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 6, 2000) do not apply to this rule. In addition, This 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: November 26, 2007.

Donald R. Stubbs,

Acting 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 180.416 is amended by removing the current tolerance on ''Canola, seed'' and alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§180.416 Ethalfluralin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Dill, dried leaves	0.05
Dill, fresh leaves	0.05
Mustard, seed	0.05
* * *	* *
Potato	0.05
Rapeseed, seed	0.05
* * *	* *

* * * * *

[FR Doc. E7–23578 Filed 12–4–07; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0310; FRL–8339–8]

Spinosad; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spinosad in or on spice, subgroup 19B, except black pepper; pineapple; and pineapple, process residue. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 5, 2007. Objections and requests for hearings must be received on or before February 4, 2008, 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–2007–0310. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 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 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 an electronic copy of this **Federal Register** document through the electronic docket 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 pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2007–0310 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 January 4, 2008.

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–2007–0310, 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'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 9, 2007 (72 FR 26375) (FRL–8128–1), 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 6E7148) by Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W, Princeton, NJ 08540–6635. The petition requested that 40 CFR 180.495 be amended by establishing a tolerance for residues of the insecticide spinosad, in or on Spice crop subgroup 19B, except black pepper at 1.7 parts per million (ppm); pineapple at 0.02 ppm; and pineapple, process residue at 0.08 ppm. Spinosad is a fermentation product of *Saccharopolyspora spinosa*, consisting of two related active ingredients: Spinosyn A (Factor A; CAS # 131929–60–7) or 2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione; and Spinosyn D (Factor D; CAS # 131929–63–0) or 2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethyl-amino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione. That notice referenced a summary of the petition prepared by Dow AgroSciences LLC, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. Comments were received on the notice of filing from a private citizen. EPA's response to these comments is discussed in Unit IV.C. below.

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....'' These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

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 residues of spinosad on spice, subgroup 19B, except black pepper at 1.7 ppm; pineapple at 0.02 ppm; and Pineapple, process residue at 0.08 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 adverse effects caused by spinosad as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the final rule published in the **Federal Register** of September 27, 2002 (67 FR 60923) (FRL–7199–5), available on-line at *http://www.epa.gov/fedrgstr/EPA-PEST/2002/September/Day-27/p24484.htm*.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from 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) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC 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 risks by comparing aggregate 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 LOC by all applicable UFs. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. 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*.

The Agency has concluded that spinosad should be considered toxicologically identical to another pesticide, spinetoram. This conclusion is based on the following: (1) Spinetoram and spinosad are large molecules with nearly identical structures; and (2) the toxicological profiles for each are similar (generalized systemic toxicity) with similar doses and endpoints chosen for human-health risk assessment. Spinosad and spinetoram should be considered toxicologically identical in the same manner that metabolites are generally considered toxicologically identical to the parent.

Although, as stated above, the doses and endpoints for spinosad and spinetoram are similar, they are not identical due to variations in dosing levels used in the spinetoram and spinosad toxicological studies. EPA compared the spinosad and spinetoram doses and endpoints for each exposure scenario and selected the lower of the two doses for use in human risk assessment. A summary of the toxicological endpoints for spinosad and spinetoram used for human risk assessment can be found at *http://www.regulations.gov* in the document *Spinosad and Spinetoram. Human-Health Risk Assessment for Application of Spinosad to Pineapple and the Spice Subgroup (19B, except black pepper)* at page 11 in docket ID number EPA–HQ–OPP–2007–0310.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to spinosad, EPA considered exposure under the petitioned-for tolerances as well as all existing spinosad tolerances in 40 CFR 180.495. Since spinosad and spinetoram are toxicologically identical, EPA considered exposure to both in assessing aggregate risk. EPA assessed dietary exposures from spinosad and spinetoram 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. No such effects were identified in the toxicological studies for spinosad and spinetoram; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* Spinosad and spinetoram are registered for use on the same crops; however, EPA has concluded it would overstate exposure to assume that residues of both spinosad and spinetoram would appear on the same crop. It is unlikely that both will be applied to the same crop, since spinosad and spinetoram control the same pest species. Rather, EPA aggregated exposure from residues of spinosad and spinetoram by assuming that spinosad residues would be present in all commodities, because side-by-side spinosad and spinetoram residue data indicated that spinetoram residues were less than or equal to spinosad residues. EPA assumed that 100 percent of each food crop commodity would be treated with spinosad. For feed crop commodities, EPA summed the percentage of the crop that would be treated with spinosad and the percentage expected to be treated with spinetoram and used this estimate in conjunction with spinosad residue data to develop anticipated residues for livestock commodities.

