XIII. Congressional Review Act

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 to 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 this final rule in the **Federal Register**. This final 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 27, 2006.

Lois Rossi,

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 § 180.920, the table is amended by adding alphabetically the following inert ingredients to read as follows:

§ 180.920 Exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	* *	* *
FD&C Blue No. 1, methyl-polyethylene glycol derivative (CAS Reg. No. 9079–34–9).	For seed treatment use only; Number average molecular weight (in amu) is greater than 1,000; Not to exceed 5% of the formulated pesticide product.	Dye, coloring agent
FD&C Blue No. 1, polyethylene glycol derivative (CAS Reg. No. 9079–33–8).	For seed treatment use only; Number average molecular weight (in amu) is greater than 1,000; Not to exceed 5% of the formulated pesticide product.	Dye, coloring agent
* * *	* *	* *

[FR Doc. 06–3307 Filed 4–11–06; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0212; FRL–7765–4]

Emamectin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of emamectin and its metabolites in or on pome fruit (crop group 11). It also revises the combined residues of emamectin and its metabolites in or on various livestock commodities. Syngenta Crop Protection requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective April 12, 2006. Objections and requests for hearings must be received on or before June 12, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number EPA–HQ–OPP–2005–0212. All documents in the docket are listed on the *www.regulations.gov* website. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced federal-wide electronic docket management and comment system located at *http://www.regulations.gov/*. Follow the on-line instructions.) Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Thomas Harris, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9423; e-mail address: *harris.thomas@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System

(NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of August 24, 2005 (70 FR 49607) (FRL–7728–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3F6574) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419. The original petition requested that 40 CFR 180.505 be amended by establishing a tolerance for combined residues of the insecticide emamectin benzoate, 4′-epi-methylamino- 4′-deoxyavermectin B_1 benzoate (a mixture of a minimum of 90% 4′-epi-methylamino-4′-deoxyavermectin B_{1a} and a maximum of 10% 4′-epi-methlyamino-4′-deoxyavermectin B_{1b} benzoate), and its metabolites 8,9 isomer of the B_{1a} and B_{1b} component of the parent insecticide, in or on the raw agricultural commodities pome fruit (crop group 11) at 0.02 parts per million (ppm). That notice included a summary of the petition prepared by Syngenta Crop Protection, the registrant. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based on the EPA analysis of the residue chemistry and toxicological databases, the petition was subsequently revised to establish:

1. Permanent tolerances for the combined residues of emamectin (a mixture of a minimum of 90% 4′-epi-methylamino-4′-deoxyavermectin B_{1a} and maximum of 10% 4′-epi-methylamino-4′-deoxyavermectin B_{1b}) and its metabolites 8,9-isomer of the B_{1a} and B_{1b} component of the parent (8,9-ZMA), or 4′-deoxy-4′-epi-amino-avermectin B_{1a} and 4′-deoxy-4′-epi-amino-avermectin B_{1b}; 4′-deoxy-4′-epi-amino avermectin B_{1a} (AB_{1a}); 4′-deoxy-4′-epi-(N-formyl-N-methyl)amino-avermectin (MFB_{1a}); and 4′-deoxy-4′-epi-(N-formyl)amino-avermectin B_{1a} (FAB_{1a}) in or on the following commodities: Fruit, pome, group 11 at 0.025 ppm and apple, wet pomace at 0.075 ppm; and

2. Permanent tolerances for the combined residues of emamectin (MAB_{1a} + MAB_{1b} isomers) and the associated 8,9-Z isomers (8,9-ZB_{1a} + 8,9-ZB_{1b}) in/on the following commodities: Cattle, fat at 0.010 ppm; cattle, liver at 0.050 ppm; cattle, meat at 0.003 ppm; cattle, meat byproducts, except liver at 0.020 ppm; milk at 0.003 ppm; goat, fat at 0.010 ppm; goat, liver at 0.050 ppm; goat, meat at 0.003 ppm; goat, meat byproducts, except liver at 0.020 ppm; horse, fat at 0.010 ppm; horse, liver at 0.050 ppm; horse, meat at 0.003 ppm; horse, meat byproducts, except liver at 0.020 ppm; sheep, fat at 0.010 ppm; sheep, liver at 0.050 ppm; sheep, meat at 0.003 ppm; and sheep, meat byproducts, except liver at 0.020 ppm. With the previous emamectin tolerance final rule, published in the **Federal Register** of July 9, 2003 (68 FR 40791) (FRL–7316–6), the livestock tolerances were mistakenly placed in paragraph (d) of 40 CFR 180.505 for inadvertent residues. In this action, the livestock tolerances are being moved to paragraph (a)(2) of 40 CFR 180.505 which contains general tolerances.

