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. 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 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: September 23, 2002.

Peter Caulkins,

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), 346(a) and 371.

2. Section 180.493 is amended by removing the entry for ''Hops, cones, dried [1]'', and by alphabetically adding the following commodities to the table in paragraph (a)(1) to read as follows:

§ 180.493 Dimethomorph; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
* * * *	*
Hop, dried cones	60
* * * *	*
Lettuce, head	10
Lettuce, leaf	10
* * * *	*
Vegetable, bulb, group	2.0
Vegetable, cucurbit, group	0.5

* * * * *

[FR Doc. 02–24485 Filed 9–26–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0195; FRL–7199–5]

Spinosad; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spinosad in or on fig at 0.10 part per million (ppm); herb, fresh, subgroup at 3.0 ppm; herb, dried, subgroup at 22 ppm; vegetable, root and tuber, group at 0.10 ppm; caneberry subgroup at 0.70 ppm; grape at 0.50 ppm; grape, raisin at 0.70 ppm; peanut at 0.02 ppm; and beet, sugar, molasses at 0.75 ppm. This regulation also increases established tolerances for cattle, meat to 0.50 ppm; cattle, meat byproducts to 2.0 ppm; cattle, fat to 6.5 ppm; milk to 2.5 ppm; and milk, fat to 27 ppm. The Interregional Research Project Number 4 (IR-4) and Elanco Animal Health, A Division of Eli Lily and Company, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation is effective September 27, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0195, must be received on or before November 26, 2002.

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**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0195 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; 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 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 codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing 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 under **FOR FURTHER INFORMATION CONTACT**.

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,'' ''Regulations and Proposed Rules,'' 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/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html,* a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

2. *In person*. The Agency has established an official record for this action under docket ID number OPP–2002–0195. 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 May 3, 2000, 65 FR 2572, FRL–6555–9 and August 21, 2002, 67 FR 54200, (FRL–7191–6), EPA issued notices pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of pesticide petition (PP 0F6115) by Elanco Animal Health, a Division of Eli Lilly and Company, 2001 W. Main St., Greenfield, IN 46140, and (PP 1E6321, 2E6354, 2E6370, 2E6384, 2E6400, and 2E6422) by the Interregional Research Project Number 4 (IR–4), 681 U.S. Highway #1, South, North Brunswick, NJ 08902–3390. These notices included summaries of the petitions prepared by Dow AgroScience LLC, Indianapolis, IN 46268, the registrant. There were no comments received in response to the notices of filing.

The petitions requested that 40 CFR 180.495 be amended by establishing tolerances for residues of the insecticide spinosad, in or on food commodities as follows:

1. PP 1E6321 proposed establishment of a tolerance for fig at 0.1 ppm,

2. PP 2E6354 proposed establishment of a tolerance for herbs subgroup at 8.0 ppm. The petition was revised to propose tolerances for the herb, fresh, subgroup at 3.0 ppm; and the herb, dried, subgroup at 22 ppm.

3. PP 2E6384 proposed establishment of tolerances for root vegetable subgroup at 0.10 ppm, and dry bulb onion at 0.1 ppm. The petition was revised to propose a tolerance for the vegetable, root and tuber, group at 0.10 ppm; and a separate tolerance for beet, sugar, molasses at 0.75 ppm.

4. PP 2E6400 proposed establishment of a tolerance for caneberry subgroup at 0.7 ppm,

5. PP 2E6422 proposed establishment of tolerances for grape at 0.6 ppm, grape juice at 1.2 ppm, and raisin at 0.6 ppm. The petition was amended to propose tolerances for grape at 0.50 ppm; and grape, raisin at 0.70 ppm. The Agency determined that a tolerance for grape juice is not needed.

6. PP 2E6370 proposed establishment of a tolerance for peanut at 0.02 ppm,

7. PP 0F6115 proposed to increase the established tolerances for cattle meat, meat byproducts, fat, milk and milk fat. The increased tolerances are needed in support of proposed registration for direct application to beef and dairy cattle for insect control. Tolerances were proposed for cattle, meat at 0.45 ppm; cattle, meat byproducts at 2.25 ppm; cattle, fat at 5.75 ppm; milk at 0.75 ppm; and milk, fat at 8.0 ppm. The petition was subsequently revised to propose tolerances for cattle, meat at 0.50 ppm; cattle meat byproducts at 2.0 ppm; cattle, fat at 6.5 ppm; milk at 2.5 ppm; and milk, fat at 27 ppm.