The chronic dietary exposure assessment was conducted using the Dietary Exposure Evaluation Model - Food Consumption Intake Database (DEEM™-FCID), Version 2.03, which incorporates food consumption data from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Continuing Surveys of Food Intakes by Individuals (CSFII). In addition to the Percent Crop Treated (PCT) assumptions described above, EPA, in estimating chronic exposure, relied upon average field trial residues for apple, leafy vegetables (except Brassica), citrus and fruiting vegetables; tolerance level residues for the remaining food crop commodities; average feed crop residues for feed commodities from the following crops: Sweet corn forage, leaves of root and tuber vegetables and aspirated grain fractions; average residues from animal feeding and dermal magnitude of residue studies; and DEEM™ (Version 7.81) default processing factors for all commodities, excluding field corn (meal, starch, flour and oil), grape juice and wheat (flour and germ), where processing factors based on the results of processing studies were assumed.

iii. *Cancer.* Based on the results of carcinogenicity studies in rats and mice, spinosad has been classified as ''Not likely to be carcinogenic to humans.'' Preliminary results of a carcinogenicity study in mice indicate that spinetoram is not carcinogenic to mice at doses up to 37.5 milligram/kilogram/day (mg/kg/day). Based on these preliminary results and spinetoram's structural and toxicological similarity to spinosad, spinetoram is also considered to be ''Not likely to be carcinogenic to humans.'' Consequently, a quantitative cancer exposure and risk assessment is not appropriate for spinosad or spinetoram.

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 pursuant to FFDCA 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. 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 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:

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 such pesticide residue.

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

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:

One-hundred percent crop treated was assumed for all food crop commodities and some feed crop commodities (aspirated grain fractions, sugarbeet molasses and cottonseed). For certain feed crop commodities, the Agency summed the projected PCT for spinosad and spinetoram and used the combined estimates in conjunction with average field trial residues to calculate cattle dietary burdens and anticipated residues of spinosad in meat and milk. The following combined projected PCT estimates were used: sweet corn forage (39%), sorghum grain (5%), soybean seed meal (5%) and leaves of root and tuber vegetables (50%).

Spinetoram is a new, recently registered pesticide. EPA estimates an upper bound of projected percent crop treated (PPCT) for a new pesticide use by assuming that its actual PCT during the initial 5 years of use on a specific use site will not exceed the recent PCT of the market leader (i.e., the one with the greatest PCT) on that site. EPA calls this the market leader PPCT estimate. In this specific case, the new use to be estimated is the combined use of spinosad together with that of spinetoram since the most new use of spinetoram will likely replace previous use of spinosad. An average market leader PCT, based on three recent surveys of pesticide usage, if available, is used for chronic risk assessment. The average market leader PCT may be based on one or two survey years if three are not available. Also, with limited availability of data, the average market leader PCT may be based on a cross-section of state PCTs. Comparisons are only made among pesticides of the same pesticide type (i.e., the leading insecticide on the use site is selected for comparison with the new insecticide), or, for refined estimates, among pesticides targeting the same pests. The market leader PCTs used to determine the average may be each for the same pesticide or for different pesticides for any year since the same or different pesticides may dominate for each year. Typically, EPA uses U.S. Department of Agriculture/National Agricultural Statistics Service (USDA/NASS) as the source for raw PCT data because it is publicly available. When a specific use site is not surveyed by USDA/NASS, EPA uses other sources including proprietary data.

