Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs

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Connecticut

(a) *Department of Environmental Protection:* submitted on September 28, 1995; interim approval effective on April 23, 1997; interim approval expires April 26, 1999.

(b) [Reserved]

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[FR Doc. 97–7349 Filed 3–21–97; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 136

Guidelines Establishing Test Procedures for the Analysis of Pollutants

CFR Correction

In title 40 of the Code of Federal Regulations, parts 136 to 149, revised as of July 1, 1996, on page 26 § 136.3 (e), table II, under metals, the third entry should read as follows:

TABLE II—REQUIRED CONTAINERS, PRESERVATION TECHNIQUES, AND HOLDING TIMES

Parameter No./name	Container [1]	Preservation [2,3]	Maximum holding time [4]
* * * * *	*	*	*
Metals:[7]			
* * * * *	*	*	*
3, 5–8, 12, 13, 19, 20, 22, 26, 29, 30, 32–34, 36, 37, 45, 47, 51, 52, 58–60, 62, 63, 70–72, 74, 75. Metals, except boron, chromium VI and mercury.	P, G	.....do	6 months.
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BILLING CODE 1505-01-D

40 CFR Part 180, 185 and 186

[OPP–300465; FRL–5597–7]

RIN No. 2070–AB78

Avermectin B_1 and Its Delta-8,9-Isomer; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This document establishes time-limited tolerances for residues of the insecticide avermectin and its delta-8,9-isomers in or on the following raw agricultural commodities: cottonseed, citrus, dried hops, potatoes, meat and meat byproducts, milk and processed food/feed commodities. Merck Co., Inc. submitted a petition to EPA under the Federal Food, Drug and Cosmetic Act as amended by the Food Quality Protection Act of 1996 requesting the tolerances.

DATES: This regulation becomes effective March 24, 1997. The entries in the table expire on September 1, 1999. Objections and requests for hearings must be received by May 23, 1997.

ADDRESSES: Written objections and hearing requests identified by the docket control number [OPP–300465/PP 7F3500; 8F3592; 5F4508; 4E4419 and FAP 8H5660], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St. SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the docket 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 copy of objections and hearing requests to Rm 1132, CM#2, 1921 Jefferson-Davis Hwy, Arlington, VA. Fees accompanying objections shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP(Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. An electronic copy of objections and hearing requests filed with the Hearing Clerk may be submitted to OPP by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov.

Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300465/PP 7F3500; 8F3592; 5F4508; 4E4419 and FAP 8H5660]]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submission can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: George LaRocca, Product Manager (PM) 13, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St, SW., Washington, DC 20460. Office location, telephone number and e-mail address: Rm. 204, CM #2, 1921 Jefferson-Davis Hwy, Arlington, VA 22202, (703) 305–6100; e-mail: larocca.george@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** dated May 8, 1996 (61 FR 20745), EPA proposed to renew time-limited tolerances for the insecticide avermectin and its delta-8,9-isomer (avermectin) in or on cottonseed at 0.005 parts per million (ppm); citrus, whole fruit, at 0.02 ppm; citrus oil, at 0.1 ppm; citrus dried pulp, at 0.1 ppm; cattle, meat, at 0.02 ppm; cattle, meat byproducts, at 0.02 ppm; cattle, fat, at 0.015 ppm; milk, at 0.005 ppm; and hops, dried, at 0.5 ppm. These tolerances were originally established in response to pesticide petitions 7F3500, 8F3592, 4E4419, and food additive petition 8H5550 and have since expired. They were time-limited due to aquatic pesticide exposure issues. The Agency was unable to publish a final rule prior to the enactment of Food Quality Protection Act of 1996. Because of new procedures under FQPA, Merck was required to submit a new notice of filing requesting reissuance of these tolerances in compliance with FQPA.