In addition, the following established tolerances will be deleted from 40 CFR 180.505 since a tolerance for ''milk'' will be established: Cattle, milk at 0.003 ppm; goats, milk at 0.003 ppm; hogs, milk at 0.003 ppm; horses, milk at 0.003 ppm; sheep, milk at 0.003 ppm.

Section 408(b)(2)(A)(i) of 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) of FFDCA 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) of FFDCA 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 of the FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, 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 and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for:

1. Permanent tolerances for the combined residues of emamectin (a mixture of a minimum of 90% 4′-epi-methylamino-4′-deoxyavermectin B_{1a} and maximum of 10% 4′-epi-methylamino-4′-deoxyavermectin B_{1b}) and its metabolites 8,9-isomer of the B_{1a} and B_{1b} component of the parent (8,9-ZMA), or 4′-deoxy-4′-epi-amino-avermectin B_{1a} and 4′-deoxy-4′-epi-amino-avermectin B_{1b}; 4′-deoxy-4′-epi-amino avermectin B_{1a} (AB_{1a}); 4′-deoxy-4′-epi-(N-formyl-N-methyl)amino-avermectin (MFB_{1a}); and 4′-deoxy-4′-epi-(N-formyl)amino-avermectin B_{1a} (FAB_{1a}) in or on the following commodities: Fruit, pome, group 11 at 0.025 ppm and apple, wet pomace at 0.075 ppm; and

2. Permanent tolerances for the combined residues of emamectin (MAB_{1a} + MAB_{1b} isomers) and the associated 8,9-Z isomers (8,9-ZB_{1a} + 8,9-ZB_{1b}) in/on the following commodities: Cattle, fat at 0.010 ppm; cattle, liver at 0.050 ppm; cattle, meat at 0.003 ppm; cattle, meat byproducts, except liver at 0.020 ppm; milk at 0.003 ppm; goat, fat at 0.010 ppm; goat, liver at 0.050 ppm; goat, meat at 0.003 ppm; goat, meat byproducts, except liver at 0.020 ppm; horse, fat at 0.010 ppm; horse, liver at 0.050 ppm; horse, meat at 0.003 ppm; horse, meat byproducts, except liver at 0.020 ppm; sheep, fat at 0.010 ppm; sheep, liver at 0.050 ppm; sheep, meat at 0.003 ppm; and sheep, meat byproducts, except liver at 0.020 ppm.

EPA's assessment of 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. Specific information on the studies received and the nature of the toxic effects caused by emamectin as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies can be found in Unit III of the final rule published in the **Federal Register** of July 9, 2003 (68 FR 40791).

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the LOAEL is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at *http://www.epa.gov/pesticides/health/human.htm*.

A summary of the toxicological endpoints for emamectin used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of July 9, 2003 (68 FR 40791).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.505) for the combined residues of emamectin, in or on a variety of raw agricultural commodities and livestock. Tolerances range from 0.002 to 0.150 ppm. Risk assessments were conducted by EPA to assess dietary exposures from emamectin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and 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 Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: A highly refined, Tier 3, acute dietary exposure assessment was conducted for the general U.S. population and various other population subgroups. This was a probabilistic assessment using anticipated residue estimates as well as EPA percent crop treated (PCT) estimates for a number of commodities. For acute assessments, maximum (rather than average) PCT estimates were used, specifically: Apples 73%, pears 60%, broccoli 20%, cabbage 15%, celery 25%, cauliflower 30%, cotton commodities 2.5%, lettuce 20%, peppers 2.5%, spinach 2.5%, and tomatoes 2.5%. For crops not listed 100% PCT was used. Anticipated residues were used for pome fruit based on average field trial data. The recommended tolerance level residues were used for all other crops and meat products. Additionally, default DEEM™ (version 7.87) concentration factors were used for all commodities except apple juice, for which a concentration factor was based on a processing study.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A refined chronic dietary (food only) exposure assessment was conducted for the general U.S. population and various other population subgroups. The proposed and registered food uses of emamectin were represented by a single point estimate of anticipated emamectin residues in food. For chronic assessments, average (rather than maximum) PCT estimates were used, specifically: Apples 14%, pears 15%, broccoli 10%, cabbage 5%, celery 10%, cauliflower 10%, cotton commodities 1%, lettuce 10%, peppers 1%, spinach 1%, and tomatoes 1%. For crops not listed 100% PCT was used. Anticipated residues were used for pome fruit based on average field trial. The recommended tolerance level residues were used for all other crops and meat products. Additionally, default DEEM™ (version 7.87) concentration factors were used for all commodities except apple juice, for which a concentration factor was based on a processing study.

iii. *Cancer.* Emamectin is classified as a ''not likely'' human carcinogen based on the lack of evidence of carcinogenicity in male and female rats or male and female mice at doses that were judged to be adequate to assess the carcinogenic potential of the chemical.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. For the present action, EPA will issue such data call-ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such data call-ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as detailed above under Units III.C.1.i and III.C.1.ii. Different PCTs were used for the acute versus the chronic dietary risk from food and feed uses as explained in these sections.

EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available Federal, State, and private market survey data for that use, averaging by year, averaging across all years, and rounding up to the nearest multiple of 5 percent except for those situations in which the average PCT is less than one. In those cases <1% is used as the average and <2.5% is used as the maximum. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the single maximum value reported overall from available Federal, State, and private market survey data on the existing use, across all years. In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (USDA/NASS), Proprietary Market Surveys, and the National Center for Food and Agriculture Policy (NCFAP) for the most recent 6 years.

EPA projects PCT for a new pesticide use by assuming that the PCT for the pesticide's initial 5 years will not exceed the average PCT of the dominant pesticide (the one with the largest PCT) within its type over 3 latest available years. The PCTs included in the average may be each for the same pesticide or for different pesticides since the same or different pesticides may dominate for each year selected. Typically, EPA uses USDA/NASS as the source for raw PCT data because it is non-proprietary and directly available without computation. When a specific site is not covered in USDA/NASS, EPA uses proprietary data, which may require computation. This method of projecting PCT for a new pesticide, with or without regard to specific pest(s), produces an upper-end projection that is unlikely, in most cases, to be exceeded in actuality in the next 5 years because one or more of the following conditions will likely apply: The dominant pesticide is better established and accepted by farmers than the new pesticide, the dominant pesticide is more efficacious than the new pesticide, the dominant pesticide controls a broader spectrum and/or more important pests than the new pesticide, the dominant pesticide is more cost-effective than the new pesticide, and other conditions. These factors have been considered for this pesticide's new use, and they indicate that it is unlikely that actual PCT for this new use will exceed the PCT for the dominant pesticide in the next 5 years.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for emamectin in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of emamectin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of emamectin for acute exposures are estimated to be 0.57 parts per billion (ppb) for surface water and 2.7 X 10^{-4} ppb for ground water. The EDWCs for chronic exposures are estimated to be 0.22 ppb for surface water and 2.7 X 10^{-4} ppb for ground water.

Modeled EDWCs were directly entered into the dietary exposure model (DEEM-FCID). For the acute dietary risk assessment, the full distribution of estimated residues in surface water generated by the PRZM-EXAMS model was input into the model. For chronic dietary risk assessment, the annual average concentration of 0.22 ppb was used to access the contribution to drinking water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Emamectin is not registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the FFDCA 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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to emamectin and any other substances and emamectin 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 emamectin has a common mechanism of toxicity with other substances. For 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. Emamectin causes increased sensitivity of offspring relative to adults (as seen in the rat reproductive toxicity study and the rat developmental neurotoxicity study). EPA determined that the concern is low as to the qualitative sensitivity seen in the reproduction study because:

i. There was a clear NOAEL for offspring toxicity;

ii. Effects unique to offspring (decreased fertility in F_1 adults, and clinical signs tremors and hind limb extensions during and following lactation) were seen at the same dose that caused parental systemic toxicity (decreased body weight gain and histopathological lesions in the brain and spinal cord), and

iii. The decreased fertility seen in F_1 adults may have been due to histopathological lesions in the brain

and central nervous system (seen in both F_0 and F_1 generations), rather than due to a direct effect on the reproductive system.

As to the increased qualitative and quantitative susceptibility in the rat developmental neurotoxicity study, EPA determined that the concern is low because:

- Although multiple offspring effects (including decreased pup body weight, head and body tremors, hindlimb extension and splay, changes in motor activity and auditory startle) were seen at the highest dose, and no maternal effects were seen at any dose, there was a clear NOAEL for offspring toxicity at the low dose, and
- The offspring LOAEL (at the mid dose) is based on a single effect seen on only one day (decreased motor activity on PND 17) and no other offspring toxicity was seen at the LOAEL. Additionally, concern is lessened because the dose selected for overall risk assessment (based on a 15–day study in adult mice) is lower than the doses that caused offspring toxicity in reproduction and developmental neurotoxicity studies in rats; the endpoint selected is the most sensitive end point (neurotoxicity) in the most sensitive species (mice) and thus would address the concerns for any potential toxicity in the offspring.

3. *Conclusion*. Although there is a complete toxicity database for emamectin, exposure is estimated based on data that reasonably accounts for potential exposures, and increased sensitivity in the young is addressed by selection of a protective endpoint, EPA has retained a 10X FQPA safety factor for chronic/long-term and intermediate-term assessments due to the steepness of the dose-response curve, severity of effects at the LOAEL (death and neuropathology), and the use of a short-term study for long-term risk assessment. The steepness of the dose-response curve and the severity of the effects at the LOAEL also are the basis for EPA retaining a 3X FQPA safety factor for acute assessments. A 3X FQPA factor was judged to be adequate (as opposed to a 10X) because:

i. A NOAEL was established in this study;

ii. Although the effects of concern are seen after repeated dosing, the NOAEL here is used for a single exposure risk assessment; and

iii. The most sensitive endpoint in the most sensitive species is selected.

The exposure estimate was judged to reasonably account for exposure based on:

- The acute dietary food exposure assessment utilizes anticipated residue estimates based on carefully reviewed field trial data and PCT data for several commodities (100 PCT was assumed for remaining commodities). By using the 99.9th percentile exposure values for comparison to the aPAD, actual risks are not likely to be underestimated.
- The chronic dietary food exposure assessment utilizes tolerance level residue estimates and PCT data for several commodities (100 PCT was assumed for remaining commodities). This assessment is somewhat refined and based on reliable data that is not likely to underestimate exposure/risk.
- The dietary drinking water assessment utilizes water concentration values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be exceeded.
- There are no proposed or existing residential uses for emamectin.

E. Aggregate Risks and Determination of Safety

The Agency currently has two ways to estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses. First, a screening assessment can be used, in which the Agency calculates drinking water levels of comparison (DWLOCs) which are used as a point of comparison against estimated environmental concentrations (EECs). The DWLOC values are not regulatory standards for drinking water, but are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure milligram/kilogram/day (mg/kg/day) = CPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the EPA's Office of Water are used to calculate DWLOCs: 2 liter (L) / 70 kg (adult male), 2L / 60 kg (adult female), and 1L / 10 kg (child). Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concluded with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposures for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. When new uses are added EPA reassesses the potential impacts of residues of the pesticide in drinking water as a part of the aggregate assessment process.

More recently the Agency has used another approach to estimate aggregate exposure through food, residential and drinking water pathways. In this approach, modeled surface water and ground water EECs are directly incorporated into the dietary exposure analysis, along with food. This provides a more realistic estimate of exposure because actual body weights and water consumption from the CSFII are used. The combined food and water exposures are then added to estimated exposure from residential sources to calculate aggregate risks. The resulting exposure and risk estimates are still considered to be high end, due to the assumptions used in developing drinking water modeling inputs.

1. *Acute risk*. The acute aggregate risk assessment takes into account exposure estimates from dietary (food + drinking water) consumption of emamectin. A highly refined, Tier 3, acute assessment was conducted for all supported food uses and drinking water. The Tier 3 assessment was a probabilistic assessment using anticipated residue estimates from the current and previously submitted field trial data, PCT/projected market share estimates for a number of commodities (100% for the rest), and default DEEM™ 7.87 processing factors for all commodities except apple juice, for which a concentration factor was based on a processing study. The assessment was conducted using the full distribution of estimated residues in surface water generated by the PRZM-EXAMS model using the pome fruit crop group scenario for drinking water.

The acute aggregate risk estimates for emamectin are below EPA's LOC (<100% aPAD) at the 99.9th percentile for the general U.S. population (at 41% of the aPAD) and various other population subgroups. The most highly exposed population subgroup was all infants (<1 year old) at 77% of the aPAD. Results are shown in the following Table.

