governments, or to the private sector, result from this action.

G. Submission to Congress and the Comptroller General

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 the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

H. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 22, 1999. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 62

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Non-methane organic compounds, Methane, Municipal solid waste landfills, Reporting and recordkeeping requirements.

Dated: September 10, 1999.

David P. Howekamp,

Acting Regional Administrator, Region IX.

40 CFR part 62 is amended as follows:

PART 62—[AMENDED]

1. The authority citation for part 62 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

2. The heading of subpart F is revised to read as follows:

Subpart F—California

3. Subpart F is amended by adding a new undesignated center heading preceding § 62.1100 to read as follows:

Plan for the Control of Designated Pollutants From Existing Facilities (Section 111(d) Plan)

4. Section 62.1100 is amended by adding and reserving paragraphs (b)(4) and (c)(4) and by adding paragraphs (b)(5) and (c)(5) to read as follows:

§ 62.1100 Identification of plan.

* * * * *

(b) * * *

(4) [Reserved]

(5) State of California's Section 111(d) Plan For Existing Municipal Solid Waste Landfills, submitted on September 26, 1997, June 26, 1998, November 9, 1998, and July 14, 1999 by the California Air Resources Board.

(c) * * *

(4) [Reserved]

(5) Existing municipal solid waste landfills.

5. Subpart F is amended by adding a new undesignated center heading and § 62.1115 to read as follows:

Landfill Gas Emissions From Existing Municipal Solid Waste Landfills

§ 62.1115 Identification of sources.

The plan applies to existing municipal solid waste landfills for which construction, reconstruction, or modification was commenced before May 30, 1991, as described in 40 CFR part 60, subpart Cc.

[FR Doc. 99–24257 Filed 9–22–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300920; FRL–6381–9]

RIN 2070–AB78

Spinosad; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spinosad in or on succulent shelled pea and bean legumes at 0.02 parts per million (ppm), dried shell pea and bean (except soybean) legumes at 0.02 ppm, and wheat (flour, bran, middlings, and shorts, only) at 0.15 ppm; cucurbit vegetables at 0.30 ppm; edible-podded legume vegetables at 0.30 ppm; soybeans at 0.02 ppm; stone fruits at 0.20 ppm; corn, grain, including field, and pop at 0.020 ppm; sorghum, grain at 1.0 ppm; wheat, grain at 0.020 ppm; forage, fodder, hay, stover, and straw of cereal grains at 1.0 ppm; aspirated grain fractions at 20 ppm; poultry, fat at 0.20 ppm; and poultry, meat, meat byproducts, and eggs at 0.020 ppm. This regulation increases current livestock residue tolerances as follows: meat of cattle, goats, hogs, horses and sheep from 0.04 to 0.15 ppm, meat by-products of cattle, goats, hogs, horses and sheep from 0.20 ppm to 1.0 ppm; fat of cattle, goats, hogs, horses and sheep from 0.6 ppm to 3.5 ppm; milk, whole from 0.04 ppm to 0.50 ppm and milk fat from 0.5 ppm to 5 ppm. This regulation also removes time limitations for residues of spinosad on corn, sweet; kernel plus cob with husk removed, stover and forage, which expire on June 20, 2001 and raises the tolerance on corn, sweet, forage to 1.0 ppm. Dow AgroSciences requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective September 23, 1999. Objections and requests for hearings, identified by docket control number OPP–300920, must be received by EPA on or before November 22, 1999.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the ''SUPPLEMENTARY INFORMATION'' section. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300920 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: William Sproat, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: 703-308-8587; and e-mail address: sproat.william@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111 112 311	Crop production Animal production Food manufacturing

Categories	NAICS	Examples of Potentially Affected Entities
	32532	Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the ''FOR FURTHER INFORMATION CONTACT'' section.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''Federal Register--Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–300920. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of September 16, 1998 (63 FR 49568) (FRL–6025–8), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) announcing the filing of a pesticide petition (PP) for tolerance by Dow AgroSciences, 9330 Zionsville Road, Indianapolis, IN 46254. This notice included a summary of the petition prepared by Dow AgroSciences, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.495 be amended by establishing tolerances for residues of the insecticide spinosad, in or on cucurbit vegetables at 0.30 parts per million (ppm); legume vegetables (succulent including soybeans) at 0.30 ppm; stone fruits at 0.20 ppm; corn, grain, including field, sweet (K+CHWR), and pop at 0.020 ppm; sorghum grain at 1.0 ppm; sorghum aspirated grain fractions at 3.0 ppm; wheat, grain at 0.020 ppm; forage, fodder, hay, stover, and straw of cereal grains at 1.0 ppm; poultry, fat at 0.20 ppm; and poultry, meat, meat byproducts at 0.020 ppm; and eggs at 0.020 ppm. The petition further requested that the following increases in livestock residue tolerances be established: livestock, meat residue tolerance of 0.10 ppm; livestock, meat byproduct residue tolerance of 0.40 ppm; livestock, fat residue tolerance of 1.50 ppm; a milk residue tolerance of 0.10 ppm; and a milk fat residue tolerance of 1.50 ppm.

The proposal for tolerances for legume vegetables (succulent including soybeans) was revised by the petitioner at EPA's request to reflect separate listings for Crop Subgroup 6A - Edible-podded legume vegetables at 0.30 ppm; Crop Subgroup 6B - Succulent shelled pea and bean at 0.02 ppm; Crop Subgroup 6C Dried shelled pea and bean at 0.02 ppm; and soybeans at 0.02 ppm. Based upon EPA's review of data, the proposal for tolerances in aspirated grain fractions and livestock community need to be revised as follows: aspirated grain fractions (20ppm); meat (0.15 ppm), meat by-products (1 ppm), and fat (3.5 ppm) of cattle, goats, hogs, horses, and sheep; whole milk (0.50 ppm); and milk fat (5 ppm). In addition, tolerances processed wheat commodities need to be added as follows; wheat bran, flour, middlings, and shorts (0.15 ppm).