In the **Federal Register** dated December 10, 1996 (61 FR 65043), EPA issued a notice of filing which announced that Merck had filed a request to amend 40 CFR 180.449 by

reissuing the regulations that established tolerances for residues in or on the raw agricultural commodities cottonseed at 0.005 ppm; citrus, whole fruit at 0.02 ppm; citrus oil at 0.1 ppm; citrus dried pulp at 0.1 ppm; cattle, meat at 0.02 ppm; cattle, meat byproducts at 0.02 ppm; cattle fat at 0.015 ppm; milk at 0.005 ppm and hops, dried at 0.5 ppm and bring them into compliance with the FQPA. The notice contained a summary of the petitions and conclusions and argument in support of the petitioner's conclusion that the petition complied with FQPA. Also included in the notice was a request to establish permanent tolerance in/on the raw agricultural commodity potatoes at 0.005 ppm.

Based on review of new residue data for dried hops (PP 5E4566), EPA concluded that 0.2 ppm, rather than 0.05 ppm, is the more appropriate tolerance level and therefore the subject petition is amended accordingly.

There were no comments received in response to the notices of filing.

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. 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.

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 for 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 aggregated exposure to the pesticide chemical. Section 408 (b)(2)(D) specified factors EPA is to consider in establishing a tolerance. Section 408 (b)(3) requires EPA to determine that there is a practical method for detecting and measuring levels of the pesticide chemical residue in or on food and that the tolerance be set at a level at or above the limit of detection of the designated method. Section 408 (b)(4) requires EPA to determine whether a maximum residue level has been established for the pesticide chemical by the Codex Alimentarius Commission. If so, and EPA does not propose to adopt that level, EPA must publish for public comment a notice explaining the reasons for departing from the Codex level.

II. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregated exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies may address 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 (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 aggregated exposure over a lifetime will not pose an appreciable risk 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.

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 (MOE) calculations 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 aggregated exposure, FQPA 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 residues 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 crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Consistent with sections 408(b)(2)(C) and (D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has also assessed the toxicology data base for avermectin and its delta-8,9-isomers in its evaluation of applications for registration on cotton, citrus, hops, and potatoes. EPA has sufficient data to assess the hazards of avermectin and its delta-8,9-isomers and to make a determination on aggregate exposure, consistent with section 408(b)(2), for granting time-limited tolerances for residues of avermectin

and its delta-8,9-isomers on cottonseed at 0.005 ppm; citrus, whole fruit at 0.02 ppm; citrus oil at 0.1 ppm; citrus dried pulp at 0.1 ppm; cattle, meat at 0.02 ppm; cattle, meat byproducts at 0.02 ppm; cattle fat at 0.015 ppm; milk at 0.005 ppm, potatoes at 0.005 ppm and hops at 0.2 ppm.

The data submitted in the petitions and other relevant material have been evaluated. The toxicology data listed below were considered in support of these tolerances.

A. Toxicology Data Base

1. *Acute studies.* A battery of acute toxicity studies placing technical avermectin in Toxicity Categories I and III.

2. *Subchronic studies.* i. A rat 8–week feeding study with a NOEL of 1.4 milligrams per kilograms per day (mg/kg/day) based upon tremors.

ii. A rat 14–week oral toxicity study with a NOEL of 0.4 mg/kg/day, the highest dose tested.

iii. A dog 12–week feeding study with a NOEL of 0.5 mg/kg/day based upon mydriasis.

iv. A dog 18–week oral study with a NOEL of 0.25 mg/kg/day based upon mortality.

v. A CD-1 mouse 84–day feeding study with a NOEL of 4 mg/kg/day based upon decreased body weights.

3. *Chronic studies.* i. A rat 105–week oncogenicity feeding study, negative for oncogenicity with dose levels up to and including 2.0 mg/kg/day, the highest dose tested (HDT), with a NOEL of 1.5 mg/kg/day based upon tremors.

ii. A CD-1 mouse 94–week oncogenicity feeding study, negative for oncogenicity at dose levels up to and including 8 mg/kg/day (HDT), with a NOEL of 4 mg/kg/day based upon decreased body weights.

iii. A dog 53–week chronic feeding study, with a NOEL of 0.25 mg/kg/day based upon mydriasis.

