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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301097; FRL–6760–2]

RIN 2070–6760–2

Spinosad; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of spinosad in or on alfalfa forage, alfalfa hay, sugar beets, sugar beet tops, sugar beet molasses, grass forage, grass hay, peanuts, and peanut hay and, modifies tolerances for livestock commodities on a time-limited basis. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on alfalfa, sugar beets, pastureland and rangeland, and peanuts. This regulation establishes maximum permissible levels for residues of spinosad on these food commodities. These tolerances will expire and are revoked on December 31, 2002.

DATES: This regulation is effective January 9, 2001. Objections and requests for hearings, identified by docket control number OPP–301097, must be received by EPA on or before March 12, 2001.

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 VII. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301097 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number:(703)308-9367; and e-mail address: ertman.andrew@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS	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 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/. 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 control number OPP–301097. 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, 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

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for residues of the insecticide spinosad, in or on the following commodities: alfalfa, forage at 4.0 parts per million (ppm); alfalfa, hay at 4.0 ppm; beet, sugar at 0.020 ppm; beet, sugar, tops at 10.0 ppm; beet, sugar, molasses at 0.250 ppm; grass, forage at 7.0 ppm; grass, hay at 7.0 ppm; peanut at 0.020 ppm; and peanut, hay at 10.0 ppm.

Furthermore, tolerances for livestock commodities are being modified, on a time-limited basis, as follows: meat of cattle, horses, goats, hogs, and sheep from 0.15 to 0.60 ppm; fat of cattle, horses, goats, hogs, and sheep from 3.5 to 15.0 ppm; meat byproducts (mbyp) of cattle, horses, goats, hogs, and sheep from 1.0 ppm to 3.50 ppm; milk, whole from 0.5 to 2.0 ppm; milk, fat from 5.0 ppm to 20.0 ppm; eggs from 0.02 to 0.030 ppm; and poultry, fat from 0.2 ppm to 0.30 ppm. These tolerances will expire and are revoked on December 31, 2002. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of Federal Insecticide, Fungicide, and Rodenticide Act FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having

received any petition from an outside party.

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. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the Food Quality Protection Act (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Spinosad on Alfalfa, Pastureland and Rangeland, Peanuts, and Sugarbeets and FFDCA Tolerances

The states of Texas, New Mexico, Kansas and Oklahoma all requested the use of spinosad to control an emergency situation with the beet armyworm on alfalfa. The states of Texas and New Mexico requested the use of spinosad to control an emergency situation with the beet armyworm in peanuts. The state of California requested the use of spinosad on sugar beets to control armyworms, and the state of Arkansas requested the use of spinosad to control armyworms in pastureland and rangeland. EPA has authorized under FIFRA section 18 the use of spinosad on alfalfa in Texas, New Mexico, Kansas, and Oklahoma to control the beet armyworm; on peanuts in Texas and in New Mexico to control the beet armyworm; on sugar beets in California to control armyworms; and on pastureland and rangeland in Arkansas for control of armyworms. After having reviewed the submissions, EPA concurs that emergency conditions exist for these states.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of spinosad in or on alfalfa, peanuts, sugar beets and pastureland and rangeland. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemptions in order to address urgent non-routine situations and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6). Although these tolerances will expire and are revoked on December 31, 2002, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on alfalfa forage, alfalfa hay, sugar beets, sugar beet tops, sugar beet molasses, grass forage, grass hay, peanuts, peanut hay and the modified livestock commodity tolerances after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether spinosad meets EPA's registration requirements for use on many or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of spinosad by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any States other than Texas, New Mexico, Kansas and Oklahoma for alfalfa; Texas and New Mexico for peanuts; California for sugarbeets; or Arkansas for pastureland and rangeland to use this pesticide on these crops under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for spinosad, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

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).