Existing tolerances under § 180.495(a) for beet, garden, roots at 0.10 ppm, beet, sugar, roots at 0.10 ppm, and tuberous and corm vegetables (crop group 1C) at 0.02 ppm are no longer needed and will be removed. They are replaced with the new tolerance for vegetable, root and tuber, group at 0.10 ppm. Existing tolerances for section 18 emergency exemption under §180.495(b) for beet, sugar at 0.020 ppm; beet, sugar, molasses at 0.25 ppm; peanut at 0.02 ppm; milk, whole at 2.0 ppm and milk, fat at 20.0 ppm are also not needed and will be removed. Tolerances established by this regulation under §180.495 (a) for the vegetable, root and tuber, group at 0.10 ppm; beet, sugar, molasses at 0.75 ppm; peanut at 0.02 ppm; milk at 2.5 ppm; and milk, fat at 27 ppm obviate the need for these section 18 emergency exemptions.

Spinosad is a fermentation product of Saccharopolyspora spinosa. The product consists of two related active ingredients: Spinosyn A (Factor A; CAS No. 131929–60–7) or 2-[(6-deoxy-2,3,4-tri-O-methyl-″N-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 No. 131929–63–0) or 2-[(6-deoxy-2,3,4-tri-O-methyl-″N-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.

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 fig at 0.10 ppm; herb, fresh, subgroup at 3.0 ppm; herb, dried, subgroup at 22 ppm; vegetable, root and tuber, group at 0.10 ppm; caneberry subgroup at 0.7 0 ppm; grape at 0.50 ppm; grape, raisin at 0.70 ppm; peanut at 0.02 ppm; beet, sugar, molasses at 0.75 ppm; cattle, meat at 0.50 ppm; cattle, meat byproducts at 2.0 ppm; cattle, fat at 6.5 ppm; milk at 2.5 ppm and milk, fat at 27 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by spinosad are discussed in the following Table 1 as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity rodents—mouse	NOAEL = 7.5 mg/kg/day in males and females. LOAEL = 22.5 mg/kg/day in males and females; based on cytoplasmic vacuolation of lymphoid organs, liver, kidney, stomach, female reproductive tract, and epididymis. Other tissues less severely affected are heart, lung, pancreas, adrenal cortex, bone marrow, tongue, and pituitary gland.
870.3100	90-Day oral toxicity rodents—rat	NOAEL = 33.9 mg/kg/day in males; 38.8 mg/kg/day in females LOAEL = 68.5 mg/kg/day in males; 78.1 mg/kg/day in females based on adrenal cortical vacuolation in males, lymph node histiocytosis in both sexes.
870.3100	90-Day oral toxicity rodents—rat	NOAEL = 42.7 mg/kg/day in males; 52.1 mg/kg/day in females, highest dose tested (HDT). LOAEL = Not observed in males and females.
870.3150	90-Day oral toxicity nonrodents—dog	NOAEL = 4.89 mg/kg/day in males; 5.38 mg/kg/day in females LOAEL = 9.73 mg/kg/day in males; 10.47 mg/kg/day in females based on microscopic changes in a variety of tissues, clinical signs of toxicity, decreases in mean body weights and food consumption and biochemical evidence of anemia and possible liver damage.
870.3200	Repeated dose dermal toxicity—rabbit (21 days)	NOAEL = 1,000 mg/kg/day in males and females (HDT). LOAEL = Not observed.
870.3700	Prenatal developmental in rodents—rat	Maternal NOAEL = 200 mg/kg/day (HDT). LOAEL = Not observed. Developmental NOAEL = 200 mg/kg/day (HDT). LOAEL = Not observed.
870.3700	Prenatal developmental in nonrodents—rabbit	Maternal NOAEL = 50 mg/kg/day (HDT). LOAEL = Not observed. Developmental NOAEL = 50 mg/kg/day (HDT). LOAEL = Not observed.
870.3800	Reproduction and fertility effects—rat	Parental/systemic NOAEL = 10 mg/kg/day . LOAEL = 100 mg/kg/day based on increases in heart, kidney, liver, spleen, and thyroid weights (both sexes), corroborative histopathology in the spleen and thyroid (both sexes), heart and kidney (males only), and histopathologic lesions in the lungs and mesenteric lymph nodes (both sexes), stomach (females only), and prostate. Reproductive NOAEL = 10 mg/kg/day. LOAEL = 100 mg/kg/day based on increased incidence of dystocia and/or vaginal bleeding after parturition with associated increases in mortality in the dams. Offspring NOAEL = 10 mg/kg/day. LOAEL = 100 mg/kg/day based on decreases in litter size, survival and body weights.
870.4100	Chronic toxicity—dog	NOAEL = 2.68 mg/kg/day in males, 2.72 mg/kg/day in females. LOAEL = 8.46 mg/kg/day in males; 8.22 mg/kg/day in females based on increases in serum alanine aminotransferase, aspartate aminotransferase, and triglycerides levels, and the presence of tissue abnormalities, including vacuolated cell aggregations, arteritis, and glandular cell vacuolation (parathyroid).