4. *Developmental toxicity studies.* i. An oral teratology study in the CF-1 mouse with a maternal NOEL of 0.05 mg/kg/day based upon decreased body weights and tremors. The fetal NOEL was 0.20 mg/kg/day based upon cleft palates.

ii. An oral teratology study with the delta 8,9-isomer in CF-1 mice with a maternal NOEL of 0.10 mg/kg/day based upon decreased body weights. The fetal NOEL was 0.06 mg/kg/day based upon cleft palate.

iii. An oral teratology study in rabbits with a maternal NOEL of 1.0 mg/kg/day based upon decreased body weights and tremors at the lowest observed effect level (LOEL) of 2.0 mg/kg/day. The fetal NOEL was 1.0 mg/kg/day based upon clubbed feet and delayed ossification of sternebrae, metacarpels and phalanges at the lowest effect level (LEL) of 2.0 mg/kg/day.

iv. An oral teratology study in rats with a maternal and fetal NOEL at 1.6 mg/kg/day (HDT).

5. *Reproductive effects study.* i. A 2-generation study in rats with a NOEL of 0.12 mg/kg/day in pups based upon retinal folds, decreased body weight, and mortality at the LEL of 0.4 mg/kg/day. The NOELs for systemic and reproductive toxicity were 0.4 mg/kg/day (HDT).

6. *Mutagenicity studies.* i. The Ames assays conducted with and without metabolic activation were both negative.

ii. The V-79 mammalian cell mutagenesis assays conducted with and without metabolic activation did not produce mutations. In an alkaline elution/rat hepatocyte assay, abamectin was found to induce single strand DNA breaks without significant toxicity in rat hepatocytes treated *in vitro* at doses greater than 0.2 millimole (mM). This *in vitro* dose of 0.2 mM is biologically unobtainable *in vivo*, due to the toxicity of the compound. However, at these potentially lethal doses, *in vivo* treatment did not induce DNA single strand breaks in hepatocytes. In the mouse bone marrow assay, abamectin was not found to induce chromosomal damage.

B. Toxicological Profile

1. *Dietary risks*—i. *Acute toxicity.* Because of the developmental effects seen in animal studies, EPA used the mouse developmental toxicity study (with a pup NOEL of 0.06 mg/kg/day for developmental toxicity for the delta-8,9-isomer) to assess acute dietary exposure and determine a MOE for the overall U.S. population and certain subgroups. Since the toxicological endpoints pertain to developmental toxicity, the risk assessment evaluated acute dietary risk to females 13+ years old, the subgroup which most closely approximates women of child bearing ages. For purposes of these time-limited tolerances, an MOE of 300 is considered necessary to be adequately protective for dietary exposure.

(Note: EPA notes that the petitioner has used a NOEL of 0.05 mg/kg/day in its assessment. EPA currently considers the appropriate NOEL to be 0.06 mg/kg/day; therefore the petitioner's MOE values have been corrected to reflect this higher NOEL.)

ii. *Chronic risk.* Based on the available chronic toxicity data, EPA has established the Reference Dose (RfD) for avermectin and its delta-8,9-isomer at 0.0004 mg/kg/day based on a 2-generation rat reproduction study with a NOEL of 0.12 mg/kg/day and an uncertainty factor of 300. In addition to the uncertainty factor of 100 for inter- and intra-species variations, a modifying factor (MF) of 3 was used for a total uncertainty factor of 300. The MF was used because of the effects (pup deaths) and the steep dose-response curve. At the LEL of 0.40 mg/kg/day, there was decreased pup body weight and viability during lactation as well as an increase of incidence of retinal rosettes in F2b weanlings.

iii. *Carcinogenicity.* Using EPA Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 3392), EPA has classified avermectin as Group ''E'' for carcinogenicity (no evidence of carcinogenicity) based on the results of a carcinogenicity studies in two species. Infants and Children: EPA has concluded that avermectin and related compounds induce developmental toxicity in several species. To assess the potential for additional sensitivity of infants and children to residues of avermectin, EPA used the rat 2-generation reproduction study NOEL of 0.12 mg/kg/day based upon toxicity observed in nursing pups and the mouse oral teratology study NOEL of 0.06 mg/kg/day based upon cleft palate in developing fetuses.

2. *Non-dietary risks*— i. *Short-and intermediate term occupational or residential dermal or inhalation risks.* EPA used the developmental NOEL of 0.2 mg/kg/day from the oral developmental toxicity study of CF-1 mice. At the LEL of 0.4 mg/kg/day, there was an increased incidence of cleft palate.

ii. *Chronic occupational or residential risk.* For chronic MOE calculations, EPA used the developmental NOEL of 0.12 mg/kg/day from a 2-generation rat reproduction study. At a LEL of 0.4 mg/kg/day, there was increased pup deaths during lactation decreased pup body weight and increased incidence of retinal rosettes.

iii. *Dermal absorption.* EPA used a value of 1% based on a monkey dermal absorption study.

C. Aggregate Exposure

1. *From food and feed uses.* The primary source for human exposure to avermectin will be from ingestion of both raw and processed agricultural commodities proposed in the December 10, 1996 Notice of Filing cited above and from the commodities in 40 CFR 180.449, 185.300 and 186.300.

Any secondary residues occurring in cattle meat, meat byproduct, milk and fat from the addition of the feed items potato culls and processed potato waste

will be covered by the existing tolerances for these commodities. There is no reasonable expectation of finite residues in poultry and swine, therefore no tolerances are necessary at this time. Although data indicates avermectin residues accumulate in some rotational crops at levels up to 10 to 12 ppb, the residue was due to polar degradates that are of little toxicological concern. Thus, it is unlikely that residues will accumulate in rotational crops.

The dietary risk assessment will be reevaluated with respect to secondary residues in ruminant tissues and milk upon submission and review of field trail data for cotton gin-byproducts.

2. *From potable (drinking) water use.* There is no established Maximum Concentration Level for residues of avermectin in drinking water. No Health Advisory Levels for avermectin in drinking water have been established. Because the Agency lacks specific water related exposure data for most 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. EPA 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 aggregated risk contributed by consumption of contaminated water. This analysis can be found in the Special Record for the FQPA. While EPA has not yet pinpointed the appropriate bounding figure for consumption of contaminated water, the ranges EPA is continuing to examine are all below the level that would cause avermectin to exceed the RfD, if the tolerances being considered in this document are granted. EPA has therefore concluded that the potential exposure associated with avermectin in water, even at the higher levels EPA is considering as a conservative upper bound, would not prevent EPA from determining that there is a reasonable certainty of no harm if the proposed tolerances are granted.

3. *From non-dietary uses.* Avermectin is registered for various uses including use on ornamentals (herbaceous and woody), household dwellings (indoor and outdoor), and non-food areas of food handling establishments. The exposure from these uses are expected to be oral, dermal and respiratory in nature. Based on the nature of the outdoor residential uses (spot treatment), EPA has concluded that residential exposure resulting from outdoor uses will not be significant. Likewise, based upon the nature of the indoor and outdoor residential uses, EPA has concluded that a chronic residential exposure study is not necessary. The indoor residential exposure assessment to determine risk from exposure to children and adults was based on a California EPA (Medical Toxicology and Worker Health and Safety Branches) review of an avermectin residential exposure study.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically and structurally 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 avermectin 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, avermectin 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 avermectin has a common mechanism of toxicity with other substances.