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 spinosad and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for residues of spinosad in or on alfalfa, forage at 4.0 ppm; alfalfa, hay at 4.0 ppm; beet, sugar at 0.020 ppm; beet, sugar, tops at 10.0 ppm; beet, sugar, molasses at 0.250 ppm; grass, forage at 7.0 ppm; grass, hay at 7.0 ppm; peanut at 0.020 ppm; and peanut, hay at 10.0 ppm, as well as the modified tolerances for livestock commodities as follows: meat of cattle, horses, goats, hogs, and sheep from 0.15 to 0.60 ppm; fat of cattle, horses, goats, hogs, and sheep from 3.5 to 15.0 ppm; meat byproducts of cattle, horses, goats, hogs, and sheep from 1.0 ppm to 3.50 ppm; milk, whole from 0.5 to 2.0 ppm; milk, fat from 5.0 ppm to 20.0 ppm; eggs from 0.02 to 0.03 ppm; and poultry, fat from 0.2 ppm to 0.30 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

A. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for 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 level of concern (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 1:

TABLE 1.—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 females 13–50 years of age	N/A	N/A	No appropriate endpoint available; risk assessment not required
Acute Dietary general population including infants and children	N/A	N/A	No appropriate endpoint available; risk assessment not required
Chronic Dietary all populations	NOAEL = 2.68 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 - Dog LOAEL = 8.22 mg/kg/day based on vacuolation in glandular cells (parathyroid) and lymphatic tissues, arteritis and increases in serum enzymes such as alanine aminotransferase, and aspartate aminotransferase, and triglyceride levels
Short-Term Dermal (1 to 7 days) (Residential)	N/A	N/A	No appropriate endpoint available. No dermal absorption expected based on lack of toxicity at 1000 mg/kg/day in a 21–day dermal toxicity study in rats as well as molecular structure and size.
Intermediate-Term Dermal (1 week to several months) (Residential)	N/A	N/A	No appropriate endpoint available. No dermal absorption expected based on lack of toxicity at 1000 mg/kg/day in a 21–day dermal toxicity study in rats as well as molecular structure and size.
Long-Term Dermal (several months to lifetime) (Residential)	N/A	N/A	No appropriate endpoint available; use pattern does not indicate a need for this risk assessment
Short-Term Inhalation (1 to 7 days) (Residential)	N/A	N/A	The low toxicity, use pattern and application rate does not indicate a need for risk assessment via this route.
Intermediate-Term Inhalation (1 week to several months) (Residential)	N/A	N/A	The low toxicity, use pattern and application rate does not indicate a need for risk assessment via this route.
Long-Term Inhalation (several months to lifetime) (Residential)	N/A	N/A	The low toxicity, use pattern and application rate does not indicate a need for risk assessment via this route.
Cancer (oral, dermal, inhalation)	N/A	N/A	No cancer endpoints were identified, and thus a cancer risk assessment is not required.

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

B. 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. Tolerances range from 0.02 ppm (many commodities; limit of quantitation) to 20 ppm (aspirated grain fractions). 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 acute dietary exposure risk assessment is not required because the Agency did not identify an acute dietary endpoint that was applicable to females (13+ years) or to the general population, including infants and children.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. Tolerance level residues were used for all commodities with the exception of the following: anticipated residues were used for the livestock feed commodities from alfalfa, peanuts, pastures and rangeland, and sugar beets. This Tier 2 DEEM analysis shows that dietary (food only) exposure estimates are below the Agency's level of concern for all population subgroups. The highest chronic dietary exposure was for children 1-6 years old at 0.015291 mg/kg/day, representing 57% of the chronic PAD (cPAD). Exposure for the U.S. population was 0.007679 mg/kg/day, representing 28% of the cPAD.

iii. *Cancer*. No cancer endpoints were identified, and thus a cancer risk assessment is not required.

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.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for spinosad in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of spinosad.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. 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 coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever 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 PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of spinosad for chronic exposures are estimated to be 0.057 parts per billion (ppb) for surface water and 0.006 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

No acute dietary, cancer, short-term, intermediate-term, or chronic dermal or inhalation endpoints were identified by the Agency. Spinosad is currently 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), the Agency 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, the Agency believes that residues of spinosad on turf grass after application would be low and decrease rapidly over time. The Agency believes that it is inappropriate to perform a quantitative dietary risk representing a chronic scenario from children eating spinosad residues on turf grass. Qualitatively, the risk from children eating spinosad residues on turf grass does not exceed the Agency'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).

C. 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. *Developmental toxicity studies*. There were no developmental effects that could be attributed to administration of spinosad technical to either rats or rabbits. The NOAEL for developmental toxicity is greater than or equal to 200 mg/kg/day (highest dose tested) for rats and greater than or equal to 50 mg/kg/day (highest dose tested) for rabbits.