An estimated PPCT, based on the average PCT of the market leaders, is appropriate for use in chronic dietary risk assessment. This method of estimating PPCT for a new use of a registered pesticide or a new pesticide produces a high-end estimate that is unlikely, in most cases, to be exceeded during the initial 5 years of actual use. Predominant factors that bear on whether the PPCT could be exceeded may include PCTs of similar chemistries, pests controlled by alternatives, pest prevalence in the market and other factors. All relevant information currently available for predominant factors has been considered for the combined use of spinetoram and spinosad on each of these several crops. It is the Agency's opinion that it is unlikely that actual combined PCTs for spinetoram and spinosad will exceed the corresponding estimated PPCTs during the next 5 years.

The PPCTs for the combined use of spinosad and spinetoram for chronic risk assessment were determined using the market leader approach for the feed commodities of sweet corn, grain sorghum, soybeans and turnip greens. For turnip greens, the PCTs of market leaders were averaged over states rather than years because only 1–year of data was available.

The Agency believes that the three conditions listed in this Unit have been met. With respect to Condition 1, 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 2 and 3, 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 information on the regional consumption of food to which spinosad may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for spinosad 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 environmental fate characteristics of spinosad. 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 First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of spinosad for acute exposures are estimated to be 34.5 parts per billion (ppb) for surface water and 1.1 ppb for ground water. The EECs for chronic exposures are estimated to be 10.5 ppb for surface water and 1.1 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. As explained above, an acute dietary risk assessment was not conducted for spinosad and spinetoram. For chronic dietary risk assessment, the water concentration of value 10.5 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).

The Agency has concluded that spinosad and spinetoram are toxicologically equivalent; therefore, residential exposure to both spinosad and spinetoram was evaluated. Spinosad is currently registered for the following residential non-dietary sites: Homeowner application to turf grass and ornamentals to control a variety of worms, moths, flies, beetles, midges, thrips, leafminers and fire ants (granular formulation). Spinetoram is registered for homeowner applications to gardens, lawns/ornamentals and turf grass for control of lepidopterous larvae (worms or caterpillars), dipterous leafminers, thrips, sawfly larvae, certain psyllids and leaf-feeding beetles and red imported fire ants.

There is potential for residential handler and post-application exposures to both spinosad and spinetoram. Since spinosad and spinetoram control the same pests, EPA concludes that these products will not be used in

combination with each other and combining the residential exposures is unnecessary. Short-term residential inhalation risks were estimated for adult residential handlers, as well as short-term post-application incidental oral risks for toddlers, based on applications to home lawns, home gardens and ornamentals. Dermal exposures were not assessed, since no dermal endpoints of concern were identified in the toxicology studies for spinosad and spinetoram.

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.''

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 spinosad and any other substances and spinosad 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 spinosad 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 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 (''10X'') 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. This additional margin of safety is commonly referred to as the FQPA safety factor. 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 FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. The following acceptable studies are available for both spinosad and spinoteram: developmental toxicity studies in rats and rabbits and a two–generation reproduction study in rats. There is no evidence of increased susceptibility of rat or rabbit fetuses to *in utero* exposure to spinosad or spinetoram. In the spinosad and spinetoram rat and rabbit developmental toxicity studies, no developmental toxicity was observed at dose levels that induced maternal toxicity. In the spinosad two–generation reproduction study, maternal and offspring toxicity were equally severe, indicating no evidence of increased susceptibility. In the spinetoram 2–generation reproduction study, no adverse effects were observed in the offspring at dose levels that produced parental toxicity. Therefore, there is no evidence of increased susceptibility and there are no concerns or residual uncertainties for pre and/or post-natal toxicity.

3. *Conclusion*. EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicity database for spinosad is complete. The toxicity database for spinetoram is adequate for this risk assessment despite the lack of a chronic toxicity study in rats. The preliminary review of a mouse carcinogenicity study for spinetoram provides evidence that the chronic toxicity of spinosad and spinetoram are comparable, since spinetoram produced similar toxicity at doses similar to those seen previously with spinosad. Therefore, it is expected that the ongoing spinetoram chronic carcinogenicity study in rats would produce similar chronic toxicity at a similar dose as was seen in the chronic toxicity study in rats with spinosad.

ii. There is no indication that spinosad or spinetoram are neurotoxic chemicals and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that spinosad or spinetoram results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction studies.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on tolerance-level residues or anticipated residues derived from reliable field trial data. 100 PCT was assumed for all commodities except certain feed crop commodities. The projected PCT estimates used for these commodities are conservative, high-end estimates developed using the market leader approach that are unlikely to be exceeded. Conservative ground and surface water modeling estimates were used. Similarly, conservative Residential SOPs were used to assess incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by spinosad and spinetoram.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. None of the toxicology studies available for spinosad or spinetoram has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure; therefore, spinosad and spinetoram are not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to spinosad and spinetoram from food and water will utilize 81% of the cPAD for children, 1 to 2 years old, the population group with the greatest estimated exposure. Based on the use patterns, chronic residential exposure to residues of spinosad or spinetoram is not expected.

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

Spinosad and spinetoram are currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for spinosad and spinetoram. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food, water, and residential exposures aggregated result in aggregate MOEs of 650 to 710 for adults and 180 to 300 for infants and children. The aggregate MOEs for adults are based on the residential turf scenario and include combined food, drinking water and handler inhalation exposures

to spinetoram. Inhalation exposures are not expected for residential handlers of spinosad, based on its granular formulation and low vapor pressure. The aggregate MOEs for infants and children include food, drinking water and incidental oral exposures on turf areas previously treated with spinosad or spinetoram. Dermal exposures were not assessed for adults or children, since a dermal endpoint of concern was not identified in the toxicology studies for spinosad or spinetoram.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Spinosad is not registered for use on any sites that would result in intermediate-term (1–6 months) residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which does not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. Based on the results of carcinogenicity studies with spinosad in rats and mice and the preliminary results of a carcinogenicity study with spinetoram in mice, spinosad and spinetoram are considered ''Not likely to be carcinogenic to humans.'' Spinosad and spinetoram are 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 spinosad and spinetoram residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

DowElanco Method 97.05, an immunoassay particle-based method, and Dow AgroSciences Method GRM 03.15, a high performance liquid chromatography method with ultraviolet absorption detection (HPLC/UV), have been adequately validated and determined to be acceptable to enforce the tolerance expression in spices and pineapple, respectively. The 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 established Codex, Canadian, or Mexican maximum residue levels (MRLs) for spinosad (i.e., the combined residues of spinosyn A and D).

C. Response to Comments

Several comments were received from a private citizen, B. Sachau, objecting to establishing these tolerances for a variety of generalized and unsubstantiated reasons, including the lack of ''combinant'' testing and long-term testing, pesticide residues and unacceptable risk to Americans. The Agency has received these same or similar comments from this commenter on numerous previous occasions. Refer to **Federal Registers** of June 30, 2005 (70 FR 37683) (FRL–7718–3), January 7, 2005 (70 FR 1349) (FRL–7691–4), and October 29, 2004 (69 FR 63083) (FRL–7681–9) for the Agency's response to these objections. The commenter also objected to issuance of ''exemptions'' for this pesticide, an irrelevant comment in the context of this tolerance-setting action. Finally, this same commenter raised concerns about risk to insects and other animals from spinosad. EPA considers such environmental risks in deciding whether to register pesticide products under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); however, the safety standard for approving tolerances under section 408 of the FFDCA focuses on potential harms to human health and does not permit consideration of effects on the environment. Therefore, the comment regarding risk to insects and other animals is not relevant to this tolerance action.

V. Conclusion

Therefore, tolerances are established for residues of spinosad, consisting of two related active ingredients: Spinosyn A (Factor A; CAS # 131929–60–7) or 2-[(6-deoxy-2,3,4-tri-*O* -methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione; and Spinosyn D (Factor D; CAS # 131929–63–0) or 2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethyl-amino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione, in or on Spice, subgroup 19B, except black pepper at 1.7 ppm; Pineapple at 0.02 ppm; and Pineapple, process residue at 0.08 ppm.

The table of spinosad tolerances at 40 CFR 180.495(a) currently includes a third column for expiration/revocation dates. Since none of the existing tolerances are time-limited and EPA is not time-limiting the new tolerances for spice and pineapple commodities, there is no need for this column. Therefore, the third column of the table is being deleted.

Time-limited tolerances were established at 40 CFR 180.495(b) for residues of spinosad in or on livestock commodities in connection with FIFRA section 18 emergency exemptions granted by EPA. All of these time-limited tolerances have expired and are no longer necessary, because permanent tolerances have been established on these commodities at higher levels. Therefore, these expired, time-limited tolerances for residues of spinosad (Factor A and Factor D) are revoked.

Finally, EPA is correcting the commodity terminology for ''Vegetable, brassica, leafy, group 5'' in 40 CFR 180.495(a) to read ''Brassica, leafy greens, subgroup 5B'' at 10.0 ppm, to undo a transcription error. In 1998, EPA established spinosad tolerances for the two subgroups in Crop Group 5 - Brassica (Cole) Leafy Vegetables (40 CFR 180.41(c)(5). (63 FR 18329, April 15, 1998). The two subgroups in Group 5 are Crop Subgroup 5A - Head and Stem Brassica and Crop Subgroup 5B - Leafy Brassica Greens. Tolerances were established for the subgroups at levels of 2 ppm and 10 ppm respectively. No tolerance applying across the whole brassica crop group was established. Subsequently, in a rulemaking establishing spinosad tolerances for various non-brassica commodities the tolerance for the ''greens'' subgroup was incorrectly transcribed as a tolerance for the entire brassica group (70 FR 1349, January 7, 2005). This transcription error occurred when the tolerance table, as revised by the addition of the new non-brassica tolerances, was printed in the **Federal Register**. The changing of the subgroup tolerance to a group tolerance was clearly nothing more than a transcription error, because it was not mentioned in the notice of filing for the rulemaking or the preamble to the final rule. Moreover, it is inconsistent with the generic crop group regulation to establish both a crop group and subgroup of that crop group for the same pesticide because the former would displace the latter. This change merely corrects the tolerance regulation to specify the crop subgroup tolerance that was actually promulgated, since this tolerance is intended to cover only those commodities in the ''greens'' subgroup. A separate, lower tolerance of 2.0 ppm has been established to cover head and stem Brassica in subgroup 5A. The tolerance for the ''greens'' subgroup was incorrectly modified in connection with the establishment of new spinosad

tolerances in the **Federal Register** of January 7, 2005 (70 FR 1349).

EPA finds there is good cause to make these latter three changes without prior notice and comment because they are technical corrections which either eliminate obsolete or unused portions of the regulation or correct a transcription error. EPA concludes notice and comment are unnecessary on such changes.

VI. 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, 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (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 6, 2000) do not apply to this rule. In addition, This 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: November 27, 2007.

Donald R. Stubbs,

Acting 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 180.495 is revised to read as follows:

§ 180.495 Spinosad; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide spinosad in or on the food commodities in the table to this paragraph. Spinosad is a fermentation product of *Saccharopolyspora spinosa*. The product consists of two related active ingredients: Spinosyn A (Factor A: CAS # 131929–60–7) or 2-[(6-deoxy-2,3,4-tri-*O* -methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione; and Spinosyn D (Factor D; CAS # 131929–63–0) or 2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethyl-amino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione.

