claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

XIII. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or 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 in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since tolerance exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption 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. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) was provided to the Chief Counsel for Advocacy of the Small Business.

XIV. 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 the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: April 3, 1998.

Marcia E. Mulkey,

Director, Office of Pesticide Programs.

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. Section 180.1194 is added to read as follows:

§ 180.1194 Canola oil; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biochemical pesticide, canola oil, conforming to the following definition when used as an insecticide, in or on all food commodities: Canola oil, also known as low erucic rapeseed oil, is the fully refined, bleached, and deodorized edible oil obtained from certain varieties of *Brassica Napus* or *B. Campestris* of the family Cruciferae. Canola oil contains no more than 2 percent erucic acid.

[FR Doc. 98–10013 Filed 4–14–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300644; FRL–5785–7]

RIN 2070–AB78

Spinosad; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes permanent tolerances for residues of spinosad in or on almonds at 0.02 parts per million (ppm); almond hulls at 2.0 ppm; apples at 0.2 ppm; apple pomace, wet at 0.5 ppm; citrus fruits group at 0.3 ppm; citrus pulp, dried at 0.5 ppm; citrus oil at 3.0 ppm; cottonseed at 0.02 ppm; cotton gin byproducts at 1.5 ppm; fruiting vegetables (except cucurbits) group at 0.4 ppm; Brassica (cole), leafy vegetables, head and stem subgroup at 2.0 ppm; Brassica (cole), leafy vegetables, greens subgroup at 10.0 ppm; leafy vegetables (except Brassica vegetables) group at 8.0 ppm; fat of cattle, goats, hogs, horses, and sheep at 0.6 ppm; meat of cattle, goats, hogs, horses, and sheep at 0.04; meat byproducts of cattle, goats, hogs, horses, and sheep at 0.2 ppm; milk fat at 0.5 ppm; and whole milk at 0.04 ppm. This regulation also removes the time limitation for the tolerance for residues of spinosad on cottonseed which expires on November 15, 1999. DowElanco requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170). In addition, this regulation removes time-limited tolerances set under section 408(1)(6) of the FFDCA, as amended by the FQPA for residues of spinosad on fruiting vegetables (except cucurbits) group, tomato paste, leafy vegetables (except Brassica vegetables) group, and Brassica (cole), leafy vegetables, group at 0.25, 0.50, 10.0, and 10.0 ppm, respectively. These tolerances were set under the

section 18 emergency exemption provision of the FQPA and they expire on September 30, 1998. With this regulation, permanent tolerances are now being established to replace these time-limited tolerances with the exception of tomato paste. A tolerance will not be established for tomato paste because EPA has determined that the maximum amount of spinosad residues expected in tomato paste is less than the proposed tolerance for tomatoes. Therefore, no tolerance is required for tomato paste.

DATES: This regulation is effective April 15, 1998. Objections and requests for hearings must be received by EPA on or before June 15, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300644], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300644], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300644]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Beth Edwards, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5400, e-mail: edwards.beth@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: On February 26, 1997, EPA established a time-limited tolerance under section 408 and 409 of the FFDCA, 21 U.S.C. 346a(d) and 348 for residues of spinosad on cottonseed (62 FR 8626) (FRL–5590–8). This tolerance expires on November 15, 1999. DowElanco, on December 11, 1997, requested that the time limitation be removed based on a cotton gin trash residue study that they had submitted as a condition of the registration and the time-limited tolerance. DowElanco also submitted a summary of its petition as required under the FFDCA as amended by the Food Quality Protection Act (FQPA) of 1996 (Pub. L. 104-170).