Spinosad (CAS Reg. No. 131929-60-7) is a fermentation product of Saccharopolyspora spinosa. Spinosad consists of two related spinosyn compounds, Factor A and Factor D, both of which serve as active ingredients. They are typically present at an 85:15 A:D ratio. Spinosad is currently proposed for use on cucurbit crops including cucumber, summer and winter squash, muskmelons (cantaloupe, honeydew, etc.), pumpkin, edible gourds, and watermelon to control cabbage looper, armyworms, melon worms, pickleworm, rindworms, leafminers, and thrips; stone fruit including peaches, plums, cherries, nectarines, prunes and apricots to control peach twig borer, oriental fruit moth, leafminers, leafrollers, green fruitworm, cherry fruit fly, and western cherry fruit fly; succulent beans and peas to control European corn borers, armyworms, corn earworms, loopers, thrips, and leafminers; field corn, including popcorn, to control European corn borer larvae, armyworms, corn earworm, southeastern corn borer, and western bean cutworms; sorghum, including milo and grain, to control sorghum midge, armyworms, corn earworm, southwestern corn borer, and web worms; soybeans to control soybean looper, velvet bean caterpillar, green clover worm, armyworms, and corn earworms; and wheat to control armyworms and grasshoppers.

Time-limited tolerances were established for residues of spinosad on corn, sweet; kernel plus cob with husk removed, stover and forage, based on a preliminary risk assessment. After complete evaluation, the Agency has determined that time limitations on sweet corn are unnecessary and has established permanent tolerances for spinosad residues on sweet corn: kernel plus cob with husk removed, stover and forage.

Section 408(b)(2)(A)(i) of the 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) 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) 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 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2), for tolerances for residues of spinosad on cucurbit vegetables at 0.30 parts per million (ppm); edible-podded legume vegetables at 0.30 ppm; succulent shelled pea and bean legumes at 0.02 ppm; dried shell pea and bean (except soybean) legumes at 0.02 ppm; soybeans at 0.02 ppm; stone fruits at 0.20 ppm; corn, grain, including field, and pop at 0.020 ppm; corn, sweet at 1.0 ppm; sorghum, grain at 1.0 ppm; wheat, grain at 0.020 ppm; forage, fodder, hay, stover, and straw of cereal grains at 1.0 ppm; aspirated grain fractions at 20 ppm; poultry, fat, at 0.20 ppm; and poultry, meat, meat byproducts and eggs at 0.020 ppm; and wheat (flour, bran, middlings, and shorts, only) at 0.15 ppm. This regulation increases the current livestock residue tolerances as follows: meat, meat by-products, and fat of cattle, goats, hogs, horses and sheep from 0.04 to 0.15 ppm, 0.20 ppm to 1.0 ppm; and 0.6 ppm to 3.5, respectively; and increases milk, whole and milk fat from 0.04 ppm to 0.50 ppm and 0.5 ppm to 5 ppm, respectively. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by are discussed in this unit.

1. Acute toxicity studies with technical grade active ingredient spinosad (88 - 90.4%) product: Oral LD_{50} in the rat is > 5,000 mg/kg for males and females - Toxicity Category IV; dermal LD_{50} in the rat is > 2,800 mg/kg for males and females - Toxicity Category III; inhalation LC_{50} in the rat is > 5.18 mg/L - Toxicity Category IV; primary eye irritation in the rabbit (slight conjunctival irritation) - Toxicity Category IV; primary dermal irritation in the rabbit (no erythema and edema) - Toxicity Category IV. Spinosad is not a sensitizer.

2. Acute toxicity studies with the end-use (44% formulation) product for spinosad: Oral LD_{50} in the rat is > 5,000 mg/kg for males and females - Toxicity Category IV; dermal LD_{50} in the rat is > 2,800 mg/kg for males and females - Toxicity Category III; inhalation LC_{50} in the rat is > 5.0 mg/L - Toxicity Category IV; primary eye irritation in the rabbit (slight conjunctival irritation) - Toxicity Category IV; primary dermal irritation in the rabbit (slight transient erythema and edema) - Toxicity Category IV. Spinosad is not a sensitizer.

3. In a subchronic feeding study in rats, the no-observed adverse effect level (NOAEL) was 33.9 and 38.8 mg/kg/day for males and females, respectively. The lowest observed adverse effect level (LOAEL) was 68.5 and 78.1 mg/kg/day for males and females, respectively, based on decreased body weight gain, anemia, vacuolation in multiple organs (kidney, liver, heart, spleen, adrenals, thyroid).

4. In a subchronic feeding study in mice, the NOAEL was 7.5 mg/kg/day and the LOAEL was 22.5 mg/kg/day, based on cytoplasmic vacuolation in multiple organs (kidney, liver, heart, stomach, lymphoid organs, ovary).

5. In a subchronic feeding study in dogs, the NOAEL was 4.89 mg/kg/day for males and 5.38 mg/kg/day for females, respectively. The LOAEL was 9.73 mg/kg/day for males and 10.5 mg/kg/day for females, respectively, based on decreased mean body weights & food consumption, and anemia.

6. In a 21-day dermal study in rats, the NOAEL for systemic effects was > 1,000mg/kg/day (limit dose). No systemic toxicity was observed at any dose tested.

7. In a chronic feeding study in dogs, the NOAEL was 2.68 mg/kg/day and the LOAEL was 8.22 mg/kg/day, based on increased liver enzymes (ALT, AST), triglycerides; vaculated cells (parathyroid), and arteritis.

