For the reasons set out in this document, the Postal Service is amending 39 CFR part 501 as follows:

PART 501—AUTHORIZATION TO MANUFACTURE AND DISTRIBUTE POSTAGE METERS

■ 1. The authority citation for part 501 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 404, 410, 2601, 2605; Inspector General Act of 1978, as amended (Pub. L. 95–452, as amended); 5 U.S.C. App. 3.

■ 2. Revise current § 501.13 title to read ''Reporting and Communications'' and add new paragraph (e) to read as follows:

§ 501.13 Reporting and Communications.

* * * * *

(e) Authorized postage meter manufacturers and distributors, and their agents and employees, must not intentionally misrepresent to customers of the Postal Service decisions, actions, or proposed actions of the Postal Service respecting its regulation of postage meters in the United States. The Postal Service reserves the right to suspend and/or revoke the authorization to manufacture and/or distribute postage meters throughout the United States or in any part thereof under § 501.5 when the manufacturer, distributor, or agent or employee of either fails to comply with this requirement.

Neva Watson,

Attorney, Legislative.

[FR Doc. 05–279 Filed 1–6–05; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0042; FRL–7691–4]

Spinosad; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of spinosad in or on grain, cereal, group 15 at 1.5 ppm; grain as aspirated fractions at 200 ppm; rice hulls at 4 ppm; meat of cattle, goats, hogs, horse and sheep at 1.5 ppm; fat of cattle, goats, hogs, horse and sheep at 33 ppm; meat byproducts of cattle, goats, hogs, horse and sheep at 8 ppm; milk at 6 ppm; milk fat at 75 ppm; fat of poultry at 0.5 ppm; meat byproducts of poultry at 0.03 ppm; eggs at 0.05 ppm. EPA is also deleting certain spinosad tolerances that are no longer needed as a result of this action. Dow AgroScience requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective January 7, 2005. Objections and requests for hearings must be received on or before March 8, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0042. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: George LaRocca, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 308–8587; e-mail address: *larocca.george@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

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

II. Background and Statutory Findings

In the **Federal Register** of June 23, 2004 (69 FR 35024) (FRL–7358–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition PP 3F6754 by Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The petition requested that 40 CFR 180.495 be amended by establishing a tolerance for residues of the insecticide spinosad, in or on the raw agricultural commodity stored grain (wheat, barley, corn, oats, rice, and sorghum milo) at 1 ppm , soybean, sunflower, peanut, and cotton seed at 1 part per million (ppm); and birdseed at 3 ppm. That notice included a summary of the petition prepared by DowAgroScience LLC, the registrant.

Based on EPA's review, the petition described in Unit II. was revised by the petitioner (Dow AgroSciences) to propose tolerances for residues of spinosad for cereal grains group at 1.5 ppm; grain as aspirated fractions at 200 ppm; rice hulls at 4 ppm; meat of cattle, goats, hogs, horse and sheep at 1.5 ppm; fat of cattle, goats, hogs, horse and sheep at 33 ppm; meat byproducts of cattle, goats, hogs, horse and sheep at 8 ppm; milk at 6 ppm; milk fat at 75 ppm; fat

of poultry at 0.5 ppm; meat byproducts of poultry at 0.03 ppm; eggs at 0.05 ppm. Residue data on stored seed (soybean, sunflower, cottonseed) and peanuts were not submitted, and thus not considered under this petition. The Agency does not establish tolerances for birdseed commodities.

EPA is also revising or deleting existing tolerances for spinosad that are superceded or no longer needed, correcting administrative errors in existing tolerances, and updating tolerance terminology as follows:

1. Tolerances for residues of spinosad in or on barley, grain; buckwheat, grain; corn, grain; corn, pop; corn pop, grain; grain, aspirated fractions; millet, pearl, grain; millet, proso, grain; oat grain; rye, grain; sorghum, grain; stored grains (barley, corn, oats, rice, sorghum/milo, and wheat); teosinte, grain; wheat bran; wheat, flour; wheat, grain; wheat midlings; wheat shorts are being revised or replaced as appropriate to reflect the new commodity terms and tolerance levels specified in Unit II.