On October 22, 1997, EPA established time-limited tolerances under section 408(1)(6) of the FFDCA, as amended by the FQPA of 1996 for residues of spinosad on fruiting vegetables (except cucurbits) group, tomato paste, leafy vegetables (except Brassica vegetables) group, and Brassica (cole), leafy vegetables group at 0.25, 0.50, 10.0, and 10.0 ppm, respectively (62 FR 54771) (FRL–5746–6). These tolerances were set under the Section 18 emergency exemption provision of the FQPA and they expire on September 30, 1998. These emergency exemption tolerances for spinosad were granted to control Western Flower Thrips on fruiting vegetables (excluding cucurbits) in the states of Florida, Georgia and Arkansas, and to control beet armyworm on leafy vegetables (except Brassica) and Brassica leafy vegetables in Arizona.

In the **Federal Register** issues of December 24, 1996 (61 FR 67801) (FRL–5578–2), October 8, 1997 (62 FR 52558) (FRL–5748–6), and March 4, 1998 (63 FR 10609) (FRL–5774–1), EPA issued notices pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e) announcing the filing of pesticide petitions (PP) 7F4797, 7F4871, and 8F4942 for tolerances by DowElanco, 9330 Zionsville Road, Indianapolis IN 46268-1054. These notices included a summary of the petitions prepared by DowElanco, the registrant. There were no comments received in response to the notices of filing.

The petitions requested that 40 CFR 180.495 be amended by removing the time limitation for the tolerance for residues of the insecticide spinosad in or on cottonseed at 0.02 ppm and by establishing tolerances in or on almonds at 0.02 ppm; almond hulls at 2.0 ppm; apples at 0.2 ppm; apple pomace, wet at 0.5 ppm; citrus fruits group at 0.3 ppm; citrus pulp, dried at 0.5 ppm; citrus oil at 3.0 ppm; cotton gin byproducts at 1.5 ppm; fruiting vegetables (except cucurbits) group at 0.4 ppm; leafy vegetables (except Brassica vegetables) group at 8.0 ppm; Brassica (cole), leafy vegetables, head and stem subgroup at 2.0 ppm; Brassica (cole), leafy vegetables, greens subgroup at 15.0 ppm; fat of cattle, goats, hogs, horses, and sheep at 0.7 ppm; meat of cattle, goats, hogs, horses, and sheep at 0.04 ppm; meat byproducts of cattle, goats, hogs, horses, and sheep at 0.2 ppm; milk fat at 0.5 ppm; and whole milk at 0.04 ppm. EPA determined that the requested tolerances for fat of cattle, goats, hogs, horses, and sheep at 0.7 ppm and Brassica (cole), leafy vegetables, greens subgroup at 15.0 ppm were too high based on magnitude of the residue studies. EPA recommended that the tolerances be set at 0.6 ppm and 10.0 ppm, respectively.

I. Risk Assessment and Statutory Findings

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

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures

that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action.

EPA has sufficient data to assess the hazards of spinosad and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of spinosad on almonds at 0.02 ppm; almond hulls at 2.0 ppm; apples at 0.2 ppm; apple pomace, wet at 0.5 ppm; citrus fruits group at 0.3 ppm; citrus pulp, dried at 0.5 ppm; citrus oil at 3.0 ppm; cottonseed at 0.02 ppm; cotton gin byproducts at 1.5 ppm; fruiting vegetables (except cucurbits) group at 0.4 ppm; leafy vegetables (except Brassica vegetables) group at 8.0 ppm; Brassica (cole), leafy vegetables, head and stem subgroup at 2.0 ppm; Brassica (cole), leafy vegetables, greens subgroup at 10.0 ppm; fat of cattle, goats, hogs, horses, and sheep at 0.6 ppm; meat and meat byproducts of cattle, goats, hogs, horses, and sheep at 0.04 ppm; milk fat at 0.5 ppm; and whole milk at 0.04 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

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

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

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

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

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

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

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

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

8. In a carcinogenicity study in mice, the NOEL was 11.4 mg/kg/day. The LOEL was 50.9 mg/kg/day based on decreased body weight gains, increased mortality, hematologic effects, increased thickening of the gastric mucosa, and histologic changes in the stomach of males.