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.4200	Carcinogenicity— mouse	NOAEL = 11.4 mg/kg/day in males, 13.8 mg/kg/day in females. LOAEL = 50.9 mg/kg/day in males; 67.0 mg/kg/day in females based on decreased weight gains, increased mortality, the hematologic effects, and the gross finding of increased thickening of the gastric mucosa in females and the histologic changes in the stomach of males. No evidence of carcinogenicity.
870.4200	Carcinogenicity—mouse	NOAEL not established. LOAEL = 1.1 mg/kg/day in males; 1.3 mg/kg/day in females. No evidence of carcinogenicity.
870.4300	Chronic/carcinogenicity—rat	NOAEL = 9.5 mg/kg/day in males, 12.0 mg/kg/day in females. LOAEL = 24.1 mg/kg/day in males; 30.3 mg/kg/day in females based on vacuolation of the epithelial follicular cells of the thyroid in both sexes. No evidence of carcinogenicity.
870.5300	Mouse lymphoma cell/ mammalian activation gene forward mutation assay	In a forward mutation assay using mouse lymphoma cells, spinosad did not induce forward mutations in mouse lymphoma L5178Y Tk+/- cells at concentrations of 0, 1, 5, 10, 15, 20, or 35 μg/ml without metabolic activation or at concentrations of 15 through 50 μg/ml with metabolic activation.
870.5375	*In vitro* mammalian cytogenetic assay	In a chromosomal aberrations assay, spinosad did not increase the number of Chinese hamster ovary (CHO) cells with chromosome aberrations at concentrations of 20, 26, or 35 μg/ml without metabolic activation or at concentrations of 100, 250, or 500 μg/ml with metabolic activation.
870.5385	Micronucleus assay	In a mouse micronucleus test, spinosad did not increase the frequency of micronuclei in replicate assays with bone marrow cells from ICR mice treated with doses of 0, 500, 1,000, or 2,000 mg/kg/day for 2 consecutive days.
870.5550	Unscheduled DNA Synthesis	In the unscheduled DNA synthesis assay using primary rat hepatocytes, Spinosad did not induce unscheduled DNA synthesis (UDS) in adult rat hepatocytes *in vitro* at concentrations of 0.01 to 5 μg/ml. Concentrations from 10 to 1,000 μg/ml of XDE-105 were cytotoxic.
870.6200	Acute neurotoxicity–rat	NOAEL = 2,000 mg/kg in males and females (HDT). LOAEL = Not established in both sexes.
870.6200	Repeat dose neurotoxicity—rat	NOAEL = 42.7 mg/kg/day in males; 52.1 mg/kg /day in females (HDT). LOAEL = Not established in both sexes.
870.6200	Repeat dose neurotoxicity—rat	NOAEL = 46.0 mg/kg/day in males; 57.0 mg/kg/day in females (HDT). LOAEL = Not established in both sexes.
870.7485	Metabolism and pharmacokinetics—rat	At high (100 mg/kg) and single or multiple low (10 mg/kg) doses, there are no major differences in the bioavailability, routes or rates of excretion or metabolism of ^{14}C–XDE–105 (Factor A) following oral administration. The feces were the major route of excretion (82 to 87% of the doses at 168 hours after dosing), and ~7–10% of the dose was excreted in the urine. Approximately 70–80% of the dose was absorbed with ~20% of the dose eliminated unabsorbed in the feces. Blood levels of ^{14}C after the single and multiple 10 mg/kg doses were highest at 1 hour in both sexes. At 168 hour after administration of the low dose, the kidney, liver and fat of males and females had higher levels than other tissues. In the high dose group however, the adrenals (females only), kidney, lymph nodes, fat, and thyroids had higher levels than other tissues. The total radioactivity remaining in the tissues and carcass of the low and high dose animals was <0.6% and <3% of the administered dose, respectively. The primary metabolites excreted were identified as the glutathione conjugates of the parent and O-demethylated XDE-105 (Factor A). Metabolites in the tissues were characterized as the — and O-demethylated (Factor A). The absorption, disposition, and elimination of ^{14}C–XDE–105 (Factor A) demonstrated no appreciable differences based on, dose or repeated dosing.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.7485	Metabolism and pharmacokinetics—rat	Results of these experiments indicated that at 100 mg/kg dose, the feces were the major route of excretion (84 to 92% of the dose at 168 hours after dosing), and 3–5% of the dose was excreted in the urine. Greater than 68% of the administered radioactivity was recovered in the feces within the first 24 hours following dosing. The excretion kinetics was biphasic with the ″ and β excretion halftimes ($t_{\frac{1}{2}}$) of approximately 6 and 30 hours, respectively. The primary metabolites excreted were identified as the glutathione conjugates of the parent and O-demethylated XDE-105 (Factor D). Metabolites in the tissues were characterized as the — and O-demethylated (Factor D). The absorption, disposition, and elimination of ^{14}C–XDE–105 (Factor D) demonstrated no appreciable differences based on, dose or repeated dosing.
870.7485	Metabolism and pharmacokinetics—rat	The feces contained from 23 to 55% of the dose (an average of 34%), and the bile had an average of approximately 36% (range of 28 to 40%) of the administered radioactivity. Approximately 21% of the dose was found in the tissues and carcass (range of 12 to 26%). The urine and CO_2 accounted for 3.3 and <0.1% of the dose. The bile excretion rate results suggested an uptake phase for the first 4 hour after dosing which preceded a biphasic decrease in the biliary excretion rate. The maximum rate of bile excretion was −644 :g equivalents per hour at 2–4 hour; then the rate decreased to −123 :g equivalents per hour at the 12–24 hour interval. The results of the study suggested that metabolites in the bile included the glutathione conjugates of the unchanged form, as well as — and O-demethylated forms of XDE–105 (Factor D).

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 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 intra species differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, 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 FQPA 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 is expressed as 1×10^{-6} or one in a million). 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 shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR SPINOSAD FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary	Not applicable	Not applicable	There were no effects observed in oral toxicity studies including oral developmental toxicity studies in rats and rabbits that could be attributable to a single dose (exposure). Therefore, a dose and endpoint were not selected for this risk assessment.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR SPINOSAD FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Chronic Dietary all populations	NOAEL = 2.7 mg/kg/day UF = 100 Chronic RfD = 0.027 mg/kg/day	FQPA SF = 1x cPAD = chronic RfD FQPA SF= 0.027 mg/kg/day	Chronic Toxicity Study in Dogs LOAEL = 8.22 mg/kg/day based on the occurrence of vacuolation in glandular cells (parathyroid) and lymphatic tissues, arteritis, and increases in serum alanine aminotranferase, and aspartate aminotransferase, and triglyceride levels.
Incidental Oral (Short-Term, 1 to 30 days)(Residential)	NOAEL = 4.9 mg/kg/day	FQPA SF = 1x LOC for MOE = 100	Subchronic Feeding Study in Dogs LOAEL = 9.73 mg/kg/day based on microscopic changes in multiple organs, clinical signs of toxicity, decreases in mean body weights and food consumption and biochemical evidence of anemia and possible liver damage.
Incidential Oral (Intermediate-Term, 1 to 6 months)(Residential)	NOAEL = 2.7 mg/kg/day	FQPA SF = 1x LOC for MOE = 100	Chronic Toxicity Study in Dogs LOAEL = 8.22 mg/kg/day based on vacuolation in glandular cells (parathyroid) and lymphatic tissues, arteritis, and increases in serum alanine aminotransferase, aspartate aminotransferase, and triglyceride levels.
Dermal (Any time period) (Residential)	Not applicable.	Not applicable.	Short-, Intermediate-, and Long-Term dermal risk assessments were not performed because: (1) Lack of concern for pre and/or post natal toxicity; (2) the combination of molecular structure and size as well as the lack of dermal or systemic toxicity at 1000 mg/kg/day in a 21-day dermal toxicity study in rats which indicates poor dermal absorption; and (3) the lack of long-term exposure based on the current use pattern.
Inhalation (Short-Term, 1-30 days) (Residential)	Oral NOAEL = 4.9 mg/kg/day (absorption = 100%)	FQPA SF = 1x LOC for MOE = 100	Subchronic Feeding Study in Dogs LOAEL = 9.73 mg/kg/day based on microscopic changes in a multiple organs, clinical signs of toxicity, decreases in mean body weights and food consumption and biochemical evidence of anemia and possible liver damage.
Inhalation (Intermediate-Term, 1-6 months)(Residential)	Oral NOAEL = 2.7 mg/kg/day (absorption = 100%)	FQPA SF = 1x LOC for MOE = 100	Chronic Toxicity Study in Dogs LOAEL = 8.22 mg/kg/day based on vacuolation in glandular cells (parathyroid) and lymphatic tissues, arteritis, and increases in serum alanine aminotransferase, aspartate aminotransferase, and triglyceride levels.
Inhalation (Long-Term, >6 months) (Residential)	Oral NOAEL = 2.7 mg/kg/day (absorption = 100%)	FQPA SF = 1x LOC for MOE = 100	Chronic Toxicity Study in Dogs LOAEL = 8.22 mg/kg/day based on vacuolation in glandular cells (parathyroid) and lymphatic tissues, arteritis, and increases in serum alanine aminotransferase, aspartate aminotransferase, and triglyceride levels.
Cancer (oral, dermal, inhalation)	Not applicable.	Not applicable.	Spinosad is classified as a ''Not Likely'' carcinogen.

*The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

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 raw agricultural commodities. Spinosad is registered for use on a large number of agricultural commodities. Due to Section 18 emergency exemption use for control of Mediterranean fruit fly, tolerances for residues of spinosad have been established at 0.02 ppm for all agricultural commodities not covered by other pesticide tolerances. 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 one day or single exposure. An endpoint was not identified for acute dietary exposure and risk assessment because no effects were observed in oral toxicity studies including developmental toxicity studies in rats or rabbits that could be attributable to a single dose (exposure). Therefore, an acute dietary exposure assessment was not performed.

ii. *Chronic exposure.* Spinosad chronic dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model (DEEM™) software Version 7.76, which incorporates consumption data from USDA's 1989–1992– nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The chronic dietary (food only) analysis represents a moderately refined estimate of dietary exposure to spinosad due to the use of default

processing factors, percent crop treated estimates for commodities having previously registered uses, and anticipated residues for meat and milk.

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 cancer risk assessment was not performed.

iv. *Anticipated residue and percent crop treated information.* Section 408(b)(2)(E) 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), 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.

Section 408(b)(2)(F) 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 percent crop treated (PCT) as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used percent crop treated (PCT) information as follows:

Almond 5 %; apple 28%; apricot 5%; avocado 5%, bean, snap 9%; broccoli 62%; cabbage 32%; cauliflower 54%; celery 78%; collards 24%; cherry 5%; eggplant 14%; grapefruit 1%; grape, wine 1%; kale 32%; lemon 11%; lettuce, head 59%; Lettuce, other 42%; mustard greens 17%; orange 6%; peach 4%; pepper 45%; pistachio 1%; prune/plum 5%; spinach 32%; pumpkin 1%; squash 1%; sweet corn 1%; tangerine 6%; turnip, greens 6%; tomato, fresh 30%; tomato, processed 2%; watermelon 1%; cotton 3%; dry bean/pea 1%; peanut 1%; potato 1%; wheat, winter 1%.

The Agency believes that the three conditions listed in this Unit have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which spinosad may be applied in a particular area.

2. *Dietary exposure from drinking water.* Spinosad and its degradates are not very persistent and are relatively immobile. The potential for its residues to leach to groundwater and runoff to surface water is very low. Spinosad (containing Factors A and D) is expected to dissipate rapidly in the environment with a low potential to leach or runoff to surface water. Slow metabolic degradation was observed only in flooded sediment (half-lives 161–250 days in the laboratory, >25 days outdoors). Transformation products (Factor B and N-demethyl spinosad Factor D) are persistent (half-lives >6 months) in aerobic soil metabolism studies, but are relatively immobile.

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.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water.

DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to spinosad they are further discussed in the aggregate risk sections below.

Based on the First and SCI-GROW models the estimated environmental concentrations (EECs) of spinosad for chronic exposures is estimated to be 2.3 parts per billion (ppb) for surface water and 0.037 ppb for ground water. The EECs for spinosad are based on application of the insecticide to turf at a maximum of four applications at a rate of 0.41 pound active per acre per application.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Spinosad is currently registered for use on residential turf and ornamentals to control a variety of insect pests. The registered residential products for spinosad are Conserve SC Turf and Ornamental (EPA Reg No. 62719–291) and Conserve Fire Ant Bait (EPA Reg No. 62719–304).

Conserve Fire Ant Bait is a ready-to-use granular formulation that may be applied by homeowners. For adults, residential exposures may result from dermal and inhalation exposure while applying Conserve Fire Ant Bait and/or from dermal contact with treated turf. However, dermal post-application exposure is not of concern since no toxicological endpoint was established for dermal exposure. Inhalation exposure is not expected due to the low vapor pressure of spinosad and because the homeowner product is formulated as a granular. Post-application exposure to toddlers was not assessed for the Conserve Fire Ant Bait product since children are not likely to ''habit'' lawn areas where fire ant mounds are present.

Conserve SC is labeled for use on turfgrass and ornamentals by commercial applicators. Since this product will be applied by commercial applicators, homeowner applicator exposure was not assessed. For toddlers, dermal and non-dietary oral post-application exposures may result from dermal contact with treated turf as well as hand-to-mouth transfer of residues from turfgrass. Since dermal post-application exposure is not of concern, only hand-to-mouth, object-to-mouth and incidential ingestion of soil exposures for the turf and ornamental uses were performed. The average aerobic soil metabolism half-life of spinosad (containing factors A and D) is 13–14 days. For the intermediate-term duration, typical lawn maintenance practices, such as mowing and watering, are expected to expedite the dissipation of spinosad on turfgrass. Since residue on turf that is available for transfer after day 30 is expected to be negligible, intermediate-term post-application incidental oral exposures were not assessed.

The Agency developed exposure formulas and estimated doses to theoretically assess residential post-application incidental oral exposure scenarios including: (1) Hand-to-mouth, (2) object-to-mouth (turfgrass), and (3) incidental ingestion of soil. The resulting incidental oral ingestion MOEs from residential use of spinosad on turf are as follow:

- MOE for oral hand-to-mouth activities on treated lawns is 800 for short-term (1-30 days).
- MOE for oral object-to-mouth (turfgrass) from treated lawns is 3300 for short-term.
- MOE for incidental ingestion of soil from treated lawns is 240,000 for short-term.
- Combined Incidental Oral MOE (hand-to-mouth, object-to-mouth, and soil ingestion) is 640. All MOEs are below EPA's level of concern.

4. *Cumulative exposure to substances with a 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. Safety Factor for Infants and Children

1. *In general*. 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 prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure 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.

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

3. *Conclusion*. There is a complete toxicity data base for spinosad and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10x safety factor to protect infants and children should be removed. This recommendation is based on:

i. 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;

ii. 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 percent crop treated information (100% crop treated is assumed for proposed new uses) and,

iii. The dietary drinking water exposure is based on conservative modeling estimates,

iv. OPP's Health Effect Division Residential Standard Operating Procedures 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,

v. A developmental toxicity study is not required.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a

point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOCS values are not regulatory standards for drinking water. DWLOCs 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 DWLOCS, 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 DWLOCS.

A DWLOCS will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOCS is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP 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 change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

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 harm from acute aggregate exposure to spinosad.

2. *Chronic risk*. Using the exposure assumptions described in unit C for chronic exposure, EPA has concluded that exposure to spinosad from food will utilize 30% of the cPAD for the U.S. population, 41% of the cPAD for infant <1 year old and 69% of the cPAD for children 1-6 years old (subpopulation at greatest exposure). Based 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. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO SPINOSAD

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOCS (ppb)
U.S. Population	0.027	30	2.3	0.037	660
All infants (<1 year old)	0.027	41	2.3	0.037	160
Children 1-6 years old	0.027	69	2.3	0.037	85
Children 7-12	0.027	45	2.3	0.037	150
Female 13-50	0.027	24	2.3	0.037	620

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

Spinosad is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for spinosad.

Using the exposure assumptions described in unit C for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 600 for the U.S. Population, 260 for all infants <1 year old, 190 for children 1–6 years old (greatest risk subpopulation) and 250 for children 7–12 years old. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of spinosad in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO SPINOSAD

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOCS (ppb)
U. S. Population	600	100	2.3	0.037	1400
All infants <1 year old	260	100	2.3	0.037	300
Children 1-6 years old	190	100	2.3	0.037	230
Children 7-12 years old	250	100	2.3	0.037	290
Females 13-50 years	760	100	2.3	0.037	1300

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

Adequate 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, US 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: RAM Mailbox.

B. International Residue Limits

No Codex, Canadian, or Mexican maximum residue limits (MRLs) have been established for residues of spinosad on the caneberry subgroup, root and tuber vegetables, the herb subgroup, fig, grape, peanut, or livestock commodities.

V. Conclusion

Therefore, tolerances are established for residues of spinosad, in or on fig at 0.10 ppm; herbs, fresh, subgroup at 3.0 ppm; herbs, dried, subgroup at 22 ppm; vegetable, root and tuber, group at 0.10 ppm; caneberry subgroup at 0.70 ppm; grape at 0.50 ppm; grape, raisin at 0.70 ppm; peanut at 0.02 ppm; beet, sugar, molasses at 0.75 ppm; cattle, meat at 0.50 ppm; cattle, meat byproducts at 2.0 ppm; cattle, fat at 6.5 ppm, milk at 2.5; and milk, fat at 27 ppm.

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 ID number OPP–2002–0195 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 26, 2002.

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 (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

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.'' 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 by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., 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, 1200 Pennsylvania Ave., NW., 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., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket ID number OPP–2002–0195, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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 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 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 FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this 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 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. 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 FFDCA section 408(n)(4). 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. 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 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: September 23, 2002.

Peter Caulkins,

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), 346(a) and 371.

2. Section 180.495 is amended as follows:

a. In the table to paragraph (a) by alphabetically adding the entries for beet, sugar, molasses; caneberry subgroup; fig; grape; grape, raisin; herb, dried, subgroup; herb, fresh, subgroup; milk; peanut; vegetable, root and tuber, group;

b. By revising the entries for cattle, fat; cattle, meat; cattle, meat byproducts; and milk, fat; and

c. By removing the entries for beet, garden, roots; beet, sugar, roots; milk, whole; and tuberous and corm vegetables (crop subgroup 1C).

d. In the table to paragraph (b) by removing the entries for beet, sugar; beet, sugar, molasses; milk, whole; milk, fat; and peanut.

§180.495 Spinosad; tolerances for residues.

(a) * * *

Commodity	Parts per million	Expiration/ Revocation Date
* *	*	* *
Beet, sugar, molasses	0.75	None
* *	*	* *
Caneberry subgroup	0.70	None
* *	*	* *
Cattle, fat	6.5	None
Cattle, meat	0.50	None
Cattle, meat byproducts	2.0	None
* *	*	* *
Fig	0.10	None
* *	*	* *
Grape	0.50	None
Grape, raisin	0.70	None
* *	*	* *
Herb, dried, subgroup	22	None
Herb, fresh, subgroup	3.0	None
* *	*	* *
Milk	2.5	None
Milk, fat	27	None
* *	*	* *
Peanut	0.02	None
* *	*	* *
Vegetable, root and tuber, group	0.10	None
* *	*	* *

* * * * *

[FR Doc. 02–24484 Filed 9–26–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0232; FRL–7200–2]

Glyphosate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of glyphosate in or on animal feed, nongrass group; grass, forage, fodder and hay, group and adds the potassium salt of glyphosate to the tolerance expression. Monsanto Company 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 27, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0232, must be received on or before November 26, 2002.

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**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0232 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Tompkins (PM 25), Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5697; e-mail address: *Tompkins.Jim@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 codes	Examples of potentially affected entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	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 under **FOR FURTHER INFORMATION CONTACT**.

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 homp page at *http://www.epa.gov/*. To access this document, on the home page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' 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/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

2. *In person*. The Agency has established an official record for this action under docket ID number OPP–2002–0232. 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

In the **Federal Register** of April 17, 2002 (FR 67 18894) (FRL–6830–5), 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) (Public Law 104–170), announcing the filing of pesticide petitions (PP 0F06130, 0F06195, and 0F06273) by Monsanto, 600 13th St., NW., Suite 660, Washington, DC 20005.