2. Time-limited tolerances established for residues of spinosad in or on beet, sugar, tops at 10 ppm in connection with Section 18 exemption granted by EPA has expired and is being deleted. In a prior action, EPA established a spinosad tolerance for vegetables, leaves of root and tuber, group 2, which covers beet, sugar, tops. Time limited tolerances established for residues of spinosad in/or on coffee beans at 0.02 ppm in connection with an experimental use permit granted by EPA has expired and is being deleted.

3. Administrative errors in existing tolerances for corn, stover; sorghum, grain stover and wheat straw are being corrected as follows: The existing tolerances for these commodities are repeated more than once in the table in paragraph (a) under § 180.495 and are being deleted.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA 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) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for residues of spinosad on the commodities listed in Unit II. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

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

B. Toxicological Endpoints

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

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

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

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

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}).

Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

A summary of the toxicological endpoints for spinosad used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of September 27, 2002 (67 FR 60923) (FRL–7199–5).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Tolerances have been established (40 CFR 180.495) for the residues of spinosad, in or on a variety of raw agricultural commodities. 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*. In conducting the chronic dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A chronic dietary exposure assessment (using tolerance-level residues, DEEM default processing factors, and percent crop treated (CT) information including 10% CT for all proposed commodities) was conducted for the general U.S. population and various population subgroups. The estimated chronic dietary exposures for the U.S. population and all population subgroups, as represented by percent of the chronic Population Adjusted Dose (cPAD), is below EPA's level of concern (< 100% cPAD). The estimated exposure for the U.S. population is 21% of the cPAD. The estimated exposure for the most highly exposed subpopulation, children 1-2 years, is 62% of the cPAD.

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

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E) of FFDCA, EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

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

The Agency used PCT information as follows:

The chronic analysis assumed tolerance level residues for all crop, poultry, and egg commodities, and anticipated residues for ruminant and milk commodities. Percent crop treated for several crop commodities were reduced from 100% based on data submitted to EPA. The Agency used PCT information as follows:

Almond—5%;
Apple—28%;
Apricot —5%;
Avocado—5%;
Bean, snap—9%;
Bean/pea, dry—1%;
Broccoli—62%;
Cabbage—32%;
Cauliflower—54%;
Celery—78%;
Cherry—4%;
Collards—24%;
Cotton—3%;
Eggplant—14%;
Grapefruit—1%;
Grape, wine—1%;
Kale—32%;
Lemon—11%;
Lettuce, head—59%;
Lettuce, other—42%;
Mustard greens—17%;
Orange—6%;
Potato—1%;
Peach—4%;
Peanut—1%;
Pepper—45%;
Pistachio—1%;
Prune/plum—5%;
Spinach—32%;
Squash—1%;
Tangerine—6%;
Tomato, fresh—30%;
Tomato, processed—2%;
Turnip, greens—6%;
Watermelon—1%

Furthermore, an estimated 10% seed treatment for cereal grains was used.

The Agency believes that the three conditions listed in Unit III.C. have been met. With respect to Condition 1, PCT estimates for existing uses 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. With respect to the projected PCT for the proposed used, the 10% projection is based upon a maximum percent seed supply treated with chlorphyrifos-methyl of 8% for wheat and 5% for barley and oats. Since spinosad is likely to be used in place of chlorphyrifos-methyl, historically the

most widely used insecticide for control of insects pests on stored grain this assessment assumes that the percent of seed treatment would approximate the maximum percent of the seed supply treated with chlorphyrifos-methyl. 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 spinosid may be applied in a particular area.

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 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 ground water. 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. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include 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 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), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used 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 in Unit III.E.

Based on the FIRST and SCI-GROW models, the EECs of spinosad for chronic exposures are estimated to be 2.3 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). A summary of the residential uses for spinosad is discussed in Unit III.C. of the final rule published in the **Federal Register** of September 27, 2002 (67 FR 60923) (FRL–7199–5).

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

EPA does not have, at this time, available data to determine whether spinosad has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to spinosad and any other substances and spinosad does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that spinosad has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

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

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

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 SF to protect infants and children should be removed. The FQPA factor is removed because:

i. The toxicological data base for spinosad is complete for FQPA assessment.

ii. There is no evidence of increased susceptibility of rat or rabbit fetuses following *in utero* exposure in the developmental studies with spinosad,

and there is no evidence of increased susceptibility of young rats in the reproduction study with spinosad.

iii. There are no residual uncertainties identified in the exposure databases; the dietary food exposure assessment (chronic only; no acute endpoint was identified) is refined using Anticipated Residues calculated from field trial data and available percent crop treated (%CT) information.

iv. EPA has indicated that the dietary drinking water exposure is based on conservative modeling estimates.

v. EPA Residential SOPs were used to assess post-application exposure to children as well as incidental oral exposure of toddlers, so these assessments do not underestimate the exposure and risks posed by spinosad.