9. In a chronic feeding/carcinogenicity/neurotoxicity study in rats, the NOEL (systemic) was 9.5 and 12.0 mg/kg/day for males and females, respectively. The LOEL (systemic) was 24.1 and 30.3 mg/kg/day for males and females, respectively based on vacuolation of epithelial follicular cells of the thyroid. The neurological NOEL was 46 and 57 mg/kg/day for males and females, respectively. The neurological LOEL was not determined.

10. In a developmental study in rabbits, the maternal NOEL was ≥50 mg/kg/day. The maternal LOEL was not established. The developmental NOEL was ≥50 mg/kg/day. The developmental LOEL was not established.

11. In a developmental study in rats, the maternal NOEL was >200 mg/kg/day. The maternal LOEL was not established. The developmental NOEL was >200 mg/kg/day. The developmental LOEL was not established.

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

13. Studies on gene mutation and other genotoxic effects: In a Gene Mutation Assay (mouse forward mutation) there was no forward mutation induction in mouse lymphoma L5178Y Tk +/- cells at concentrations of 0, 1, 5, 10, 15, 20, or 25 µg/ml without metabolic activation or at concentrations of 15 through 50 µg/ml with metabolic activation. In a Structural Chromosomal Aberration Assay *in vitro* there was no increase in the number of CHO (chinese hamster ovary) cells with chromosomal aberrations at concentratioins from 20 to 35 µg/ml (without activation) or concentrations from 100 to 500 µg/ml (with activation). In a Micronucleus Test in mice, there was no increase in the frequencey of micronuclei in bone marrow cells from mice treated at concentratioins from 500 to 2,000 µg/ml for two days. In Other Genotoxicity Assays, unscheduled DNA synthesis was not induced in adult rat hepatocytes in vitro at concentrations of 0.01 to 5 µg/ml tested.

14. The results of three metabolism studies are as follows: (i) Approximately 95% of technical spinosad was eliminated by 24 hours mainly in the urine (34%), bile (36%), and tissues and carcass (21%). Metabolites include the glutathione conjugates of the unchanged form as well as N- and O-demethylated forms of XDE-105 (Factor D). (ii) At 100 mg/kg/dose, the radiolabeled XDE-105 (Factor D) was primarily excreted in the feces (68%) after 24-hours. The absorption, distribution, and elimination of 14C-XDE-105 (Factor A) demonstrated no appreciable differences based on dose or repeated dosing. (iii) At high (100 mg/kg) doses, there are no major differences in the bioavailability, routes or rates of excretion or metabolism of 14C-XDE-105 (Factor A) following oral administration.

15. In an acute neurotoxicity study, groups of Fischer 334 rats (10/sex/dose) received a single oral (gavage) administration of spinosad (87.9%) at dose levels of 0, 200, 630, or 2,000 mg/

kg. There were no effects on neurobehavioral endpoints or histopathology of the nervous system. For neurotoxicity, the NOEL was ≥ 2,000 mg/kg/day, highest dose tested (HDT). A LOEL was not established.

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

17. In the 2-year chronic neurotoxicity study, groups of Fischer 344 rats (65/sex/dose) received diets containing spinosad at dose levels of 0, 0.005, 0.02, 0.05, or 0.1% (0, 2.4, 9.5, 24.1, or 49.4 mg/kg/day for males and 0, 3.0, 12.0, 30.3, or 62.2 mg/kg/day for females, respectively). Neurobehavioral testing performed at 3, 6, 9, and 12 months of study was negative, and histopathological evaluation of perfused tissues at study termination did not identify pathology of the central or peripheral nervous system. There was no evidence of neurotoxicity. For neuropathology, the NOEL was 0.1% (≥ 46 mg/kg/day for males and 57 mg/kg/day for females (HDT).

B. Toxicological Endpoints

1. *Acute toxicity*. EPA did not select a dose and endpoint for an acute dietary risk assessment due to the lack of toxicological effects attributable to a single exposure (dose) in studies available in the data base including oral developmental toxicity studies in rats and rabbits. In the acute neurotoxicity study the NOEL was ≥2,000 mg/kg/day.

