may be disclosed publicly by EPA without prior notice.

IX. Public Docket

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number [OPP–300492] (including comments and data submitted electronically as described below). 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 official rulemaking record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can 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. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number [OPP–300492]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

X. 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. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because tolerance established on the basis of a petition under section 408(d) of FFDCA do not require issuance of a proposed rule, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act (RFA), 5 U.S.C. 604(a), do not apply. Prior to the recent amendment of the FFDCA, EPA had treated such rulemakings as subject to the RFA; however, the amendments to the FFDCA clarify that no proposal is required for such rulemakings and hence that the RFA is inapplicable. 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 Administrative Procedure Act (APA) as amended by 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: May 7, 1997.

Stephen L. Johnson,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is amended as follows:

PART 180— [AMENDED]

1. In part 180:

a. The statutory authority for part 180 continues to read as follows:

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

b. By revising § 180.494 to read as follows:

§ 180.494 Pyridaben; tolerance for residues.

(a) *General.* Time limited tolerances are established for residues of the insecticide pyridaben [2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one] on the following plants, and of the insecticide pyridaben and its metabolites (2-tert-butyl-5-[4-(1-carboxy-1-methylethyl)benzylthio]-4-chloropyridazin-3(2H)-one) and (2-tert-butyl-4-chloro-5-[4-(1,1-dimethyl-2-hydroxyethyl)benzylthio]-chloropyridazin-3(2H)-one) on animals, as indicated in the following table. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Almonds	0.05	5/31/2001
Almond hulls	4.0	do.
Apple	0.6	do.
Apple pomace, wet	1.0	do.
Cattle, fat	0.05	do.
Cattle, meat	0.05	do.
Cattle, meat by-products	0.05	do.
Citrus	0.5	do.
Citrus oil	10.0	do.
Citrus pulp, dried	1.5	do.
Goat, fat	0.05	do.
Goat, meat	0.05	do.
Goat, meat by-products	0.05	do.
Hog, fat	0.05	do.
Hog, meat	0.05	do.
Hog, meat by-products	0.05	do.
Horse, fat	0.05	do.
Horse, meat	0.05	do.
Horse, meat by-products	0.05	do.
Milk	0.01	do.
Pears	0.75	do.
Sheep, fat	0.05	do.
Sheep, meat	0.05	do.
Sheep, meat by-products	0.05	do.

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

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

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

[FR Doc. 97–12912 Filed 5–15–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300489; FRL–5717–5]

RIN 2070–AB78

Propamocarb Hydrochloride; Pesticide Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of the fungicide propamocarb hydrochloride in or on the food commodities tomatoes, tomato puree, and tomato paste in connection with EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of propamocarb hydrochloride on

tomatoes in the states of California, Florida, Maryland, New Jersey, New York, Pennsylvania, and Virginia. The tolerances will expire and are revoked by EPA on May 15, 1999.

DATES: This regulation becomes effective May 16, 1997. Objections and requests for hearings must be received by EPA on or before July 15, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300489], 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 document control number, [OPP–300489], 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–300489]. 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: Libby Pemberton, Registration Division (7505W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA (703) 308–8326, e-mail: pemberton.libby@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 residues of propamocarb hydrochloride on tomatoes at 0.5 parts per million (ppm), in tomato puree at 1.0 ppm, and in tomato paste at 3.0 ppm. These tolerances will expire and be revoked by EPA on May 15, 1999. After May 15, 1999, 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 FFDCA, 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* 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 CFR 58135, November 13, 1996)(FRL–5572–9).

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

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166. Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

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

II. Emergency Exemptions for Propamocarb hydrochloride on Tomatoes and FFDCA Tolerances

Recent failures to control late blight in tomatoes and potatoes with the registered fungicides, have been caused almost exclusively by immigrant strains of late blight (*Phytophthora infestans*), which are resistant to the control of choice, metalaxyl. Before the immigrant strains of late blight arrived, all of the strains in the United States were previously controlled by treatment with metalaxyl. Presently, there are no fungicides registered in the United States that will provide adequate control of the immigrant strains of late blight. After having reviewed their submissions, EPA concurs that emergency conditions exist for the states previously listed.

As part of its assessment of these specific exemptions, EPA assessed the potential risks presented by residues of propamocarb hydrochloride on tomatoes, in tomato puree, and in tomato paste. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would clearly be consistent with the new safety standard and with FIFRA section 18. These tolerances will permit the marketing of tomatoes treated in accordance with the provisions of the section 18 emergency exemptions and the marketing of tomato puree and tomato paste containing residues resulting from the processing of treated tomatoes. Consistent with the need to move quickly on these emergency exemptions 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 by EPA on May 15, 1999, under FFDCA section 408(l)(5), residues of propamocarb hydrochloride not in excess of the amount specified in these tolerances remaining in or on tomatoes, tomato puree and tomato paste after that date will not be unlawful, provided the pesticide is applied during the term of, and in accordance with all the conditions of, section 18 of 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.

