

that we felt there are clearly times when other land use changes could warrant being considered a significant revision. However, it is not our intent to indicate that all other land use changes must be considered a significant revision. Nor is it our intent to alter OSM's position as reflected in other regulatory actions relating to significant permit revisions, such as those for the Federal program in Tennessee. We do feel that it is essential for Indiana to continue to have the discretion to determine, on a case-by-case basis, that other land use changes besides those listed in section 8.1(8) may constitute a significant revision. Therefore, this provision was disapproved.

Dated: May 18, 1999.

**Brent Wahlquist,**

*Regional Director, Mid-Continent Regional Coordinating Center.*

[FR Doc. 99-13336 Filed 5-25-99; 8:45 am]

BILLING CODE 4310-05-P

## DEPARTMENT OF VETERANS AFFAIRS

### 38 CFR Part 36

RIN 2900-A192

#### Loan Guaranty: Requirements for Interest Rate Reduction Refinancing Loans

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Final rule; correction and delay of effective date.

**SUMMARY:** This document makes a correction to a final rule amending our loan guaranty regulations concerning the requirements for Interest Rate Reduction Refinancing Loans (IRRRLs). This document also delays for 14 days the effective date of the final rule. Under the final rule, generally to obtain an IRRRL the veteran's monthly mortgage payment must decrease. Also, the final rule provides that the loan being refinanced must not be delinquent or the veteran seeking the loan must meet certain credit standard provisions. The new effective date is June 7, 1999. These actions are needed because of a lawsuit concerning the final rule.

**DATES:** The final rule published in the **Federal Register** on April 23, 1999 (64 FR 19906), with changes made by this document, is effective June 7, 1999.

**FOR FURTHER INFORMATION CONTACT:** R.D. Finneran, Acting Assistant Director for Loan Policy and Valuation (262), Loan Guaranty Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420, (202) 273-7368.

**SUPPLEMENTARY INFORMATION:** Under the authority of 38 U.S.C. chapter 37, VA guarantees loans made by lenders to eligible veterans to purchase, construct, improve, or refinance their homes (the term veteran as used in this document includes any individual defined as a veteran under 38 U.S.C. 101 and 3701 for the purpose of housing loans). This document amends VA's loan guaranty regulations by revising the requirements for VA-guaranteed IRRRLs.

The IRRRL program was established by Public Law No. 96-385, October 7, 1980. IRRRLs are designed to assist veterans by allowing them to refinance an outstanding VA-guaranteed loan with a new loan at a lower rate. The provisions of 38 U.S.C. 3703(c)(3) and 3710(e)(1)(C) allow the veteran to do so without having to pay any out-of-pocket expenses. The veteran may include in the new loan the outstanding balance of the old loan plus reasonable closing costs, including up to two discount points.

We published a final rule in the **Federal Register** on April 23, 1999 (64 FR 19906), to amend the loan guaranty regulations concerning the requirements for IRRRLs. Under the final rule, generally to obtain an IRRRL the veteran's monthly mortgage payment must decrease. Also, the final rule provides that the loan being refinanced must not be delinquent or the veteran seeking the loan must meet certain credit standard provisions.

We are changing 38 CFR 36.4306a(a)(6) in the final rule to reflect statutory provisions at 38 U.S.C. 3710(e)(1)(D) which state that the dollar amount of guaranty on IRRRLs may not exceed the greater of the original guaranty amount of the loan being refinanced or 25 percent of the loan. Since this change merely restates statutory provisions there is a basis for dispensing with notice-and-comment and delayed effective date provisions of 5 U.S.C. 553.

We are also changing the effective date of the final rule. The effective date for the final rule was scheduled to be May 24, 1999. This document changes the effective date to June 7, 1999.

These actions are needed because of a lawsuit concerning the final rule.