2. *Short - (1 day to 7 days), intermediate- (1 week to several months), and chronic - term occupational and residential dermal and inhalation toxicity*. EPA did not select a dose or endpoint for short-, intermediate and long-term dermal risk assessments because (i) lack of appropriate endpoints; (ii) the combination of molecular structure and size as well as the lack of dermal or systemic toxicity at 2,000 mg/kg/day in a 21-day dermal toxicity study in rats which indicates the lack of dermal absorption; and (iii) the lack of long-term exposure based on the current use pattern. Therefore, a dermal risk assessment is not required. EPA also determined that based on the current use pattern and exposure scenario, an inhalation risk assessment is not required.

3. *Chronic toxicity*. EPA has established the RfD for spinosad at 0.027 mg/kg/day. This RfD is based on a chronic toxicity study in dogs using a NOEL of 2.68 mg/kg/day. The LOEL was 8.46 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 in dogs fed spinosad in the diet at dose levels of 1.44, 2.68, or 8.46 mg/kg/day for 52 weeks. A 100-fold uncertainty factor (UF) was applied to the NOEL of 2.68 mg/kg/day to account for inter- and intra-species variation.

EPA determined that the 10X factor to account for enhanced sensitivity of infants and children (as required by FQPA) should be removed. Thus, an uncertainty factor of 100 is adequate and the RfD remains at 0.027 mg/kg/day.

The FQPA factor is removed because: (i) The data provided no indication of increased susceptibility of rats or rabbits to in utero and/or post-natal exposure to spinosad. In the prenatal developmental toxicity studies in rats and rabbits and the two-generation reproduction study in rats, effects in the offspring were observed only at or below treatment levels which resulted in evidence of parental toxicity. (ii) No neurotoxic signs have been observed in any of the standard required studies conducted. (iii) The toxicology data base is complete and there are no data gaps.

4. *Carcinogenicity*. There is no evidence of carcinogenicity in studies in either the mouse or rat.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.495) for the residues of spinosad in or on cottonseed at 0.02 ppm (to expire on 11/15/99). Time-limited tolerances for Section 18 emergency exemptions are established under 40 CFR 180.495 for residues of spinosad in or on Brassica (cole) leafy vegetables at 10 ppm, fruiting vegetables (except cucurbit vegetables) at 0.25 ppm, leafy vegetables (except Brassica vegetables) at 10 ppm, and tomato paste at 0.5 ppm. Risk assessments were conducted by EPA to assess dietary exposures and risks from spinosad as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. No acute toxicological endpoints were identified for spinosad due to the lack of toxicological effects attributable to a single exposure (dose). Therefore, the Agency concludes that there is a reasonable certainty of no harm from acute dietary exposure.

ii. *Chronic exposure and risk.* The RfD used for the chronic dietary analysis is 0.027 mg/kg/day. In conducting this chronic dietary risk assessment, EPA made very conservative assumptions: 100% of citrus, almonds, apples, fruiting (except cucurbit) vegetables, Brassica leafy vegetables, leafy vegetables, cottonseed, and ruminant commodities having spinosad tolerances will contain spinosad residues and those residues will be at the level of the established tolerance. This results in an overestimate of human dietary exposure. This chronic dietary risk assessment used 10 ppm tolerances for the leafy vegetables (except Brassica vegetables) crop group and for the Brassica leafy vegetables head and stem subgroup from section 18 tolerances that were established last year. For the section 3 registrations on these groups, EPA has recommended tolerances of 8 ppm (leafy vegetables) and 2 ppm (Brassica head and stem leafy vegetables). The use pattern for these section 18 registrations is identical to the section 3 registrations proposed in this risk assessment, but due to an incomplete data base at the time the Section 18s were reviewed, the tolerances were set high which resulted in a conservative risk assessment. With this action, these section 18 tolerances are replaced by the new section 3 tolerances. Thus, in making a safety determination for this tolerance, EPA is taking into account this conservative exposure assessment.