EPA has not made any decisions about whether propamocarb hydrochloride meets EPA's registration requirements for use on tomatoes or whether permanent tolerances for this use would be appropriate. These tolerances do not serve as a basis for registration of propamocarb hydrochloride by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any states other than California, Florida, Maryland, New Jersey, New York, Pennsylvania and Virginia 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 exemptions for propamocarb hydrochloride, 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 percent 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 hundredfold margin of exposure is based on the same rationale as the hundredfold 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.

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. 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 percent 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 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.

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 propamocarb hydrochloride are discussed below.

1. *Acute toxicity.* Agency toxicologists have recommended that the developmental NOEL of 150 milligrams per kilogram per day (mg/kg/day) from the rabbit developmental toxicity study be used for acute dietary risk calculations. The developmental lowest observable effect level (LOEL) of 300 mg/kg/day is based on increased post-implantation loss (developmental) and decreased body weight gain (maternal). The population of concern for this risk assessment is females 13+ years old.

2. *Short- and intermediate-term toxicity.* OPP recommends use of the developmental toxicity study in rabbits for short- and intermediate term MOE calculations. The maternal NOEL was 150 mg/kg/day and the LOEL of 300 mg/kg/day was based on decreased body weight gain during gestation days 6 to 18. The developmental NOEL was 150 mg/kg/day. The developmental LOEL of 300 mg/kg/day was based on increased post-implantation loss.

3. *Chronic risk*. Based on the available chronic toxicity data, the Office of Pesticide Programs (OPP) has established the RfD for propamocarb hydrochloride at 0.11 milligrams(mg)/kilogram(kg)/day. The RfD was established based on a threshold LOEL of 33.31 mg/kg/day in males and 33.27 mg/kg/day in females in a 1–year dog feeding study. The LOEL was based on body weight gain depression, decreased food efficiency and gastritis. An uncertainty factor (UF) of 100 was used to account for both interspecies extrapolation and intraspecies variability. An additional UF of 3 was used to account for the lack of a NOEL.

4. *Cancer risk*. Propamocarb hydrochloride is classified as a ''Group D'', not classifiable as to human carcinogenicity due to inadequacy of the data. Dietary rodent studies conducted in 1983 in Germany showed no evidence of carcinogenicity. The registrant is currently conducting studies in accordance with U.S. protocols.

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). In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers including infants and children. There are no established U.S. tolerances for propamocarb hydrochloride, and there are no registered uses for propamocarb hydrochloride on food or feed crops in the United States.

1. *Acute exposure*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. Drinking water is also considered a component of the acute dietary exposure, however, EPA generally will not include residential or other non-dietary exposure as a component of the acute exposure assessment. Theoretically, it is also possible that a residential, or other non-dietary, exposure could be combined with the acute total dietary exposure from food and water. However, the Agency does not believe that aggregating multiple exposure to large amounts of pesticide residues in the residential environment via multiple products and routes for a 1 day exposure is a reasonably probable event. It is highly unlikely that, in 1 day, an individual would have multiple high-end exposures to the same pesticide by treating their house via crack and crevice application, swimming in a pool, and be maximally exposed in the food and water consumed. Additionally, the concept of an acute exposure as a single exposure does not allow for including post-application exposures, in which residues decline over a period of days after application. Therefore, the Agency believes that residential exposures are more appropriately included in the short-term exposure scenario. In conjunction with this Section 18 use, the acute dietary (food only) risk assessment used tolerance level residue values and assumed 100% crop treated for all commodities requiring tolerances, as did the time-limited tolerance established for the Section 18 exemption for potatoes.

2. *Chronic exposure*— i. *Dietary - food exposures*. For the purpose of assessing chronic dietary exposure from propamocarb hydrochloride, EPA assumed tolerance level residues and 100% of crop treated for the proposed use of propamocarb hydrochloride on tomatoes. These conservative assumptions result in overestimation of human dietary exposures. Secondary residues of propamocarb hydrochloride are not expected to transfer to animal commodities as a result of the proposed use.

ii. *Drinking water exposure*. 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 propamocarb hydrochloride to exceed the RfD if the tolerances being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with propamocarb hydrochloride 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 tolerances are granted.