E. Aggregate Risks and Determination of Safety

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 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 + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). 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 ground water 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 this unit for chronic exposure, EPA has concluded that exposure to spinosad from food will utilize 21% of the cPAD for the U.S. population, 22% of the cPAD for all infants, and 62 % of the cPAD for children 1-2 years old. Based on the use pattern, chronic residential exposure to residues of spinosad is not expected. In addition, there is potential for chronic dietary exposure to spinosad in drinking water. 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 Table below:

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	36	2.3	0.037	600
All infants < 1 year	0.027	36	2.3	0.037	170
Children 1 - 2 years old	0.027	82	2.3	0.037	50
Children 3 - 5 years old	0.027	79	2.3	0.037	60

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).

A summary of the short-term risk for spinosad is discussed in Unit III.E. of the final rule published in the **Federal Register** of September 27, 2002 (67 FR 60923) (FRL–7199–5).

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 raw agricultural commodity cereal grains.

C. Public Comments

One comment was received in response to the notice of filing. In that comment, a B. Sachau objected to the proposed tolerances because of the amounts of pesticides already consumed and carried by the American population. She further indicated that testing conducted on animals have absolutely no validity and cruel to the test animals.

The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned completely. However, under the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute.

The Agency disagrees with the commenter's claims regarding animal testing. Since humans and animals have complex organ systems and mechanisms for the distribution of chemicals in the body, as well as processes for eliminating toxic substances from their systems, EPA relies on laboratory animals such as rats and mice to mimic the complexity of human and higher-order animal physiological responses when exposed to a pesticide. EPA is committed, however, to reducing the use of animals whenever possible. EPA-required studies include animals only when the requirements of sound toxicological science make the use of an animal absolutely necessary. The Agency's goal is to be able to predict the potential of pesticides to cause harmful effects to humans and wildlife by using fewer laboratory animals as models and have been accepting data from alternative (to animals) test methods for several years. As progress is made on finding or developing non-animal test models that reliably predict the potential for harm to humans or the environment, EPA expects that it will need fewer animal studies to make safety determinations.

Finally, because the commenter has not provided the Agency with a specific rationale (including supporting information) as to why the Agency's action is inconsistent with the legal standards in section 408 of FFDCA, EPA can not provide any more detailed response to the commenter's disagreement with the Agency's decision.

V. Conclusion

Therefore, the tolerances are established for residues of spinosad, in or on the raw agricultural commodity grain, cereal, group 15 at 1.5 ppm; grain as aspirated fractions at 200 ppm; rice hulls at 4 ppm; meat of cattle, goats, hogs, horse and sheep at 1.5 ppm; fat of cattle, goats, hogs, horse and sheep at 33 ppm; meat byproducts of cattle, goats, hogs, horse and sheep at 8 ppm; milk at 6 ppm; milk fat at 75 ppm; fat of poultry at 0.5 ppm; meat byproducts of poultry at 0.03 ppm; eggs at 0.05 ppm.

VI. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0042 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 8, 2005.

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

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 20460–0001.

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 20460–0001.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0042, 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 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. 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. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant o section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: December 20, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.495 is amended by revising the table in paragraph (a) and by removing from the table in paragraph (b) the entry ''Beet, sugar, tops'' to read as follows:

§ 180.495 Spinosad; tolerances for residues.