The existing spinosad tolerances (published, pending, and including the Section 18 tolerances) result in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to the following percentages of the RfD: U.S. Population (24% of RfD); Nursing Infants (<1 year old)(8% of RfD); Non-Nursing Infants (<1 year old) (24% of RfD); Children (1-6 years old) (34% of RfD); Children (7-12 years old) (29% of RfD); Northeast Region (25% of RfD); Western Region (27% of RfD); Non-Hispanic Blacks (27% of RfD); Non-Hispanic Others (37% of RfD); Females 13+ years, Nursing (27% of RfD).

2. *From drinking water.* The Agency has determined that spinosyns Factor A and Factor D are immobile in soil and will not leach into ground water. Based on structure/activity relationships, the Agency concluded that the spinosad metabolites/fermentation impurities

(spinosyns Factor B, Factor B of D, Factor K, and other related factors) were of no more toxicological concern than the two parent compounds (spinosyns Factor A and Factor D) and therefore, only these were considered in the drinking water assessment. EPA used the ''Interim Approach for Addressing Drinking Water Exposure in Tolerance Decision Making'' issued on November 17, 1997. Thus, the PRZM/EXAMS Models were run to produce estimates of spinosad in surface water. The primary use of these models is to provide a screen for sorting out pesticides for which OPP has a high degree of confidence that the true levels of the pesticide in drinking water will be less than the human health drinking water levels of concern (DWLOCs). A human health DWLOC is the concentration of a pesticide in drinking water which would result in acceptable aggregate risk, after having already factored in all food exposures and other non-occupational exposures for which OPP has reliable data. PRZM/EXAMS was used to conduct a Tier 2 surface water analysis. The Tier 2 estimated drinking water concentration (EEC) of spinosad from surface water sources is not likely to exceed 0.059 µg/L from use on apples, 0.092 µg/L from use on Brassica vegetables, 0.065 µg/L from use on cotton, and 0.075 µg/L from use on citrus.

i. *Acute exposure and risk.* Because no acute dietary endpoint was determined, the Agency concludes that there is a reasonable certainty of no harm from acute exposure from drinking water.

ii. *Chronic exposure and risk.* Based on the chronic dietary (food) exposure and using default body weights and water consumption figures, chronic drinking water levels of concern (DWLOC) for drinking water were calculated. The chronic drinking water exposure and risk estimates are 0.019890 mg/kg/day (690 µg/L DWLOC) for the overall U.S. population; 0.01896 mg/kg/day (570 µg/L DWLOC) for females 13+ years, nursing; and 0.016865 mg/kg/day (170 µg/L DWLOC) for children age 1-6 years.

3. *From non-dietary exposure.* There are no current residential uses for spinosad. However, the proposed use of a 0.5% spinosad product on structural lumber may have residential uses. This product is injected into drilled holes and then sealed after treatment. Due to the lack of toxicity endpoints (hazard) and minimal contact with the active ingredient during and after application, exposure to residential occupants is not expected.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Spinosad has not yet been grouped with any other insecticides into a class.

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.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

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 these tolerance actions, therefore, EPA has not assumed that spinosad has a common mechanism of toxicity with other substances.

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

Chronic risk. Using the TMRC exposure assumptions described in Unit I.B. of this Preamble, EPA has concluded that aggregate exposure to spinosad from food will utilize 24% of the RfD for the U.S. population. For the most highly exposed populations subgroup, children (1-6 years old) and non-Hispanic others, chronic dietary (food only) exposure occupies 34% and 37% of the RfD, respectively. This is a conservative risk estimate for reasons described above. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The chronic DWLOC for the infants and children subgroup is 170 ppb. The chronic modeling estimates (EECs) for spinosad residues in surface water are as high as 0.092 ppb from use on Brassica leafy vegetables. The maximum estimated concentrations of spinosad in surface water are less than EPA's levels of concern for spinosad in drinking water as a contribution to chronic aggregate exposure. Taking into account present uses and uses proposed in this risk assessment, EPA concludes with reasonable certainty that residues of spinosad in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Therefore, the Agency concludes that there is a reasonable certainty that no harm will result from chronic aggregate exposure to spinosad residues from food and water.