Accordingly, in FR Doc. 99-10146 published on April 23, 1999 (64 FR 19906) make the following correction. On page 19910, in § 36.4306a, paragraph (a)(6) is corrected to read as follows:

#### **§ 36.4306a Interest rate reduction refinancing loan.**

(a) \* \* \*

(6) The dollar amount of guaranty on the 38 U.S.C. 3710(a)(8) or (a)(9)(B)(i)

loan may not exceed the greater of the original guaranty amount of the loan being refinanced or 25 percent of the loan; and

\* \* \* \* \*

Approved: May 21, 1999.

**Togo D. West, Jr.,**

*Secretary of Veterans Affairs.*

[FR Doc. 99-13396 Filed 5-21-99; 3:38 pm]

BILLING CODE 8320-01-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

OPP-300864; FRL-6081-8]

RIN 2070-AB78

#### Spinosad; Pesticide Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances for residues of spinosad in or on sweet corn at 0.02 parts per million (ppm), sweet corn forage at 0.6 ppm, sweet corn stover at 1.0 ppm, and a permanent tolerance for tuberous and corm vegetables (crop subgroup 1C) at 0.02 ppm. The Interregional Research Project Number 4 (IR-4) requested the tolerance for tuberous and corm vegetables (crop subgroup 1C). Dow AgroScience Company requested tolerances for sweet corn. These tolerances were requested under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

**DATES:** This regulation is effective May 26, 1999. Objections and requests for hearings must be received by EPA on or before July 26, 1999.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number, [OPP-300864], 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-300864], 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, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: [opp-docket@epa.gov](mailto:opp-docket@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-300864]. 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: Sidney Jackson, 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: Rm. 272, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-7610, [jackson.sidney@epa.gov](mailto:jackson.sidney@epa.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of April 8, 1999 (64 FR 17174) (FRL-6071-2), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) announcing the filing of a pesticide petition (PP) for tolerance by the Interregional Research Project Number 4 (IR-4), New Jersey Agricultural Experimental Station: P.O. Box 231, Rutgers University, New Brunswick, NJ and on September 16, 1998 (63 FR 49568) (FRL-6025-8) by the Dow AgroScience Company, 9330 Zionsville Road, Indianapolis, IN 46254. Each notice included a summary of the petition prepared by Dow AgroSciences, the registrant.

These petitions requested that 40 CFR 180.495 be amended by establishing tolerances for residues of the insecticide spinosad, in or on sweet corn at 0.02 ppm, sweet corn forage at 0.6 ppm, sweet corn stover at 1.0 ppm, and for tuberous and corm vegetables (crop subgroup 1C) at 0.02 ppm. Spinosad is a fermentation product of *Saccharopolyspora spinosa*. Spinosad

consist of two related spinosyn compounds, Factor A and Factor D both of which serve as active ingredients. They are typically present at an 85:15 A:D ratio.

### **I. Background and Statutory Findings**

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

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

### **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 sweet corn at 0.02 ppm, sweet corn forage at 0.6 ppm, sweet corn stover at 1.0 ppm and a tolerance for tuberous and corm vegetables (crop subgroup 1C) at 0.02 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 in this unit.

1. *Acute toxicity.* Spinosad has low acute toxicity. The rat oral lethal dose (LD<sub>50</sub>) is 3,738 milligram(mg)/kilogram(kg) for males and > 5,000 mg/kg for females, whereas the mouse oral (LD<sub>50</sub>) is >5,000 mg/kg. The rabbit dermal LD<sub>50</sub> is >5,000 mg/kg and the rat inhalation lethal concentration (LC<sub>50</sub>) is >5.18 mg/liter(l) air. In addition, spinosad is not a skin sensitizer in guinea pigs and does not produce significant dermal or ocular irritation in rabbits. End use formulations of spinosad that are water based suspension concentrates have similar low acute toxicity profiles.