Commodity	Parts per million
Acerola	1.5
Alfalfa, seed	0.15
Alfalfa, seed screenings	2.0
Almond, hulls	2.0
Amaranth, grain, grain	1.0
Amaranth, grain, stover	10
Animal feed, nongrass, group, 18	0.02
Animal feed, nongrass, group, 18, forage	35.0
Animal feed, nongrass, group, 18, hay	30.0
Apple pomace	0.5
Artichoke, globe	0.3
Asparagus	0.2
Atemoya	0.3
Avocado	0.3
Banana	0.25
Beet, sugar, molasses	0.75
Biriba	0.3
Brassica, head and stem, subgroup 5A	2.0
Brassica, leafy greens, subgroup 5B	10.0
Bushberry subgroup 13B	0.250
Caneberry subgroup 13A	0.7
Canistel	0.3
Cattle, fat	50
Cattle, liver	10
Cattle, meat	2.0
Cattle, meat byproducts, except liver	5.0
Cherimoya	0.3
Citrus, oil	3.0
Citrus, dried pulp	0.5
Coriander, leaves	8.0
Corn, sweet, kernel plus cob with husks removed	0.02
Cotton, gin byproducts	1.5
Cotton, undelinted seed	0.02
Cranberry	0.01
Custard apple	0.3
Egg	0.30
Feijoa	.05
Fig	0.10
Fish	4.0
Fish-shellfish, crustacean	4.0
Fish-shellfish, mollusc	4.0
Food commodities	0.02
Fruit, citrus, group 10	0.3
Fruit, pome, group 11	0.20

Commodity	Parts per million
Fruit, stone, group 12	0.20
Goat, fat	50
Goat, liver	10
Goat, meat	2.0
Goat, meat byproducts, except liver	5.0
Grain, aspirated fractions	200
Grain, cereal, group 15	1.5
Grain, cereal, group 16, forage, except rice	2.5
Grain, cereal, group 16, hay, except rice	10.0
Grain, cereal, group, 16, stover, except rice	10.0
Grain, cereal, group, 16, straw, except rice	1.0
Grape	0.50
Grape, raisin	0.70
Grass, forage, fodder and hay, group 17, forage	10.0
Grass, forage, fodder and hay, group 17, hay	5.0
Guava	0.3
Herb subgroup 19A, dried	22
Herb subgroup 19A, fresh	3.0
Hog, fat	33
Hog, meat byproducts	8.0
Hog, meat	1.5
Hop, dried cones	22
Horse, fat	50
Horse, liver	10
Horse, meat	2.0
Horse, meat byproducts, except liver	5.0
Ilama	0.3
Jaboticaba	0.3
Juneberry	0.25
Lingonberry	0.250
Longan	0.3
Lychee	0.3
Mango	0.3
Milk	7.0
Milk, fat	85
Nut, tree, group 14	0.02
Okra	0.40
Onion, green	2.0
Papaya	0.3
Passionfruit	0.3
Pea and bean, dried shelled, except soybean, subgroup 6C	0.02
Pea and bean, succulent shelled, subgroup 6B	0.02
Peanut	0.02
Peanut, hay	11.0
Peppermint, tops	3.5
Pineapple	0.02
Pineapple, process residue	0.08
Pistachio	0.020
Poultry, fat	1.3
Poultry, meat	0.10
Poultry, meat byproducts	0.10
Pulasan	0.3
Rambutan	0.3
Rice, hulls	4.0
Salal	0.250
Sapodilla	0.3
Sapote, black	0.3
Sapote, mamey	0.3
Sapote, white	0.3
Sheep, fat	50
Sheep, liver	10
Sheep, meat	2.0
Sheep, meat byproducts, except liver	5.0
Soursop	0.3
Soybean	0.02
Spanish lime	0.3
Spearmint, tops	3.5
Spice, subgroup 19B, except black pepper	1.7
Star apple	0.3
Starfruit	0.3
Strawberry	1.0
Sugar apple	0.3
Ti, leaves	10.0
Vegetable, bulb, group 3, except green onion	0.10
Vegetable, cucurbit, group 9	0.3
Vegetable, foliage of legume, group 7	8.0
Vegetable, fruiting, group 8	0.4
Vegetable, leafy, except brassica, group 4	8.0
Vegetable, leaves of root and tuber, group 2	10.0
Vegetable, legume, edible podded, subgroup 6A	0.30
Vegetable, root and tuber, group 1	0.10
Watercress	8.0
Wax jambu	0.3

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertant residues.* [Reserved]

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