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

E. Aggregate Cancer Risk for U.S. Population

The RfD Committee determined that there is no evidence of carcinogenicity in studies in either the mouse or rat. Therefore, a carcinogenic risk assessment is not required.

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

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

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

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

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

iii. *Reproductive toxicity study.* In a two-generation reproduction study, groups of Sprague-Dawley rats (30/sex/group) received diets containing spinosad (88%) at dose levels of 0, 0.005, 0.02, or 0.2% (3, 10, or 10 mg/kg/day, respectively) for two successive generations. For parental systemic toxicity, the NOEL was 0.02% (10 mg/kg/day) and the LOEL was 0.2% (100 mg/kg/day), based on increased heart, kidney, liver, spleen, and thyroid weights (both sexes), histopathology in the spleen and thyroid (both sexes), heart and kidney (males), and histopathologic lesions in the lungs and mesenteric lymph nodes (both sexes), stomach (females), and prostate. For offspring toxicity, the NOEL was 0.02% (10 mg/kg/day) and the LOEL was 0.2% (100 mg/kg/day) based on decreased litter size, survival (F2), and body weights. Reproductive effects at that dose level included increased incidence of dystocia and/or vaginal bleeding after parturition with associated increase in mortality of dams.

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

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

c. In the 2-year chronic toxicity study, groups of Fischer 344 rats (65/sex/dose) received diets containing spinosad at dose levels of 0, 0.005, 0.02, 0.05, or 0.1% (0, 2.4, 9.5, 24.1, or 49.4 mg/kg/day for males and 0, 3.0, 12.0, 30.3, or 62.2 mg/kg/day for females, respectively). Neurobehavioral testing performed at 3, 6, 9, and 12 months of study was negative, and histopathological evaluation of perfused tissues at study termination did not identify pathology of the central or peripheral nervous system. There was no evidence of neurotoxicity. For neuropathology, the NOEL was 0.1% (>49.4 mg/kg/day for males and 62.8 mg/kg/day for females).

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

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

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

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

levels which resulted in evidence of parental toxicity.

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

(iii) The toxicology data base is complete and there are no data gaps.

2. *Acute risk.* An acute risk assessment is not required because no acute toxicological endpoints were identified for spinosad.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to spinosad from food will utilize 34% of the RfD for children age 1-6 years old. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to spinosad residues.

G. Endocrine Disruption

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

III. Other Considerations

A. Metabolism In Plants and Animals

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

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

B. Analytical Enforcement Methodology

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

Method RES 94094 (method for determination of spinosad residues in ruminant commodities using HPLC/UV) underwent successful independent lab validation and EPA lab validation. This method is adequate for regulation of the tolerance expression.

Method RES 95114 (method for determination of spinosad residues in ruminant commodities using immunoassay) underwent successful independent lab validation and EPA lab validation.This method is adequate for regulation of the tolerance expression.

C. Magnitude of Residues

Adequate residue data were provided to support tolerances of 0.02 ppm for almonds; 2.0 ppm for almond hulls; 0.2 for apples; 2.0 ppm for the head and stem subgroup of the Brassica leafy vegetables crop group; 10.0 ppm for the greens subgroup of the Brassica leafy vegetables crop group; 0.3 ppm for the citrus fruits crop group; 0.02 ppm on cottonseed; 1.5 ppm on cotton gin byproducts; 0.4 ppm for the fruiting vegetables (except cucurbit vegetables) crop group; and, 8.0 ppm for the leafy vegetables (except Brassica vegetables) crop group.