2. *Genotoxicity.* Short term assays for genotoxicity consisting of a bacterial reverse mutation assay (Ames test), an *in vitro* assay for cytogenetic damage using the Chinese hamster ovary cells, an *in vitro* mammalian gene mutation assay using mouse lymphoma cells, an *in vitro* assay for DNA damage and repair in rat hepatocytes, and an *in vivo* cytogenetic assay in the mouse bone marrow (micronucleus test) have been conducted with spinosad. These studies show a lack of genotoxicity.

3. *Reproductive toxicity.* In a 2-generation reproduction study, groups of Sprague-Dawley rats (30/sex/group) received diets containing Spinosad (88.0%) at dose levels of 0, 0.005, 0.02, or 0.2% (3, 10, or 100 mg/kg/day, respectively) for two successive generations. For parental systemic toxicity, the no-observed adverse effect level (NOAEL) was 0.02% (10 mg/kg/day) and the lowest-observed adverse effect level (LOAEL) 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 NOAEL was 0.02% (10 mg/kg/day) and the LOAEL 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.

4. *Developmental toxicity.* In a prenatal developmental toxicity study, groups of pregnant Sprague-Dawley rats (30/group) received oral (gavage)

administration of Spinosad (88.6%) in aqueous 0.5% methylcellulose at dose levels of 0, 10, 50, or 200 mg/kg/day during gestation days 6 through 17. For maternal toxicity, the NOAEL was >200 mg/kg/day (the highest dose tested (HDT)); a LOAEL 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 NOAEL was >200 mg/kg/day; a LOAEL was not established. In the range-finding study, fetal body weight decrements occurred at 300 mg/kg/day.

In a prenatal developmental toxicity study, groups of pregnant New Zealand White rabbits (20/group) received oral (gavage) administration of Spinosad (88.6%) in 0.5% aqueous methylcellulose at doses of 0, 2.5, 10, or 50 mg/kg/day during gestation days 7 through 19. For maternal toxicity, the NOAEL was  $\geq$ 50 mg/kg/day HDT; a LOAEL 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 NOAEL was  $\geq$ 50 mg/kg/day; a LOAEL was not established. (No fetal effects were noted for fetuses of the range-finding study at doses up to 50 mg/kg/day).

5. *Subchronic toxicity.* Spinosad was evaluated in 13-week dietary studies and showed NOAELs of 4.89 and 5.38 mg/kg/day, respectively in male and female dogs; 6 and 8 mg/kg/day, respectively in male and female mice; and 33.9 and 38.8 mg/kg/day, respectively in male and female rats. The LOAELs in the male rat and female rat were 68.5 and 78.1 mg/kg/day, respectively based on decreased body weight gain, anemia, and vacuolation in multiple organs (kidney, liver, heart, spleen, adrenals, and thyroid). No dermal irritation or systemic toxicity occurred in a 21-day repeated dose dermal toxicity study in rats given 1,000 mg/kg/day.

6. *Chronic toxicity and carcinogenicity.* Based on chronic testing with spinosad in the dog and the rat, the EPA has set a reference dose

(RfD) of 0.027 mg/kg/day for spinosad. The RfD has incorporated a 100-fold safety factor to the NOAELs found in the chronic dog study to account for inter- and intra-species variation. The NOAELs shown in the dog chronic study were 2.68 and 2.72 mg/kg/day, respectively for male and female dogs. The NOAELs (systemic) shown in the rat chronic/carcinogenicity/neurotoxicity study were 9.5 and 12.0 mg/kg/day, respectively for male and female rats. The LOAEL (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.

Using the Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), it is proposed that spinosad be classified as Group E for carcinogenicity (no evidence of carcinogenicity) based on the results of carcinogenicity studies in two species. There was no evidence of carcinogenicity in an 18-month mouse feeding study and a 24-month rat feeding study at all dosages tested. The NOAELs shown in the mouse carcinogenicity study were 11.4 and 13.8 mg/kg/day, respectively for male and female mice. A maximum tolerated dose was achieved at the top dosage level tested in both of these studies based on excessive mortality. Thus, the doses tested are adequate for identifying a cancer risk. Accordingly, a cancer risk assessment is not needed.

