TABLE 2—INERT INGREDIENTS PERMITTED IN MINIMUM RISK PESTICIDE PRODUCTS—Continued

Label display name	Chemical name	CAS No.
Walnut shells	Walnut shells	N/A
Wheat	Wheat	N/A
Wheat flour	Wheat flour	N/A
Wheat germ oil	Wheat germ oil	8006–95–9
Wheat oil	Oils, wheat	68917–73–7
Whey	Whey	92129–90–3
White mineral oil	White mineral oil (petroleum)	8042–47–5
Wintergreen oil	Wintergreen oil	68917–75–9
Wollastonite	Wollastonite ($Ca(SiO_3)$)	13983–17–0
Wool	Wool	N/A
Xanthan gum	Xanthan gum	11138–66–2
Yeast	Yeast	68876–77–7
Zeolites	Zeolites (excluding erionite (CAS Reg. No. 66733–21–9))	1318–02–1
Zeolites, NaA	Zeolites, NaA	68989–22–0
Zinc iron oxide	Zinc iron oxide	12063–19–3
Zinc oxide	Zinc oxide (ZnO)	1314–13–2
Zinc stearate	Octadecanoic acid, zinc salt	557–05–1

(3) *Other conditions of exemption.* All of the following conditions must be met for products to be exempted under this section:

(i) Each product containing the substance must bear a label identifying the label display name and percentage (by weight) of each active ingredient as listed in table 1 in paragraph (f)(1) of this section. Each product must also list all inert ingredients by the label display name listed in table 2 in paragraph (f)(2)(iv) of this section.

(ii) The product must not bear claims either to control or mitigate microorganisms that pose a threat to human health, including but not limited to disease transmitting bacteria or viruses, or claims to control insects or rodents carrying specific diseases, including, but not limited to ticks that carry Lyme disease.

(iii) Company name and contact information.

(A) The name of the producer or the company for whom the product was produced must appear on the product label. If the company whose name appears on the label in accordance with this paragraph is not the producer, the company name must be qualified by appropriate wording such as ''Packed for [insert name],'' ''Distributed by [insert name], or ''Sold by [insert name]'' to show that the name is not that of the producer.

(B) Contact information for the company specified in accordance with paragraph (f)(3)(iii)(A) of this section must appear on the product label including the street address plus ZIP code and the telephone phone number of the location at which the company may be reached.

(C) The company name and contact information must be displayed prominently on the product label.

(iv) The product must not include any false and misleading labeling statements, including those listed in 40 CFR 156.10(a)(5)(i) through (viii).

(4) *Providing guidance.* Guidance on minimum risk pesticides is available at *http://www2.epa.gov/minimum-risk-pesticides* or successor Web pages.

[FR Doc. 2015–32325 Filed 12–24–15; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0727; FRL–9933–41]

Spinosad; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spinosad in or on multiple commodities that are identified and discussed later in this document. In addition, this regulation removes a number of existing tolerances for residues of spinosad that are superseded by tolerances being established in this action. Interregional Research Project #4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 28, 2015. Objections and requests for hearings must be received on or before February 26, 2016, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2013–0727, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

• Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 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–2013–0727 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before February 26, 2016. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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 (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2013–0727, by one of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of December 30, 2013 (78 FR 79359) (FRL–9903–69), and November 4, 2015 (80 FR 68289) (FRL–9936–13), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing and subsequent filing of an amendment to pesticide petition (PP 3E8204) by IR–4, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.495 be amended by establishing tolerances for residues of the insecticide spinosad, a fermentation product of *Saccharopolyspora spinosa,* consisting of two related active ingredients: Spinosyn A (Factor A: CAS Registry No. 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 Registry No. 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 the raw agricultural commodities: Coffee, green bean at 0.2 parts per million (ppm); coffee, instant at 0.4 ppm; coffee, roasted bean at 0.4 ppm; cottonseed subgroup 20C at 0.02 ppm; caneberry subgroup 13–07A at 0.7 ppm; bushberry subgroup 13–07B, except lingonberry at 0.25 ppm; fruit, small, vine climbing, except fuzzy kiwifruit subgroup 13–07F at 0.5 ppm; berry, low growing, subgroup 13–07G, except blueberry, lowbush, and cranberry at 1.0 ppm; fruit, pome group 11–10 at 0.2 ppm; vegetable, fruiting, group 8–10 at 0.4 ppm; fruit, citrus, group 10–10 at 0.3 ppm; fruit, stone, group 12–12 at 0.2 ppm; onion, bulb, subgroup 3–07A at 0.1 ppm; onion, green, subgroup 3–07B at 2.0 ppm; and nuts, tree, group 14–12 at 0.1 ppm. In addition, the petitioner proposes based upon establishment of the new tolerances above, to remove the following established tolerances that are superseded by this action: bushberry subgroup 13B at 0.25 ppm; caneberry subgroup 13A at 0.70 ppm; fruit, citrus, group 10 at 0.30 ppm; fruit, pome, group 11 at 0.20 ppm; fruit, stone, group 12 at 0.20 ppm; grape at 0.50 ppm; Juneberry at 0.25 ppm; lingonberry at 0.25 ppm; nut tree, group 14 at 0.10 ppm; okra at 0.40 ppm; onion, green at 2.0 ppm; pistachio at 0.10 ppm; quinoa, grain at 1.0 ppm; salal at 0.25 ppm; strawberry at 1.0 ppm; vegetable, bulb, group 3, except green onion at 0.10 ppm; vegetable, fruiting group 8 at 0.4 ppm; and cotton, undelinted seed at 0.02 ppm. That document referenced a summary of the petition prepared by Dow AgroSciences, the registrant, which is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filings. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has made certain modifications to the petitioned-for tolerances. The reasons for these changes are explained in Unit IV.C.

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 FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for spinosad including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with spinosad follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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.

Spinosad and spinetoram are considered by EPA to be toxicologically identical for human health risk assessment based on their very similar chemical structures and similarity of the toxicological databases for currently available studies. The primary toxic effect observed from exposure to spinosad or spinetoram was histopathological changes in multiple organs (specific target organs were not identified). Vacuolization of cells and/or macrophages was the most common histopathological finding noted across both toxicological databases with the dog being the most sensitive species. In addition to the numerous organs observed with histopathological changes, anemia was noted in several studies.

There was no evidence of increased quantitative or qualitative susceptibility from spinosad or spinetoram exposure. In developmental studies, no maternal or developmental effects were seen in rats or rabbits. In the rat reproduction toxicity studies, offspring toxicity was seen in the presence of parental toxicity at approximately the same dose for both chemicals (75–100 mg/kg/day). Parental toxicity was evidenced by increased organ weights, mortality, and histopathological findings in several organs. Offspring effects included decreased litter size, survival, and body weights with spinosad while an increased incidence of late resorptions and post-implantation loss was seen with spinetoram. Dystocia and/or other parturition abnormalities were observed with both chemicals.

Spinosad and spinetoram are classified as having low acute toxicity via the oral, dermal, and inhalation routes of exposure. Neither chemical is an eye or dermal irritant. Spinetoram was found to be a dermal sensitizer. No hazard was identified for dermal exposure; therefore a quantitative dermal assessment is not needed. In acute and subchronic neurotoxicity studies, there was no evidence of neurotoxicity from exposure to spinosad or spinetoram. In an immunotoxicity study with spinosad, systemic effects (decreased body weights, increased liver weights, and abnormal hematology results) were seen at the highest dose tested (141 mg/kg/day); however, there was no evidence of immunotoxicity.

Spinosad and spinetoram are classified as ''not likely to be carcinogenic to humans'' based on lack of evidence of carcinogenicity in mice and rats and negative findings in mutagenicity assays.

Specific information on the studies received and the nature of the adverse effects caused by spinetoram 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 documents including: (1) ''Spinosad and Spinetoram—Human Health Risk Assessment to Support the Section 3 Registration Request for Application to Coffee and for Updates to Several Crop Group/Subgroup Commodity Definitions'', dated March 15, 2015 at page 31, and (2) ''Spinosad/Spinetoram. Addendum to Human Health aggregate Risk assessment D415812 (T. Bloem *et al.,* March 10, 2015) to Support a New Use on Quinoa'', dated November 19, 2015 in docket ID number EPA–HQ–OPP–2013–0727.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). 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 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

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/spinetoram used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR SPINOSAD/SPINETORAM FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations) ..	A dose and endpoint of concern attributable to a single dose was not observed.		
Chronic dietary (All populations)	NOAEL= 2.49 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.0249 mg/kg/day. cPAD = 0.0249 mg/kg/day	Chronic Toxicity—Dog Study (with spinetoram) LOAEL = 5.36/5.83 mg/kg/day (males/females) based on arteritis and necrosis of the arterial walls of the epididymides in males and of the thymus, thyroid, larynx, and urinary bladder in females.
Incidental oral short-term (1 to 30 days) and intermediate-term (1 to 6 months).	NOAEL= 4.9 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE <100.	*Subchronic Oral Toxicity—Dog Study (with spinosad)* LOAEL = 9.73 mg/kg/day based on microscopic changes in multiple organs, clinical signs of toxicity, decreases in body weights and food consumption, and biochemical evidence of anemia and liver damage.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR SPINOSAD/SPINETORAM FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Inhalation short-term (1 to 30 days) and Intermediate-Term (1–6 months).	Inhalation (or oral) study NOAEL= 4.9 mg/kg/day (inhalation assumed equivalent to oral). UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE <100.	*Subchronic Oral Toxicity—Dog Study (with spinosad)* LOAEL = 9.73 mg/kg/day based on microscopic changes in multiple organs, clinical signs of toxicity, decreases in body weights and food consumption, and biochemical evidence of anemia and liver damage.
Cancer (Oral, dermal, inhalation).	Classified as ''not likely to be carcinogenic to humans''.		

LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to spinosad and spinetoram, EPA considered exposure under the petitioned-for tolerances as well as all existing spinosad tolerances in 40 CFR 180.495 and existing spinetoram tolerances. 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 or spinetoram; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* Spinosad is registered for application to all of the same crops as spinetoram, with similar pre-harvest and retreatment intervals, and application rates greater than or equal to spinetoram. Further, both products control the same pest species. For this reason, EPA has concluded it would overstate exposure to assume that residues of both spinosad and spinetoram would appear on the same food. Rather, EPA aggregated exposure by either assuming that all commodities contain spinosad residues (because side-by-side spinetoram and spinosad residue data indicated that spinetoram residues were less than or equal to spinosad residues).

In conducting the chronic dietary exposure assessment for spinetoram, EPA used the Dietary Exposure Evaluation Model—Food Consumption Intake Database (DEEM–FCID, ver. 3.16) which incorporates food consumption data from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/ WWEIA; 2003–2008). The chronic analysis assumed 100 percent crop treated (PCT), average field-trial residues or tolerance-level residues for crop commodities, average residues from the livestock feeding studies, residue estimates for fish/shellfish, experimental processing factors when available, and modeled drinking water estimates.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that spinosad does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and 100 percent crop treated (PCT) information were used.* 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.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for spinosad and spinetoram in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of spinosad. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Surface Water Concentration Calculator (SWCC) and Screening Concentration in Ground Water (SCIGROW) models, the estimated drinking water concentrations (EDWCs) of spinosad for acute exposures are estimated to be 25.0 ppb for surface water and 1.1 ppb for ground water. For chronic exposures for non-cancer assessments, EDWCs of spinosad are estimated to be 21.7 ppb for surface water and 1.1 ppb for ground water. EDWCs of spinetoram for acute exposures are estimated to be 8.6 parts per billion (ppb) for surface water and 0.072 ppb for ground water. For chronic exposures for non-cancer assessments, EDWCs of spinetoram are estimated to be 5.9 ppb for surface water and 0.072 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 21.7 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).

Spinosad and spinetoram are currently registered for uses that could result in residential exposures including lawns, gardens, turfgrass, ornamentals, fire ant mounds, and spot-on pet applications. 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 for the same uses in combination with each other and thus combining spinosad and spinetoram residential exposures would overstate exposure. EPA assessed residential exposure for both spinosad and spinetoram using the most conservative residential exposure scenarios for either chemical.

EPA assessed residential exposure using the following assumptions: Residential handler (short-term inhalation exposures) and post-application (short-term incidental oral) exposures are expected as a result of the following registered uses: (1) application of spinosad to gardens, turfgrass, ornamentals and fire ant mounds; (2) application of spinetoram to lawns, gardens, and ornamentals; and (3) spot-on application of spinetoram to cats and kittens. The Agency determined the ''worst-case'' scenarios for handler and post-application exposures as: (1) adult residential handler inhalation exposure from mixing/loading/applying liquid formulations to turf via backpack sprayer, and (2) child (1-<2 years) residential post-application incidental oral (hand-to-mouth) exposure from liquid formulation on turf/home gardens/ornamentals. These worst-case exposure estimates were used in the aggregate assessment of residential exposure to spinosad and spinetoram.

Aggregating exposure resulting from the turf and pet uses was not conducted as the products control different pests and, therefore, application on the same day is unlikely. Use survey data indicate that concurrent use of separate pesticide products that contain the same active ingredient to treat the same or different pests does not typically occur. Furthermore, a number of issues are considered when combining residential exposure scenarios, including whether aggregating additional uses is appropriate in light of the already conservative assumptions inherent in the assessment. When assessing individual short-term residential postapplication exposure scenarios, EPA assumes exposure occurs to zero-day residues (*i.e.,* day of application residues) day after day. EPA also assumes that an individual performs the same postapplication activities, intended to represent high end exposures as described in the Residential SOPS, day after day for the same amount of time every day (*i.e.,* no day to day variation), although doing intense contact activities on the day of application subsequent to application for multiple chemicals would not be anticipated. Once calculated, these exposure estimates are then compared to points of departure that are typically based on weeks of dosing in test animals. For spinosad/spinetoram, the short-term risk assessment has the additional conservatism of basing the level of concern for short-term exposure (30-days) on a toxicity study involving continuous exposure over 90 days.

Current EPA policy requires assessment for residential post-application exposures of short- (1 to 30 days), intermediate- (1 to 6 months), and long-term (greater than 6 months) exposures from spot-on products due to the preventative nature of these products and the potential for extended usage in more temperate parts of the country. However, for spinetoram, there is no progression of toxicity with time; therefore, the short-term assessment is protective of intermediate- and long-term exposure.

Available turf transferable residue (TTR) data on spinosad in support of the turf uses and spinetoram data on dislodgeable residues from petting after topical administration to cats were incorporated into the exposure assessment. Spinosad and spinetoram dislodgeable-foliar residue (DFR) studies are unnecessary at this time as there is no hazard via the dermal route of exposure.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticides-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

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 spinosad or spinetoram to share a common mechanism of toxicity with any other substances, and neither spinosad nor spinetoram appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that spinosad and spinetoram do 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 Web site at *http://www2.epa.gov/pesticides-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

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.* There was no evidence of increased quantitative or qualitative susceptibility of rat and rabbit fetuses to *in-utero* exposure to spinetoram or spinosad. In developmental studies, no maternal or developmental effects were seen in rats or rabbits. In the rat reproduction toxicity studies, offspring toxicity was seen in association with parental toxicity at approximately the same dose for both spinetoram and spinosad. Therefore, there is no evidence of increased susceptibility and there are no concerns or residual uncertainties for pre-natal and/or post-natal toxicity.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for spinosad and spinetoram is complete. There is no evidence of neurotoxicity, developmental/reproductive toxicity, immunotoxicity, mutagenicity, or carcinogenicity from spinetoram or spinosad exposure. Therefore, no additional database uncertainty factor (UF) is needed.

ii. There is no indication of spinosad or spinetoram neurotoxicity from available acute and subchronic

neurotoxicity studies in rats 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 study.

iv. There are no residual uncertainties identified in the spinosad and spinetoram exposure databases. The dietary exposure assessment is conservative as it assumes 100 PCT and residue estimates are based on field trial data and fish nature of the residue studies. Moreover, EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to spinosad and spinetoram in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as 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

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. 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 chronic exposure to spinosad and spinetoram from food and water will utilize 64% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of spinosad and spinetoram is not expected.

3. *Short- and Intermediate-term risks.* 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).

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 exposure through food and water with short-term residential exposures to spinosad and spinetoram.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 220 for children 1–2 years old and 1,000 for adults 20–49 years old. Because EPA's level of concern for spinosad and spinetoram is a MOE of 100 or below, these MOEs are not of concern.

EPA has concluded that the combined intermediate-term and long-term food, water, and residential exposures result in aggregate MOEs that will not fall below the short-term aggregate MOEs since there is no progression of spinetoram toxicity with time. Because EPA's level of concern for spinetoram and spinosad is a MOE of 100 or below, these MOEs are not of concern.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, spinosad is not expected to pose a cancer risk to humans.

5. *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 residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Method RES 94025 (GRM 94.02) is a high-performance liquid chromatography method with ultraviolet detection (HPLC/UV)) is available to enforce the tolerance expression. Additional methods have also been determined to be adequate for tolerance enforcement purposes.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Codex maximum residue limits (MRLs) for spinosad are currently established in or on several of the relevant crops or crop groups or subgroups affected by this action. EPA harmonizes with existing Codex MRLs whenever feasible. The recommended fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F and raisin tolerances and the Codex MRLs are harmonized. But harmonization with the Codex MRLs for the following tolerances is inappropriate as doing so may result in exceedances of the tolerances when the pesticide is applied using the labeled instructions: Fruit, pome, group 11–10; nut, tree, group 14–12; and cottonseed, subgroup 20C. Harmonization with the currently established vegetable, fruiting, group 8–10 Codex MRL is inappropriate as the Codex MRL is too high to allow for enforcement of the labeled instructions.

C. Response to Comments

In response to the notice of filing, EPA received two (2) comments on December 4, 2015. One comment was received from a private citizen in support of EPA's regulatory initiatives to control potentially harmful substances in order to protect human health and the environment.

The other comment was from the Center for Biological Diversity and concerned endangered species, specifically stating that EPA cannot approve these new uses prior to completion of consultations with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (''the Services''). This comment is not relevant to the Agency's evaluation of the safety of the spinosad tolerances;

section 408 of the FFDCA focuses on potential harms to human health and does not permit consideration of effects on the environment.

D. Revisions to Petitioned-For Tolerances

Based on the available field-trial and processing data and the OECD tolerance calculation procedure, EPA: (1) concludes that proposed tolerances in or on coffee processed commodities are unnecessary; (2) made revisions to proposed tolerance values in order to harmonize with Canada and/or Codex MRLs where supporting data allowed; (3) made revisions to the commodity definitions to conform with current Agency practices, and (4) is reducing the requested tolerance for coffee, green bean from 0.2 ppm to 0.04 ppm. Also, although a spinosad tolerance in/on quinoa, grain was requested at 1.0 ppm for the purpose of harmonizing with the Codex cereal grain MRL, EPA is establishing a tolerance at 0.02 ppm. EPA considered the fact that the Codex MRL is based on post-harvest treatment and, therefore, is not reflective of the proposed foliar-only quinoa application scenario. Based on the available wheat grain data and adjusting these data for the proposed application rate, EPA concluded that a 0.02-ppm spinosad tolerance in/on quinoa grain is appropriate.

In addition, the Agency is updating the tolerance expression for spinosad as follows to reflect current EPA policies: Tolerances are established for residues of the insecticide spinosad, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of *spinosyn A* (Factor A: CAS # 131929–60–7; (2*R,*3a*S,*5a*R,*5b*S,*9*S,*13*S,*14*R,*16a*S,*16b*R*)-2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-6-methyl-2*H*-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1*H-as*-indaceno[3,2-d]oxacyclododecin-7,15-dione); and *spinosyn D* (Factor D; CAS # 131929–63–0; (2*S,*3a*R,*5a*S,*5b*S,*9*S,*13*S,*14*R,*16a*S,*16b*S*)-2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethyl-amino)-tetrahydro-6-methyl-2*H*-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-methyl-1*H-as*-indaceno[3,2-d]oxacyclododecin-7,15-dione), calculated as the stoichiometric equivalent of spinosad.

V. Conclusion

Therefore, EPA is establishing tolerances for residues of the insecticide spinosad, including its metabolites and degradates, in or on the following commodities. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of *spinosyn A* (Factor A: CAS # 131929–60–7; (2*R,*3a*S,*5a*R,*5b*S,*9*S,*13*S,*14*R,*16a*S,* 16b*R*)-2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-6-methyl-2*H*-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1*H-as*-indaceno[3,2-d]oxacyclododecin-7,15-dione; and *spinosyn D* (Factor D; CAS # 131929–63–0; (2*S,*3a*R,*5a*S,*5b*S,*9*S,*13*S,* 14*R,*16a*S,*16b*S*)-2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethyl-amino)-tetrahydro-6-methyl-2*H*-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-methyl-1*H-as*-indaceno[3,2-d]oxacyclododecin-7,15-dione, calculated as the stoichiometric equivalent of spinosad, in or on berry, low growing, subgroup 13–07G, except cranberry at 0.90 ppm; bushberry, subgroup 13–07B at 0.40 ppm; caneberry subgroup 13–07A at 1.0 ppm; coffee, green bean at 0.04 ppm; cottonseed subgroup 20C at 0.02 ppm; fruit, citrus, group 10–10 at 0.30 ppm; fruit, pome, group 11–10 at 0.20 ppm; fruit, small, vine climbing, subgroup13–07F, except fuzzy kiwifruit at 0.50 ppm; fruit, stone 12–12 at 0.20 ppm; nut, tree, group 14–12 at 0.10 ppm; onion, bulb, subgroup 3–07A at 0.10 ppm; onion, green, subgroup 3–07B at 4.0 ppm; quinoa, grain at 0.02 ppm; and vegetable, fruiting, group 8–10 at 0.40 ppm. In addition, EPA is removing the following existing spinosad tolerances that are superseded by this action including: Bushberry subgroup 13B at 0.25 ppm; caneberry subgroup 13A at 0.70 ppm; fruit, citrus, group 10 at 0.30 ppm; fruit, pome, group 11 at 0.20 ppm; fruit, stone, group 12 at 0.20 ppm; grape at 0.50 ppm; Juneberry at 0.25 ppm; lingonberry at 0.25 ppm; nut tree, group 14 at 0.10 ppm; okra at 0.40 ppm; onion, green at 2.0 ppm; pistachio at 0.10 ppm; strawberry at 1.0 ppm; vegetable, bulb, group 3, except green onion at 0.10 ppm; vegetable, fruiting group 8 at 0.4 ppm; and cotton, undelinted seed at 0.02 ppm. In addition, EPA is increasing the existing tolerance for grape, raisin to 1.0 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) 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 action has been exempted from review under Executive Order 12866, this action 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 Safety Risks'' (62 FR 19885, April 23, 1997). This action 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 FFDCA section 408(d), such as the tolerances 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 action 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 FFDCA section 408(n)(4). 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action 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: December 15, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.495, paragraph (a):

■ a. Revise the introductory text.

■ b. Remove the entries in the table for ''Bushberry subgroup 13B''; ''Caneberry subgroup 13A''; ''Cotton, undelinted seed''; ''Fruit, citrus, group 10''; ''Fruit, pome, group 11''; ''Fruit, stone, group 12''; ''Grape''; ''Juneberry''; ''Lingonberry''; ''Nut tree, group 14''; ''Okra''; ''Onion, green''; ''Pistachio''; ''Salal''; ''Strawberry''; ''Vegetable, bulb, group 3, except green onion''; and ''Vegetable, fruiting, group 8''.

■ c. Revise the entry in the table for ''Grape, raisin''.

■ d. Add alphabetically entries to the table for ''Berry, low growing, subgroup 13–07G, except cranberry''; ''Bushberry subgroup 13–07B''; ''Caneberry subgroup 13–07A''; ''Coffee, green bean''; ''Cottonseed subgroup 20C''; ''Fruit, citrus, group 10–10''; ''Fruit, pome, group 11–10''; ''Fruit, small, vine climbing, subgroup13–07F, except fuzzy kiwifruit''; ''Nut, tree, group 14–12''; ''Onion, bulb, subgroup 3–07A''; ''Onion, green, subgroup 3–07B''; ''Quinoa, grain''; and ''Vegetable, fruiting, group 8–10''.

The additions and revision read as follows:

§ 180.495 Spinosad; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide spinosad, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of *spinosyn A* (Factor A: CAS # 131929–60–7; (2*R*,3a*S*,5a*R*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*R*)-2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-6-methyl-2*H*-pyran-2-yl]oxy]-9-ethyl-,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1*H*-*as*-indaceno[3,2-d]oxacyclododecin-7,15-dione; and *spinosyn D* (Factor D; CAS # 131929–63–0; (2*S*,3a*R*,5a*S*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*S*)-2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethyl-amino)-tetrahydro-6-methyl-2*H*-pyran-2-yl]oxy]-9-ethyl-,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-methyl-1*H*-*as*-indaceno[3,2-d]oxacyclododecin-7,15-dione, calculated as the stoichiometric equivalent of spinosad.

Commodity	Parts per million
* * * * *	
Berry, low growing, subgroup 13–07G, except cranberry	0.90
* * * * *	
Bushberry subgroup 13–07B	0.40
Caneberry subgroup 13–07A	1.0
* * * * *	
Coffee, green bean	0.04
* * * * *	
Cottonseed subgroup 20C	0.02
* * * * *	
Fruit, citrus, group 10–10	0.30
Fruit, pome, group 11–10	0.20
Fruit, small, vine climbing, subgroup13–07F, except fuzzy kiwifruit	0.50
Fruit, stone 12–12	0.20
* * * * *	
Grape, raisin	1.0
* * * * *	
Nut, tree, group 14–12	0.10
* * * * *	
Onion, bulb, subgroup 3–07A	0.10
Onion, green, subgroup 3–07B	4.0
* * * * *	
Quinoa, grain	0.02
* * * * *	
Vegetable, fruiting, group 8–10	0.40
* * * * *	

Commodity	Parts per million
* * * * *	

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 271 and 272

[EPA–R06–RCRA–2015–0110; FRL–9939–51–Region 6]

Texas: Final Authorization of State-Initiated Changes and Incorporation by Reference of State Hazardous Waste Management Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: During a review of Texas' regulations, the Environmental Protection Agency (EPA) identified a variety of State-initiated changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). We have determined that these changes are minor and satisfy all requirements needed to qualify for Final authorization and are authorizing the State-initiated changes through this direct Final action. In addition, this document corrects technical errors made in the September 3, 2014, **Federal Register** authorization document for Texas.

The Solid Waste Disposal Act, as amended, commonly referred to as the Resource Conservation and Recovery Act (RCRA), allows the Environmental Protection Agency (EPA) to authorize States to operate their hazardous waste management programs in lieu of the Federal program. The EPA uses the regulations entitled ''Approved State Hazardous Waste Management Programs'' to provide notice of the authorization status of State programs and to incorporate by reference those provisions of the State statutes and regulations that will be subject to the EPA's inspection and enforcement. The rule codifies in the regulations the prior approval of Texas' hazardous waste management program and incorporates by reference authorized provisions of the State's statutes and regulations.

DATES: This regulation is effective February 26, 2016, unless the EPA receives adverse written comment on this regulation by the close of business January 27, 2016. If the EPA receives such comments, it will publish a timely