Based on the available studies used in EPA's assessment of environmental risk, propamocarb hydrochloride is relatively non-persistent and mobility varies as a function of soil texture and soil reaction. There is no entry for propamocarb hydrochloride in the ''Pesticides in Groundwater Data Base'' (EPA 734–12–92–001, September 1992). There is no established Maximum Concentration Level (MCL) for residues of propamocarb hydrochloride in drinking water. No drinking water health advisory levels have been established for propamocarb hydrochloride.

iii. Non-dietary, non-occupational exposure—short and intermediate term exposure. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be background exposure level) plus indoor and outdoor residential exposure. Propamocarb hydrochloride is registered for uses, such as lawn and ornamentals, that could result in non-occupational exposure and EPA acknowledges that there may be short-, intermediate-, and long-term non-occupational, non-dietary exposure scenarios. At this time, the Agency has insufficient information to assess the potential risks from such exposure.

C. Cumulative Exposure to Substances with Common Mechanisms 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 propamocarb hydrochloride 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, propamocarb hydrochloride 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 propamocarb hydrochloride has a common mechanism of toxicity with other substances.

D. Determination of Safety for U.S. Population

1. *Acute risk.* The acute dietary MOE for females 13+ years old (accounts for both maternal and fetal exposure) is 8,333. This MOE calculation was based on the developmental NOEL of 150 mg/kg/day from the developmental toxicity study in rabbits. 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 large acute dietary MOE calculated for females 13+ years old provides assurance that there is a reasonable certainty of no harm for both females 13+ and infants and children resulting from pre-natal exposure to propamocarb hydrochloride, even if an additional tenfold safety factor were applied.

2. *Short- and intermediate-term risk.* Propamocarb hydrochloride is registered for use on turf and ornamentals and EPA acknowledges that there may be short-, intermediate-, and long-term non-occupational exposure scenarios. OPP has identified a toxicity endpoint for short- and intermediate-term residential risk assessment. However, no acceptable reliable exposure data to assess these potential risks are available at this time. Given the time-limited nature of these requests, the need to make emergency exemption decisions quickly, and the significant scientific uncertainty at this time about how to aggregate non-occupational exposure with dietary exposure, the Agency will make its safety determination for this tolerance based on those factors which it can reasonably integrate into a risk assessment.

3. *Chronic risk.* Using the conservative TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to propamocarb hydrochloride from food will utilize 3 percent of the RfD for the U.S. population. EPA generally has no concern for exposures below 100 percent 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 propamocarb hydrochloride in drinking water 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 propamocarb hydrochloride residues.

E. Determination of Safety for Infants and Children

In assessing the potential for additional sensitivity of infants and children to residues of propamocarb hydrochloride, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from 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.

Based on current toxicological data requirements, the data base for propamocarb hydrochloride relative to pre- and post-natal toxicity is not complete. Although two acceptable prenatal developmental toxicity studies (in rats and rabbits) have been submitted to the Agency, the available rat reproductive toxicity study is not adequate. The RfD Committee considered it to be supplementary and not upgradeable based on the lack of systemic toxicity at dose levels, which did not achieve the limit dose, indicating inadequacy of the high dose for reproductive toxicity. Thus conclusions concerning post-natal sensitivity cannot be made.

In the developmental toxicity study in rabbits, the developmental and maternal NOELs were both 150 mg/kg/day. The developmental and maternal LOELs of 300 mg/kg/day were based on increased post-implantation loss (developmental) and decreased body weight gain (maternal). The NOELs and LOELs occurred at the same doses for developmental and maternal findings; there was no indication of pre-natal sensitivity for infants and children.

In the developmental toxicity study in rats, the developmental NOEL was 221 mg/kg/day and was below the maternal NOEL (740 mg/kg/day). The

developmental LOEL of 740 mg/kg/day was based on increased fetal death, and an increased incidence of minor skeletal anomalies (incomplete ossification of some vertebrae and sternebrae). The maternal NOEL was 740 mg/kg/day, based on increased maternal death, spastic gait and decreased body weight at the LOEL of 2,210 mg/kg/day. These findings indicate the possibility of increased prenatal sensitivity of fetuses to *in utero* exposure to propamocarb.

An additional uncertainty factor of 10x for infants and children is appropriate for propamocarb hydrochloride, based upon the lack of data to evaluate postnatal exposure (due to the inadequate reproduction study) and based upon the increased sensitivity to prenatal exposure (indicated by the rat developmental study NOELs). EPA has concluded that the percent of the RfD that will be utilized by chronic dietary (food) exposure to residues of propamocarb hydrochloride ranges from 2% for nursing infants (<1 year old) up to 8% for non-nursing infants (<1 year old). The uncertainty factor will not raise the percent of the RfD utilized above the level of concern (100%). Additionally, the RfD calculation assumes tolerance level residues for all commodities and is therefore an over-estimate of dietary risk. Refinement of the dietary risk assessment by using anticipated residue data would reduce dietary exposure. The addition of potential exposure from propamocarb hydrochloride residues in drinking water is not expected to result in an exposure which would exceed the RfD.