3. *Reproductive toxicity study*. The LOAEL for reproductive toxicity is 100 mg/kg/day based on both maternal and reproductive effects in rats including decreases in litter size, survival (F2 litters only), and body weights in the offspring, and increased incidence of dystocia and/or vaginal bleeding after parturition with associated increases in mortality in the dams. The NOAEL for reproductive (offspring and dams) and systemic (parental) toxicity is the same and is 10 mg/kg/day.

4. *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. The Agency has removed the 10x Safety Factor to account for enhanced sensitivity of infants and children based on (i) the completeness of the toxicological database, (ii) no indication of increased susceptibility of rat or rabbit fetuses to *in utero* and/or postnatal exposure, and (iii) no requirement for a developmental neurotoxicity study.

D. 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). DWLOC 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 DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + chronic non-dietary, non-occupational exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the 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 DWLOC 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 spinosad 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 spinosad on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. No acute toxicological endpoint was identified by the Agency, and therefore this risk assessment is not required.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to spinosad from food will utilize 28% of the cPAD for the U.S. population, 25% of the cPAD for all infants and 57% of the cPAD for children 1-6 years of age. Although spinosad is currently registered on turf grass, creating a potential for non-dietary oral exposure to children who ingest grass, the Agency believes that it is inappropriate to perform a quantitative dietary risk representing a chronic scenario from children eating spinosad residues on turf grass. Qualitatively, the risk from children eating spinosad residues on turf grass does not exceed the Agency's level of concern. In addition, despite the potential for chronic dietary exposure to spinosad in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of spinosad in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 2:

TABLE 2.—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 DWLOC (ppb)
U.S. Population	0.027	28	0.057	0.006	680
All Infants	0.027	25	0.057	0.006	200
Children 1-6 years of age	0.027	57	0.057	0.006	120
Children 7-12 years of age	0.027	40	0.057	0.006	160
Females 13-50 years of age	0.027	24	0.057	0.006	610

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO SPINOSAD—Continued

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
Males 13-19 years of age	0.027	26	0.057	0.006	700
Males 20+ years of age	0.027	23	0.057	0.006	730
Seniors 55+ years of age	0.027	24	0.057	0.006	720

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).

Though residential exposure could occur with the use of spinosad, no toxicological effects have been identified for short-term toxicity. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level).

Though residential exposure could occur with the use of spinosad, no toxicological effects have been identified for intermediate-term toxicity. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

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.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate high performance liquid chromatography using ultra violet detection and immunoassay methods exist to enforce tolerances for residues of spinosad in/on plant and animal matrices. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue levels (MRLs) established for spinosad. There are no international residue limits that affect this Section 18 exemption.

VI. Conclusion

Therefore, the tolerance is established for residues of spinosad in or on alfalfa, forage at 4.0 ppm; alfalfa, hay at 4.0 ppm; beet, sugar at 0.020 ppm; beet, sugar, tops at 10.0 ppm; beet, sugar, molasses at 0.250 ppm; grass, forage at 7.0 ppm; grass, hay at 7.0 ppm; peanut at 0.020 ppm; and peanut, hay at 10.0 ppm. Furthermore, tolerances for livestock commodities are being modified, on a time-limited basis, as follows: meat of cattle, horses, goats, hogs, and sheep from 0.15 to 0.60 ppm; fat of cattle, horses, goats, hogs, and sheep from 3.5 to 15.0 ppm; meat byproducts of cattle, horses, goats, hogs, and sheep from 1.0 ppm to 3.50 ppm; milk, whole from 0.5 to 2.0 ppm; milk, fat from 5.0 ppm to 20.0 ppm; eggs from 0.02 to 0.03 ppm; and poultry, fat from 0.2 ppm to 0.30 ppm.

VII. 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–301097 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 March 12, 2001.

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, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, 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.'' 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 VII.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 the docket control number OPP–301097 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).

VIII. Regulatory Assessment Requirements

This final rule establishes time limited tolerances under FFDCA section 408. 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) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by 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 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 FIFRA section 18 exemption under FFDCA section 408, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. 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).

IX. 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: December 21, 2000.

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), 346(a) and 371.

2. Section 180.495 is amended by alphabetically adding commodities to the table in paragraph (b) to read as follows:

§ 180.495 Spinosad; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ revocation date
Alfalfa, forage	4.0	12/31/02
Alfalfa, hay	4.0	12/31/02
* *	*	* *
Beet, sugar	0.020	12/31/02
Beet, sugar, tops	10.0	12/31/02
Beet, sugar, molasses	0.250	12/31/02
Cattle, fat	15.0	12/31/02
Cattle, mbyp	3.50	12/31/02
Cattle, meat	0.60	12/31/02
* *	*	* *
Eggs	0.030	12/31/02
Goats, fat	15.0	12/31/02
Goats, mbyp	3.50	12/31/02
Goats, meat	0.60	12/31/02
Grass, forage	7.0	12/31/02
Grass, hay	7.0	12/31/02
Hogs, fat	15.0	12/31/02
Hogs, mbyp	3.50	12/31/02
Hogs, meat	0.60	12/31/02
Horses, fat	15.0	12/31/02
Horses, mbyp	3.50	12/31/02
Horses, meat	0.60	12/31/02
Milk, fat	20.0	12/31/02
Milk, whole	2.0	12/31/02
Peanut	0.020	12/31/02
Peanut, hay	10.0	12/31/02
Poultry, fat	0.30	12/31/02
Sheep, fat	15.0	12/31/02
Sheep, mbyp	3.50	12/31/02
Sheep, meat	0.60	12/31/02

* * * * *

[FR Doc. 01–119 Filed 1–8–01; 8:45am]

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 413 and 489

[HCFA–1005–F3]

RIN 0938–AI56

Medicare Program; Prospective Payment System for Hospital Outpatient Services; Correction

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Correcting amendments.

SUMMARY: In the April 7, 2000 issue of the **Federal Register** (65 FR 18434), we published a final rule with a comment period that implemented a prospective payment system for hospital outpatient services furnished to Medicare beneficiaries. In addition, the final rule established requirements and standards for facilities or organizations seeking provider-based status. This document corrects technical errors in the preamble and regulations text made in that part of the final rule related to provider-based requirements. (A document published in the **Federal Register** on October 3, 2000 (65 FR 58919) delayed the effective date of the provider-based regulations from October 10, 2000 to January 10, 2001 and made a conforming change in the regulations text.)

EFFECTIVE DATE: January 10, 2001.

FOR FURTHER INFORMATION CONTACT: Linda McKenna, (410) 786–4537.

SUPPLEMENTARY INFORMATION: In FR Doc. 00–8215 of April 7, 2000 (65 FR 18434), there were several typographical errors. The provisions in this document are effective as if they had been included in the document published in the **Federal Register** on April 7, 2000.

Correction of Errors

In FR Doc. 00–8215 on April 7, 2000 (65 FR 18434), make the following corrections:

Corrections to the Preamble

On page 18434, column 1, in the **DATES** section, ''§ 412.24(d)(6)'' is corrected to read ''§ 413.24(d)(6)'', ''§ 489.24(h)'' is corrected to read ''§ 489.24''.

Corrections to the Regulations Text

List of Subjects

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

Accordingly, 42 CFR parts 413 and 489 are corrected by making the following correcting amendments:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

1. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395f(b), 1395g, 13951, 13951(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww).

§ 413.65 [Corrected]

2. In § 413.65, the following corrections are made:

A. In paragraph (d)(7)(iii), the reference to paragraph ''(d)(7)'' is corrected to read ''(d)(7)(i)''.

B. In paragraph (f)(3), the reference to paragraph ''(b)(3)(ii)'' is corrected to read ''(d)(3)(ii)''.

C. In paragraph (j)(3), the reference to paragraph ''(h)'' is corrected to read ''(i)''.

D. In paragraph (j)(4), the reference to paragraph ''(i)(5)'' is corrected to read ''(j)(5)''.

E. In paragraph (j)(5), in the second sentence, the reference to paragraph ''(i)(5)'' is corrected to read ''(j)(5)''.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

1. The authority citation for part 489 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 489.24 [Corrected]

2. In § 489.24, in paragraph (i), the reference to ''§ 416.35'' is corrected to read ''§ 413.65''.

Authority: Section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)).

(Catalog of Federal Domestic Assistance Program No. 93.774; Medicare—Supplementary Medical Insurance Program)

Dated: December 18, 2000.

Brian P. Burns,

Deputy Assistant Secretary for Information Resources Management.

[FR Doc. 01–654 Filed 1–8–01; 8:45 am]

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