2. *Chronic risk*. The chronic aggregate risk assessment takes into account average exposure estimates from dietary consumption of emamectin (food and drinking water).

The chronic aggregate risk estimates for emamectin are below EPA's LOC for all population subgroups (8% of the cPAD for the U.S. population and 23% of the cPAD for all infants (<1 year old), the most highly exposed subgroup). Results are shown in the following Table.

TABLE—SUMMARY OF DIETARY (FOOD + DRINKING WATER) EXPOSURE AND RISK ESTIMATES FOR EMAMECTIN USING DEEM™-FCID

Population Subgroup	Acute Dietary[1]		Chronic Dietary[2]		Cancer Dietary
	Exposure (mg/kg/day)	% aPAD at 99.9th percentile	Exposure (mg/kg/day)	% cPAD	
General U.S. Population	0.000103	41	0.000006	8	NA[3]
All Infants (< 1 year old)	0.000193	77*	0.000017	23*	NA[3]
Children 1–2 years old	0.000172	69	0.000011	15	NA[3]
Children 3–5 years old	0.000149	59	0.000010	13	NA[3]
Children 6–12 years old	0.000105	42	0.000006	9	NA[3]
Youth 13–19 years old	0.000094	38	0.000004	6	NA[3]
Adults 20–49 years old	0.000058	23	0.000005	7	NA[3]
Adults 50+ years old	0.000052	21	0.000005	7	NA[3]
Females 13–49 years old	0.000060	24	0.000005	7	NA[3]

* The value for the highest exposed population.
[1] Acute dietary endpoint of 0.00025 mg/kg/day applies to the general U.S. population and all population subgroups.
[2] Chronic dietary endpoint of 0.000075 mg/kg/day applies to the general U.S. population and all population subgroups.
[3] NA = not applicable. Emamectin is classified as a ''not likely'' human carcinogen based on the lack of evidence of carcinogenicity in male and female rats or male and female mice at doses that were judged to be adequate to assess the carcinogenic potential of the chemical.

3. *Short- and intermeditate-term risk*. Short- and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because there are no residential uses proposed for emamectin, short- and intermediate-term aggregate risk assessments based on exposure from oral, inhalation, and dermal routes were not performed. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's LOC.

5. *Aggregate cancer risk for U.S. population*. EPA has classified emamectin as a ''not likely'' human carcinogen. This classification was based on the lack of evidence of carcinogenicity in male and female rats or male and female mice at doses that were judged to be adequate to assess the carcinogenic potential of the chemical. Therefore, exposure to emamectin is not expected to pose a cancer risk.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

1. *Enforcement method for plant commodities*. A high performance liquid chromatography method with fluorescence detection (HPLC/FLD Method 244–92–3) is available for the enforcement of established tolerances for residues of emamectin and its metabolites in/on plants.

Method 244–92–3, Revision 1, is a similar HPLC/FLD method which is available for enforcement of the tolerances on pome fruit. Method 244–92–3, Revision 1, determines residues of B_{1a} isomers (total emamectin B_{1a} and 8,9-ZB_{1a}), B_{1b} isomers (emamectin B_{1b} + 8,9-ZB_{1b}), and the photodegradates AB_1 (L649), and MFB_1 + FAB_1 (L599 + L831) in/on apple and pear and in apple processed commodities. The LOQ is 0.005 ppm for each analyte in each matrix.

2. *Enforcement method for livestock commodities*. An analytical method (Method 244–95–1) is available for enforcement of tolerances for residues of emamectin (MAB_{1a} and MAB_{1b}) and the 8,9-Z isomers in/on ruminant commodities. The LOQs are 0.0005 ppm for each analyte (MAB_{1a} + 8,9-ZB_{1a} and MAB_{1b} + 8,9-ZB_{1b}) in whole and skim milk and 0.002 ppm for each analyte (MAB_{1a} + 8,9-ZB_{1a} and MAB_{1b} + 8,9-ZB_{1b}) in fat, liver, kidney, and meat.

3. *Multiresidue methods testing*. Data previously submitted show that residues of emamectin are not likely to be recovered by the Food and Drug Administration (FDA) multiresidue methods. The petitioner submitted data pertaining to the multiresidue methods testing of emamectin (B_{1a} and B_{1b} components), AB_{1a}, FAB_{1a}, MFB_{1a} and the 8,9-Z isomer (B_{1a} component).