D. Safety Determinations

1. *U.S. population and non-nursing infants.* A chronic dietary exposure/risk assessment was conducted for avermectin using a RfD of 0.0004 mg/kg/day based on a NOEL of 0.12 mg/kg/day from a 2–year generation rat reproduction study and an uncertainty factor of 300. Available information on anticipated residues and 100% crop treated was incorporated into the analysis to estimate the Anticipated Residue Contribution (ARC). The ARC is generally considered a more realistic estimate than an estimate based on tolerance-level residues. The cumulative total of established and proposed uses will result in exposure estimates of 0.000020 mg/kg/day for the overall U.S. population and utilize 5% of the RfD. For the most highly exposed population subgroup, non-nursing infants less than 1 year old, the ARC for established and current uses is estimated at 0.00043 mg/kg/day utilizing 11% of RfD. EPA generally has no concern for exposure below 100% of the RfD because the RfD represents the level at or below which daily aggregated dietary exposure over a life time will not pose an appreciable risk to human health. EPA therefore concludes that there is reasonable certainty that no harm will result from dietary exposure to avermectin residues.

Due to developmental toxicity concerns, an acute dietary exposure/risk assessment for these tolerances and pending tolerances have been performed. The acute dietary risk assessment used Monte Carlo modeling incorporating anticipated residues and percent of crop treated refinement. The subgroup of concern in this analysis is

women aged 13 and above which is the subgroup most closely approximating women of child bearing age. At the calculated high-end exposure of 0.00078 mg/kg/day, the acute dietary MOE is 769 for females 13+ years old. Based on these results, EPA has no acute dietary concerns since EPA considers an MOE of greater than 300 adequately protective.

EPA notes that the acute dietary risk assessment used Monte Carlo modeling (in accordance with Tier 3 of EPA June 1996 ''Acute Dietary Exposure Assessment'' guidance document) incorporating anticipated residues and percent of crop treated refinements. For the purpose of these time limited tolerances, EPA concludes that this analysis is adequate to assess acute dietary exposure, but prior to establishment of permanent tolerances a full review of this analysis will be required.

Section 408 (b)(2)(E) requires that, if EPA relies upon anticipated residue levels in setting a tolerance, EPA must require that data be submitted 5 years after approval of the tolerance on whether the anticipated residue level remains accurate. Because this tolerance is limited to approximately 2 1/2 years, data are not being required at this time.

2. *Infants and children.* FFDCA section 408 provides that EPA shall apply an additional tenfold 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 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 and children, and the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard margin of exposure.

In assessing the potential for additional sensitivity of infants and children to residues of avermectin, EPA considered data from developmental toxicity studies in the rat, mouse and rabbit and a 2-year 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 the mothers. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

3. *Prenatal effects.* The developmental and maternal NOELs for avermectin in rats are both > 1.6 mg/kg/day, highest dose tested. For rabbits, the developmental and maternal NOELs and LOELs are both 1.0 and 2.0 mg/kg/day, respectively. These studies suggest that avermectin does not exhibit any special prenatal sensitivity. However, both avermectin and its delta-8,9-isomer exhibit cleft palate in the CF-1 mouse developmental studies. For avermectin and its delta,-8,9-isomer, the NOEL for cleft palate is 0.2 mg/kg/day with the LOEL at 0.4 mg/kg/day and NOEL 0.06 mg/kg/day with the LOEL at 0.10 mg/kg/day, respectively. Therefore, prenatal sensitivity to the regulated residue for avermectin is demonstrated when considering these effects in the CF-1 mouse. To evaluate the prenatal risk, the acute dietary MOE calculation for women 13+ years old has been conducted, resulting in a MOE of 769, which is considered adequate to protect prenatal exposure.

4. *Post-natal effects.* Post-natal effects were determined by a 2-year generation rat reproduction study with a NOEL of 0.12 mg/kg/day and LOEL of 0.4 mg/kg/day, where effects in the pups included death, decreased body weight and retinal folds. In contrast, the NOEL for parental toxicity is 0.4 mg/kg/day. This suggests post-natal sensitivity for infants and children. However, with respect to the post-natal sensitivity for the delta-8,9-isomer, a 1-generation rat reproduction study at doses up to 0.4 mg/kg/day did not produce any parental or pup toxicity. The established RfD is 0.0004 mg/kg/day based on the 2–year generation rat reproduction study with a NOEL of 0.12 mg/kg/day and an uncertainty factor of 300. The post-natal sensitivity for infants and children has been considered by employing a 300-fold uncertainty factor in the calculation of the RfD. The highest calculated aggregate percentage of the RfD is 11% for non-nursing infants. At this level, risk to infants and children due to post-natal exposure do not raise concerns.

Therefore, EPA concludes the reliable data support use of a 300-fold safety factor, which incorporates an additional modifying factor (MF) for the effect and dose response curve, and thus no additional safety factor is not needed to protect the safety of infants and children. (EPA notes that the petitioner, in their Notice of Filing, indicated that some of the studies EPA used in its risk assessments are not appropriate for assessing the risk potential of avermectin and/or overstate the risk and that an additional MF is unnecessary and submitted additional data in this regard. EPA has not yet completed its review of these data, but will take it into account in later reassessment of the tolerances.)

E. Aggregate Risk Assessment

1. *Acute risk assessment.* The acute aggregate risk assessment takes into account exposure from food only. As indicated above, although EPA has not identified a water exposure figure based upon available environmental data, avermectin is not expected to be mobile in soil or water environments and poses relatively little threat to drinking water. The combined exposure to avermectin from food and residential uses is considered in the short-and intermediate-term risk assessment. An acute dietary MOE of greater than 300 would not be of concern to EPA. As indicated earlier, the MOE for females 13+ years was calculated to be 769. Under any bounding assumption EPA is considering for exposure from drinking water, this MOE would not be significantly reduced. Therefore, EPA has no acute aggregate concern due to exposure to avermectin through food and drinking water.

2. *Short-and intermediate risk assessment.* The short-and intermediate term aggregate risk takes into account exposure from chronic dietary food and indoor/outdoor residential exposure. Based on the nature of the outdoor residential uses (spot treatment), residential outdoor exposure for avermectin is insignificant. The residential indoor exposure was based on the California EPA review of an indoor residential exposure study. A total indoor MOE of 800 was calculated for short-and intermediate-term risk, taking into account and residential exposures. For the most highly exposed population subgroup (non-nursing infants less than 1 year old), an aggregate short-and intermediate-term MOE of 733 was calculated. Under any bounding assumption EPA is considering for exposure from drinking water, this MOE would not be significantly reduced. As indicated earlier, an MOE of greater than 300 would not be of concern to EPA, therefore current uses of avermectin is below the level of concern.

For the purposes of these time-limited tolerances, EPA has concluded that the California EPA assessment is adequate to estimate residential exposure from registered non-dietary uses of avermectin but prior to establishment of

permanent tolerances, a full review of the indoor residential risk assessment will be required.

3. *Chronic risk assessment.* The aggregated chronic risk is equal to the sum of the chronic risk from food, drinking water, and indoor and outdoor residential exposures. For avermectin, the residential uses are not of the type that would be expected to produce a long-term exposure. Therefore, residential exposure was aggregated with dietary exposure only in the short- and intermediate-term risk assessment. The aggregated chronic risk (food only) is 5% of the RfD for the U.S. population and 11% of the RfD for the population subgroup non-nursing infants less than 1 year old. Under any bounding assumptions EPA is considering for exposure from drinking water, exposure to avermectin would not exceed the RfD. EPA therefore concludes that there is reasonable certainty that no harm will result to consumers, including infants and children from aggregate exposure to avermectin residues.

F. Other Considerations

1. *Endocrine effects.* No evidence of effects on the endocrine systems of mammals were reported in the toxicology studies described above. There is no evidence at this time that avermectin causes endocrine effects.

2. *Metabolism and nature of residues.* The metabolism of avermectin and nature of residues in plants and animals is adequately understood for the purpose of these tolerances. The residues of concern are avermectin B1 and its delta-8,9-isomer.

3. *International tolerances.* There are no Codex maximum residue levels established for residues of avermectin on citrus, cotton, potato and hop commodities.

