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, is kept in paper form. Accordingly, in the event there are objections and hearing requests, 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. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and, since this action does not impose any information collection requirements as defined by the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., it is not subject to review by the Office of Management and Budget. This action does not impose any enforceable duty, or contain any ''unfunded mandates'' as described in Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), entitled Enhancing the Intergovernmental Partnership, or special consideration as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because FFDCA section 408(l)(6) permits establishment of this regulation without a notice of proposed rulemaking, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act, 5 U.S.C. 604(a), do not apply. Nonetheless, the Agency has previously assessed whether establishing tolerances or exemptions from tolerance, raising tolerance levels, or expanding exemptions adversely impact small entities and concluded, as a generic matter, that there is no adverse impact. (46 FR 24950, May 4, 1981).

Under 5 U.S.C. 801(a)(1)(A) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104–121, 110 Stat. 847), EPA 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 the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2) of the APA as amended.

List of Subjects in 40 CFR Part 180

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

Dated: April 16, 1997.

Stephen L. Johnson,

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. Section 180.381 is amended as follows:

i. In paragraph (a) by adding the heading *''General.''*

ii. By redesignating paragraph (b) as paragraph (c), and adding a new paragraph (b).

iii. In newly designated paragraph (c) by adding a paragraph heading *''Tolerances with regional registrations.''*

iv. By adding and reserving new paragraph (d) with the heading *''Indirect or inadvertent residues.''*

v. By revising the phrase ''raw agricultural'', to read ''food'' throughout the section.

§ 180.381 Oxyfluorfen; tolerances for residues.

(a) *General.* * * *

(b) *Section 18 emergency exemptions.* Tolerances are established for residues of the herbicide oxyfluorfen [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene] in or on the following food commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Strawberries	0.05	April 15, 1998

(c) *Tolerances with regional registrations.* * * *

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

[FR Doc. 97–10724 Filed 4–24–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300476; FRL–5712–7]

RIN 2070–AB78

Fenoxycarb; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of the insecticide fenoxycarb in or on the commodity pear in connection with EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of fenoxycarb on pears in Oregon and Washington. This regulation establishes maximum permissible levels for residues of fenoxycarb in this food pursuant to section 408(l)(6) of the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on April 30, 1998.

DATES: This regulation becomes effective April 25, 1997. Objections and requests for hearings must be received by EPA on or before June 24, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300476], 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–300476], must also be submitted to: Public Response and Program Resources Branch, Field Operations 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. Such 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–300476]. 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: Pat Cimino, Registration Division (7505W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA 22202. (703) 308–8328, e-mail: cimino.pat@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, 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 residues of the insecticide fenoxycarb, ethyl(2-[4-phenoxyphenoxy] ethyl) carbamate, in or on pears, at 0.10 part per million (ppm). This tolerance will expire and be revoked by EPA on April 30, 1998. After April 30, 1998, EPA will publish a document in the **Federal Register** to remove the revoked tolerance 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) 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, 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) 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. Section 408(l)(6) also requires EPA to promulgate regulations by August 3, 1997, governing the establishment of tolerances and exemptions under section 408(l)(6) and requires that the regulations be consistent with section 408(b)(2) and (c)(2) and FIFRA section 18.

Section 408(l)(6) allows EPA to establish tolerances or exemptions from the requirement for a tolerance, in connection with EPA's granting of FIFRA section 18 emergency exemptions, without providing notice or a period for public comment. Thus, consistent with the need to act expeditiously on requests for emergency exemptions under FIFRA, EPA can establish such tolerances or exemptions under the authority of section 408(e) and (l)(6) without notice and comment rulemaking.

In establishing section 18-related tolerances and exemptions during this interim period before EPA issues the section 408(l)(6) procedural regulation and before EPA makes its broad policy decisions concerning the interpretation and implementation of the new section 408, EPA does not intend to set precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Rather, these early section 18 tolerance and exemption decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further rulemaking and policy development. EPA intends to act on section 18-related tolerances and exemptions that clearly qualify under the new law.