Adequate enforcement methodology is available to enforce the tolerance expression. The above methods have been forwarded to the Food and Drug Administration for inclusion in PAM I or II. Alternately, methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are currently no Codex, Canadian, or Mexican maximum residue limits or tolerances on emamectin or its metabolites.

C. Response to Comments

Public comments were received from B. Sachau who objected to the proposed tolerances stating that only a zero residue should be allowed. She objected to utilizing a 1994 database since America has changed a great deal since 1994 thus making the database outdated. She further stated that testing conducted on mice and other animals has absolutely no relevance to toxic effects on humans.

B. Sachau's comments contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to emamectin including all anticipated dietary exposures and all other exposures for which there is reliable information. EPA does update the analysis inputs when new information becomes available. For example, the risk assessment for this final rule utilized dietary information from the USDA's CSFII from 1994–1996 and 1998. EPA has responded to B. Sachau's generalized comments on numerous previous occasions. (See the **Federal Register** of January 7, 2005 (70 FR 1349, 1354) (FRL–7691–4) and the **Federal Register** of October 29, 2004 (69 FR 63083, 63096) (FRL–7681–9).

V. Conclusion

Therefore, the tolerances are established for combined residues of 1) emamectin (a mixture of a minimum of 90% 4′-epi-methylamino-4′-deoxyavermectin B_{1a} and maximum of 10% 4′-epi-methylamino-4′-deoxyavermectin B_{1b}) and its metabolites 8,9-isomer of the B_{1a} and B_{1b} component of the parent (8,9-ZMA), or 4′-deoxy-4′-epi-amino-avermectin B_{1a} and 4′-deoxy-4′-epi-amino-avermectin B_{1b}; 4′-deoxy-4′-epi-amino avermectin B_{1a} (AB_{1a}); 4′-deoxy-4′-epi-(N-formyl-N-methyl)amino-avermectin (MFB_{1a}); and 4′-deoxy-4′-epi-(N-formyl)amino-avermectin B_{1a} (FAB_{1a}) in or on the following commodities: Fruit, pome, group 11 at 0.025 ppm and Apple, wet pomace at 0.075 ppm; and 2) for the combined residues of emamectin (MAB_{1a} + MAB_{1b} isomers) and the associated 8,9-Z isomers (8,9-ZB_{1a} + 8,9-ZB_{1b}) in/on the following commodities: Cattle, fat at 0.010 ppm; cattle, liver at 0.050 ppm; cattle, meat at 0.003 ppm; cattle, meat byproducts, except liver at 0.020 ppm; milk at 0.003 ppm; goat, fat at 0.010 ppm; goat, liver at 0.050 ppm; goat, meat at 0.003 ppm; goat, meat byproducts, except liver at 0.020 ppm; horse, fat at 0.010 ppm; horse, liver at 0.050 ppm; horse, meat at 0.003 ppm; horse, meat byproducts, except liver at 0.020 ppm; sheep, fat at 0.010 ppm; sheep, liver at 0.050 ppm; sheep, meat at 0.003 ppm; and sheep, meat byproducts, except liver at 0.020 ppm. In addition, the following established tolerances will be deleted from 40 CFR 180.505 since a tolerance for ''milk'' will be established: Cattle, milk at 0.003 ppm; goats, milk at 0.003 ppm; hogs, milk at 0.003 ppm; horses, milk at 0.003 ppm; sheep, milk at 0.003 ppm. With the previous emamectin tolerance final rule, published in the **Federal Register** of July 9, 2003 (68 FR 40791) the livestock tolerances were mistakenly placed in paragraph (d) of 40 CFR 180.505 for inadvertent residues. In this action, the livestock tolerances are being moved to paragraph (a)(2) of 40 CFR 180.505 which contains general tolerances.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2005–0212 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before June 12, 2006.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). 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 objector (40 CFR 178.27). 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.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number EPA–HQ–OPP–2005–0212, to: Public Information and Records Integrity Branch, Information Technology and Resources Management Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid 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 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

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 of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. 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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

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 to 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 this final rule in the **Federal Register**. This final 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 27, 2006.

Lois Rossi,

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. Section 180.505 is revised to read as follows:

§ 180.505 Emamectin; tolerances for residues.