(a) * * *

Commodity	Parts per million	Expiration/Revocation Date
Acerola	1.5	None
Almond, hulls	2.0	None
Amaranth, grain, grain	1.0	None
Animal feed, nongrass, group, 18	0.02	None
Apple pomace	0.5	None
Artichoke, globe	0.3	None
Asparagus	0.2	None
Atemoya	0.3	None
Avocado	0.3	None
Beet, sugar, molasses	0.75	None
Biriba	0.3	None
Brassica, head and stem, subgroup 5A	2.0	None
Bushberry subgroup 13B	0.250	None
Cranberry subgroup 13A	0.7	None
Canistel	0.3	None
Cattle, fat	33	None
Cattle, meat	1.5	None
Cattle, meat byproducts	8	None
Cherimoya	0.3	None
Citrus, oil	3.0	None
Citrus, dried pulp	0.5	None
Coriander, leaves	8.0	None
Corn, forage	1.0	None
Corn, hay	1.0	None
Corn, stover	1.0	None
Corn, straw	1.0	None
Corn, sweet, kernel plus cob with husks removed	0.02	None
Cotton gin byproducts	1.5	None
Cotton, undelinted seed	0.02	None
Cranberry	0.01	None
Custard apple	0.3	None
Egg	0.05	None
Feijoa	.05	None
Fig	0.10	None
Fruit, citrus group	0.3	None
Fruit, pome, group 11	0.20	None
Fruit, stone, group 12	0.20	None
Goat, fat	33	None
Goat, meat byproducts	8	None
Goat, meat	1.5	None
Grain, aspirated fractions	200	None
Grain, cereal, group 15	1.5	None
Grape	0.50	None
Grape, raisin	0.70	None
Grass, forage, fodder and hay, group 17	0.02	None
Guava	0.3	None
Herb, dried, subgroup	22	None
Herb, fresh, subgroup	3.0	None
Hog, fat	33	None
Hog, meat byproducts	8.0	None
Hog, meat	1.5	None
Horse, fat	33	None
Horse, meat byproducts	8.0	None
Horse, meat	1.5	None
Ilama	0.3	None
Jaboticaba	0.3	None
Juneberry	0.25	None
Leafy vegetables (except Brassica vegetables group)	8.0	None
Legume vegetables, edible podded (Crop Subgroup 6A)	0.30	None
Legume vegetables, dried shell pea and bean (Crop Subgroup 6C)	0.02	None
Legume vegetables, succulent shelled pea and bean (Crop Subgroup 6B)	0.02	None
Lingonberry	0.250	None
Longan	0.3	None
Lychee	0.3	None
Mango	0.3	None

Commodity	Parts per million	Expiration/Revocation Date
Milk	6.0	None
Milk, fat	75	None
Nut, tree, group 14	0.02	None
Okra	0.40	None
Papaya	0.3	None
Passionfruit	0.3	None
Peanut	0.02	None
Pistachio	0.020	None
Poultry, fat	0.5	None
Poultry, meat byproducts	0.03	None
Poultry, meat	0.02	None
Pulasan	0.3	None
Rambutan	0.3	None
Rice, hulls	4.0	None
Salal	0.250	None
Sapodilla	0.3	None
Sapote, black	0.3	None
Sapote, mamey	0.3	None
Sapote, white	0.3	None
Sheep, fat	33	None
Sheep, meat byproducts	8.0	None
Sheep, meat	1.5	None
Sorghum, forage	1.0	None
Sorghum, forage, hay	1.0	None
Sorghum, grain, stover	1.0	None
Sorghum, straw	1.0	None
Soursop	0.3	None
Soybean	0.02	None
Spanish lime	0.3	None
Star apple	0.3	None
Starfruit	0.3	None
Strawberry	1.0	None
Sugar apple	0.3	None
Ti, leaves	10.0	None
Vegetable, brassica, leafy, group 5	10.0	None
Vegetable, cucurbit (cucumber, melon, squashes), group 9	0.3	None
Vegetable, foliage of legume, group 7	8.0	None
Vegetable, fruiting, group 8	0.4	None
Vegetable, leaves of root and tuber, group 2	10.0	None
Vegetable, root and tuber, group 1	0.10	None
Watercress	8.0	None
Wax jambu	0.3	None
Wheat, forage	1.0	None
Wheat, hay	1.0	None
Wheat, straw	1.0	None

[FR Doc. 05–88 Filed 1–6–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0001; FRL–7694–5]

Peanuts, Tree Nuts, Milk, Soybeans, Eggs, Fish, Crustacea, and Wheat; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of peanuts, tree nuts, milk, soybeans, eggs, fish, crustacea, and/or wheat when used as inert or active ingredients in pesticide products, for certain use patterns, under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The Agency is acting on its own initiative.

DATES: This regulation is effective on January 7, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit IV. of the SUPPLEMENTARY INFORMATION. EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0001. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket*. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 South Bell St., Arlington, VA., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6304; fax number: (703) 305–0599; e-mail address: *boyle.kathryn@epa.gov*.

SUPPLEMENTARY INFORMATION: