2. Section 701.118, is amended by removing and reserving paragraph (h), and revising paragraph (i), and revising the heading and introductory text of paragraph (n) as follows:

§ 701.118 Exemptions for specific Navy record systems.

* * * * *

(h) *[Reserved].*

(i) *System identifier and name:* N05041–1, Inspector General (IG) Records.

(1) *Exemption:* Portions of this system of records may be exempt from the provisions of 5 U.S.C. 552a(c)(3); (d); (e)(1); (e)(4)(G), (H), and (I); and (f).

(2) *Authority:* 5 U.S.C. 552a(k)(1) and (k)(2).

(3) *Reasons:* (i) From subsection (c)(3) because the release of the disclosure accounting would permit individuals to obtain valuable information concerning the nature of the investigation and would present a serious impediment to the orderly conduct of any investigative activities. Such accounting could result in the release of properly classified information which would compromise the national defense or disrupt foreign policy.

(ii) From subsections (d) and (f) because access to the records would inform individuals of the existence and nature of the investigation; provide information that might result in the concealment, destruction, or fabrication of evidence; possibly jeopardize the safety and well-being of informants, witnesses and their families; likely reveal and render ineffectual investigatory techniques and methods and sources of information; and possibly result in the invasion of the personal privacy of third parties. Access could result in the release of properly classified information which could compromise the national defense or disrupt foreign policy. Amendment of the records would interfere with the ongoing investigation and impose an impossible administrative burden by requiring investigations to be continually reinvestigated.

(iii) From subsection (e)(1) because in the course of the investigation it is not always possible, at least in the early stages of the inquiry, to determine relevance and or necessity as such determinations may only occur after the information has bee evaluated. Information may be obtained concerning the actual or potential violation of laws or regulations other than those relating to the ongoing investigation. Such information should be retained as it can aid in establishing patterns of improper activity and can provide valuable leads in the conduct of other investigations.

(iv) From subsection (e)(4)(G) and (H) because this system of records is exempt from individual access pursuant to subsection (k)(1) and (k)(2) of the Privacy Act of 1974.

(v) From subsection (e)(4)(I) because it is neccessary to protect the confidentiality of sources and to protect the privacy and physical safety of witnesses. Although the system is exempt from this requirement, the Department of the Navy has published a notice in broad, generic terms in the belief that this is all that subsection (e)(4)(I) of the Act requires.

* * * * *

(n) *System identifier and name:* N05520–5, Personnel Security Program Management Records System. * * *

Dated: March 26, 1997.

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 97–8138 Filed 3–31–97; 8:45 am]

BILLING CODE 5000–04–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300464; FRL–5597–2]

RIN 2070-AC78

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 raw agricultural commodities potatoes, milk; and meat, meat by-products, and fat of cattle, goat, horse, sheep, and hogs 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 potatoes in the states of California, and Texas. This regulation establishes maximum permissible levels for residues of propamocarb hydrochloride in these foods pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and be revoked by EPA on March 15, 1999.

DATES: This regulation becomes effective April 2, 1997. Objections and requests for hearings must be received by EPA on or before June 2, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300464], 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–300464], 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. 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–300464]. 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: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA 22202. (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 potatoes at 0.5 parts per million (ppm) and in milk; and meat, meat by-products, and fat of cattle, goat, horse, sheep, and hogs at 0.1

ppm. These tolerances will expire on March 15, 1999.

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) 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. 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 Exemptions for Propamocarb Hydrochloride on Potatoes and FFDCA Tolerances

EPA has authorized use under FIFRA section 18 of propamocarb hydrochloride on potatoes for control of late blight. Recent failures to control late blight in potatoes as well as tomatoes 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 U.S. were previously controlled by treatment with metalaxyl. Presently, there are no fungicides registered in the U.S. that will provide adequate control of the immigrant strains of late blight. After having reviewed their submission, EPA concurs that an emergency condition exists.

As part of its assessment of these specific exemptions, EPA assessed the potential risks presented by residues of propamocarb hydrochloride on potatoes and milk; and meat, meat by-products, and fat of cattle, goat, horse, sheep, and hogs. 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 for residues of propamocarb hydrochloride will permit the marketing of potatoes treated in accordance with the provisions of the section 18 emergency exemptions and the marketing of milk; and meat, meat by-products, and fat of cattle, goat, horse, sheep, and hogs with secondary residues resulting from the feeding of the feedstuffs of treated potatoes. 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 be revoked by EPA on March 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 potatoes and milk; and meat, meat by-products, and fat of cattle, goat, horse, sheep, and hogs 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 these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicates that the residues are not safe.

EPA has not made any decisions about whether propamocarb hydrochloride meets the requirements for registration under FIFRA section 3 for use on potatoes or whether a permanent tolerance for propamocarb hydrochloride for potatoes and milk; and meat, meat by-products, and fat of cattle, goat, horse, sheep, and hogs would be appropriate. This action by EPA does not serve as a basis for registration of propamocarb hydrochloride by a State for special local needs under FIFRA section 24(c). Nor does this action serve as the basis for any States other than California, Texas and States which are subsequently granted specific exemptions for this use 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 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% or less of the RfD) is generally considered acceptable by EPA.