II. Emergency Exemption for Fenoxycarb on Pears and FFDCA Tolerances

The Oregon and Washington Departments of Agriculture requested specific exemptions under FIFRA section 18 for the use of fenoxycarb on pears to control pear psylla. Oregon and Washington stated that an emergency situation was present due to the pests' resistance to pesticides registered for this use. Pear psyllas reduce pear tree vigor and yield by injecting a toxin into the trees during feeding. They also secrete honeydew which causes deformed fruit, russeting, and growth of black sooty mold, leading to downgrading of fruit and increased cullage. If the pest is left totally uncontrolled, it will cause eventual tree debilitation and dramatic yield decreases. After reviewing the applicants' submissions, the Agency concluded that an emergency condition existed which would result in significant economic loss.

As part of its assessment of these crisis declarations, EPA assessed the potential risks presented by residues of fenoxycarb in or on pears. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided to grant the section 18 exemptions only after concluding that the necessary tolerance under FFDCA section 408(l)(6) would clearly be consistent with the new safety standard and with FIFRA section 18. This tolerance for fenoxycarb will permit the marketing of pears treated in accordance with the provisions of the section 18 emergency exemptions. Consistent with the need to move quickly on the emergency exemptions and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e) as provided for in section 408(l)(6). Although this tolerance will expire and is revoked on April 30, 1998, under FFDCA section 408(l)(5), residues of fenoxycarb not in excess of the amount specified in the tolerance remaining in or on pears after that date will not be unlawful, provided the pesticide is applied during the term of, and in accordance with all the conditions of, the emergency exemptions. EPA will take action to revoke this tolerance earlier if any experience with, scientific

data on, or other relevant information on this pesticide indicate that the residues are not safe.

EPA has not made any decisions about whether fenoxycarb meets the requirements for registration under FIFRA section 3 for use on pears, or whether a permanent tolerance for fenoxycarb for pears would be appropriate. This action by EPA does not serve as a basis for registration of fenoxycarb by a State for special local needs under FIFRA section 24(c). Nor does this action serve as the basis for any State other than Oregon and Washington to use this product 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 exemptions for fenoxycarb, 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. For many of these 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 by EPA to pose a reasonable certainty of no harm.

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 relationships. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low-dose extrapolations or margin of exposure (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.

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, and other non-occupational exposures, such as where residues leach into groundwater or surface water that is consumed as drinking water. 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. 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.

IV. Aggregate Risk Assessments, Cumulative Risk Discussion, 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. Fenoxycarb is registered by EPA for indoor and outdoor residential use. The registrant, Novartis, has proposed voluntarily canceling all home-owner applied uses of fenoxycarb. There are no permanent fenoxycarb food tolerances at this time. EPA is not in possession of a registration application for fenoxycarb on pears; however, the Agency has received petitions to establish tolerances for use of fenoxycarb on citrus fruits crop group, tree nut crops group, almond hulls, grass forage crop group and grassy hays. Based on information submitted to the Agency, EPA has sufficient data to assess the hazards of fenoxycarb and to make a determination on aggregate exposure, consistent with section 408(b)(2), for the time-limited tolerance for residues of fenoxycarb on pears at 0.10 ppm. EPA's assessment of the dietary exposures and risks associated with establishing this tolerance follows.

A. Toxicological Profile

1. *Acute toxicity.* No appropriate acute dietary endpoint was identified by the Agency. This risk assessment is not required.

2. *Short- and intermediate term toxicity.* For short-and intermediate-term inhalation MOE calculations, the Agency (March 28, 1994) recommended use of the 21–day inhalation NOEL of 1.13 milligrams per liter (mg/L) (186 milligrams per kilogram per day (mg/kg/day)), the highest dose tested, from the 21–day inhalation study in rats. A risk assessment is not required for dermal exposure. The following equation was used to calculate the MOEs: MOE = NOEL (21–day inhalation study)/dietary exposure.

3. *Chronic risk.* Based on the available chronic toxicity data, the Office of Pesticide Programs (OPP) has established the RfD for fenoxycarb at 0.8 mg/kg/day. The RfD is based on a 2–year chronic toxicity/carcinogenicity study in rats with a NOEL of 8.1 mg/kg/day and an uncertainty factor of 100. The LEL was 24.7 mg/kg/day based on liver toxicity in male rats.

4. *Cancer risk.* Fenoxycarb has been classified as a Group B2 chemical by the Agency's Cancer Peer Review Committee based on lung carcinomas and Hardeian gland carcinomas in mice. The Committee recommended using the Q_1* approach for calculating cancer risk

estimates. The Q_1* is 5.6×10^{-2} (mg/kg/day)$^{-1}$.