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

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

In the 2-year chronic toxicity study, groups of Fischer 344 rats (65/sex/dose) received diets containing Spinosad at dose levels of 0, 0.005, 0.02, 0.05, or 0.1% (0, 2.4, 9.5, 24.1, or 49.4 mg/kg/day for males and 0, 3.0, 12.0, 30.3, or 62.2 mg/kg/day for females,

respectively). Neurobehavioral testing performed at 3, 6, 9, and 12 months of study was negative, and histopathological evaluation of perfused tissues at study termination did not identify pathology of the central or peripheral nervous system. There was no evidence of neurotoxicity. For neuropathology, the NOAEL was 0.1% (>49.4 mg/kg/day for males and >62.8 mg/kg/day for females).

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

The residue of concern for tolerance setting purposes is the parent material (spinosyn A and spinosyn D). Thus, there is no need to address metabolite toxicity.

## 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 NOAEL was not shown at 2,000 mg/kg/day HDT. A risk assessment is not required as no appropriate endpoint is available.

2. *Short- and intermediate-term toxicity—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 of: (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. 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 NOAEL of 2.68 mg/kg/day established in a chronic toxicity study in dogs. The LOAEL 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 NOAEL of 2.68 mg/kg/day to account for inter- and intra- species variation. The resulting RfD was calculated to be 0.0268 mg/kg/day.

4. *Carcinogenicity.* 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.

### C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.495) for the residues of spinosad, in or on a variety of raw agricultural commodities. Spinosad is registered for use on a number of agricultural commodities, including apples, Brassica vegetables, and fruiting vegetables (excluding cucurbits). Additionally, spinosad is registered for pest control in turfgrass and ornamental plants. Application rates range from 0.023 to 0.156 lb a.i./acre/A, depending on the target pest and the crop. The maximum seasonal application rate is 0.45 lb a.i./A. Application intervals range from 7 to 14 days, with restriction against too many applications per season and/or pest generation, to avoid resistance. Pre-harvest intervals range from 1 to 14 days. Risk assessments were conducted by EPA to assess dietary exposures from spinosad as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological

study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. The Agency 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 NOAEL was  $\geq 2,000$  mg/kg/day.

Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No acute toxicological endpoints were identified for spinosad due to the lack of toxicological effects attributable to a single exposure (dose). Therefore, the Agency concludes that there is a reasonable certainty of no harm from acute dietary exposure. Acute dietary risk assessment is not required.

ii. *Chronic exposure and risk.* In conducting this chronic dietary risk assessment, EPA has 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. Additionally, residues of 0.02 ppm were assumed for all other forms to support a pending section 18 action on spinosad. This results in an overestimate of human dietary exposure. Thus, in making a safety determination for proposed tolerance(s), EPA is taking into account this conservative exposure assessment.

The existing spinosad tolerances (published, pending, and including the necessary section 18 tolerances) result in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to the following percentages of the FQPA chronic population adjusted dose (cPAD) for the following population subgroups: for the U.S. population (48 states) the TMRC is 0.005658 mg/kg/day which represents 21% of the cPAD, and for children (1 to 6 years old), the highest exposed subgroup, the TMRC is 0.010522 mg/kg/day utilizing 39% of the cPAD.

2. *From drinking water.* Monitoring data depicting residue levels of spinosad in drinking water are not available. Therefore, EPA cannot perform a quantitative risk assessment for drinking water exposure. Instead, EPA had used modeled estimated environmental concentrations (EECs),

and back-calculated drinking water levels of comparison (DWLOCs) to determine whether exposure to spinosad via drinking water is likely to be of concern.