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 margin of exposure 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 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 these actions. Propamocarb hydrochloride is registered by EPA for turf and ornamental use. EPA believes it has sufficient data to assess the hazards of propamocarb hydrochloride and to make a determination on aggregate exposure, consistent with section 408(b)(2), for the time-limited tolerances for residues of propamocarb hydrochloride on potatoes at 0.5 parts per million (ppm) and in milk; and meat, meat by-products, and fat of cattle, goat, horse, sheep, and hogs at 0.1 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

1. *Chronic toxicity*. Based on the available chronic toxicity data, EPA's Office of Pesticide Programs (OPP) has established the RfD for propamocarb hydrochloride at 0.11 milligrams (mg)/kilograms (kg)/day. The RfD was established based on a threshold LOEL (lowest observable effect level) of 33.31 mg/kg/day in males and 33.27 mg/kg in females in a 11–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 inter-species extrapolation and intra-species variability. An additional UF of 3 was used to account for the lack of a NOEL.

2. *Acute toxicity*. Agency toxicologists have recommended that the developmental NOEL of 150 mg/kg/day from the rabbit developmental toxicity study be used for acute dietary risk calculations. The developmental 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.

3. *Short-term non-dietary inhalation and dermal 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 6-18. The developmental NOEL was 150 mg/kg/day. The developmental LOEL of 300 mg/kg/day was based on increased post-implantation loss.

4. *Carcinogenicity*. 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

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.

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. These conservative assumptions result in overestimation of human dietary exposures.

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).

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.

Propamocarb hydrochloride is registered for uses, such as lawn and ornamental, 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. However, available data for propamocarb hydrochloride indicate no evidence of toxicity by the dermal or inhalation routes.

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 subtances.

C. Safety Determinations For U.S. Population

Taking into account the completeness and reliability of the toxicity data, EPA has concluded that dietary exposure to propamocarb hydrochloride in food from published tolerances will utilize 2% of the RfD for the U.S. population. A dietary (food only) MOE of greater than 118 would not be of Agency concern. A MOE of 30,000 was calculated.

EPA does not believe exposure to propamocarb hydrochloride in drinking water or from residential uses would raise the percent of RfD utilized or lower the MOE, to such extent that there was not an adequate margin of exposure. 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 tolerance 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 tolerance is granted. An appropriate bounding figure for residential exposure is expected to be lower than for drinking water. Therefore, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to propamocarb hydrochloride residues.

D. Determination of Safety for Infants and Children.

FFDCA section 408 provides that EPA shall apply an additional ten-fold

margin of exposure (safety) for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the data base unless EPA determines that a different margin of 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 ten-fold 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 margin of exposure. Based on current toxicological data requirements, the data base for propamocarb hydrochloride relative to pre- and post-natal toxicity is not complete.

The pre- and post-natal toxicology data base for propamocarb is not complete with respect to current toxicological data requirements. 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 would be deemed appropriate for propamocarb, 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). However, considering the large dietary MOE calculated for females 13+ years (MOE = 30,000), even if an additional ten-fold uncertainty factor were applied, aggregate acute risk estimates would not exceed the margin of exposure. Therefore, EPA concludes that this tolerance will pose reasonable certainty of no harm to infants and children.

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 7% for non-nursing infants (<1 year old). However, this 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 potatoes is adequately understood for the purposes of this tolerance. There are no Codex maximum residue levels established for residues of propamocarb hydrochloride. The residue of concern, for the purposes of this tolerance, 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; however, an independent laboratory validation has not been submitted. Further the method has not undergone Agency method validation. 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, tolerances in connection with the FIFRA section 18 emergency exemptions are established for residues of propamocarb hydrochloride in or on potatoes at 0.5 parts per million (ppm) and in milk; and meat, meat by-products, and fat of cattle, goat, horse, sheep, and hogs at 0.1 ppm. These tolerances will expire and be revoked by EPA on March 15, 1999.

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 2, 1997, file written objections to any aspect of this regulation (including the 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 number [OPP–300464]. 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 tolerances, 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 this 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: March 17, 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. By adding § 180.499 to read as follows:

§ 180.499 Propamocarb hydrochloride, tolerances for residues.

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 are specified in the following table. The tolerances expire and will be revoked on the date specified in the table by EPA.

Commodity	Parts per million	Expiration/ Revocation Date
Potatoes	0.5	March 15, 1999
Cattle, fat	0.1	March 15, 1999
Cattle, meat	0.1	March 15, 1999
Cattle, mbyp (except kidney and liver)	0.1	March 15, 1999
Goats, fat	0.1	March 15, 1999
Goats, meat	0.1	March 15, 1999
Goats, mbyp (except kidney and liver)	0.1	March 15, 1999
Hogs, fat	0.1	March 15, 1999
Hogs, meat	0.1	March 15, 1999
Hogs, mbyp (except kidney and liver)	0.1	March 15, 1999
Horse, fat	0.1	March 15, 1999
Horse, meat	0.1	March 15, 1999
Horse, mbyp (except kidney and liver)	0.1	March 15, 1999
Sheep, fat	0.1	March 15, 1999
Sheep, meat	0.1	March 15, 1999
Sheep, mbyp (except kidney and liver)	0.1	March 15, 1999
Milk	0.1	March 15, 1999

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DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 29

RIN 2105–AC25

Nonprocurement Debarment and Suspension

ACTION: Final rule.

DATES: This document is effective April 2, 1997.

FOR FURTHER INFORMATION CONTACT: Paul B. Larsen, Office of the General Counsel, C–10, Room 10102, (202) 366–9161, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Background

On June 26, 1995 the Department of Transportation joined in the governmentwide common rule on