requirements

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 prior consultation with State, local, and tribal government officials as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993) and Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998), or special consideration of environmental justice related issues 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 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). 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 12612, entitled *Federalism* (52 FR 41685, October 30, 1987). This action 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 the Federal Food Drug Cosmetic Act, 21 U.S.C. section 346a(b)(4). 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). In addition, since tolerances and exemptions that are established 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.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this 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: September 23, 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. 321(q), 346(a), and 371.

2. Section 180.490 is revised to read as follows:

§ 180.490 Imazapic-ammonium; tolerances for residues.

(a) *General.* Tolerance is established for residues of the herbicide; (+)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-methyl-3-pyridinecarboxylic acid applied as its ammonium salt and its metabolite (+)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-hydromethyl-3-pyridinecarboxylic acid both free and conjugated; in or on the following food commodity:

Commodities	Parts per million
Peanut nutmeat	0.1

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for combined residues of the herbicide imazapic-ammonium, (+)-2-[4,5-dihydro-4-methyl-4-(1- methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-methyl-3-pyridinecarboxylic acid, applied as its ammonium salt and its metabolite (+)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*- imidazol-2-yl]-5-hydromethyl-3-pyridinecarboxylic acid both free and conjugated in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances are specified in the table.

Commodity	Parts per million	Expiration/ revocation date
Cattle, fat	0.10	12/31/01
Cattle, kidney ..	1.0	12/31/01
Cattle, mbyp (except kidney).	0.1	12/31/01
Cattle, meat	0.1	12/31/01
Goats, fat	0.1	12/31/01
Goats, kidney ..	1.0	12/31/01
Goats, mbyp (except kidney).	0.1	12/31/01
Goats, meat	0.1	12/31/01
Grass, forage ..	30	12/31/01
Grass, hay	15	12/31/01
Hogs, fat	0.1	12/31/01
Hogs, kidney ...	1.0	12/31/01
Hogs, mbyp (except kidney).	0.1	12/31/01
Hogs, meat	0.1	12/31/01
Horses, fat	0.1	12/31/01
Horses, kidney	1.0	12/31/01
Horses, mbyp (except kidney).	0.1	12/31/01
Horses, meat ...	0.1	12/31/01
Sheep, fat	0.1	12/31/01
Sheep, kidney	1.0	12/31/01
Sheep, mbyp (except kidney).	0.1	12/31/01
Sheep, meat	0.1	12/31/01

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

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

[FR Doc. 99–25842 Filed 10–5–99; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 99–1837; MM Docket No. 99–170; RM–9545]

Radio Broadcasting Services; Oceanside and Encinitas, CA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document reallots Channel 271B from Oceanside to Encinitas, California, as that community's first local aural transmission service and modifies the license for Station KXST(FM), a pre-1964 grandfathered facility, as requested, pursuant to the provisions of section 1.420(i) of the Commission's Rules. *See* 64 FR 28427, May 26, 1999. Coordinates used for Channel 271B at Encinitas are the currently authorized site for Station KXST(FM) at 33–06–40 NL and 117–12–05 WL. At that site, Station KXST(FM) will remain short spaced to pre-1964 grandfathered Station KSCA(FM), Channel 270B, Glendale, California, but will not result in an increase in interference potential to other stations as no technical changes for Station KXST(FM) are involved. A previously referenced short spacing to pre-1964 grandfathered Station KGB–FM, Channel 268B, San Diego, California, is not a consideration as the Commission has eliminated the distance separation requirements and interference protection requirements with respect to second and third adjacent channel grandfathered stations that have existed continuously since November 16, 1964. *See* Grandfathered Short-Spaced FM Stations, 62 FR 187, September 26, 1977. As Encinitas is located within 320 kilometers (199 miles) of the U.S.-Mexico border, the Mexican government will be notified of the technical changes to the FM Table of Allotments to reflect the reallotment of Channel 271B from Oceanside to Encinitas. With this action, the proceeding is terminated.

DATES: Effective October 25, 1999.

FOR FURTHER INFORMATION CONTACT: Nancy Joyner, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 99–170, adopted September 1, 1999, and released September 10, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room CY–A257), 445 Twelfth Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., 1231 20th Street, NW., Washington, DC 20036, (202) 857–3800.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

47 CFR PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under California is amended by adding Encinitas, Channel 271B.

3. Section 73.202(b), the Table of FM Allotments under California, is