Processing data provided for apples indicated concentration of residues in wet apple pomace. Based on the concentration factor of 5.6X and the highest average field trial (HAFT) residue level of 0.089 ppm for apples, the data support a tolerance of 0.5 ppm for wet apple pomace.

Processing data provided for citrus indicated concentration of residues in dried citrus pulp and citrus oil. Based on the concentration factor of 2.4X in dried pulp and 12.7X in oil and the highest average field trial (HAFT) residue level of 0.200 ppm for oranges, the data support tolerances of 0.5 ppm for dried citrus pulp and 3.0 ppm for citrus oil.

Processing data provided for cottonseed did not indicate any concentration of residues in meal or hulls. No tolerances are required for processed cotton commodities.

There are no livestock feedstuffs associated with Brassica leafy vegetables, fruiting vegetables, and leafy vegetables.

A ruminant feeding study was submitted. Based on the results of this study, the data support the following tolerances: fat (or cattle, goats, hogs, horses, and sheep) at 0.6 ppm; meat (of cattle, goats, hogs, horses, and sheep) at 0.04 ppm; meat byproducts (of cattle, goats, hogs, horses, and sheep) at 0.2 ppm; milk fat at 0.5 ppm; and whole milk at 0.04 ppm. These levels are adequate for the feed items associated with all existing and proposed uses covered in this risk assessment.

Requirements for a poultry feeding study have been waived based on the minimal impact of spinosad residues in a typical poultry diet.

D. International Residue Limits

No CODEX, Canadian, or Mexican MRLs have been established for residues of spinosad on any crops.

IV. Conclusion

Therefore, the tolerances are established for residues of spinosad in almonds at 0.02 ppm; almond hulls at 2.0 ppm; apples at 0.2 ppm; apple pomace, wet at 0.5 ppm; citrus fruits group at 0.3 ppm; citrus pulp, dried at 0.5 ppm; citrus oil at 3.0 ppm; cottonseed at 0.02 ppm; cotton gin byproducts at 1.5 ppm; fruiting vegetables (except cucurbits) group at 0.4 ppm; Brassica (cole), leafy vegetables, head and stem subgroup at 2.0 ppm; Brassica (cole), leafy vegetables, greens subgroup at 10.0 ppm; leafy vegetables (except Brassica vegetables) group at 8.0 ppm; fat of cattle, goats, hogs, horses, and sheep at 0.6 ppm; meat of cattle goats, hogs, horses, and sheep at 0.04; meat byproducts of cattle, goats, hogs, horses, and sheep at 0.2 ppm; milk fat at 0.5 ppm; and whole milk at 0.04 ppm.

In addition, EPA is removing the time limitation for the tolerance for residues of spinosad on cottonseed. Also, EPA is removing the time limited tolerances established under section 408(1)(6) of the FFDCA, as amended by FQPA, in 40 CFR 180.495 (b) Section 18 emergency exemptions.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by June 15, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). 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.

VI. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300644] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or 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 in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), 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. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: April 9, 1998.

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. 346a and 371.

2. In § 180.495, paragraphs (a) and (b) are revised to read as follows:

§ 180.495 Spinosad; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide Spinosad. Factor A is 2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,6b-tetradecahydro-14-methyl-1*H*-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione. Factor D is 2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydri-6-methyl-2*H*-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl-1*H*-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione.