4. *Analytical method.* There is a practical analytical method for detecting and measuring the levels of avermectin and its delta-8,9-isomer 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 (high performance liquid chromatography with fluorescence detection, with crop specific clean up methods). EPA has provided information on this method to the Food and Drug Administration. The method is available to anyone who is interested in pesticide residue enforcement from: Calvin Furlow, Public Response and Program Resources Branch, 401 M St. SW., Washington, DC 20460. Office location and telephone number: CM #2, Rm 1128, 1921 Jefferson Davis Highway, Arlington, VA, 703–305–5805.

III. Summary of Findings

Tolerances are time-limited to allow for development and review of residue field trials on cotton gin byproducts and to complete full review of the Monte Carlo acute dietary and indoor residential risk assessments. These tolerances will expire and be revoked without any further action by EPA (other than publishing a notice in the **Federal Register** so that the CFR can be corrected) on September 1, 1999

Residues remaining in or on the above RAC's after expiration of these tolerances will not be considered actionable if the pesticide is legally applied during the term and in accordance with the provisions of the conditional registrations.

EPA concludes that the proposed time-limited tolerances will be safe. Therefore it is proposed that the tolerances be established as set forth below.

IV. 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 (1)(6) as was provided in the old section 408 and in section 409. However, the period of filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulation will require some modification to reflect the new law. However, until these modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may by May 23, 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 issue(s) 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 a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more 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 with prior notice.

V. Public Docket

A record has been established for this rulemaking under docket number [OPP–300465/PP 7F3500; 8F3592; 5F4508; 4E4419 and FAP 8H5660]. A public version of this record, which does not include any information claimed as CBI, is available for inspection form 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, 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 the 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 ''ADDRESSEE'' at the beginning of this document.

VI. 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 tolerances 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 rulemaking 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).

Pursuant to 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

40 CFR Part 180

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

40 CFR Part 185

Environmental protection, Food additives, Pesticides and pests.

40 CFR Part 186

Environmental protection, Animal feeds, Pesticides and pests.

Dated: March 14, 1997.

Penelope A. Fenner-Crisp,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is amended as follows:

1. In part 180:

PART 180—[AMENDED]

a. The authority citation of part 180 continues to read:

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

b. In § 180.449 by revising paragraph (a) to read as follows:

§ 180.449 Avermectin B_1 and its delta-8,9-isomer; tolerances for residues.

(a) Tolerances are established for the combined residues of the insecticide avermectin (a mixture of avermectins containing greater that or equal to 80% avermectin B_{1a}(5-*O*-dimethyl avermectin A_{1a}) and less than or equal to 20% avermectin b(5-*O*-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A_{1a})) and its delta-8, 9-isomer in or on the following commodities:

Commodity	Parts per million	Expiration/Revocation Date
Cattle, fat	0.015 ppm	September 1, 1999
Cattle, mbyp	0.02 ppm	September 1, 1999
Cattle, meat	0.02 ppm	September 1, 1999
Citrus, dried pulp	0.10 ppm	September 1, 1999
Citrus, oil	0.10 ppm	September 1, 1999
Citrus, whole fruit	0.02 ppm	September 1, 1999
Cottonseed	0.005 ppm	September 1, 1999
Hops, dried	0.2 ppm	September 1, 1999
Milk	0.005 ppm	September 1, 1999
Potatoes	0.005 ppm	September 1, 1999

* * * * *

2. In part 185:

PART 185—[AMENDED]

a. The authority citation for part 185 is revised to read as follows:

Authority: 21 U.S.C. 348.

§ 185.300 [Removed]

b. By removing § 185.300 in its entirety.

3. In part 186:

PART 186—[AMENDED]

a. The authority citation for part 186 is revised to read as follows:

Authority: 21 U.S.C. 348.

§ 186.300 [Removed]

b. By removing § 186.300 in its entirety.

[FR 97–7352 Filed 3–21–97; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 961217360–7052–02; I.D. 112596C]

RIN 0648–AI62

Fisheries of the Exclusive Economic Zone Off Alaska; Groundfish of the Bering Sea and Aleutian Islands Area; Prohibited Species Catch Limits for Tanner Crab

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.