Commodity	Parts per million
Tomato Paste	0.6

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300511; FRL–5729–4]

RIN 2070–AB78

Imidacloprid; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of imidacloprid in or on the crop group citrus fruits and processed commodity dried citrus pulp. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on citrus. This regulation establishes a maximum permissible level for residues of imidacloprid in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. These tolerances will expire and are revoked on December 31, 1998.

DATES: This regulation is effective July 9, 1997. Objections and requests for hearings must be received by EPA on or before September 8, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300511], 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–300511], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300511]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, 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: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-9367, e-mail: ertman.andrew@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for combined residues of the insecticide imidacloprid, in or on the crop group citrus fruits at 1 part per million (ppm) and the processed commodity dried citrus pulp at 5 ppm. These tolerances will expire and are revoked on December 31, 1998. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 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 below 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 tolerance to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Imidacloprid on Citrus and FFDCA Tolerances

The State of Florida has requested a specific exemption for the use of imidacloprid on citrus for the control of

the brown citrus aphid (BrCA) and the citrus leafminer (CLM). The BrCA is a potentially devastating pest that impacts citrus by feeding on newly developing foliage and by transmitting citrus tristeza virus (CTV). The citrus leafminer, since its initial discovery in May 1993, has become a major economic pest to citrus nurseries and young citrus groves by feeding on newly developing foliage.

The Applicant asserts that CTV could potentially affect citrus yield in the following three ways: (1) threatened losses of $500 million for sweet orange and grapefruit trees budded on sour orange rootstock; (2) if CTV stem pitting strains became endemic throughout the Florida grapefruit industry, yields from grapefruit trees on CTV tolerant rootstock could be reduced by 45% on a continuing basis, fruit size would be reduced, and production costs increased; and (3) if CTV became endemic throughout Florida, yields of sweet orange would be reduced by 5-20%, and production costs increased.

As for yield losses caused by the CLM, the Applicant indicates that defoliation caused by CLM could result in up to a 44% reduction in yield, translating into a net loss of approximately $145/acre.

For the BrCA, the registered alternatives are either ineffective due to labeled use restrictions and length of efficacy or are broad spectrum insecticides that, if used as needed to control the BrCA, would dramatically upset established populations of beneficials. The registered alternatives for the CLM have not provided adequate control of this pest, with the most effective alternatives demonstrating a 14-day suppression of the CLM. Additionally, the CLM is difficult to control with foliar sprays because it is protected from foliar-applied insecticides by the mined leaf cuticle, and leaf margins role inward over the pupae, protecting it. Florida indicated that imidacloprid had demonstrated as much as 15 weeks of control, and since it is a systemic insecticide, would be particularly effective against these type of pests, due to their feeding habits.

EPA has authorized under FIFRA section 18 the use of imidacloprid on citrus for control of the brown citrus aphid and citrus leafminer in Florida. After having reviewed the submission, EPA concurs that emergency conditions exist for this state.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of imidacloprid in or on citrus fruits and dried citrus pulp. In doing so, EPA considered the new 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 new 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 under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on December 31, 1998, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on citrus fruits and dried citrus pulp after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA. 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 imidacloprid meets EPA's registration requirements for use on citrus or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerance serve as a basis for registration of imidacloprid 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 Florida to use this pesticide on this crop under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for imidacloprid, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute'', ''short-term'', ''intermediate term'', and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High-end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all 3 sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (children 1-6 years old) was not regionally based.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of imidacloprid and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for combined residues of imidacloprid on the citrus fruits crop group at 1 ppm and the processed commodity dried citrus pulp 5 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these 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 imidacloprid are discussed below.

1. *Acute toxicity.* NOEL = 24 mg/kg/day. The Agency recommends use of the NOEL of 24 mg/kg/day, based on decreased body weight, increased resorptions, increased abortions, and increased skeletal abnormalities at the lowest effect level (LEL) of 72 mg/kg/day, from the developmental toxicity study in rabbits. This risk assessment should evaluate acute dietary risk to females 13+ years.

2. *Short - and intermediate - term toxicity.* For short- and intermediate-term MOE calculations, the Agency determined that available data do not demonstrate that imidacloprid has dermal or inhalation toxicity potential. Therefore, short-or intermediate-term dermal and inhalation risk assessments are not required. This decision was based on the fact that no effects were observed at the highest dose level tested (0.191 mg/L) in a 28-day inhalation toxicity study in rats, and that no systemic toxicity was observed at dose

levels up to 1,000 mg/kg/day in a 21-day dermal toxicity study in rabbits.

3. *Chronic toxicity*. EPA has established the RfD for imidacloprid at 0.057 milligrams/kilogram/day (mg/kg/day). This RfD is based on a NOEL of 5.7 mg/kg/day from a 2-year feeding/carcinogenicity study in rats. An uncertainty factor of 100 was applied to take into account inter-species sensitivity and intra-species variation. The lowest observed effect level (LOEL) of 16.9 mg/kg/day was based on increased thyroid lesions in males.

4. *Carcinogenicity*. Imidacloprid has been classified as a Group E chemical, no evidence of carcinogenicity for humans, by the Agency.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.472) for the combined residues of imidacloprid, in or on a variety of raw agricultural commodities. Tolerances range from 0.02 ppm in eggs to 6 ppm in cottonseed. Risk assessments were conducted by EPA to assess dietary exposures and risks from imidacloprid 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 one day or single exposure. The acute dietary (food only) risk assessment used Theoretical Maximum Residue Contribution (TMRC). The resulting high-end exposure estimate of 0.1 mg/kg/day, which results in a dietary (food only) MOE of 240 for females 13+ years, 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 this exposure assessment, the Agency has made very conservative assumptions -- 100% of citrus commodities and all other commodities having imidacloprid tolerances will contain imidacloprid residues and those residues would be at the level of the tolerance -- which result in an overestimate of human dietary exposure. This chronic dietary (food only) exposure should be viewed as a conservative risk estimate; refinement using anticipated residue levels and percent crop-treated values analysis would result in a lower dietary exposure estimate. Thus, in making a safety determination for this tolerance, EPA is taking into account this conservative exposure assessment. The existing imidacloprid tolerances (published, pending, and including the necessary Section 18 tolerances) result in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to the following percentages of the RfD:

Subpopulation	TMRC	%RfD
U.S. population	0.011276	20%
Nursing infants	0.009403	17%
Non-nursing infants (<1 year old)	0.022489	40%
Children (1-6 years old)	0.024609	43%
Children (7-12 years old)	0.016932	30%
U.S. population - winter	0.011763	21%
Northeast Region	0.012362	22%
Western Region	0.011992	21%
Hispanics	0.012485	22%
Non-Hispanic others	0.013116	23%

The subgroups listed above are: (1) the U.S. population (48 states); (2) those for infants and children; and, (3) 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.* Based on data available to the Agency, imidacloprid is persistent and could potentially leach into groundwater. There is no established Maximum Contamination Level (MCL) for residues of imidacloprid in drinking water. No health advisory levels for imidacloprid in drinking water have been established. The ''Pesticides in Groundwater Database'' has no entry for imidacloprid.

Chronic exposure and risk. Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water-related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfDs or acute dietary NOELs) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for exposure from contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause imidacloprid to exceed the RfD if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with imidacloprid in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

3. *From non-dietary exposure.* Imidacloprid is currently registered for use on the following residential non-food sites: ornamental flowering plants, ornamental ground covers, ornamental woody plants, ornamental turf, ornamental lawns, household and domestic dwellings (indoor/outdoor), wood protection, and pets. Because the Agency has determined that imidacloprid has no dermal or inhalation toxicological potential and has not identified a chronic toxicological endpoint, EPA does not expect any harm from non-dietary exposure to imidacloprid.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

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

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

EPA does not have, at this time, available data to determine whether imidacloprid 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, imidacloprid 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 imidacloprid has a common mechanism of toxicity with other substances.