B. Aggregate Exposure

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

There are no permanent fenoxycarb food tolerances at this time. There are no livestock feed items associated with these Section 18 requests. Fenoxycarb is registered for indoor and outdoor residential uses (lawns, turf, pets, and inside domestic dwellings).

In conducting this exposure assessment, EPA has made very conservative assumptions - 100% of pears will contain fenoxycarb tolerance residues and those residues would be at the level of the tolerance - which result in an overestimate of human dietary exposure. Thus, in making a safety determination for this tolerance, EPA is taking into account this conservative exposure assessment.

1. *Acute exposure.* The Agency has determined that there are no acute dietary endpoints of concern and an acute assessment is not required.

2. *Chronic exposure.*— i. *Dietary-food exposure*. Given the emergency nature of these requests for the use of fenoxycarb and the resulting need for a timely analysis and risk assessment, EPA has utilized the TMRC to estimate chronic dietary exposure from the tolerance for fenoxycarb on pears at 0.10 ppm. The TMRC is obtained by multiplying the tolerance level residue for pears by the average consumption data, which estimate the amount of pears eaten by various population subgroups. The risk assessment is therefore considered to be overestimated.

ii. *Drinking water exposure.* Available studies indicate that fenoxycarb is moderately persistent (half lives ranging from 24 to 37 days) and does not appear to be very mobile. The most likely routes of dissipation are sorption to soil particles, aerobic and anaerobic soil metabolism and aerobic aquatic metabolism to CO_2. There is no established Maximum Concentration Level for residues of fenoxycarb in drinking water and there have been no drinking water Health Advisory Levels established for fenoxycarb. The ''Pesticides in Groundwater Database'' (EPA 734–12–92–001, September 1992) has no information concerning fenoxycarb.

The Agency has reviewed these section 18 requests and concluded that for these uses, fenoxycarb has little potential for contamination of ground water. There is a slight potential for surface water contamination by erosion of soil particles to which fenoxycarb is sorbed. However for these section 18 requests, the potential is lessened by: (a) The requirement of a 100 yard buffer strip between treated areas and water bodies, and (b) the practice of growing grass cover crops in most pear orchards.

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 (RfD's or acute dietary NOEL's) 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 consumption of contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause fenoxycarb 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 fenoxycarb 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.

iii. *Non-dietary, non-occupational exposure*. Fenoxycarb is registered for use on lawns, turf, pets, and inside domestic dwellings. The Agency, at this time, does not have exposure data with which to determine risk from these non-dietary, non-occupational uses. However, upon considering the registered uses, formulation types, persistence, and toxicological endpoints, the Agency has determined that, in the absence of exposure data, the registered non-dietary, non-occupational uses of fenoxycarb will be assigned a value of 20% of the acceptable aggregate chronic, and short- and intermediate-term risk. The registrant, Novartis, has proposed voluntarily canceling all home-owner applied uses of fenoxycarb.

iv. *Cancer considerations*. Fenoxycarb has been classified as a Group B2 chemical by the Agency's Cancer Peer Review Committee based on lung carcinomas and Hardeian gland carcinomas in mice. The Committee recommended using the Q_1* approach for calculating cancer risk estimates. The Q_1* is 5.6×10^{-2} (mg/kg/day)$^{-1}$. A dietary (food only) cancer risk assessment was calculated for the U.S. population and was adjusted for the duration of exposure of the Section 18 (5 years) over a 70 year lifetime. The total oncogenic risk (food only) is 4.9×10^{-8}. In the best scientific judgment of the Agency, chronic exposure to fenoxycarb residues resulting from potential residential and/or water exposure would not increase the total cancer risk so that it exceeds the Agency's level of concern.

3. *Short- and intermediate-term exposure.* 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.