(a) *General.* (1) Tolerances are established for combined residues of emamectin (a mixture of a minimum of 90% 4′-epi-methylamino-4′-deoxyavermectin B_{1a} and maximum of 10% 4′-epi-methylamino-4′-deoxyavermectin B_{1b}) and its metabolites 8,9-isomer of the B_{1a} and B_{1b} component of the parent (8,9-ZMA), or 4′-deoxy-4′-epi-amino-avermectin B_{1a} and 4′-deoxy-4′-epi-amino-avermectin B_{1b}; 4′-deoxy-4′-epi-amino avermectin B_{1a} (AB_{1a}); 4′-deoxy-4′-epi-(N-formyl-N-methyl)amino-avermectin (MFB_{1a}); and 4′-deoxy-4′-epi-(N-formyl)amino-avermectin B_{1a} (FAB_{1a}) in or on the following commodities:

Commodity	Parts per million
Apple, wet pomace	0.075
Cotton, gin byproduct	0.050
Cotton, undelinted seed	0.025
Fruit, pome, group 11	0.025
Tomato, paste	0.150
Turnip, greens	0.050
Vegetable, Brassica, leafy, group 5	0.050
Vegetable, fruiting (except Cucurbits), group 8	0.020
Vegetable, leafy, except Brassica, group 4	0.100

(2) Tolerances are also established for combined residues of emamectin (MAB_{1a} + MAB_{1b} isomers) and the associated 8,9-Z isomers (8,9-ZB_{1a} + 8,9-

ZB_{1b}) in/on the following commodities when present therein as a result of the application of emamectin to crops listed in the table in paragraph (a)(1) of this section:

Commodity	Parts per million
Cattle, fat	0.010
Cattle, liver	0.050
Cattle, meat	0.003
Cattle, meat byproducts, except liver	0.020
Goat, fat	0.010
Goat, liver	0.050
Goat, meat	0.003
Goat, meat byproducts, except liver	0.020
Horse, fat	0.010
Horse, liver	0.050
Horse, meat	0.003
Horse, meat byproducts, except liver	0.020
Milk	0.003
Sheep, fat	0.010
Sheep, liver	0.050
Sheep, meat	0.003
Sheep, meat byproducts, except liver	0.020

(b) Section 18 emergency exemptions. [Reserved]

(c) Tolerances with regional registrations. [Reserved]

(d) Indirect and inadvertant residues. [Reserved]

[FR Doc. 06–3308 Filed 4–11–06; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[EPA–HQ–OPPT–2003–0006; FRL–7751–7]

RIN 2070–AD42

Revocation of TSCA Section 4 Testing Requirements for Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to amend the final test rule, ''*In Vitro* Dermal Absorption Rate Testing of Certain Chemicals of Interest to the Occupational Safety and Health Administration,'' promulgated under section 4 of the Toxic Substances Control Act (TSCA). This amendment removes dimethyl sulfate (DMS) from the list of chemical substances regulated under the test rule and also removes the requirement that testing be conducted to determine a permeability constant (Kp) for methyl isoamyl ketone (MIAK) and dipropylene glycol methyl ether (DPGME). However, the requirement to conduct testing to measure short-term dermal absorption rates remains for MIAK and DPGME. EPA is basing its decisions to take these actions on information it received since publication of the final rule. Also, upon the effective date of the revocation of the TSCA section 4 testing requirements for DMS, persons who export or intend to export DMS will no longer be subject to the TSCA section 12(b) export notification requirements to the extent that they were triggered by the testing requirements being revoked by this action.

DATES: This direct final rule is effective June 12, 2006 without further notice, unless EPA receives adverse comment in writing, or a request to present comment orally, on or before May 12, 2006. If EPA receives adverse comment, or a written request for an opportunity to present oral comments, EPA will publish a timely withdrawal in the **Federal Register** informing the public that this direct final rule, or relevant portions of this direct final rule, will not take effect. If you write EPA to request an opportunity to present oral comments on or before May 12, 2006, EPA will hold a public meeting on this direct final rule in Washington, DC. The announcement of such a meeting would be published in the **Federal Register**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2003–0006, by one of the following methods:

- *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Hand Delivery*: OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA–HQ–OPPT–2003–0006. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPPT–2003–0006. EPA's policy is that all comments received will be included in the public docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/docket.htm*.

Docket: All documents in the docket are listed in the regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically at *http://www.regulations.gov* or in hard copy at the OPPT Docket, EPA Docket Center (EPA/DC), EPA West, Rm. B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.