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

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure from dietary food and water. For imidacloprid, no data were available to EPA from possible exposure to contaminated drinking water. Thus, this risk assessment is based on acute dietary risk from food only. For the population subgroup of concern, females 13+ years, the calculated MOE value is 240. This MOE does not exceed the Agency's level of concern for acute dietary exposure.

2. *Chronic risk.* Using the conservative exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, EPA has concluded that aggregate dietary exposure to imidacloprid will utilize 20% of the RfD for the U.S. population. 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 imidacloprid in drinking water, the Agency does not expect the aggregate dietary exposure to exceed 100% of the RfD. Since EPA has determined that there is no dermal or inhalation toxicity potential for imidacloprid, non-dietary, non-occupational exposure is not a concern. The Agency concludes that there is a reasonable certainty that no harm will result from chronic aggregate exposure to imidacloprid residues.

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 residential exposure. Because the Agency has determined that imidacloprid has no dermal or inhalation toxicity potential, short-term or intermediate-term dermal and inhalation risk assessments are not required.

D. Aggregate Cancer Risk for U.S. Population

Since imidacloprid has been classified as a Group E chemical, no evidence of carcinogenicity for humans, a cancer risk assessment was not required.

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

1. *Safety factor for infants and children.*—a. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of imidacloprid, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. 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 database 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.

b. *Developmental toxicity studies.* From the developmental toxicity study in rats, the maternal (systemic) NOEL was 30 mg/kg/day. The maternal (systemic) LOEL of 100 mg/kg/day was based on decreased weight gain. The developmental (fetal) NOEL was 30 mg/kg/day. The developmental (fetal) LEL of 100 mg/kg/day was based on increased wavy ribs.

From the developmental toxicity study in rabbits, the maternal (systemic) NOEL was 24 mg/kg/day. The maternal (systemic) LOEL of 72 mg/kg/day was based on decreased body weight, increased abortions, and death. The developmental (fetal) NOEL was 24 mg/kg/day. The developmental (fetal) LOEL of 72 mg/kg/day was based on decreased body weight and increased skeletal anomalies.

c. *Reproductive toxicity study.* From the reproductive toxicity study in rats, the maternal (systemic) NOEL was 55 mg/kg/day at the highest dose tested (HDT). The reproductive/developmental (pup) NOEL was 8 mg/kg/day. The reproductive/developmental (pup)

LOEL of 19 mg/kg/day was based on decreased pup body weight during lactation in both generations.

d. *Pre- and post-natal sensitivity.* The toxicological database for evaluating pre- and post-natal toxicity for imidacloprid is complete. In the case of the developmental toxicity studies, the developmental and maternal NOELs for both rats and rabbits occur at the same dose level for each species (24 mg/kg/day for rabbits and 30 mg/kg/day for rats) which suggests that there is no extra sensitivity for unborn children in the absence of maternal toxicity. However, a detailed analysis of the developmental toxicity studies indicates that the skeletal findings (wavy ribs and other anomalies) in both the rat and rabbit fetuses are severe effects which occurred in the presence of slight maternal toxicity (decreases of body weight). Additionally, in rabbits, there were increases in resorptions and abortions which can be attributed to acute maternal exposure. This information has been interpreted by the Agency as indicating a potential acute dietary risk for pre-natally exposed infants. The acute dietary MOE for females 13+ years is 240. This large MOE, based on conservative exposure assumptions, demonstrates that pre-natal exposure to imidacloprid is not a toxicological concern at this time.

In the case of the 2-generation reproductive toxicity study in rats, the parental NOEL is 55 mg/kg/day (HDT). The reproductive NOEL is 8 mg/kg/day based on decreased pup body weight during lactation observed at the LOEL of 19 mg/kg/day. The results of this study indicate that adverse reactions to imidacloprid by the pups occurs at levels (19 mg/kg/day) which are lower than the NOEL for the parental animals (55 mg/kg/day). Therefore, the pups are more sensitive to the effects of imidacloprid than parental animals and for the purpose of this Section 18 an additional 3X safety factor should be added to the RfD.

The aggregate risk estimate for the most highly exposed infant and children subgroup (children 1-6 years old) occupies 129% of the RfD (including the 3X additional safety factor). Both chronic and acute dietary exposure risk assessments assume 100% crop treated and use tolerance level residues for all commodities. Refinement of these dietary risk assessments by using percent crop treated information and anticipated residue data would reduce dietary exposure. Therefore, both of these risk assessments are over-estimates of dietary risk. Consideration of anticipated residues and percent crop treated would likely result in an anticipated residue contribution (ARC) which would occupy a percentage of the RfD that is likely to be significantly lower than the currently calculated TMRC value, and aggregate risk estimates. Therefore, EPA concludes that extension of this time-limited tolerance should not pose an unacceptable risk to infants and children.

2. *Acute risk.* At present, the acute dietary MOE for females 13+ years (accounts for both maternal and fetal exposure) is 240. This risk assessment also assumed 100% crop-treated with tolerance level residues on all treated crops consumed, resulting in a significant over-estimate of dietary exposure. The Agency does not expect that aggregate exposure (food plus water) would result in an unacceptable acute dietary MOE. The large acute dietary MOE calculated for females 13+ years provides assurance that there is a reasonable certainty of no harm for both females 13+ years and the pre-natal development of infants from exposure to imidacloprid.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to imidacloprid from food will utilize 48% of the RfD for nursing infants, and 129% of the RfD for children 1-6 years old (including the additional 3X safety factor). This chronic aggregate (food only) exposure should be viewed as a conservative risk estimate; refinement using anticipated residue levels and percent crop-treated values analysis would result in a lower aggregate exposure estimate. Despite the potential for exposure to imidacloprid in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. Therefore, taking into account the completeness and reliability of the toxicity data and the conservative exposure assessment, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to imidacloprid residues.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants and animals, is adequately understood. The residue of concern is imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent as specified in 40 CFR 180.472.

B. Analytical Enforcement Methodology

An adequate common moiety GC/MS enforcement method is available for the determination of the regulated imidacloprid residues in citrus commodities. Bayer Method 00200 has successfully completed an EPA Tolerance Method Validation. Copies of the method have been forwarded to FDA for publication in PAM Volume II.

C. Magnitude of Residues

Combined residues of imidacloprid and its regulated metabolites are not expected to exceed 1.0 ppm in/on the citrus crop group or 5 ppm in/on the processed commodity dried citrus pulp as a result of this Section 18 use. Secondary residues in animal commodities are not expected to exceed existing tolerances as a result of this Section 18 use.

D. International Residue Limits

There are no CODEX, Canadian, or Mexican residue limits, therefore harmonization is not an issue for this action.

E. Rotational Crop Restrictions

Citrus crops are not rotated to other crops, thus rotational crop concerns are not germane to this action.

VI. Conclusion

Therefore, tolerances are established for combined residues of imidacloprid on the citrus fruits crop group at 1 ppm and dried citrus pulp at 5 ppm.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) 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 8, 1997, 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 above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40

CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual 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 Confidential Business Information (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.

VIII. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300511] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408 (d), such as the tolerances 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 has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. 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.

X. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: June 30, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. In § 180.472, by adding the text of paragraph (b) to read as follows:

§ 180.472 1-[(6-Chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine].

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the insecticide imidacloprid in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. These tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Citrus fruits crop group	1.0	December 31, 1998

Commodity	Parts per million	Expiration/Revocation Date
Dried citrus pulp	5.0	December 31, 1998

* * * * *

[FR Doc. 97–17930 Filed 7–8–97; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 281

[FRL–5854–8]

District of Columbia; Final Approval of State Underground Storage Tank Program

AGENCY: Environmental Protection Agency.

ACTION: Notice of final determination on the District of Columbia's application for program approval.

SUMMARY: The District of Columbia has applied for approval of its underground storage tank program under Subtitle I of the Resource Conservation and Recovery Act (RCRA). The Environmental Protection Agency (EPA) has reviewed the District of Columbia's application and has made a final determination that the District of Columbia's underground storage tank program satisfies all of the requirements necessary to qualify for approval. Thus, EPA is granting final approval to the District of Columbia to operate its program.

EFFECTIVE DATES: Program approval for the District of Columbia shall be effective on August 8, 1997.

FOR FURTHER INFORMATION CONTACT: Karen L. Bowen, State Programs Branch (3HW60), U.S. EPA Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107, (215) 566–3382.

SUPPLEMENTARY INFORMATION:

A. Background

Section 9004 of the Resource Conservation and Recovery Act (RCRA) authorizes EPA to approve State underground storage tank programs to operate in the State in lieu of the Federal underground storage tank (UST) program. To qualify for approval, a State's program must be ''no less stringent'' than the Federal program in all seven elements set forth at section 9004(a) (1) through (7) of RCRA, 42 U.S.C. 6991c(a) (1) through (7), as well as the notification requirements of section 9004(a)(8) of RCRA, 42 U.S.C. 6991c(a)(8) and must provide for adequate enforcement of compliance with UST standards (section 9004(a) of RCRA, 42 U.S.C. 6991c(a)).

On October 3, 1996, the District of Columbia submitted an official application for approval to administer its underground storage tank program. On April 28, 1997, EPA published a tentative determination announcing its intent to approve the District's program. Further background on the tentative decision to grant approval appears at 62 FR 22898 (April 28, 1997).

Along with the tentative determination, EPA announced the availability of the application for public review and comment and the date of a tentative public hearing on the application and EPA's tentative determination. EPA requested advance notice for testimony and reserved the right to cancel the public hearing in the event of insufficient public interest. Since there were no requests to hold a public hearing, it was cancelled. One person provided written comments relating to the District of Columbia's regulations pertaining to heating oil tanks. The commenter felt the District's regulations are excessive for underground heating oil tanks and are not in conformance with Federal law, or that of the surrounding states and suggested that since the District of Columbia is predominantly a Federal city, it should follow the Federal UST regulations.

The District of Columbia has identified in their application that the regulation of heating oil tanks is an area where its program is broader in scope than the Federal program. The Federal underground storage tank program does not cover tanks used for storing heating oil for consumptive use on the premises where stored, and, therefore, the District of Columbia is free to regulate such tanks as it deems appropriate. Since state programs which are broader in scope than the Federal program may be approved, EPA is granting final approval to the District of Columbia's Underground Storage Tank Program.

B. Final Decision

I conclude that the District of Columbia's application for program approval meets all of the statutory and regulatory requirements established by Subtitle I of RCRA and 40 CFR part 281. Accordingly, the District of Columbia is granted approval to operate its underground storage tank program in lieu of the Federal program.

Compliance With Executive Order 12866

The Office of Management and Budget has exempted this action from the requirements of section 6 of Executive Order 12866.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), P.L. 104–4, establishes requirements for Federal agencies to assess the effects of certain regulatory actions on State, local, and tribal governments and the private sector. Under sections 202 and 205 of the UMRA, EPA generally must prepare a written statement of economic and regulatory alternatives analyses for proposed and final rules with Federal mandates, as defined by the UMRA, that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. The section 202 and 205 requirements do not apply to today's action because it is not a ''Federal mandate'' and because it does not impose annual costs of $100 million or more.

Today's rule contains no Federal mandates for State, local or tribal governments or the private sector for two reasons. First, today's action does not impose new or additional enforceable duties on any State, local or tribal governments or the private sector because the requirements of the District of Columbia program are already imposed by the District of Columbia and subject to the District of Columbia law. Second, the Act also generally excludes from the definition of a ''Federal mandate'' duties that arise from participation in a voluntary Federal program. The District of Columbia's participation in an authorized UST program is voluntary.

Even if today's rule did contain a Federal mandate, this rule will not result in annual expenditures of $100 million or more for State, local, and/or tribal governments in the aggregate, or the private sector. Costs to State, local and/or tribal governments already exist under the District of Columbia program, and today's action does not impose any additional obligations on regulated entities. In fact, EPA's approval of state