The Agency considers dietary (food) MOEs of greater than 100 to be acceptable for fenoxycarb. In the absence of data for drinking water and non-dietary, non-occupational sources of exposure, 20% of the acceptable short-term risk will be reserved for indoor and outdoor non-dietary, non-occupational exposure and the ranges of exposure for consumption of contaminated water, described above, will be reserved for drinking water. The aggregate MOE level of concern for dietary plus indoor and outdoor residential exposure is 125 and the addition of drinking water is not likely to raise the MOE level of concern above 200. Despite the potential for short- and intermediate-term exposure to fenoxycarb in drinking water and from indoor and outdoor residential use, EPA does not expect the aggregate exposure to exceed the Agency's level of concern if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential short- and intermediate-term exposures associated with fenoxycarb in water, even at the higher levels the Agency is considering as a conservative upper bound, and from indoor and outdoor residential uses would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

C. 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 fenoxycarb 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, fenoxycarb 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 fenoxycarb has a common mechanism of toxicity with other substances.

D. Determination of Safety for U.S. Population

1. *Acute risk.* The Agency has determined that there are no acute dietary endpoints of concern and an acute assessment is not required.

2. *Short- and intermediate-term risk.* The calculated aggregate MOEs for short- and intermediate-term exposure were greater than 1,000,000 (one million). The Agency typically considers dietary MOEs greater than 100 to be acceptable. Despite the potential for short- and intermediate-term exposure to fenoxycarb in drinking water and from indoor and outdoor residential use, the calculated MOEs (>1,000,000) are well above the Agency's aggregate MOE level of concern.

3. *Chronic risk.* Using the conservative TMRC exposure assumptions described above and taking into account the completeness and reliability of the toxicity data, EPA has concluded that aggregate dietary exposure to fenoxycarb will utilize < 1% 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 fenoxycarb in drinking water and from non-dietary/non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to fenoxycarb residues.

4. *Cancer risk.* Fenoxycarb has been classified as a Group B2 chemical by the Agency's Cancer Peer Review Committee based on lung carcinomas and Hardeian gland carcinomas in mice. The Committee recommended using the Q1* approach for calculating cancer risk estimates. The Q_1* is 5.6×10^{-2} $(mg/kg/day)^{-1}$. A dietary (food only) cancer risk assessment was calculated for the U.S. population and was adjusted for the duration of exposure of the section 18 (5 years) over a 70 year lifetime. The total oncogenic risk (food only) is 4.9×10^{-8}. In the best scientific judgment of the Agency, chronic exposure to fenoxycarb residues resulting from potential residential and/or water exposure would not increase the total cancer risk so that it exceeds the Agency's level of concern.

E. Determination of Safety for Infants and Children

In assessing the potential for additional sensitivity of infants and children to residues of fenoxycarb, 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. The pre- and post-natal toxicology data base for fenoxycarb is complete with respect to current toxicological data requirements. There are no pre- or post-natal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies and the two-generation rat reproduction study. The NOEL for developmental toxicity in rats was 500 mg/kg/day, the highest dose tested. The NOEL for maternal toxicity in rats was also 500 mg/kg/day, the highest dose tested. In the rabbit developmental study, the developmental NOEL was 300 mg/kg/day, the highest dose tested, whereas the maternal toxicity NOEL/ lowest observed effect level (LOEL) in rabbits was 100/300 mg/kg/day based on decreased weight gain.

In the two-generation rat reproduction study, the parental NOEL was 10 mg/kg/day and the pup NOEL was 30 mg/kg/day. The parental LOEL was 30 mg/kg/day based on decreased weight gain and the pup LOEL was 90 mg/kg/day based on decreased weight gain and developmental delays. This study demonstrates that both the parental effects and the pup effects are the same and that parental rats are more sensitive than pups to the effects of fenoxycarb. There are no indications for post-natal sensitivity with respect to infants and children.

1. *Chronic risk.* Using the conservative exposure assumptions described above, taking into account the completeness and reliability of the toxicity data, EPA has concluded that aggregate dietary exposure to fenoxycarb will utilize <1% of the RfD for infants and children. EPA generally has no

concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to fenoxycarb in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to fenoxycarb residues.

2. *Short- and intermediate-term risk.* At present, the aggregate MOEs for short- and intermediate-term risk are >1,000,000. The Agency typically considers dietary MOEs greater than 100 to be acceptable. Despite the potential for short- and intermediate-term exposure to fenoxycarb in drinking water and from indoor and outdoor residential use, the calculated MOEs (> 1,000,000) are well above the Agency's aggregate MOE level of concern.

