flats. Although DALS are letter-size, they are allowed to be entered at DDUs when they accompany either flats or parcels. This final rule does not propose to change the current standards that allow the DALs to be dropped at the DDU and does not change price eligibility for flats.

The Postal Service adopts the following changes to *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), which is incorporated by reference in the *Code of Federal Regulations.* See 39 CFR 111.1.

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

■ Accordingly, 39 CFR 111 is amended as follows:

PART 111—[AMENDED]

■ 1. The authority citation for 39 CFR Part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 404, 414, 416, 3001–3011, 3201–3219, 3403–3406, 3621, 3622, 3626, 3632, 3633, and 5001.

2. Revise the following sections of *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), as follows:

* * * * *

600 Basic Standards for All Mailing Services

* * * * *

602 Addressing

1.0 Elements of Addressing

* * * * *

1.5 Return Addresses

* * * * *

1.5.3 Required Use of Return Addresses

The sender's domestic return address must appear legibly on:

* * * * *

[Revise text of 1.5.3 to add new item m as follows:]

m. Detached addressed labels (DALs).

* * * * *

4.0 Detached Address Labels (DALs)

4.1 DAL Use

* * * * *

4.1.2 Periodicals or Standard Mail Flats Saturation Mailings

[Revise text of 4.1.2 to require that DALs accompanying saturation mailings of Periodicals or Standard Mail flats be automation-compatible as follows:]

Saturation mailings of unaddressed Periodicals or Standard Mail flats may be mailed with detached address labels (DALs). DALs accompanying saturation mailings of Periodicals or Standard Mail flats must be automation-compatible under 201.3.0. This standard does not apply to DALs with simplified addressing. For this standard, saturation mailing means a mailing sent to at least 75% of the total addresses on a carrier route or 90% of the residential addresses on a route, whichever is less. Deliveries are not required to every carrier route of a delivery unit. Saturation flats mailings presented with DALs that are not automation-compatible and barcoded do not qualify for saturation prices but may be entered at the basic carrier route price for Periodicals mailings or the basic Enhanced Carrier Route price for Standard Mail mailings.

* * * * *

4.2 Label Preparation

4.2.1 Label Construction

Each DAL must be made of paper or cardboard stock that is not folded, perforated, or creased, and that meets these measurements:

[Revise text of 4.2.1 to modify item c and add new item d and new item e as follows:]

* * * * *

c. At least .007 inch thick except under 4.2.1.d.

d. If more than 4¼ inches high or more than 6 inches long, must be at least 0.009 inch thick.

e. Must have an aspect ratio (length divided by height) from 1.3 to 2.5, inclusive.

4.2.2 Addressing

[Revise text of 4.2.2 by deleting the current last sentence in its entirety and adding a new last sentence to require a POSTNET or Intelligent Mail barcode with a delivery point routing code as follows:]

* * * In addition, if DALs accompany saturation mailings of Periodicals or Standard Mail flats, a correct delivery point POSTNET barcode or Intelligent Mail barcode with an 11-digit routing code must be included (see 708.4) except when using a simplified address.

* * * * *

Neva R. Watson,

Attorney, Legislative.

[FR Doc. E9–859 Filed 1–15–09; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0261; FRL–8397–9]

Emamectin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of emamectin and its metabolites in or on tree nuts (crop group 14) and pistachios. Syngenta Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also makes a technical correction reinstating hog tolerances that were inadvertently omitted from the previous rule.

DATES: This regulation is effective January 16, 2009. Objections and requests for hearings must be received on or before March 17, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0261. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Thomas C. Harris, Registration Division (7505P), 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 those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide 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?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite 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*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0261 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 as required by 40 CFR part 178 on or before March 17, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2008–0261, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of May 16, 2008 (73 FR 28461) (FRL–8361–6), 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 7F7263) by Syngenta Crop Protection, Inc., PO Box 18300, Greensboro, NC 27419–8300. The petition requested that 40 CFR 180.505 be amended by establishing tolerances for combined residues of the insecticide emamectin, 4′-epi-methylamino- 4′-deoxyavermectin B1 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}), and its metabolites 8,9 isomer of the B_{1a} and B_{1b} component of the parent insecticide, in or on the food commodities tree nuts (crop group 14) and pistachios at 0.02 parts per million (ppm); and almond hulls at 0.25 ppm. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon EPA review of the data supporting the petition, the petition was subsequently revised to establish 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/on almond, hulls at 0.20 ppm; nut, tree, group 14 at 0.02 ppm; and pistachio at 0.02 ppm. The reason for these changes are explained in Unit IV.D.