Commodity	Parts per million
Almonds	0.02
Almond hulls	2.0
Apples	0.2
Apple pomace, wet	0.5
Brassica (cole), leafy vegetables, greens subgroup	10.0
Brassica (cole), leafy vegetables, head and stem subgroup	2.0
Cattle, fat	0.6
Cattle, mbyp	0.2
Cattle, meat	0.04
Citrus fruits group	0.3
Citrus oil	3.0
Citrus pulp, dried	0.5
Cotton gin byproducts	1.5
Cottonseed	0.02
Fruiting vegetables (except cucurbits) group	0.4
Goat, fat	0.6
Goat, mbyp	0.2
Goat, meat	0.04
Hogs, fat	0.6
Hogs, mbyp	0.2
Hogs, meat	0.04
Horses, fat	0.6
Horses, mbyp	0.2
Horses, meat	0.04
Leafy vegetables (except Brassica vegetables) group	8.0
Milk, fat	0.5
Milk, whole	0.04
Sheep, fat	0.6
Sheep, mbyp	0.2
Sheep, meat	0.04

(b) *Section 18 emergency exemptions.* [Reserved]

* * * * *

[FR Doc. 98–10023 Filed 4–14–98; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 4700

[NV–960–1060–00–24–1A]

RIN 1004–AD28

Wild Horse and Burro Adoptions; Power of Attorney

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rule.

SUMMARY: The Bureau of Land Management is amending its regulations to prohibit anyone from adopting wild horses and burros on behalf of another person using a written authorization to act as that person's agent or attorney (power of attorney). This action is necessary to implement a portion of a court-approved settlement agreement between BLM and the Animal Protection Institute of America, Inc. The effect of this action is to eliminate the potential for adopters to misuse the power of attorney to obtain large numbers of wild horses and burros for commercial sale.

DATES: This rule is effective May 15, 1998.

FOR FURTHER INFORMATION CONTACT: Bud Cribley, (202) 452–5073; or Lili Thomas, (702) 785–6457.

SUPPLEMENTARY INFORMATION:

I. Background

In 1971, Congress passed legislation to protect, manage, and control wild horses and burros on the public lands. The Wild Free-Roaming Horses and Burros Act (WHA) declared these animals to be ''living symbols of the historic and pioneer spirit of the West.'' Pub. L. 92–195, section 1, 85 Stat. 649 (1971) (current version at 16 U.S.C. 1331 (1994)). Congress further declared that all wild free-roaming horses and burros are under the jurisdiction of the Secretary of the Interior for the purpose of management and protection, and that the Secretary shall manage them in a manner that is designed to achieve and maintain a thriving natural ecological balance on the public lands. 16 U.S.C. 1333(a). Section 3(b) of the WHA authorized the Secretary, where an area is found to be overpopulated, to cause additional excess wild free-roaming horses and burros to be captured and removed for private maintenance under humane conditions and care. Congress also authorized the Secretary to issue such regulations as the Secretary deems necessary to further the purposes of the law. 16 U.S.C. 1336.

The WHA protected wild horses and burros so well that within a few years their numbers exceeded the carrying capacity of the Western rangelands and posed a threat to wildlife, livestock, and the improvement of range conditions. To correct this problem, in 1978, Congress passed amendments to the WHA as part of the Public Rangelands Improvement Act. Pub. L. 95–514, section 14, 92 Stat. 1803, 1808 (1978) (current version at 16 U.S.C. 1333(b)–(d)). The amendments sought to facilitate humane adoption of excess animals by allowing adopters to take title to up to 4 animals per year after having successfully cared for them for one year. 16 U.S.C. 1333(c). Under the amendments, individuals can adopt (but not take title to) more than 4 animals per year if the Secretary finds they can humanely care for more than four. 16 U.S.C. 1333(b)(2)(B).

To carry out this mandate, the Secretary, acting through BLM, issued regulations governing, among other things, the adoption process and who is eligible to adopt animals removed from the public lands. These regulations were proposed in 1984 (49 FR 49252, December 18, 1984) and adopted in 1986 (51 FR 7410, March 3, 1986). See 43 CFR part 4700 (1997). The 1986 regulations limited adoptions to four animals per year per person, but also allowed a person to adopt animals on behalf of another person through the use of a power of attorney. A power of attorney is a written document that authorizes one person to act as an agent or attorney for another. Under the existing regulations, one agent could get powers of attorney from several people and adopt more animals than any one person is allowed to adopt.

As discussed in the proposed rule, several investigations of adopters of