This MOE calculation assumed TMRC dietary contributions, a value of 20% reserved for indoor and outdoor residential uses and considered a range of exposure contributions from drinking water. These assumptions result in a risk assessment which over-estimates dietary exposure and provides conservative estimates for contributions from drinking water and indoor and outdoor residential uses. The large aggregate MOE calculated for this use of fenoxycarb provides assurance that there is a reasonable certainty of no harm for infants and children.

F. Safety Factor Considerations

FFDCA section 408 provides that EPA shall apply an additional tenfold MOE (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 exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. EPA believes that reliable data support using the standard margin of exposure (usually 100x for combined inter- and intra-species variability) and not the additional tenfold margin of exposure 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. Based on current toxicological data requirements, the database for fenoxycarb relative to pre-(provided by rat and rabbit developmental studies) and post-natal (provided by the rat reproduction study) toxicity is complete. The data indicate that exposure pre- and post-natally to fenoxycarb did not result in unusually toxic or severe effects and that parents were more sensitive to fenoxycarb than infants and children. The additional uncertainty factor is not needed to protect the safety of infants and children. EPA concludes that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to fenoxycarb residues.

V. Other Considerations

There are no Mexican, Canadian, or Codex maximum residue levels established for residues of fenoxycarb on pears. There is a practical analytical method for detecting and measuring levels of fenoxycarb in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set in these tolerances. EPA has provided information on this method to FDA. The method is available to anyone who is interested in pesticide residue enforcement from: By mail, Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: Crystal Mall #2, Rm 1128, 1921 Jefferson Davis Hwy., Arlington, VA 22202, 703–305–5805.

VI. Conclusion

Therefore, a tolerance in connection with the FIFRA section 18 emergency exemptions is established for residues of fenoxycarb in/on pears at 0.1 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 June 24, 1997, file written objections to any aspect of this regulation (including the automatic revocation provision) 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

A record has been established for this rulemaking under docket control number [OPP–300476]. A public version of this record, 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 Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

The official record for this rulemaking, as well as the public version, as described above, is kept in paper form. Accordingly, in the event

there are objections and hearing requests, 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. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and, since this action does not impose any information collection requirements as defined by the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, it is not subject to review by the Office of Management and Budget. This action does not impose any enforceable duty, or contain any ''unfunded mandates'' as described in Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), entitled Enhancing the Intergovernmental Partnership, or special consideration as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because FFDCA section 408(l)(6) permits establishment of this regulation without a notice of proposed rulemaking, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act, 5 U.S.C. 604(a), do not apply. Nonetheless, the Agency has previously assessed whether establishing tolerances or exemptions from tolerance, raising tolerance levels, or expanding exemptions adversely impact small entities and concluded, as a generic matter, that there is no adverse impact. (46 FR 24950, May 4, 1981).

Under 5 U.S.C. 801(a)(1)(A) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104–121, 110 Stat. 847), EPA 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 the rule in today's **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: April 16, 1997.

Stephen L. Johnson,

Acting Director, 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. By adding § 180.504 as follows:

§ 180.504 Fenoxycarb; tolerances for residues.

(a) *General.* [Reserved]

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for residues of the insecticide fenoxycarb, ethyl(2-[4-phenoxyphenoxy]ethyl) carbamate, in or on the following commodity:

Commodity	Parts per million	Expiration/ Revocation Date
Pears	0.1	April 30, 1998

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

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

[FR Doc. 97–10749 Filed 4–24–97; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185, and 186

[OPP–300468; FRL–5599–5]

RIN 2070–AB78

Imidacloprid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document extends the effective date for the established time-limited tolerance for residues of the insecticide imidacloprid and its metabolites resulting from crop rotational practices in or on the food commodities of the cucurbit vegetables crop group. The Interregional Research Project (IR–4) requested this time extension under the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1966.

DATES: This regulation is effective April 25, 1997. Submit written objections and hearing requests on or before June 24, 1997.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [OPP–300468; PP–5E4598], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Room M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251.

A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of the objections and hearing requests to: Crystal Mall #2, Rm. 1132, 1921 Jefferson Davis Highway, Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically to the OPP 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 in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the document control number [OPP–300468; PP–5E4598]. 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. Additional information on electronic submissions can be found in Unit III. of this document.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt L. Jamerson, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection