and pests, Reporting and recordkeeping requirements.

Dated: March 25, 1999.

James Jones,

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. 321(q), 346(a), and 371.

§ 180.499 [Amended]

2. In § 180.499, by amending paragraph (b) by revising the date ''11/15/00'' to read ''11/15/01''.

[FR Doc. 99–8339 Filed 4–6–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300825; FRL–6070–6]

RIN 2070–AB78

Avermectin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of avermectin in or on avocado. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on avocado. This regulation establishes a maximum permissible level for residues of avermectin B_1 and its delta-8,9-isomer in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on September 30, 2000.

DATES: This regulation is effective April 7, 1999. Objections and requests for hearings must be received by EPA on or before June 7, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300825], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300825], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), 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. 119, Crystal Mall #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@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 objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300825]. 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.

FOR FURTHER INFORMATION CONTACT: By mail: Jacqueline E. Gwaltney, 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. 278 Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703/305–6792, gwaltney.jackie@epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to sections 408 and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a and (l)(6), is establishing a tolerance for combined residues of the fungicide, in or on avocado at 0.02 ppm part per million (ppm). This tolerance will expire and is revoked on September 30, 2000. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Findings

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 in this preeamble and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL–5572–9).

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

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and

implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Avermectin on Avocado and FFDCA Tolerances

California submitted information to EPA that indicates that the avocado thrip (*Scirthothrips perseae*) poses a significant threat to the profitable production of avocado. Avocado affected by avocado thrip can be rendered unmarketable because it causes severe scarring and damage to small avocado fruit, fruit stems and tender leaf flushes. California determined that the conditions for a avocado thrip outbreak were favorable and invoked its authorities under 40 CFR 166.40 to declare a crisis situation. After considering the implications connected with the use of this pesticide under a crisis situation, EPA is establishing this tolerance for the use of avermectin on avocado for the control of avocado thrips in California.

EPA has authorized under FIFRA section 18 the use of avermectin on avocado for control of avocado thrips in California. After having reviewed the submission, EPA concurs that emergency conditions exist for this state.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of avermectin in or on avocado . In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on September 30, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on avocado after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions EPA has not made any decisions about whether avermectin meets EPA's registration requirements for use on avocado or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of avermectin by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than California to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for avermectin, contact the Agency's Registration Division at the address provided under the ''ADDRESSES'' section.

III. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7) .

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of avermectin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for combined residues of avermectin on avocado at 0.02ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by avermectin are discussed in this unit.

B. Toxicological Endpoint

1. *Acute toxicity*. The acute dietary Reference Dose (RfD) is 0.0025 mg/kg from a 1–year dog study. The no observed adverse effect level (NOAEL) is 0.25 mg/kg/day, and the lowest observed adverse effect level (LOAEL) is 0.50 mg/kg/day based on mydriasis (pupil dilation) which was observed after one week of dosing. An uncertainty factor of 100 to account for interspecies extrapolation (10x) and intraspecies variability (10x) was recommended (Hazard Identification Assessment Review Committee (HIARC), 7/28/98).

2. *Short- and intermediate-term toxicity*. Short- and intermediate-term dermal NOAELs of 0.25 mg/kg/day based on mydriasis after one week of dosing in a 1–year dog study. Dermal absorption is considered to be 1%. Short- and intermediate-term inhalation NOAEL is a route-to-route extrapolation from the oral NOAEL of 0.25 mg/kg/day based on mydriasis after one week of dosing in a 1–year dog study. Oral and inhalation absorption are both assumed to be 100% (HIARC, 7/28/98).

3. *Chronic toxicity*. EPA has established the RfD for avermectin at 0.0012 milligrams/kilogram/day (mg/kg/day) from a 2–generation reproduction study in rats. The developmental NOAEL is 0.12 mg/kg/day, and the developmental LOAEL is 0.40 mg/kg/day based on decreased pup body weight and viability during lactation, and increased incidence of retinal rosettes in F2b weanlings. An uncertainty factor of 100 to account for interspecies extrapolation (10x) and intraspecies variability(10x) was recommended.

4. *Long-term*. Long-term dermal NOAEL of 0.12 mg/kg/day based on decreased pup body weight and viability during lactation, and increased incidence of retinal rosettes in F2b weanlings in a 2–generation reproduction study in rats. Dermal absorption is considered to be 1% (HIARC, 7/28/98).

Long-term inhalation NOAEL is a route-to-route extrapolation from the oral NOAEL of 0.12 mg/kg/day based on decreased pup body weight and viability during lactation, and increased incidence of retinal rosettes in F2b weanlings in a 2–generation reproduction study in rats. Oral and inhalation absorption are both assumed to be 100% (HIARC, 7/28/98).

5. *Carcinogenicity*. At its July 27, 1996 meeting, the EPA RfD/Peer Review Committee classified avermectin as a Cancer Group E chemical based on the absence of significant tumor increases in two adequate rodent carcinogenicity

studies. On July 28, 1998 the HIARC retained this classification. This assessment is not required.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.449) for the combined residues of avermectin, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures and risks from avermectin as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. The avermectin acute (food only) exposure analysis was recently completed in conjunction with the section 3 human health risk assessment on grapes and peppers. The analysis included avocados at the recommended time-limited tolerance of 0.02 ppm. The risk estimate should be viewed as highly refined. Additional refinement would be unlikely to reduce risk estimates significantly. In making a safety determination for this tolerance, EPA is taking into account this refined exposure assessment. The resulting calculations are presented below at the 99.9th percentile as either a percent of the acute population adjusted dose (%PAD) or percent RfD (%RfD) depending on the population. EPA is generally concerned with acute exposures that exceed 100% of the acute RfD(aRfD)/PAD.

Subgroup	ARC (mg/kg)	Percent Population adjusted dose	Percent Reference dose
U.S. population	0.000086	35%PAD	
Children (1–6 years)	0.000176	70	
Females (13+/nursing)	0.000095	38	
Males (13–19 years)	0.000048		2

ii. *Chronic exposure and risk.* The avermectin chronic (food only) exposure analysis was recently completed in conjunction with the section 3 human health risk assessment on grapes and peppers. The analysis included avocados at the recommended time-limited tolerance of 0.02 ppm. In conducting this chronic dietary risk assessment, EPA has made somewhat conservative assumptions -- anticipated residues and percent crop-treated data were used for selected crops -- which result in an overestimate of human dietary exposure. This chronic dietary (food only) exposure should be viewed as a partially refined risk estimate; further refinement using additional percent crop-treated values would result in a lower dietary exposure estimate. Thus, in making a safety determination for this tolerance, EPA is taking into account this partially refined exposure assessment. EPA is generally concerned with chronic exposures that exceed 100% of the chronic RfD/PAD. The existing avermectin tolerances (published, pending and new) result in an ARC that is equivalent to the following percentages of the RfD or PAD:

Subgroup	ARC_{FOOD}	Percent Population adjusted dose	Percent Reference dose
U.S. Population	0.000008	7	
Non-nursing infants (< 1 year)	0.000023	19	
Females (13+/nursing)	0.000008	6	
Males (20+ years)	0.000008		< 1

2. *From drinking water.* Modeling data (Generic expected environmental concentration/Screening concentration In Ground Water (GENEEC/SCIGROW)) indicate worst case estimated environmental concentrations (EEC) of 0.485 µg/L avermectin for acute and 0.239 µg/L for chronic exposure, both in surface water from the same use of avermectin on strawberries (the maximum use rate on the label). Refined modeling data Pesticide Root Zone Model-Exposure Analysis Modeling System (PRZM—EXAM) indicate a worst case EEC of 0.88 µg/L for acute and 0.57 µg/L for chronic, both calculated for an avermectin use on strawberries grown on black plastic mulch. EPA notes that the certainty of the concentrations estimated for strawberries is low, due to uncertainty on the amount of runoff from plant beds covered in plastic mulch and uncertainty on the amount of degradation of avermectin on black plastic compared to soil.

EPA believes the estimates of avermectin exposure in water derived from the PRZM-EXAMS model are significantly overstated for several reasons. The PRZM-EXAMS model was designed to estimate exposure from ecological risk assessments and thus uses a scenario of a body of water approximating the size of a 1 hectare (2.5 acres) pond. This tends to overstate drinking water exposure levels for the following reasons. First, surface water source drinking water generally comes from bodies of water that are substantially larger than a 1 hectare (2.5 acres) pond. Second, the modeled scenario also assumes that essentially the whole basin receives an application of the pesticide. Yet in virtually all cases, basins large enough to support a drinking water facility will contain a substantial fraction of the area which does not receive pesticide. Third, there is often at least some flow (in a river) or turnover (in a reservoir or lake) of the water so the persistence of the pesticide near the drinking water facility is usually overestimated. Fourth, even assuming a reservoir is directly adjacent to an agricultural field, the agricultural field may not be used to grow a crop on

which the pesticide in question is registered for use. Fifth, the PRZM-EXAMS modeled scenario does not take into account reductions in residue-loading due to applications of less than the maximum application rate or no treatment of the crop at all (percent crop treated data). Although there is a high degree of uncertainty to this analysis, these are the best available estimates of concentrations of avermectin in drinking water.

3. *From non-dietary exposure.* The avermectin non-dietary exposure analysis was recently completed in conjunction with the section 3 human health risk assessment on grapes and peppers. Avermectin's registered residential uses include indoor crack/crevice and outdoor application to lawns. For lawn uses, a risk assessment was conducted for adult applicators and postapplication exposure to avermectin using the EPA's Draft SOPs for Residential Exposure Assessments (12/18/97). For children's postapplication exposure to avermectin from indoor crack/crevice products, exposure studies were used to estimate risk. Short- and intermediate-term risk for the registered uses do not exceed EPA's level of concern. Chronic exposures for the residential uses are not expected.

i. *Chronic exposure and risk.* Chronic exposures for the residential uses are not expected.

ii. *Short- and intermediate-term exposure and risk.* Risk for the registered uses do not exceed EPA's level of concern.

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.''

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. For more information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

In examining aggregate exposures, FQPA directs EPA to consider available information concerning exposures from the 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 ground or surface water), and exposure through pesticide use in gardens, lawns or buildings (residential and other indoor and/or outdoor uses). In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.

1. *Acute risk.* Acute aggregate exposure takes into account acute dietary food and water exposure. The registrant previously submitted an acute dietary exposure analysis using probabilistic ''Monte Carlo'' modeling. EPA examined the assumptions made in conducting the analysis and some of the residue files for accuracy and found the analysis acceptable after correcting for the current acute RfD, updating %CT data, and correcting concentration factors. EPA recalculated the assessment using the submitted acute file and the correct acute RfD, updated %CT data, correcting the residue files above to use one-half limit of detection (LOD) and one-half limit of quantitation (LOQ) where appropriate, and using the average field trial residue level and previously established processing factors for blended commodities. In addition, EPA's analysis included residues in pear juice for which no data has been previously required. Since all other juices show reductions in avermectin residues from the raw agricultural commodity, EPA used the reduction factor for apples in the analysis. The dietary (food only) acute %PAD ranges from 18% for nursing infants < 1 year old to 70% for children 1–6 yrs. This risk estimate should be viewed as highly refined since it used anticipated residue values and percent crop-treated data in conjunction with Monte Carlo analysis. The acute dietary exposure does not exceed EPA's level of concern. The registrant is reminded that future probabilistic modeling submissions should follow EPA's suggested guidelines (http://www.epa.gov/fedrgstr/EPA-PEST/1998/November/Day-05/o-p29665.htm).

Avermectin is a moderately persistent, but non-mobile compound in soil and water environments. The GENEEC and SCI-GROW modeling data for avermectin in drinking water indicate levels less than OPP's DWLOC for acute exposure. Using the refined PRZM-EXAMS modeling data in drinking water also indicates levels less than OPP's DWLOC for acute exposure, with the exception of children 1–6 years old. EPA notes that the certainty of the concentrations estimated for strawberries in the refined estimates is low, due to uncertainty on the amount of runoff from plant beds covered in plastic mulch and uncertainty on the amount of degradation of avermectin on black plastic compared to soil. Although the peak EEC of 0.88 µg/L slightly exceeds the acute DWLOC (0.74 µg/L, considering the uncertain nature of the modeling estimate, EPA does not expect aggregate acute exposure to avermectin will pose an unacceptable risk to human health.

2. *Chronic risk.* Using the probabilistic ''MonteCarlo'' exposure assumptions described in this unit, EPA has concluded that aggregate exposure to avermectin from food will utilize 7% of the PAD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants with 19% of the chronic PAD. No chronic residential exposures are expected from use of avermectin. Avermectin is a moderately persistent, but non-mobile compound in soil and water environments. EPA does not expect aggregate chronic exposure to avermectin will pose an unacceptable risk to human health.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure.

i. Short-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus short-term residential uses which include dermal, inhalation, and oral exposures. For children's postapplication exposure from crack and crevice uses, the worst case exposure scenario, risks do not exceed EPA's level of concern. The residential uses that were aggregated with chronic dietary food and water are from lawn and crack and crevice uses and include:

- ADULT dermal exposure from the highest adult residential applicator scenario (3.4E–7 mg/kg/day from belly grinder granular open pour) and crack and crevice applicator scenario (2.1E–8 mg/kg/day) with exposure from postapplication activities (3.0E–6 mg/

kg/day), and inhalation from turf and crack and crevice (3.9E–7 mg/kg/day).

• CHILDREN's oral exposure from turf and crack and crevice hand-to-mouth, with turf incidental ingestion (3.8E–5 mg/kg/day), dermal exposure from turf and crack and crevice (6.1E–6 mg/kg/day), and inhalation exposure from crack and crevice (1.1E–4 mg/kg/day). Using the exposures above, EPA calculated the short-term drinking water level of concerns (DWLOCs). The DWLOC of 8.2 µg/L for the U.S. population is greater than the water EEC's. The DWLOC for infants/children (0.75 µg/L) is slightly exceeded by the PRZM-EXAMS peak value of 0.88 µg/L. However, as noted above for the acute DWLOC, EPA is not concerned given the uncertainty of the estimated water concentrations. EPA does not expect aggregate short-term exposure to avermectin will pose an unacceptable risk to human health.

ii. The worst case intermediate-term exposures to avermectin for adults are the same as those described above for short-term exposures. Using the exposures above, EPA calculated the adult intermediate-term DWLOC of 8.2 µg/L, which is greater than the water EEC's. EPA does not expect aggregate intermediate-term exposure to avermectin will pose an unacceptable risk to adult human health.

iii. The worst case intermediate-term exposures to avermectin for infants and children are the same as those described above. Since the short- and intermediate-term NOAELs are the same, the DWLOC is also equal to the 0.75 µg/L short-term value. Again, given the uncertainty in the 0.88 µg/L PRZM-EXAMS value, EPA is not concerned with the residues in drinking water at this time. EPA does not expect aggregate intermediate-term exposure to avermectin will pose an unacceptable risk to human health.

4. *Aggregate cancer risk for U.S. population*. At its July 27, 1996 meeting, the EPA RfD/Peer Review Committee classified avermectin as a Cancer Group E chemical based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies. This risk assessment was not required.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to avermectin residues.

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

1. *Safety factor for infants and children*— i. *In general*. 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 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 maternal pesticide exposure during gestation. 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 margin of exposure (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.

ii. *Conclusion*. There is a complete toxicity database for avermectin and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

2. *Acute risk*. Acute aggregate exposure takes into account acute dietary food and water exposure. The registrant previously submitted an acute dietary exposure analysis using probabilistic ''Monte Carlo'' modeling. EPA examined the assumptions made in conducting the analysis and some of the residue files for accuracy and found the analysis acceptable after correcting for the current acute RfD, updating %CT data, and correcting concentration factors. EPA recalculated the assessment using the submitted acute file and the correct acute RfD, updated %CT data, correcting the residue files above to use one-half limit of detection (LOD) and one-half limit of quantitation (LOQ) where appropriate, and using the average field trial residue level and previously established processing factors for blended commodities. In addition, EPA's analysis included residues in pear juice for which no data has been previously required. Since all other juices show reductions in avermectin residues from the raw agricultural commodity, EPA used the reduction factor for apples in the analysis. The dietary (food only) acute %PAD range from 18% for nursing infants < 1 year old to 70% for children 1–6 yrs. This risk estimate should be viewed as highly refined since it used anticipated residue values and percent crop-treated data in conjunction with Monte Carlo analysis. The acute dietary exposure does not exceed EPA's level of concern. The registrant is reminded that future probabilistic modeling submissions should follow EPA's suggested guidelines (http://www.epa.gov/fedrgstr/EPA-PEST/1998/November/Day-05/o-p29665.htm).

Avermectin is a moderately persistent, but non-mobile compound in soil and water environments. The GENEEC and SCI-GROW modeling data for avermectin in drinking water indicate levels less than OPP's DWLOC for acute exposure. Using the refined PRZM-EXAMS modeling data in drinking water also indicates levels less than OPP's DWLOC for acute exposure, with the exception of children 1–6 years old. EPA notes that the certainty of the concentrations estimated for strawberries in the refined estimates is low, due to uncertainty on the amount of runoff from plant beds covered in plastic mulch and uncertainty on the amount of degradation of avermectin on black plastic compared to soil. Although the peak EEC of 0.88 µg/L slightly exceeds the acute DWLOC (0.74 µg/L, considering the uncertain nature of the modeling estimate, EPA does not expect aggregate acute exposure to avermectin will pose an unacceptable risk to human health.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to avermectin from food will utilize 7% of the PAD for infants and children. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants with 19% of the chronic PAD. No chronic residential exposures are expected from use of avermectin. Avermectin is a moderately persistent, but non-mobile compound in soil and water environments. EPA does not expect aggregate chronic exposure to avermectin will pose an unacceptable risk to human health.