8. In a chronic feeding carcinogenicity study in mice, the NOAEL was 11.4 mg/kg/day for males and 13.8 mg/kg/day for females, respectively. The LOAEL was 50.9 mg/kg/day for males and 67.0 mg/kg/day for females, respectively, based on decreased body weight gains, increased mortality, hematologic effects, increased thickening of the gastric mucosa, and histologic changes in the stomach of males.

9. In a chronic feeding/carcinogenicity study in rats, the NOAEL was 9.5 mg/kg/day for males and 12.0 mg/kg/day for females, respectively. The LOAEL was 24.1 mg/kg/day for males and 30.3 mg/kg/day for females, respectively, based on thyroid follicular cell vacuolation (males & females); thyroiditis (females); and increased relative and absolute thyroid weights (females).

10. In a developmental study in rabbits, the maternal NOAEL was ≥50 mg/kg/day. The maternal LOAEL was not established. The developmental NOAEL was ≥50 mg/kg/day. The developmental LOAEL was not established. No maternal or developmental effects were observed at the highest dose tested (HDT) (50 mg/kg/day).

11. In a developmental study in rats, the maternal NOAEL was ≥200 mg/kg/day. The maternal LOAEL was not established. The developmental NOAEL was ≥200 mg/kg/day. The developmental LOAEL was not established. No maternal or developmental effects were observed at the (HDT) (200 mg/kg/day).

12. In a 2-generation reproduction toxicity study in rats, the systemic NOAEL was 10 mg/kg/day. The systemic LOAEL was 100 mg/kg/day based on increased organ weights (heart, liver, kidney, spleen, thyroid), histopath lesions in the lungs and mesenteric lymph nodes, stomach (female), and prostate. The reproductive NOAEL was 10 mg/kg/day. The reproductive LOAEL was 100 mg/kg/day based on decreased litter size, decreased pup survival, decreased body weight, increased incidence of dystocia and/or vaginal bleeding post-partum with associated increased mortality of dams.

13. Studies on gene mutation and other genotoxic effects: in a Gene Mutation Assay (Ames Test), there was no appreciable increase in the reversion to histidine protrophy of 4 *S. typhimurium* strains at 1 to 10,000 µg/plate with & without S-9 activation. In a Gene Mutation Assay, there was no forward mutation in mouse lymphoma L5178Y Tk +/- cells with and without metabolic activation up to 50 µg/ml. In a Structural Chromosomal Aberration Assay In vitro, there was no increase in the number of Chinese Hamster Ovary cells with chromosome aberrations with (20, 26, or 35 µg/ml) or without (100, 250, or 500 µg/ml) activation. In a Micronuclei Test, there was no increase

in the frequency of micronuclei with bone marrow cells from mice treated at 0, 500, 100, or 2,000 mg/kg/day for 2 consecutive days. In Other Genotoxicty Assays, unscheduled DNA synthesis was not induced up to the cytotoxic dose (0.01-1,000 µg/ml tested).

14. In rat metabolism studies, there were no major differences between the bioavailability, routes of excretion, or metabolism of 14C-XDE-105 (Factor A) & 14C-XDE-105 (Factor D) in Fischer 344 rats following oral administration as a suspension of 100 mg/kg bwt. The major elimination route was fecal excretion for both factors. About 80% (Factor A) and 66% (Factor D) was absorbed with about 20% (Factor A) and 34% (Factor D) of the dose eliminated unabsorbed in the feces. By 48 hr post-dosing, >60% (Factor A) & >80% (Factor D) had been recovered in the urine and the feces. Based on the terminal half-lives for fecal and urinary excretion, the elimination half-life for Factor A ranged from 25-42 hr and the half-life for Factor D ranged from 29-33 hr. The tissues and carcass contained very low levels of radioactivity at 168 hr post-dosing, < 0.1% of the administered dose/gram tissue. The primary fecal, urinary, and the biliary metabolites were identified as the glutathione conjugates of the parent and and O-demethylated XDE-105. The absorption, distribution, metabolism, and elimination of 14C-XDE-105 were similar for Factors A & D.

15. In an acute neurotoxicity study in rats, the NOAEL was ≥ 2,000 mg/kg/day. In a subchronic neurotoxicity study in rats, the NOAEL was ≥ 42.7 mg/kg/day in males and 52.1 mg/kg/day in females, respectively. In chronic neurotoxicity study in rats, the NOAEL was ≥ 46 mg/kg/day in males and 57 mg/kg/day in females, respectively.

B. Toxicological Endpoints

1. *Acute toxicity*. EPA did not select a dose and endpoint for acute dietary risk assessment due to a lack of toxicological effects 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 mg/kg/day.

2. *Short- and intermediate-term toxicity*. EPA did not select a dose or end-point for short, intermediate and long-term dermal risk assessments because (i) lack of appropriate endpoints; (ii) the combination of molecular structure and size as well as the lack of dermal or systemic toxicity at 2,000 mg/kg/day in a 21-day dermal toxicity study in rats which indicates the lack of dermal absorption; and (iii) the lack of long- term exposure based on the current use pattern. Therefore, a dermal risk assessment is not required. EPA also determined that based on the current use pattern and exposure scenario, an inhalation risk assessment is not required.

3. *Chronic toxicity*. EPA has established the RfD for spinosad at 0.027 mg/kg/day. This Reference Dose (RfD) is based on a chronic toxicity study in dogs using a NOAEL of 2.7 mg/kg/day. The LOAEL was 8.46 mg/kg/day based on the occurrence of vacuolation in glandular cells (parathyroid) and lymphatic tissues, arteritis, and increases in serum enzymes such as alanine aminotranferase, and aspartate aminotransferase, and triglyceride levels in dogs fed spinosad in the diet at dose levels of 1.44, 2.7, 8.46 mg/kg/day for 52 weeks. A hundredfold uncertainty factor (UF) was applied to the NOAEL of 2.7 mg/kg/day to account for inter- and intra- species variation resulting in an RfD of 0.027mg/kg/day.

