

(1) EPA-APPROVED SOURCE—SPECIFIC REASONABLY AVAILABLE CONTROL TECHNOLOGY (RACT) REQUIREMENTS FOR VOLATILE ORGANIC COMPOUNDS (VOC) AND OXIDES OF NITROGEN (NO_x)—Continued

Name of source	Permit No.	County	State effective date	EPA approval date	Additional explanation/ § 52.2063 citation
PP&L—Jenkins C.T. Facility.	OP-40-0017	Luzerne	6/1/99	3/8/06 [Insert page number where the document begins].	52.2020(d)(1)(l) Except for the expiration date.

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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[EPA-HQ-OPP-2005-0510; FRL-7758-2]

Spinosad; Pesticide Tolerance**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This regulation establishes tolerances for residues of Spinosad in/on the following commodities: Alfalfa seed; alfalfa seed screenings; banana; food commodities; animal feed, nongrass, group 18, forage; animal feed, nongrass, group 18, hay; peanut, hay; vegetable, bulb, group 3, except green onion; onion, green; grass, forage, fodder and hay, group 17, forage; grass, forage, fodder and hay, group 17, hay; grain, cereal, group 16, stover, except rice; grain, cereal, group 16, forage, except rice; grain, cereal, group 16, hay, except rice; grain, cereal, group 16, straw, except rice; peppermint, tops; and spearment tops. The Interregional Research Project Number 4 (IR-4) on behalf of the registrant, Dow AgroScience, LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). In addition, EPA is deleting certain spinosad tolerances that are no longer needed as a result of this action. Also, the term "Food commodities" replaces the commodity name "all commodities in connection with the quarantine eradication programs against exotic, non-indigenous, fruit fly species, where a separate higher tolerance in not already established" as previously listed under §180.495(b).

DATES: This regulation is effective March 8, 2006. Objections and requests for hearings must be received on or before May 8, 2006.

ADDRESSES: To submit a written objection or hearing request follow the

detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number EPA-HQ-OPP-2005-0510. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>.

Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7610, e-mail address: jackson.sidney@epa.gov.

SUPPLEMENTARY INFORMATION:**I. General Information***A. Does this Action Apply to Me?*

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

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

commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

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

II. Background and Statutory Findings

In the **Federal Register** of July 20, 2005 (70 FR 41730)(FRL-7721-6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of several pesticide petitions (PP 3E6699, 3E6780, 3E6782, 3E6802, 3E6804, and 4E6811) by the Interregional Research Project Number 4 (IR-4), 681 U. S. Highway #1 South, North Brunswick, NJ 08902-3390. The petitions requested that 40 CFR 180.495 be amended by establishing a tolerance for residues of the insecticide spinosad, in or on the following raw agricultural commodities (RACs):

PP 3E6699 proposes to establish tolerances for banana and plantain at 0.25 parts per million (ppm).

PP 3E6780 proposes to establish tolerances for food commodities at 0.02 ppm.

PP 3E6782 proposes to establish tolerances for spearmint, tops at 5.0 ppm and peppermint, tops at 5.0 ppm.

PP 3E6802 proposes to establish tolerances for animal feed, nongrass, group 18, forage at 20 ppm; animal feed, nongrass, group 18 hay at 25 ppm; and peanut, hay at 25 ppm.

PP 3E6804 proposes to establish tolerances for vegetable, bulb, except green onion, group 3 at 0.1 ppm and onion, green at 2.0 ppm.

PP 4E6811 proposes to establish tolerances for: grass, forage, fodder and hay, group 17, forage at 1.5 ppm; grass, forage, fodder and hay, group 17, hay at 5 ppm; corn, field, stover; corn, pop, stover; and corn, sweet, stover at 5.0 ppm; corn, field, forage; corn, sweet, forage; and corn, pop, forage at 1.5 ppm; teosinte, forage at 1.5 ppm; millet, pearl, forage; and millet, proso, forage at 1.5 ppm; millet, pearl, hay; millet, proso, hay; millet proso, straw at 5.0 ppm; sorghum, forage, forage and sorghum, grain, forage at 1.5 ppm; sorghum, forage, hay; and sorghum, grain, stover at 5.0 ppm; wheat, forage at 1.5 ppm; wheat, hay and wheat, straw at 5.0 ppm; barley, straw and barley, hay at 5.0 ppm; rye, forage at 1.5 ppm; rye, straw at 5 ppm; oat, forage at 1.5 ppm; oat, hay and oat, straw at 5.0 ppm; triticale, forage at 1.5 ppm; and triticale, hay at 5.0 ppm.

That notice included a summary of the petition prepared by by Dow AgroSciences, LLC, Indianapolis IN, 46268, the registrant. One comment was received in response to the notice of filing. A discussion of the commenter's concerns is presented in Unit IV. C. - Public Comments.

Several of the proposed petitions described in Unit II. were subsequently amended by the petitioner as follows:

Tolerances for animal feed, nongrass, group 18, forage at 35 ppm; animal feed, nongrass, group 18 hay at 30 ppm; and separate tolerances for alfalfa seed at 0.15 ppm; and alfalfa, seed screenings at 2 ppm; banana at 0.25 ppm; grass, forage, fodder and hay, group 17, forage at 10 ppm; grain, cereal, group 16, stover, except rice at 10 ppm; grain, cereal, group 16, forage, except rice at 2.5 ppm; peppermint, tops at 3.5 ppm; and spearmint, tops at 3.5 ppm. In addition, tolerance for grain, cereal, group 16, stover, except rice at 10 ppm replaces the proposed 5.0 ppm tolerance for corn, field, stover; corn, pop, stover; corn, sweet, stover, and sorghum, grain, stover and the tolerance for grain, cereal, group 16, forage, except rice at 2.5 ppm replaces proposed tolerance of

1.5 ppm for corn, field, forage; corn, pop, forage; corn, sweet, forage; teosinte, forage; millet, pearl, forage; millet, proso, forage; sorghum, forage, forage; sorghum, grain, forage; wheat, forage; rye, forage; oat, forage; and triticale, forage. Tolerance for grain, cereal, group 16, hay, except rice at 10 ppm replaces proposed tolerance of 5.0 ppm for millet, pearl, hay; millet, proso, hay; sorghum, forage, hay; wheat, hay; barley, hay; oat, hay; and triticale, hay. Finally, tolerance for grain, cereal, group 16, straw, except rice at 1.0 ppm replaces proposed tolerance of 5.0 ppm for millet, proso, straw; wheat, straw; barley, straw; rye, straw; and oat, straw.

EPA is also deleting several established tolerances in §180.495(a) and §180.495(b) that are no longer needed, as a result of this action.

The tolerance deletions under §180.495(a) are being replaced by the establishment of the crop group tolerance for grain, cereal, group 16, stover, forage, hay, and straw. The tolerance deletions under §180.495(b) are time-limited tolerances established under section 18 emergency exemptions that are superceded by the establishment of general tolerances for spinosad under §180.495(a).

The revisions to §180.495 are as follows:

Delete the tolerances established under §180.495(a) for residues of spinosad in or on corn, forage at 1.0 ppm; corn, hay at 1.0 ppm; corn stover at 1.0 ppm; corn straw at 1.0 ppm; sorghum, forage at 1.0 ppm; sorghum, forage, hay at 1.0 ppm; sorghum, grain, stover at 1.0 ppm; sorghum, straw at 1.0 ppm; wheat, forage at 1.0 ppm; wheat, hay at 1.0 ppm and wheat, straw at 1.0 ppm. Tolerances for grain, cereal, group 16, stover, except rice at 10 ppm; grain, cereal, group 16, forage, except rice at 2.5 ppm; grain, cereal, group 16, hay, except rice at 10 ppm; and for grain, cereal, group 16, straw, except rice at 1.0 ppm replace these tolerances by this action under §180.495 (a).

Delete the time-limited tolerance for all commodities in connection with the quarantine eradication programs against exotic, non-indigenous, fruit fly species, where a separate higher tolerance is not already established at 0.02 ppm; alfalfa, forage at 4.0 ppm; alfalfa, hay at 4.0 ppm; grass, forage at 7.0 ppm; grass, hay at 7.0 ppm; peanut, hay at 10 ppm and onion, dry bulb at 0.10 ppm. Permanent tolerances for food commodities at 0.02 ppm; peanut, hay at 11 ppm; grass, forage, fodder and hay, group 17, forage at 10 ppm; grass, forage, fodder and hay, group 17, hay at 5 ppm; grain, cereal, group 16, stover, except rice at 10 ppm and vegetable, bulb, except green onion,

group 3 at 0.1 ppm are established by this action under §180.495(a).

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 define "safe" to mean that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information. This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and "to ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, at <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for residues of spinosad on: Alfalfa seed at 0.15 ppm; alfalfa seed screenings at 2.0 ppm; banana at 0.25 parts per million (ppm); food commodities at 0.02 ppm; spearmint, tops at 3.5 ppm; peppermint, tops at 3.5 ppm; animal feed, nongrass, group 18, forage at 35 ppm; animal feed, nongrass, group 18, hay at 30 ppm; alfalfa, seed at 0.15 ppm; alfalfa, seed screenings at 2.0 ppm; peanut, hay at 11 ppm; vegetable, bulb, group 3, except green onion, group 3 at 0.1 ppm; onion, green at 2.0 ppm; grass, forage, fodder and hay, group 17, forage at 10 ppm; grass, forage, fodder and hay, group 17, hay at 5 ppm; grain, cereal, group 16, stover, except rice at 10 ppm; grain, cereal, group 16, forage, except rice at 2.5 ppm; grain, cereal, group 16, hay, except rice at 10 ppm; grain, cereal, group 16, straw, except rice at 1.0 ppm.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by spinosad as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed are discussed in the **Federal Register** of September 27, 2002 (67 FR 60923) (FRL-7199-5).

B. Toxicological Endpoints

The dose at which the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified the LOAEL is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or UFs may be used: "Traditional UF" the "special FQPA safety factor;" and the "default FQPA safety factor." By the term "traditional UF," EPA is referring to those additional UF's used prior to FQPA passage to account for database deficiencies. These traditional UFs have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term "pecial FQPA safety factor" refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The "default FQPA safety factor" is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional UF or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any

traditional UFs deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1 X 10⁻⁵), one in a million (1 X 10⁻⁶), or one in ten million (1 X 10⁻⁷). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

A summary of the toxicological endpoints for spinosad used for human risk assessment is discussed in Unit III., B. of the Spinosad Final Rule published in the **Federal Register** of September 27, 2002 (67 FR 60923) (FRL-199-5).

C. Exposure Assessment

1. Dietary exposure from food and feed uses. Tolerances have been established (40 CFR 180.495) for the residues of spinosad, in or on a variety of RACs. Risk assessments were conducted by EPA to assess dietary exposures from spinosad in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-

day or single exposure. The Agency did not select a dose and endpoint for an acute dietary risk assessment due to the lack of toxicological effects of concern attributable to a single exposure (dose) in studies available in the data base including oral developmental toxicity studies in rats and rabbits. In the acute neurotoxicity study, the NOAEL was 2,000 milligram/kilograms/day (mg/kg/day), highest dose tested. An acute dietary risk assessment is not required.

ii. *Chronic exposure.* Chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model - Food Consumption Intake Database (DEEMTM/FCID), ver. 2.03; acute and cancer endpoints were not identified which incorporates the food consumption data from the U.S. Department of Agriculture Continuing Surveys of Food Intakes by Individuals (CSFII; 1994-1996, and 1998). The chronic dietary analyses assumed average/projected percent crop treated estimates, projected percent head treated resulting from the dermal and premise treatments to ruminants, average field trial residues, experimentally determined processing factors, and anticipated livestock residues. For drinking water, the chronic analyses assumed the modeled tier 1 FIRST chronic surface water estimate resulting from the application of spinosad to turf (highest registered/proposed rate). The chronic analysis used average field trial residues for grape, barley grain, corn grain, oat grain, rice grain, and wheat grain. The chronic analysis also used processing factors from the grape, corn and wheat processing studies. The resulting exposure estimates were 96% the cPAD and are therefore, less than EPA's level of concern (children 1-2 years old were the most highly exposed subpopulation).

iii. *Cancer.* Spinosad has been classified as not likely to be carcinogenic in humans based on the results of a carcinogenicity study in mice and the combined chronic toxicity and carcinogenicity study in rats. Therefore, a quantitative cancer risk assessment was not performed.

iv. *Anticipated residue and percent crop treated (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 chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels

anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E) of FFDCA, EPA will issue a Data Call-In for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance final rule.

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

The Agency used PCT information as follows:

The chronic analysis assumed tolerance level residues for all crop, poultry, and egg commodities, and anticipated residues for ruminant and milk commodities. The Agency used PCT information as follows: Almond 5%; apple 30%; apricot 10%; avocado 5%; bean, green 10%; broccoli 40%; cabbage 30%; cantaloupes 10%; cauliflower 45%; celery 50%; cherry 25%; collards 25%; cotton 5%; cucumber 20%; eggplant 15%; green, mustard 15%; green, turnip 5%; kale 30%; citrus (5%; excluding lemon and orange), lemon 10%; lettuce 50%; nectarine 30%; orange 10%; peach 5%; pear 10%; pepper 35%; potato 5%; prune and plum 10%; spinach 30%; squash 10%; strawberry 35%; corn, sweet <1%; tangerine 10%; tomato 20%; and watermelon 5%.

Exposure analysis also incorporated projected percent ruminant head treated resulting from the registered dermal and premise use (dairy cattle 23%; beef cattle 31%; actual data are not available despite this being a registered use); and projected PCT for alfalfa of 1%.

EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available federal, state, and

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

EPA projects PCT for a new insecticide use by assuming that the PCT for the insecticide's initial five years will not exceed the average PCT of the dominant insecticide (the one with the largest PCT) within all insecticides over three latest available years. The PCTs included in the average may be each for the same insecticide or for different insecticides since the same or different insecticides may dominate for each year selected. Typically, EPA uses USDA/NASS as the source for raw PCT data because it is non-proprietary and directly available without computation.

This method of projecting PCT for a new insecticide use, with or without regard to specific pest(s), produces an upper-end projection that is unlikely, in most cases, to be exceeded in actuality because the dominant insecticide is well-established and accepted by farmers. Factors that bear on whether a projection based on the dominant insecticide could be exceeded are whether the new insecticide is more efficacious or controls a broader spectrum of pests than the dominant insecticide, whether it is more cost-effective than the dominant insecticide, and whether it is likely to be readily accepted by growers and experts. These factors have been considered for this insecticide new use, and they indicate that it is unlikely that actual PCT for this new use will exceed the PCT for the dominant insecticide in the next five years.

2. Dietary exposure from drinking water. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for 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 physical 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 and Screening concentration in Groundwater models, the EECs of spinosad for acute exposures are estimated to be 25.2 parts per billion (ppb) for surface water and 0.037 ppb for ground water. The EECs for chronic exposures are estimated to be 2.3 ppb for surface water and 0.037 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the DEEM-FCID. For chronic dietary risk assessment, the surface water value (chronic; 56-day average) of 2.3 ppb was used for all direct and indirect sources of water. The surface water estimate was used for all direct and indirect sources of water. The surface water estimate was used for direct and indirect sources of water as it is greater than the ground water estimate.

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 turf/lawn and ornamental/garden pest control (i.e., worms, moths, flies, beetles, midges, thrips, leafminers, fire ants, etc.), indoor pest control, termiticides, and flea and tick control on pets). A summary of the residential uses for spinosad is discussed in Unit III.C. of the final rule published in the **Federal Register** of September 27, 2002 (67 FR 60923) (FRL-7199-5).

Spinosad is currently registered for use on the following residential non-dietary sites: Turf and ornamentals. Granular (homeowner) and emulsifiable concentrate (EC: commercial applicators) formulations are registered. No dermal endpoints were identified and based on the granular formulation and low vapor pressure for spinosad, residential handler/applicator and post-application dermal/inhalation exposure assessments were not conducted. The Agency concluded that there is potential toddler short-term, non-dietary oral exposures (hand-to-mouth, object-to-mouth, ingestion of granulars, and soil ingestion). An endpoint attributable to a single exposure (acute exposure) has not been identified; therefore, episodic ingestion of granules was not assessed. The resulting combined short-term incidental oral MOEs were 640 and are therefore, less than the Agency's level of

concern. EPA concludes that all other registered/proposed application scenarios will not result in residential exposures.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

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

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* There is no indication of increased susceptibility of rat and rabbit fetuses to *in utero* and/or postnatal exposure to spinosad.

3. *Conclusion.* There is a complete toxicity data base for spinosad and exposure data are complete or are estimated based on data that reasonably account for potential exposures. EPA determined that the 10X SF to protect infants and children should be removed. The FQPA factor is removed because:

- i. The toxicological database for spinosad is complete for FQPA assessment.
- ii. There is no evidence of increased susceptibility of rat or rabbit fetuses following *in utero* exposure in the developmental studies with spinosad, and there is no evidence of increased susceptibility of young rats in the reproduction study with spinosad.
- iii. There are no residual uncertainties identified in the exposure databases; the dietary food exposure assessment (chronic only; no acute endpoint was identified) is refined using Anticipated Residues calculated from field trial data and available PCT information.
- iv. EPA has indicated that the dietary drinking water exposure is based on conservative modeling estimates.
- v. EPA Residential SOPs were used to assess post-application exposure to children as well as incidental oral exposure of toddlers, so these assessments do not underestimate the exposure and risks posed by spinosad.

E. Aggregate Risks and Determination of Safety

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

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default

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

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

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

1. *Acute risk.* Acute aggregate risk consists of the combined dietary exposures from food and drinking water sources. The total exposure is compared to the acute RfD. An acute RfD was not identified since no effects were observed in oral toxicity studies that could be attributable to a single dose. Therefore, the Agency concludes that there is a reasonable certainty of no acute harm from aggregate exposure to spinosad.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to spinosad from food and water will utilize 30% of the cPAD for the U.S. population, 36% of the cPAD for all infants, and 96% of the cPAD for children 1-2 years old. Based on the use pattern, chronic residential exposure to

residues of spinosad is not expected. In addition, there is potential for chronic dietary exposure to spinosad in drinking water. Dietary exposure analysis included drinking water, therefore, exposure estimates represent aggregate chronic exposure. EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

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).

In general, aggregate exposures are calculated by summing dietary (food

and water) and residential exposures (residential or other non-occupational exposures). Based on the anticipated residential exposure scenarios and since acute and cancer risk assessments are not required, only short-term (residential, food and water) and chronic (food and water) aggregate exposure assessments were conducted.

Spinosad is currently registered for uses (turf and ornamental application) that could result in short-term residential exposures (incidental oral exposures to toddlers). This incidental oral exposure is combined with chronic dietary (food and water) exposure for

determination of aggregate short-term exposure. The Agency uses chronic dietary exposure when conducting short-term aggregate assessments as it has been determined this will more accurately reflect exposure from food than will acute exposure. Table 1 of this unit is a summary of the short-term aggregate exposure and risk estimates. Since the resulting aggregate MOEs are greater than or equal to 150, short-term aggregate exposure to spinosad from food and residential uses is below the Agency's level of concern.

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO SPINOSAD

Population/Subgroup	NOAEL (mg/kg/day)	Target MOE	Chronic Food and Water Exposure (mg/kg/day)	Residential Oral Exposure ¹ (mg/kg/day)	Aggregate MOE ² (food + water, and residential)
All infants (<1 year old)	4.9	100	0.009605	0.0076	280
Children (1-2 years old)	4.9	100	0.025784	0.0076	150
Children (3-5 years old)	4.9	100	0.019729	0.0076	180
Children (6-12 years old)	4.9	100	0.01259	0.0076	240

¹ residential exposure = sum of hand-to-mouth, object-to-mouth, and soil ingestion residue estimates.

² Aggregate MOE = NOAEL divided by (Chronic Food Exposure + Residential Exposure)

4. *Aggregate cancer risk for U.S. population.* Spinosad has been classified as "not likely to be carcinogenic in humans" based on the results of a carcinogenicity study in mice and the combined chronic toxicity and carcinogenicity study in rats. Therefore, 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, and to infants and children from aggregate exposure to spinosad residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The Agency concludes that currently available enforcement methods are sufficient to enforce tolerances associated with the petition under consideration. Enforcement methodology using high pressure liquid chromatography with ultraviolet detector (HPLC/UV) is available to enforce the tolerances in plants. Adequate livestock methods are available for tolerance enforcement. Method RES 94094 (GRM 95.03) is an HPLC/UV method suitable for determination of spinosad residues in ruminant commodities. Method GRM

95.03 has undergone successful independent laboratory validation (ILV) and EPA laboratory validation, and has been forwarded to FDA for inclusion in PAM Volume II. Method GRM 95.15 is another HPLC/UV method suitable for determination of spinosad residues in poultry commodities. This method has been forwarded to FDA for inclusion in PAM Volume II. Method RES 95114, an immunoassay method for determination of spinosad residues in ruminant commodities, underwent a successful ILV and EPA laboratory validation. It has been submitted to FDA for inclusion in PAM Volume II. The methods may be requested from: Paul Golden, U.S EPA/OPP/BEAD/ACB, Environmental Science Center, 701 Mapes Road, Fort Meade, MD 20755-5350; telephone number: (410) 305-2960; Fax (410) 305-3091; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

There are no Canadian or Mexican maximum residue limits in/on corn forage (5 ppm), corn fodder (5 ppm), wheat fodder (1 ppm), and wheat straw (1 ppm). The Agency concluded that the appropriate cereal grain forage, stover, hay and straw tolerances for the United States are 2.5 ppm, 10 ppm, and 1.0 ppm, respectively. There are Codex MRLs for spinosad in corn forage (5

ppm), corn fodder (5 ppm), wheat fodder (1 ppm) and wheat straw (1 ppm). Based on available data and applications proposed for the United States, the Agency concluded that the appropriate cereal grain forage, stover, hay and straw tolerances for the United States are 2.5 ppm, 10 ppm, and 1.0 ppm, respectively. The Codex MRLs for corn forage and fodder are based on field residue data from the United States. The Codex tolerances for corn forage and fodder are based on a dry weight basis whereas in the United States tolerances for corn forage and fodder are based on an as-fed basis. When evaluating data on an as-fed basis there is a high moisture content that will substantially increase the tolerance level compared to evaluating the same data on a dry weight basis. Therefore it is not appropriate to harmonize the tolerance values for these commodities. Therefore, harmonization is not an issue for these commodities.

C. Public Comments

One comment was received from a private citizen who opposed the authorization to sell to any pesticide that leaves a residue on food. The Agency has received this same comment from this commenter on numerous previous occasions and rejects it for the reasons previously stated in the **Federal**

Register of January 7, 2005 (70 FR 1349) (FRL-7691-4).

V. Conclusion

Therefore, the tolerance is established for residues of spinosad, a naturally occurring product consisting of: Spinosyn A (2-[[[6-deoxy-2,3,4-tri-O-methyl-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 (2-[[[6-deoxy-2,3,4-tri-O-methyl-L-mannopyranosyl]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-4,14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione) in/on the following commodities: Alfalfa seed at 0.15 ppm; alfalfa seed screenings at 2.0 ppm; banana at 0.25 ppm; food commodities at 0.02 ppm; spearmint, tops at 3.5 ppm; peppermint, tops at 3.5 ppm; animal feed, nongrass, group 18, forage at 35 ppm; animal feed, nongrass, group 18 hay at 30 ppm; peanut, hay at 11 ppm; vegetable, bulb, group 3, except green onion, group 3 at 0.1 ppm; onion, green at 2.0 ppm; grass, forage, fodder and hay, group 17, forage at 10 ppm; grass, forage, fodder and hay, group 17, hay at 5 ppm; grain, cereal, group 16, stover, except rice at 10 ppm; grain, cereal, group 16, forage, except rice at 2.5 ppm; grain, cereal, group 16, hay, except rice at 10 ppm; grain, cereal, group 16, straw, except rice at 1.0 ppm.

VI. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2005-0510 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before May 8, 2006.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

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

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number, EPA-HQ-OPP-2005-0510 to: Public Information and Records Integrity Branch, Information Technology and Resource Management Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. Please use an

ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary

consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCFA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCFA. For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the

relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 17, 2006.

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 amended:

■ i. In paragraph (a), in the table, by removing: Corn, forage at 1.0 ppm; corn, hay at 1.0 ppm; corn stover at 1.0 ppm; corn straw at 1.0 ppm; grass, forage, fodder and hay, group 17 at 0.02 ppm; sorghum, forage at 1.0 ppm; sorghum, forage, hay at 1.0 ppm; sorghum, grain, stover at 1.0 ppm; sorghum, straw at 1.0 ppm; wheat, forage at 1.0 ppm; wheat, hay at 1.0 ppm and wheat, straw at 1.0 ppm; and by alphabetically adding the commodities as set forth below.

■ ii. In paragraph (b), in the table, by removing: All commodities in connection with the quarantine eradication programs against exotic, non-indigenous, fruit fly species, where a separate higher tolerance in is not already established at 0.02 ppm; alfalfa,

forage at 4.0 ppm; alfalfa, hay at 4.0 ppm; grass, forage at 7.0 ppm; grass, hay at 7.0 ppm; peanut, hay at 10 ppm and onion, dry bulb at 0.10 ppm.

The additions read as follows:

§ 180.495 Spinosad; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	*
Alfalfa, seed	0.15
Alfalfa, seed screenings	2.0
Animal feed, nongrass, group, 18, forage	35.0
Animal feed, nongrass, group, 18, hay	30.0
* * * * *	*
Banana	0.25
Food commodities	0.02
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
* * * * *	*
Grass, forage, fodder and hay, group 17, forage	10.0
Grass, forage, fodder and hay, group 17, hay	5.0
* * * * *	*
Onion, green	2.0
* * * * *	*
Peanut, hay	11.0
Peppermint, tops	3.5
* * * * *	*
Spearmint, tops	3.5
* * * * *	*
Vegetable, bulb, group 3, except green onion	0.10
* * * * *	*

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BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2005-0311; FRL-7764-1]

Flumiclorac Pentyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.