4. Short- or intermediate-term risk. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure.

i. Short-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus short-term residential uses which include dermal, inhalation, and oral exposures. For children's postapplication exposure from crack and crevice uses, the worst case exposure scenario, risks do not exceed EPA's level of concern. The residential uses that were aggregated with chronic dietary food and water are from lawn and crack and crevice uses and include:

- ADULT dermal exposure from the highest adult residential applicator scenario (3.4E–7 mg/kg/day from belly grinder granular open pour) and crack and crevice applicator scenario (2.1E–8 mg/kg/day) with exposure from postapplication activities (3.0E–6 mg/kg/day), and inhalation from turf and crack and crevice (3.9E–7 mg/kg/day).
- CHILDREN's oral exposure from turf and crack and crevice hand-to-mouth, with turf incidental ingestion (3.8E–5 mg/kg/day), dermal exposure from turf and crack and crevice (6.1E–6 mg/kg/day), and inhalation exposure from crack and crevice (1.1E–4 mg/kg/day).

Using the exposures above, EPA calculated the short-term drinking water level of concerns (DWLOCs). The DWLOC of 8.2 µg/L for the U.S. population is greater than the water EEC's. The DWLOC for infants/children (0.75 µg/L) is slightly exceeded by the PRZM-EXAMS peak value of 0.88 µg/L. However, as noted above for the acute DWLOC, EPA is not concerned given the uncertainty of the estimated water concentrations. EPA does not expect aggregate short-term exposure to avermectin will pose an unacceptable risk to human health.

ii. The worst case intermediate-term exposures to avermectin for adults are the same as those described above for short-term exposures. Using the exposures above, EPA calculated the adult intermediate-term DWLOC of 8.2 µg/L, which is greater than the water EEC's provided by EFED. EPA does not expect aggregate intermediate-term exposure to avermectin will pose an unacceptable risk to adult human health.

iii. The worst case intermediate-term exposures to avermectin for infants and children are the same as those described above. Since the short- and intermediate-term NOAELs are the same, the DWLOC is also equal to the 0.75 µg/L short-term value. Again, given the uncertainty in the 0.88 µg/L PRZM-EXAMS value, EPA is not concerned with the residues in drinking water at this time. EPA does not expect aggregate intermediate-term exposure to avermectin will pose an unacceptable risk to human health.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to avermectin residues.

IV. Other Considerations

Analytical Enforcement Methodology

Adequate enforcement methodology (example - gas chromotography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5229.

V. Conclusion

Therefore, the tolerance is established for combined residues of avermectin in or on avocado at 0.02 ppm.

VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation 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 7, 1999, 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 under the ''ADDRESSES'' section (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). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, 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. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

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 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.

VII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300825] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division

(7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at: opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

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

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

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

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(l)(6), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit 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 United States prior to publication of the rule in the **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: March 24, 1999.

James Jones,

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. 321(q), 346a and 371.

2. In § 180.449, the table to paragraph (b) is amended by adding an entry for avocado to read as follows:

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

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/revocation date
Avocado	0.02	9/20/00
* * *	*	* *

* * * * *

[FR Doc. 99–8340 Filed 4–6–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300828; FRL–6072–6]

RIN 2070–AB78

Tebufenozide; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of Tebufenozide, benzoic acid, 3,5-dimethyl-, 1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl) hydrazide in or on berry (crop group 13), cranberry, and mint. The Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective April 7, 1999. Objections and requests for hearings must be received by EPA on or before June 7, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300828], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300828], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), 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. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: oppdocket@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 5.1/6.1 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–300828]. 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: Sidney Jackson, 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. 272, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–7610, e-mail: jackson.sidney@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 9, 1999 (64 FR 6351) (FRL–6058–3), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) announcing the filing of pesticide petitions (PP) 8E5021, 8E4983, and 8E5019 for tolerance by IR–4 . This notice included a summary of the petition prepared by the Rohm and Haas Company, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.482 be amended by establishing tolerances for residues of the insecticide tebufenozide, benzoic acid, 3,5-dimethyl-, 1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl) hydrazide, in or on the berry crop group at 3.0 parts per million (ppm), cranberry at 1.0 ppm, and mint at 10.0 ppm.

I. Background and Statutory Findings

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....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of tebufenozide and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of tebufenozide on the berry crop group at 3.0 ppm, cranberry at 1.0 ppm, and mint at 10.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by tebufenozide are discussed in this unit.

1. *Acute toxicity*. Results of a battery of toxicological studies using technical grade product show tebufenozide has low acute toxicity. Tebufenozide was practically non-toxic by ingestion of a single oral dose in rats and mice (LD_{50} > 5,000 milligram/kilogram (mg/kg)) and was practically non-toxic by dermal application lethal dose(LD) LD_{50} > 5,000