V. Other Considerations

The metabolism of propamocarb hydrochloride in tomatoes is adequately understood for the purposes of this tolerance. A CODEX MRL of 1 mg/kg has been established for residues of propamocarb per se in/on tomatoes. The use pattern used for determining the CODEX MRL differs from that in this section 18 exemption (maximum use rate overseas is 3.2 lbs active ingredient(ai)/acre per application, the maximum use rate in the United States is 0.9 lbs ai/acre). No Canadian or Mexican residue limits have been established. The residue of concern for the purposes of these tolerances is propamocarb hydrochloride.

The proposed enforcement method designated UPSR 22/91 (MRID No. 439840–04) submitted with petition 6F4707 is adequate to support the proposed time-limited tolerances. The method has been adequately radiovalidated for recovery of parent compound. The method is available to anyone who is interested in pesticide residue enforcement from: By mail, Calvin Furlow, 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. Office location and telephone number: Crystal Mall #2, Rm 1128, 1921 Jefferson Davis Hwy., Arlington, VA 703–305–5805.

VI. Conclusion

Therefore, tolerances in connection with the FIFRA section 18 emergency exemptions are established for residues of propamocarb hydrochloride in or on tomatoes at 0.5 parts per million (ppm), tomato puree at 1.0 ppm, and tomato paste at 3.0 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 July 15, 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

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number [OPP–300489] (including comments and data submitted electronically as described below). 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 official rulemaking record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can 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. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number [OPP–300489]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

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. In addition,

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) 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: May 8, 1997.

Peter Caulkins,

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. Section 180.499 is amended as follows:

i. By redesignating the existing text as paragraph (b), revising the introductory text of newly designated paragraph (b), in the third column to the table by changing ''March 15, 1999'' to ''3/15/99'', and alphabetically adding entries for tomatoes; tomato paste and tomato puree.

ii. By correctly alphabetizing the entry for ''milk'' in the table.

iii. By adding and reserving paragraphs (a), (c), and (d).

§ 180.499 Propamocarb hydrochloride; tolerances for residues.

(a) *General.* [Reserved]

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

Commodity	Parts per million	Expiration/ Revocation Date
* *	*	* *
Tomatoes	0.5	May 15, 1999
Tomato, puree	1.0	May 15, 1999
Tomato, paste	3.0	May 15, 1999

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

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

[FR Doc. 97–12908 Filed 5–15–97; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 3800

[WO–660–4120–02–24 1A]

RIN 1004–AC40

Mining Claims Under the General Mining Laws; Surface Management

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rule; correction.

SUMMARY: The Bureau of Land Management (BLM) published in the **Federal Register** of February 28, 1997, a final rule amending the bonding provisions of the regulations on mining on public lands under the Mining Law of 1872. The preamble of that final rule contained an editing error creating an internal contradiction in the preamble. This document corrects that error.

EFFECTIVE DATE: Effective on May 16, 1997.

ADDRESSES: Inquiries or suggestions should be sent to the Solid Minerals Group at Director (320), Bureau of Land Management, Room 501 LS, 1849 C Street, N.W., Washington, D.C. 20240.

FOR FURTHER INFORMATION CONTACT: Richard Deery, (202) 452–0350.

SUPPLEMENTARY INFORMATION: BLM published a final rule in the **Federal Register** of February 28, 1997 (62 FR 9093), amending the bonding provisions of the regulations on hardrock mining on public lands under the Mining Law of 1872 (30 U.S.C. 22 *et seq.*). In the preamble of the final rule, because of an editing error, the final two sentences in the last paragraph of the third column on page 9095 appear to contradict each other in explaining when operators working under an existing notice must provide a certification under the regulations. This document corrects that error.

In rule FR Doc. 97–5016, published on February 28, 1997 (62 FR 9093), make the following correction. On page 9095, in the last paragraph of the third column, revise the final sentence to read as follows: ''For existing notices on file with BLM under which operations have not yet begun, the claimant or operator will have to provide the certification before initiating operations.''

Dated: May 9, 1997.

Bob Armstrong,

Assistant Secretary of the Interior.

[FR Doc. 97–12822 Filed 5–15–97; 8:45 am]

BILLING CODE 4310–84–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. MM 87–268; FCC 97–116]

Advanced Television Systems

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This *Report and Order* amends the Commission's rules by adopting service rules to implement digital television. The intended effect of this action is to promote rapid conversion to and implementation of digital television. *This Report & Order* contains new or modified information collections subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. It will be submitted to the Office of Management and Budget (OMB) for review under section 3507(d) of the PRA. OMB, the general public, and other Federal agencies are invited to comment on the new or modified information collections contained in this proceeding.

DATES: *Effective Dates:* The new rules are effective June 16, 1997. Written comments by the public on the new and/or modified information collections are due July 15, 1997.