4. *Carcinogenicity*. There is no evidence of carcinogenicity in studies in either the mouse or rat. Therefore, a carcinogenic risk assessment is not required.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.495) for the residues of spinosad, in or on a variety of raw agricultural commodities. Spinosad is registered for use on a number of agricultural commodities, including apples, Brassica vegetables, leafy vegetables, tuberous and corm vegetables, and fruiting vegetables (excluding cucurbits). Additionally, spinosad is registered for pest control in turfgrass and ornamental plants. Registered formulations of spinosad are Success, SpinTor, Tracer, and Conserve. These formulations vary from 1 to 4 lb ai/gallon and may be broadcast, band, or aerially applied. Application rates range from 0.023 to 0.156 lb ai/A, depending on the target pest and the crop. The maximum seasonal application rate is 0.45 lb ai/A. Application intervals are specified as being dependent on the pest populations or as a set number of days, ranging from 3 to 14, depending on the crop. There are label restrictions against too many applications per season and/or pest generation, to avoid development of pest resistance. Pre-harvest intervals range from 1 to 28 days, depending on the crop. For most of the commodities in this petition, the application rate ranges from 0.023 to 0.094 lb ai/A, with total seasonal application not to exceed 0.45 lb ai/acre. Risk assessments were conducted by EPA to assess dietary exposures from spinosad as follows:

i. *Acute exposure and risk.* 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. No acute toxicological endpoints were identified for spinosad due to the lack of toxicological effects attributable to a single exposure (dose). Therefore, the Agency concludes that there is a reasonable certainty of no harm from acute dietary exposure.

ii. *Chronic exposure and risk.* Adequate field trials were completed with cucumber, muskmelon, and squash (cucurbit vegetables); snap beans, snow peas, and soybean (legume vegetables); cherries, peaches, plums, and prunes (stone fruits); and sweet corn, field corn, sorghum, and wheat (cereal crops). The field trials and a poultry feeding study support the establishment of tolerances on the raw agricultural commodities.

Processing studies for wheat commodities were not submitted with the petition and were noted as a data deficiency in the residue chemistry review. In the absence of processed commodity data, EPA has used the maximum theoretical concentration factor of 8X for wheat, as listed in OPPTS Guideline 860.1520, to estimate residues in processed wheat commodities. A value of 0.8 ppm has been used for all processed wheat commodities for this risk assessment. Additionally, the residue chemistry review notes that the tolerance for aspirated grain fractions, and hence ruminant commodities, need to be revised.

EPA performed a chronic dietary (food only) exposure analysis using the Dietary Exposure Evaluation Model (DEEM). This model incorporates 3-day average 1989- 1992 food consumption data from USDA's Continuing Survey of Food Intake by Individuals and accumulates exposure to the chemical for each commodity. Each analysis assumes uniform distribution of spinosad in the commodity supply. As spinosad has been shown to partition into milk fat, EPA used data from the previously submitted animal feeding study to calculate a spinosad residue for skim milk. This value was used to set the residue level for milk-based water. The chronic dietary (food only) analysis represents a highly conservative estimate of dietary exposure to spinosad. EPA has taken this into consideration as part of this human health risk assessment. The Tier 1 exposure analysis from DEEM estimates that chronic dietary (food only)

exposure will occupy 74% of the cPAD for children ages 1-6 years (the highest-exposed population subgroup). Exposure estimates for all adult populations are less than 39% of the cPAD. The primary contributor to chronic dietary exposure is milk, which alone occupies 30% of the cPAD for children 1-6 yrs.

Exposure estimates for all population subgroups except those specific to infants and children were similar to that of the general U.S. population (0.0092 mg/kg/day, 34% cPAD), ranging from 0.0073 mg/kg/day (27% cPAD) for seniors 55+ years to 0.0105 mg/kg/day (39% cPAD) for peoples of non-Hispanic/non-white/non-black origins. The similarity of the exposure estimates across these subgroups indicates that exposure to spinosad is not heavily affected by ethnic, seasonal, or regional dietary influences (note that since the FQPA Safety Factor was reduced to 1x, the cPAD and the RfD are equal).

2. *From drinking water.* Monitoring data depicting residue levels of spinosad in drinking water are not available. Therefore, EPA cannot perform a quantitative risk assessment for drinking water exposure. Instead, EPA had used modeled estimated environmental concentrations (EECs), and back-calculated drinking water levels of comparison (DWLOCs) to determine whether exposure to spinosad via drinking water is likely to be of concern.

EPA concludes that the available data on spinosad show that the compound is not mobile or persistent, and therefore has little potential to leach to ground water. Spinosad may however contaminate surface water upon the release of water from flooded fields to the environment. Additionally, EPA's Metabolism Assessment Review Committee determined that the spinosyn Factors A and D are not expected to reach groundwater (2/10/98). In order to assess drinking water exposures, EPA used the screening models PRZM (Pesticide Root Zone Model) and EXAMS (Exposure Analysis Modeling Systems) to generate surface water EECs associated with application of spinosad to various crops. Modeled scenarios were selected because they are expected to represent roughly the upper 90th percentile for surface water vulnerability, given the chemical's geographic use range. The Tier 2 chronic surface water EEC for spinosad is 0.092 µg/L and is based on application of the insecticide to cole crops (0.13 lb ai/A/application, 0.45 lb ai/A/season). The EEC value is over 500 times less than the lowest DWLOC . Based on these studies, the Agency concludes that drinking water is not expected to be a significant source of exposure to spinosad.

i. *Acute exposure and risk.* No acute toxicity endpoints were determined from testing and the Agency concludes that there is reasonable certainty of no harm from acute risk from drinking water. No acute risk is expected.

ii. *Chronic exposure and risk.* Based on dietary (food only) exposures EPA has back-calculated Drinking Water Levels of Comparison (DWLOCs) for spinosad. The DWLOCs range from 70 µg/L to 620 µg/L; these values are well above the chronic Tier II estimated environmental concentration of 0.092 µg/L. Although exposure to spinosad via drinking water may occur, exposure is not expected to exceed the calculated DWLOCs for any population subgroup.

3. *From non-dietary exposure.* No acute dietary, cancer, or short-, intermediate-, or chronic-term dermal or inhalation endpoints were identified by the Agency. Spinosad is registered on turf grass, creating a potential for non-dietary oral exposure to children who ingest grass. To calculate a quantitative dietary risk from a potential ingestion of grass (in the absence of acute-, short-, or intermediate-term oral endpoints), EPA would need to default to the chronic dietary endpoint. This scenario would represent a child eating grass for > 6 months continuously. Based on the low application rate for spinosad on turf (0.41 lbs. ai./A.), its non-systemic nature, its short half life (especially in sunlight), and the rapid incorporation of spinosad metabolites into the general carbon pool, EPA believes that residues of spinosad on turf grass after application would be low and decrease rapidly over time. EPA believes that it is inappropriate to perform a quantitative dietary risk representing a chronic scenario from children eating turf grass. Qualitatively, the risk from children eating turf grass does not exceed the Agency's level of concern.

Another registered product contains spinosad for use on structural lumber may have residential exposure potential, however, the product is injected into drilled holes which are sealed after treatment. The product can only be applied by commercial applicators with very minimal potential risk to the public. Due to the lack of toxicity endpoints (hazard) and minimal contact with the active ingredient during and after application, exposure to residential occupants is not expected. The Agency concludes that there is a reasonable certainty of no harm from non-dietary exposure.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) 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 does not have, at this time, available data to determine whether spinosad has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Aggregate Risks and Determination of Safety for U.S. Population

Conservative assumptions have been made throughout this risk assessment. Residue estimates used in the dietary assessment are at published, proposed, or suggested tolerance levels. The two exceptions to this are wheat processed commodities, which are based on a highly conservative maximum theoretical concentration factor, and milk-based water, which is conservatively based on a theoretical maximum residue concentration calculated for skim milk. Estimated concentration of spinosad in drinking water is also quite conservative. Because of the nature of the spinosad molecule, the low application rate, and need to use a chronic oral toxicological endpoint, EPA does not believe it appropriate to aggregate the potential residential exposure to spinosad via turf grass with other oral (dietary + drinking water) exposures. As drinking water is not expected to be a significant route of exposure to spinosad, dietary (food only) exposure is the only route of concern. Thus, exposures to spinosad from its proposed uses on cucurbit vegetables, legume vegetables, stone fruits, corn, sorghum, and wheat, taken in conjunction with other registered and pending uses of spinosad, are below the Agency's level of concern.

1. *Acute risk.* Because no acute dietary endpoint was determined from

toxicity testing, the Agency concludes that there is a reasonable certainty of no harm from acute aggregate risk.

2. *Chronic risk.* Using the TMRC exposure assumptions described in this unit, EPA has concluded that aggregate exposure to spinosad from food will utilize 34% of the cPAD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children ages 1-6 with 74% of the cPAD. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to spinosad residues.

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

No dermal or inhalation endpoints were identified by EPA. Due to the nature of the non-dietary use, the Agency believes that the use of spinosad in treating timbers will not result in any exposure through the oral route. Therefore. the chronic aggregate risk solely is the sum of food + water.

4. *Aggregate cancer risk for U.S. population*. The Agency has determined that there is no evidence of carcinogenicity in studies in either the mouse or rat.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to spinosad residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children—* i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of spinosad , EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines 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 margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* In a prenatal developmental toxicity study, groups of pregnant Sprague-Dawley rats (30/group) received oral (gavage) administration of Spinosad (88.6%) in aqueous 0.5% methylcellulose at dose levels of 0, 10, 50, or 200 mg/kg/day during gestation days 6 through 17. For maternal toxicity, the NOEL was >200 mg/kg/day (HDT); a LOEL was not established. Marginal maternal toxicity was reported at this dose level (decreased body weight gain). Based upon the results of a range-finding study, which showed maternal toxicity (body weight and food consumption decreases at 100 and 300 mg/kg/day), the dose level of 200 mg/kg/day in the main study was considered adequate. For developmental toxicity, the NOEL was >200 mg/kg/day; a LOEL was not established. In the range-finding study, fetal body weight decrements occurred at 300 mg/kg/day.

In a prenatal developmental toxicity study, groups of pregnant New Zealand White rabbits (20/group) received oral (gavage) administration of Spinosad (88.6%) in 0.5% aqueous methyl cellulose at doses of 0, 2.5, 10, or 50 mg/kg/day during gestation days 7 through 19. For maternal toxicity, the NOEL was ≥50 mg/kg/day (HDT); a LOEL was not established. At this dose, slight body weight loss was observed in the first few days of dosing, but this finding was not supported by other signs. In the range-finding study, inanition was observed at doses of 100, 200, and 400 mg/kg/day, with significant decreases in body weight gain during dosing. All does at these dose levels were sacrificed prior to scheduled termination; no fetal data were available. No evidence of developmental toxicity was noted. For developmental toxicity, the NOEL was ≥50 mg/kg/day; a LOEL was not established. (No fetal effects were noted for fetuses of the range-finding study at doses up to 50 mg/kg/day).