In addition, with this final rule EPA is also making a technical correction to restate existing permanent tolerances on hogs (fat, liver, meat, and meat byproducts) which were inadvertently omitted in the final rule for pome fruit published on April 12, 2006 in (71 FR 18642) (FRL–7765–4). Due to the consumption of apple pomace, that final rule altered the tolerances for most livestock but not for hogs (except to delete hog, milk as noted below). While the new livestock tolerances were listed, the tolerances for hogs, fat, liver, meat, and meat byproducts were inadvertently omitted. Hog tolerances were considered in this risk analysis for tree nuts and pistachios. Permanent tolerances continue to exist as stated in the final rule published on July 9, 2003 in (68 FR 40791) (FRL–7316–6) for emamectin (MAB_{1a} + MAB_{1b}) and the 8,9–Z isomers (8,9–ZB_{1a} and 8,9–ZB_{1b} in hog, fat at 0.003 ppm; hog, liver at 0.020 ppm; hog, meat at 0.002 ppm; and hog, meat byproducts (except liver) at 0.005 ppm. Note: As stated in the April 12, 2006 final rule, the tolerance for hog, milk was deleted along with other livestock-specific milk and replaced by a tolerance for simply ''milk.''

III. Aggregate Risk Assessment and Determination of Safety

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. . . .''

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in 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 for the petitioned-for tolerances for combined residues of emamectin and its metabolites in/on almond, hulls at 0.20 ppm; nut, tree, group 14 at 0.02 ppm; and pistachio at 0.02 ppm. EPA's assessment of exposures and risks associated with establishing tolerances 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.

Emamectin has moderate acute toxicity by the oral route and low acute toxicity by the dermal and inhalation routes. It is not irritating to the skin, nor is it a dermal sensitizer, but it is a severe eye irritant. The main target tissue is the nervous system, with neuropathology detected in many studies and several species. The dose/response curve was very steep in several studies (most notably with CF–1 mice and dogs), with severe effects (morbid sacrifice and neuropathology) sometimes seen. Although no increased sensitivity was seen in developmental toxicity studies in rats and rabbits, increased qualitative and/or quantitative sensitivity of rat pups was seen in the reproductive toxicity study and in the developmental neurotoxicity study. Review of acceptable oncogenicity and mutagenicity studies provide no indication that emamectin is carcinogenic or mutagenic.

Specific information on the studies received and the nature of the adverse 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 at *http://www.regulations.gov* in document *PP 7F7263 - Emamectin benzoate: Risk Assessment for adding new use on tree nuts and pistachios* at pages 13–22 in docket ID number EPA–HQ–OPP–2008–0261.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account 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. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for emamectin used for human risk assessment can be found at *http://www.regulations.gov* in document PP 7F7263 - Emamectin benzoate: Risk Assessment for adding new use on tree nuts and pistachios at pages 19–21 in docket ID number EPA–HQ–OPP–2008–0261.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to emamectin, EPA considered exposure under the petitioned-for tolerances as well as all existing emamectin tolerances in (40 CFR 180.505). Note: As explained above, while hog tolerances were inadvertently omitted from the last emamectin tolerance listing, previously established hog tolerances continue to exist and were considered in this risk analysis for tree nuts and pistachios. EPA assessed 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.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA used tolerance levels and 100 percent crop treated (PCT) for tree nuts and pistachios. EPA relied upon anticipated residues based on field trial data and either 100 PCT or maximum surveyed PCT for all other commodities. See Unit C.1.iv. below for full listing of PCTs.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA added tree nuts (including pistachios) to the previous pome fruit risk assessment using tolerance levels and 100 PCT for tree nuts and pistachios. EPA relied upon anticipated residues based on field trial data and either 100 PCT or averaged surveyed PCT for all other commodities. See Unit III. C.1.iv for full listing of PCTs. Additional refinements included default processing factors where appropriate and chemical-specific processing factors for apple and pear juice based on an emamectin apple processing study.

iii. *Cancer*. Based on the results of carcinogenicity studies in rats and mice, EPA classified emamectin as ''not likely to be carcinogenic to humans'' therefore, an exposure assessment for evaluating cancer risk is not needed for this chemical.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(E) of

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 residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) 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. For the present action, EPA will issue such Data Call-Ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

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:

• Condition a: 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 the pesticide residue.

• Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.

• Condition c: 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 FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows (average and maximum, respectively): Apples 5, 5; broccoli 10, 20; cabbage 10, 20; cauliflower 10, 25; celery 15, 35; cotton <1, <2.5; lettuce 10, 15; pears <1, <2.5; peppers 5, 10; spinach 5, 5; tomatoes 10, 15. EPA assumed 100 PCT (both average and maximum) for tree nuts, pistachios, other crops not listed above, and for all livestock commodities. Maximum PCT was used for analysis of acute exposure while average PCT was used for analysis of chronic exposure.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which emamectin may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for emamectin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport 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 of emamectin for chronic (non-cancer) exposures are estimated to be 0.22 ppb for surface water and 2.7 x 10^{-4} ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the full distribution of estimated residues in surface water generated by the PRZM–EXAMS model was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 0.22 ppb was used to assess 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 any specific use patterns that would result in residential exposure.

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

EPA has not found emamectin to share a common mechanism of toxicity with 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 assumed that emamectin does not have 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 EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this

provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. Prenatal exposure to emamectin results in increased sensitivity of offspring relative to adults (as seen in the rat reproductive toxicity study and the rat developmental neurotoxicity study). EPA has determined that the concern is low for the qualitative susceptibility seen in the two generation 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).

iii. The decreased fertility seen in F_1 adults may be secondary to the neurotoxicity characterized by 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.

EPA has determined that the concern is also low for the qualitative and quantitative susceptibility seen in the developmemtal-neurotoxicity study (DNT) because:

a. Although multiple offspring effects (including decreased pup body weight, head and body tremors, hind limb 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.

b. The offspring LOAEL (at the mid dose) is based on a single effect seen on only 1–day (decreased motor activity on PND 17) and no other offspring toxicity was seen at the LOAEL.

EPA has considered the differences in species sensitivity (rat NOAELs/LOAELs > dog NOAELs/LOAELs > mouse NOAELs/LOAELs) as well as the increased sensitivity of offspring relative to adults (as seen in the rat reproductive toxicity study and the rat developmental neurotoxicity study). EPA has determined that 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 reproductive toxicity 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. Therefore, there are no residual uncertainties for prenatal and/or postnatal toxicity from exposure to emamectin.

3. *Conclusion*. The 10X FQPA safety factor (SF) is retained for chronic assessments while a 3X FQPA SF is adequate for acute assessments. This conclusion is based on the following.

The toxicology database used to assess prenatal and postnatal exposure to emamectin is considered adequate at this time. Note: There is a new data requirement under 40 CFR part 158 following the Immunotixicity Test Guideline (OPPTS 870.7800) which prescribes functional immunotoxicity testing and is designed to evaluate the potential of a repeated chemical exposure to produce adverse effects (i.e., suppression) on the immune system. Because the immune system is highly complex, studies assessing functional immunotoxic endpoints are helpful in fully characterizing a pesticide's potential immunotoxicity. These data will be used in combination with data from hematology, lymphoid organ weights, and histopathology in routine chronic or subchronic toxicity studies to characterize potential immunotoxic effects. The immunotoxicty study will be required as a condition of registration of the proposed emamectin tree nut use. Although there is a complete toxicity database for emamectin (other than new immunotoxicity study), 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 SF 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), the use of a short-term study for long-term risk assessment. The 10X FQPA SF will also provide adequate protection for the lack of the new immunotoxicity study.

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 SF for acute assessments. A 3X FQPA factor was judged to be adequate (as opposed to a 10X) for the following reasons:

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

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

This risk analysis used both PCT and anticipated residues in the exposure analysis. For the reasons described in Unit III.C.1.iv the Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. Use of consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. The acute aggregate risk assessment takes into account exposure from dietary (food and water) consumption. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to emamectin will occupy 45% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to emamectin from food and water will utilize 44% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for emamectin.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Emamectin is not registered for any use patterns that would result in residential exposure. Therefore, the short-term aggregate risk is the sum of the risk from exposure to emamectin through food and water and

will not be greater than the chronic aggregate risk.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Emamectin is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to emamectin through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk..

5. *Aggregate cancer risk for U.S. population*. Emamectin is classified as ''not likely to be carcinogenic to humans'' and is, therefore, 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, or 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. The method was validated by EPA and submitted to the FDA for inclusion in the Pesticide Analytical Manual (PAM), Vol. II.

The data collection method for nuts is an liquid chromotography/mass spectrometry/mass spectrometry (LC/MS/MS) method (Syngenta Method RAM 465/01, modified). Residues of emamectin (B_{1a} and B1b), 8,9–Z isomer of B_{1a}, AB_{1a}, FAB_{1a} and MFB_{1a} in/on almond and pecan nutmeats and almond hulls are determined. The reported method limit of quantitation (LOQ) is 0.001 ppm for each analyte in nutmeats and almond hulls.

2. *Enforcement method for livestock commodities*. An analytical method is available for enforcement of tolerances for residues of emamectin and its metabolites in/on ruminant commodities. Method 244–95–1 is an HPLC/FLD method which determines residues of emamectin (MAB_{1a} and MAB_{1b}) and the 8,9–Z isomers in livestock 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_{1a} + 8,9–$2B_{1a}$) in fat, liver, kidney, and meat. The method has been validated by EPA and forwarded to FDA for publication in PAM II.

3. *Multiresidue methods testing*. Data previously submitted by the petitioner show that residues of emamectin are not likely to be recovered by 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). The data have been forwarded to FDA for inclusion in PAM, Vol. I.

Based on the methods described above, EPA has concluded that adequate enforcement methodology is available to enforce the tolerance expression. As indicated, the methods in this Unit 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 no international harmonization issues associated with proposed uses on tree nuts and pistachios as there are currently no Codex, Canadian, or Mexican maximum residue limits (MRLs) or tolerances for residues of emamectin on tree nuts and pistachios.

C. Response to Comments

No comments were received to the Notice of Filing.

D. Revisions to Petitioned-For Tolerances

Modifications were made to the petition as originally submitted. The original petition proposed nut tolerances on emamectin and its metabolites 8,9 isomer of the B_{1a} and B_{1b} component of the parent insecticide. EPA had previously determined that there are additional metabolites of concern. Therefore, the complete nut tolerances expression is set on 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 addition, while the tolerance for almond hulls was proposed at 0.25 ppm, since residues were quantifiable in/on almond hulls from all tests, the Agency's Guidelines for Setting Tolerances Based on Field Trials were utilized for determining the appropriate tolerance level for hulls. Based on the actual residue data from the 28–day pre-harvest interval samples, the calculated tolerance for almond hulls is 0.20 ppm.

V. Conclusion

Therefore, 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/on almond, hulls at 0.20 ppm; nut, tree, group 14 at 0.02 ppm; and pistachio at 0.02 ppm. In addition, permanent tolerances continue to exist as stated in the final rule published on July 9, 2003 in (68 FR 40791) (FRL–7316–6) for emamectin (MAB_{1a} + MAB_{1b}) and the 8,9–Z isomers (8,9–ZB_{1a} and 8,9–ZB_{1b}) in hog, fat at 0.003 ppm; hog, liver at 0.020 ppm; hog, meat at 0.002 ppm; and hog, meat byproducts (except liver) at 0.005 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and SafetyRisks* (62 FR 19885, April 23, 1997). 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., 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).

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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: January 6, 2009.

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 amended by alphabetically adding the following commodities to the tables in paragraphs (a)(1) and (2) to read as follows:

§ 180.505 Emamectin; tolerances for residues.

(a) * * * (1) * * *

Commodity	Parts per million
Almond, hulls	0.20
* * * *	*
Nut, tree, group 14	0.02
Pistachio	0.02
* * * *	*

* * * * *

(2) * * *

Commodity	Parts per million
* * * *	*
Hog, fat	0.003
Hog, liver	0.020
Hog, meat	0.002
Hog, meat byproducts (except liver)	0.005
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[FR Doc. E9–625 Filed 1–15–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–1561–IFC]

RIN 0938–AP59

Medicare Program; Changes to the Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) by Certain Provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period implements certain provisions of section 154 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) related to the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) Competitive Acquisition Program. Specifically, this rule: Implements certain MIPPA provisions that delay implementation of Round 1 of the program; requires CMS to conduct a second Round 1 competition (the ''Round 1 rebid'') in 2009; and mandates certain changes for both the Round 1 rebid and subsequent rounds of the program, including a process for providing feedback to suppliers regarding missing financial documentation and requiring contractors to disclose to CMS information regarding subcontracting relationships.

DATES: *Effective date:* These regulations are effective on February 17, 2009.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 17, 2009.

ADDRESSES: In commenting, please refer to file code CMS–1561–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' and enter the filecode to find the document accepting comments.