iii. *Reproductive toxicity study*. In a 2-generation reproduction study, groups of Sprague-Dawley rats (30/sex/group) received diets containing Spinosad (88.0%) at dose levels of 0, 0.005, 0.02, or 0.2% (3, 10, or 100 mg/kg/day, respectively) for two successive generations. For parental systemic toxicity, the NOEL was 0.02% (10 mg/kg/day) and the LOEL was 0.2% (100 mg/kg/day), based on increased heart, kidney, liver, spleen, and thyroid weights (both sexes), histopathology in the spleen and thyroid (both sexes), heart and kidney (males), and histopathologic lesions in the lungs and mesenteric lymph nodes (both sexes), stomach (females), and prostate. For offspring toxicity, the NOEL was 0.02% (10 mg/kg/day) and the LOEL was 0.2% (100 mg/kg/day) based on decreased litter size, survival (F2), and body weights. Reproductive effects at that dose level included increased incidence of dystocia and/or vaginal bleeding after parturition with associated increase in mortality of dams.

iv. *Neurotoxicity*. In an acute neurotoxicity study, groups of Fischer 344 rats (10/sex/dose) received a single oral (gavage) administration of Spinosad (87.9%) at dose levels of 0, 200, 630, or 2,000 mg/kg. There were no effects on neurobehavioral endpoints or histopathology of the nervous system. For neurotoxicity, the NOEL was >2,000 mg/kg (HDT); a LOEL was not established.

In a subchronic neurotoxicity study, groups of Fischer 344 rats (10/sex/dose) were administered diets containing Spinosad at levels of 0, 0.003, 0.006, 0.012, or 0.06%(0, 2.2, 4.3, 8.6, or 42.7 mg/kg/day for males and 2.6, 5.2, 10.4, or 52.1 mg/kg/day for females, respectively). There were no effects on neurobehavioral endpoints or histopathology of the nervous system. For neurotoxicity, the NOEL was ≥42.7 for males and ≥52.1 mg/kg/day for females (HDT).

In the 2-year chronic toxicity study, groups of Fischer 344 rats (65/sex/dose) received diets containing Spinosad at dose levels of 0, 0.005, 0.02, 0.05, or 0.1% (0, 2.4, 9.5, 24.1, or 49.4 mg/kg/day for males and 0, 3.0, 12.0, 30.3, or 62.2 mg/kg/day for females, respectively). Neurobehavioral testing performed at 3, 6, 9, and 12 months of study was negative, and histopathological evaluation of perfused tissues at study termination did not identify pathology of the central or peripheral nervous system. There was

no evidence of neurotoxicity. For neuropathology, the NOEL was 0.1% (>49.4 mg/kg/day for males and /62.8 mg/kg/day for females).

Based upon a review of the currently available data base for Spinosad, a developmental neurotoxicity study in rats is not required. This determination was based upon the following evidence:

a. The oral LD_{50} in rats is >5,000 mg/kg.

b. No indication of abnormalities in the development of the fetal nervous system, were observed in the prenatal developmental toxicity studies in either rats or rabbits, at minimally toxic maternal oral doses up to 200 or 50 mg/kg/day, respectively.

c. There was no evidence of neurobehavioral toxicity in the acute or subchronic neurotoxicity studies in rats, nor in the chronic toxicity study in rats.

d. There was no evidence of neuropathology of the central or peripheral nervous system following perfusion of tissues in the acute, subchronic, or chronic neurotoxicity studies in rats.

v. *Pre- and post-natal sensitivity*. There was no increased susceptibility to rats or rabbits following in utero and/or postnatal exposure to spinosad.

vi. *Conclusion*. The data provided no indication of increased susceptibility of rats or rabbits to in utero and/or postnatal exposure to spinosad. In the prenatal developmental toxicity studies in rats and rabbits and the two-generation reproduction study in rats, effects in the offspring were observed only at or below treatment levels which resulted in evidence of parental toxicity. In addition, all neurotoxicity studies were negative for effects on the central or peripheral nervous system.

EPA determined that the 10X factor to protect infants and children (as required by FQPA) should be removed. The FQPA factor is removed because:

(i) The data provided no indication of increased susceptibility of rats or rabbits to in utero and/or post natal exposure to spinosad. In the prenatal developmental toxicity studies in rats and rabbits and the 2-generation reproduction study in rats, effects in the offspring were observed only at or below treatment levels which resulted in evidence of parental toxicity.

(ii) No neurotoxic signs have been observed in any of the standard required studies conducted.

(iii) The toxicology data base is complete and there are no data gaps. There is a complete toxicity database for spinosad and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

2. *Acute risk*. An acute risk assessment is not required because no acute toxicological endpoints were identified for spinosad. The Agency concludes that there is a reasonable certainty of no harm to infants and children from aggregate exposure.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to spinosad from food will utilize 74% of the cPAD for infants and children. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

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

IV. Other Considerations

A. Metabolism in Plants and Animals

EPA has reviewed the results of plant metabolism studies (apples, cabbage, cotton, tomatoes, turnips) and livestock metabolism studies (goat and hen). The metabolism of spinosad in plants and animals is adequately understood for the purposes of these tolerances. Based on structure/activity relationships, EPA concluded that the spinosad metabolites/fermentation impurities (spinosyns Factor B, Factor B or D, Factor K, and other related Factors) were of no more toxicological concern than the two parent compounds (spinosyns Factor A and Factor D).

EPA focused on the following data/information: the overall low toxicity of spinosad; the low levels of metabolites/fermentation impurities present; and that spinosad appears to photodegrade rapidly and become incorporated into the general carbon pool. EPA concluded that only 2 parent compounds (spinosyns Factor A and Factor D) need to be included in the tolerance expression and used for dietary risk assessment purposes.

B. Analytical Enforcement Methodology

Method GRM 94.02 (method for determination of spinosad residues in cottonseed and related commodities using HPLC/UV) underwent successful independent lab validation and EPA lab validation and has been submitted to FDA for inclusion in PAM II as Method I. Additional methods have been submitted for other crop matrices leafy vegetables - GRM 95.17; citrus - GRM 96.09; tree nuts - GRM 96.14; fruiting vegetables - GRM 95.04; and cotton gin byproducts - GRM 94.02.S1. All of these methods are essentially similar to GRM 94.02 and have been submitted to FDA for inclusion in PAM II as letter methods. Method GRM 94.02 is adequate for regulation of the tolerance expression.

Method GRM 95.03.R1 (method for determination of spinosad residues in ruminant commodities using HPLC/UV) underwent successful validation by EPA's lab. The method was forwarded to FDA for inclusion in PAM II as a Roman numeral method.

Method RES 95114 (method for determination of spinosad residues in ruminant commodities using immunoassay) has also successfully passed validation by EPA's lab. The method was forwarded to FDA for inclusion in PAM II as a Roman numeral method.

Multi residue Methods (GLN 860.1360) - The results of subjecting spinosad to FDA Multi residue testing were previously reviewed . Spinosyns Factor A and D were not recovered from any of the protocols. The results have been sent to FDA.

Adequate enforcement methodology (example - gas chromotography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov..

C. Magnitude of Residues

The residue of concern for spinosad is parent spinosad (as specified in 40 CFR 180.495), which is made up of Spinosyn Factors A and D. Because of the non-systemic nature of spinosad, these residues are primarily found on the surfaces of treated commodities.

Adequate field trials were completed with cucumber, muskmelon, and squash (cucurbit vegetables); snap beans, snow peas, and soybean (legume vegetables); cherries, peaches, plums, and prunes (stone fruits); and sweet corn, field corn, sorghum, and wheat (cereal crops). The field trials and a poultry feeding study support the establishment of tolerances.

Field trials for the legume vegetables did not include representative commodities from Crop Subgroups 6B (succulent shelled pea and bean) and 6C (dried shelled pea and bean). Tolerance-level residues of 0.02 ppm were assumed for these subgroups in the risk assessment.

Processing studies for wheat commodities were not submitted with the petition. In the absence of processed

commodity data, EPA has used the maximum theoretical concentration factor of 8X for wheat, as listed in Office of Prevention, Pesticides, and Toxic Substances (OPPTS) Guideline 860.1520, to estimate residues in processed wheat commodities. A value of 0.15 ppm has been used for all processed wheat commodities for this risk assessment. Additionally, because of the amount of spinosad residue found in corn, sorghum, and wheat products, as well as those commodities with existing residue tolerances that are potentially used in animal rations , the tolerances for aspirated grain fractions, and hence ruminant commodities, need to be revised as indicated under ''SUPPLEMENARY INFORMATION'' of this document.

D. International Residue Limits

No CODEX, Canadian, or Mexican maximum residue levels (MRLs) have been established for residues of spinosad on any crops.

V. Conclusion

Therefore, tolerances are established for residues of spinosad in or on succulent shelled pea and bean legumes at 0.02 parts per million (ppm), dried shell pea and bean (except soybean) legumes at 0.02 ppm, and wheat (flour, bran, middlings, and shorts, only) at 0.15 ppm; cucurbit vegetables at 0.30 ppm; edible-podded legume vegetables at 0.30 ppm; soybeans at 0.02 ppm; stone fruits at 0.20 ppm; corn, grain, including field, and pop at 0.020 ppm; sorghum, grain at 1.0 ppm; wheat, grain at 0.020 ppm; forage, fodder, hay, stover, and straw of cereal grains at 1.0 ppm; aspirated grain fractions at 20 ppm; poultry, fat at 0.20 ppm; and poultry, meat, meat byproducts, and eggs at 0.020 ppm. This regulation increases current livestock residue tolerances as follows: meat of cattle, goats, hogs, horses and sheep from 0.04 to 0.15 ppm, meat by-products of cattle, goats, hogs, horses and sheep from 0.20 ppm to 1.0 ppm; fat of cattle, goats, hogs, horses and sheep from 0.6 ppm to 3.5 ppm; milk, whole from 0.04 ppm to 0.50 ppm and milk fat from 0.5 ppm to 5 ppm. This regulation also removes time limitations for residues of spinosad on corn, sweet; kernel plus cob with husk removed, stover and forage, which expire on June 20, 2001 and raises the tolerance on corn, sweet, forage to 1.0 ppm. As a condition of registration, field trials on representative commodities from Crop Subgroups 6B (succulent shelled pea and bean) and 6C (dried shelled pea and bean), and processing studies for wheat commodities are required.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the 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 the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409. 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 control number OPP–300920 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 November 22, 1999.

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 issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Room M3708, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' (cite). For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov* , or bymailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A. of this preamble, you should also send a copy of your request to the PIRB for its inclusion in the official record that is described in Unit I.B.2. of this preamble. Mail your copies, identified by docket number OPP–300920, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PRIB described in Unit I.B.2. of this preamble. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format 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 issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under section 408(d) of the 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). 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) (Pub. L. 104–4). Nor does it require prior consultation with State, local, and tribal government officials as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993) and Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998), or special consideration of environmental justice related issues 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 require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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 12612, entitled *Federalism* (52 FR 41685, October 30, 1987). This action 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 the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(b)(4).. This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Pub. L. 104–113, section 12(d) (15 U.S.C. 272 note). In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), 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.

VIII. Submission to Congress and the Comptroller General

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 rule in the **Federal Register**. This 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: September 9, 1999.

James Jones,

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, by revising paragraph (a) to read as follows:

§ 180.495 Spinosad; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide spinosad in or on the food commodities in the table to this paragraph. Spinosad is a fermentation product of *Saccharopolyspora spinosa*. The product consists of two related active ingredients: Spinosyn A (Factor A; CAS# 131929-60-7) or 2-[(6-deoxy-2,3,4-tri-*O*- methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione; and Spinosyn D (Factor D; CAS# 131929-63-0) or 2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethyl-amino)- tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a, 16b-tetradecahydro-4,14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione. Typically, the two factors are present at an 85:15 (A:D) ratio.

Commodity	Parts per million	Expiration/ Revocation Date
Almonds	0.020	None
Almond Hulls	2.0	None
Apples	0.2	None
Apple pomace	0.5	None
Aspirated grain fractions.	20	None
Brassica (cole), leafy vegetables, greens subgroup.	10	None
Brassica (cole), leafy vegetables, head and stem subgroup.	2.0	None
Cattle, fat	3.5	None
Cattle, meat by-products.	1.0	None
Cattle, meat	.15	None
Citrus fruits group.	.3	None
Citrus oil	3.0	None
Citrus pulp, dried.	0.5	None
Coffee	0.02	8/28/00
Corn, field	0.02	None
Corn, fodder	1.0	None
Corn, forage	1.0	None
Corn, grain	0.02	None
Corn, hay	1.0	None
Corn, pop	0.02	None
Corn, stover	1.0	None
Corn, straw	1.0	None
Corn, sweet (K+CWHR).	0.02	None

Commodity	Parts per million	Expiration/ Revocation Date
Cotton gin by-products.	1.5	None
Cottonseed	0.02	None
Cucurbit vegetables (cucumbers, melons, squashes) group.	0.3	None
Fruiting vegetables (except cucurbits) group.	0.4	None
Goat, fat	3.5	None
Goat, meat byproducts.	1.0	None
Goat, meat	.15	None
Hogs, fat	3.5	None
Hogs, meat byproducts.	1.0	None
Hogs, meat	.15	None
Horses, fat	3.5	None
Horses, meat byproducts.	1.0	None
Horses, meat ...	.15	None
Leafy vegetables (except Brassica vegetables group.	8.0	None
Legume vegetables, edible podded (Crop Subgroup 6A.	0.30	None
Legume vegetables, dried shell pea and bean (Crop Subgroup 6C.	0.02	None
Legume vegetables, succulent shelled pea and bean (Crop Subgroup 6B).	0.02	None
Milk, fat	5.0	None
Milk, whole	0.50	None
Poultry, eggs ...	0.02	None
Poultry, fat	0.20	None
Poultry, meat byproducts.	0.02	None
Poultry, meat ...	0.02	None
Sheep, fat	3.5	None
Sheep, meat byproducts.	1.0	None
Sheep, meat	.15	None
Sorghum, fodder.	1.0	None
Sorghum, forage.	1.0	None
Sorghum, grain	1.0	None
Sorghum, hay ..	1.0	None
Sorghum, stover.	1.0	None
Sorghum, straw	1.00	None
Soybeans	0.02	None
Stone fruits (cherries, peaches, plums, prunes) group.	0.20	None
Tuberous and corm vegetables (crop subgroup 1C).	0.02	None
Wheat, bran	.15	None
Wheat, flour	.15	None
Wheat, fodder ..	1.0	None
Wheat, forage ..	1.0	None
Wheat, grain	0.02	None
Wheat, hay	1.0	None
Wheat, middlings.	0.15	None
Wheat, shorts ..	0.15	None
Wheat, stover ..	1.0	None
Wheat, straw ...	1.0	None

* * * * *

[FR Doc. 99–24696 Filed 9–22–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–6441–8]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Notice of deletion of the Smuggler Mountain Superfund site from the National Priorities List (NPL).

SUMMARY: The Environmental Protection Agency (EPA) announces the deletion of the Smuggler Mountain Superfund Site located in northeastern Aspen, Pitkin County, Colorado, from the National Priorities List (NPL). The NPL is Appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended. EPA and the Colorado Department of Public Health and Environment (CDPHE) have determined that the Site poses no significant threat to public health or the environment as long as Operation and Maintenance (O&M) measures and institutional controls are in force and working. Therefore, no further remedial measures pursuant to CERCLA are appropriate.

EFFECTIVE DATE: September 23, 1999.

FOR FURTHER INFORMATION CONTACT: Armando Saenz, Remedial Project Manager, U.S. Environmental Protection Agency, Region 8, 999 18th Street, Suite 500, Mail Stop 8EPR–SR, Denver, Colorado 80202–2466, (303) 312–6559.

SUPPLEMENTARY INFORMATION: The Site to be deleted from the NPL is: Smuggler Mountain Superfund Site, Aspen, Pitkin County, Colorado.

A Notice of Intent to Delete for this site was published on August 9, 1999 (64 FR 43129). The closing date for comments on the Notice of Intent to Delete was September 8, 1999. EPA received no comments.

EPA identifies sites that appear to present significant risk to public health, welfare, or the environment and it maintains the NPL as the list of those sites. Any site deleted from the NPL remains eligible for Fund-financed remedial actions in the unlikely event that conditions at the site warrant such action in the future. 40 CFR 300.425(e)(3) of the NCP. Deletion of a site from the NPL does not affect responsible party liability or impede agency efforts to recover costs associated with response efforts.

List of Subjects in 40 CFR Part 300

Environmental protection, Hazardous substances, Hazardous waste, Intergovernmental relations, Superfund.

Dated: September 15, 1999.

Patricia D. Hull,

Acting Regional Administrator, Region 8.

For the reasons set out in the preamble, 40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR 1991 Comp., p 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p 193.

Appendix B—[Amended]

2. Table 1 of Appendix B to Part 300 is amended by removing the Site ''Smuggler Mountain, Pitkin County, Colorado.''

[FR Doc. 99–24692 Filed 9–22–99; 8:45 am]

BILLING CODE 6560–50–P