EPA concludes that the available data on spinosad show that the compound is not mobile or persistent, and therefore has little potential to leach to ground water. Spinosad may however contaminate surface water upon the release of water from flooded fields to the environment. Additionally, EPA's Metabolism Assessment Review Committee determined that the spinosyn Factors A and D are not expected to reach groundwater (2/10/98). In order to assess drinking water exposures, EPA used the screening models PRZM (pesticide root zone model) and EXAMS (exposure analysis modeling systems) to generate surface water EECs associated with application of spinosad to various crops. Modeled scenarios were selected because they are expected to represent roughly the upper 90<sup>th</sup> percentile for surface water vulnerability, given the chemical's geographic use range. The Tier 2 chronic surface water EEC for spinosad is 0.092  $\mu\text{g/L}$  and is based on application of the insecticide to cole crops (0.13 lb a.i./A/application, 0.45 lb a.i./A/season). The EEC value is over 1,000 times less than the lowest DWLOC. Based on the studies, the Agency concludes that drinking water is not expected to be a significant source of exposure to spinosad.

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

ii. *Chronic exposure and risk.* For the most highly exposed population subgroup, children (1-6 years old), chronic dietary (food only) exposure occupies 39% of the cPAD. This is a conservative risk estimate for reasons described above. The chronic lowest 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. Therefore, 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 the Agency has reliable data) would not result in unacceptable levels of aggregate human health risk at this time.

3. *From non-dietary exposure.* No acute dietary, cancer, or short-, intermediate-, or chronic-term dermal or inhalation endpoints were identified by the Agency. Spinosad is currently registered on turf grass, creating a potential for non-dietary oral exposure to children who ingest grass. To calculate a quantitative dietary risk from a potential ingestion of grass (in the absence of acute-, short-, or intermediate-term oral endpoints), EPA would need to default to the chronic dietary endpoint. This scenario would represent a child eating grass for > 6 months continuously. Based on the low application rate for spinosad on turf (0.41 lbs. ai./A.), its non-systemic nature, its short half life (especially in sunlight), and the rapid incorporation of spinosad metabolites into the general carbon pool, EPA believes that residues of spinosad on turf grass after application would be low and decrease rapidly over time. EPA believes that it is inappropriate to perform a quantitative dietary risk representing a chronic scenario from children eating turf grass. Qualitatively, the risk from children eating turf grass does not exceed the Agency's level of concern. Another registered product contains spinosad for use on structural lumber however, the product is injected into drilled holes and then sealed after treatment. The product can only be applied by commercial applicators with very minimal potential risk to the public. Due to the lack of toxicity endpoints (hazard) and minimal contact with the active ingredient during and after application, exposure to residential occupants is not expected. The Agency concludes that there is a reasonable certainty of no harm from non-dietary exposure.

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

EPA does not have, at this time, available data to determine whether spinosad has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity,

spinosad does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that spinosad has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Acute risk.* Because no acute dietary endpoint was determined from toxicity testing, the Agency concludes that there is a reasonable certainty of no harm from acute aggregate risk. An acute aggregate risk assessment is not required.

2. *Chronic risk.* Using the TMRC exposure assumptions described in this unit, EPA has concluded that aggregate exposure to spinosad from food will utilize 21 percent of the cPAD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is discussed below. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to spinosad in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the cPAD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to spinosad residues.

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

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

4. *Aggregate cancer risk for U.S. population.* The 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.

5. *Determination of safety.* Based on these risk assessments, EPA concludes

that there is a reasonable certainty that no harm will result from aggregate exposure to spinosad residues.

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

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

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

ii. *Developmental toxicity studies.* See unit II.A.— Toxicological profile above.

iii. *Reproductive toxicity study.* See unit II.A.— Toxicological profile above.

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

v. *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 2-generation reproduction study in rats, effects in the offspring were observed only at or below treatment levels which resulted in evidence of parental toxicity. 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 postnatal exposure to spinosad. In the prenatal developmental toxicity studies in rats and rabbits and the 2-generation reproduction study in rats, effects in the offspring were observed only at or below treatment levels which resulted in evidence of parental toxicity. (ii) No neurotoxic signs have been observed in any of the standard required studies conducted. (iii) The toxicology data base is complete and there are no data gaps. There is a complete toxicity database for spinosad and exposure data are complete or estimated based on data that reasonably account for potential exposures.

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

3. *Chronic risk.* Using the conservative exposure assumptions described in this unit, EPA has concluded that aggregate exposure to spinosad from food will utilize 39% of the cPAD for infants and children. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

4. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to 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 previously concluded that the nature of the spinosad residue in plants is adequately understood based on metabolism studies in apples, cabbage, cotton, tomatoes, and turnips. EPA's Metabolism Assessment Review Committee determined that the residue of concern is spinosad (a total of spinosyn A and spinosyn D), as noted in the 40 CFR 180.495 entry for cottonseed.

Similarly, EPA has previously concluded that the nature of the spinosad residue in animals is adequately understood based on metabolism studies in the goat and hen. Also noted in the 40 CFR 180.495 entry for cottonseed.

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

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

#### *B. Analytical Enforcement Methodology*

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

byproducts - GRM 94.02.S1. All of these methods are essentially similar to GRM 94.02 and have been submitted to FDA for inclusion in PAM II as letter methods. Method GRM 94.02 is adequate for regulation of the tolerance expression.

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

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

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

Adequate enforcement methodology (example - gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5229.

#### *C. Magnitude of Residues*

Magnitude of residue studies were conducted for potatoes at 14 sites. No quantifiable residues were observed in treated field samples at an application rate of 0.11 pounds active ingredient (lb a.i.) per acre or at an exaggerated application rate of 0.55 lb a.i. per acre. A potato processing study is not required because there were no quantifiable residues in the raw agricultural commodity (RAC) even at the 5X application rate (5X is the maximum theoretical concentration factor for potato). Potato is the representative crop for the tuberous and corm vegetables crop subgroup 1C.

Magnitude of residue studies were conducted for sweet corn at 12 sites, and 5X the label rate. Residues found in these studies ranged from none detected for sweet corn; 0.09 to 0.57 ppm for corn forage; and 0.03 to 0.82 ppm for corn fodder.

A ruminant feeding study was previously accepted by the Agency. Based on the results of this study, the data support the currently established tolerances: fat (of 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 maximum residue levels (MRLs) have been established for residues of spinosad on any crops.

#### **IV. Conclusion**

Therefore, the time-limited tolerances are established for residues of spinosad in or on sweet corn at 0.02 ppm, sweet corn forage at 0.6 ppm, sweet corn stover at 1.0 ppm, and a permanent tolerance for tuberous and corn vegetables (crop subgroup 1C) at 0.02 ppm.

#### **V. Objections and Hearing Requests**

The new FFDCA section 408(g) provides essentially the same process for persons to "object" to a tolerance regulation 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 July 26, 1999, 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 under the "ADDRESSES" section (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 regulation. 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). 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 tolerance objection fee waivers, contact James Tompkins, 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: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5697, [tompkins.jim@epa.gov](mailto:tompkins.jim@epa.gov). Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

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 Record and Electronic Submissions**

EPA has established a record for this regulation under docket control number [OPP-300864] (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 Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at: [opp-docket@epa.gov](mailto:opp-docket@epa.gov).

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit 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 record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in "ADDRESSES" at the beginning of this document.

#### **VII. Regulatory Assessment Requirements**

##### *A. Certain Acts and Executive Orders*

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 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 tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. 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), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

#### B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

#### C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes

substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

#### VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and 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: May 14, 1999.

**Richard P. Keigwin, Jr.,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

#### PART 180—AMENDED

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

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

2. In § 180.495, in paragraph (a), by revising the introductory text, by adding to the table entries for corn, sweet, forage; corn, sweet, kernal, plus cob with husk removed; corn, sweet, stover; and tuberous and corm vegetables (crop subgroup 1C) to read as follows:

#### § 180.495 Spinosad; tolerances for residues.

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

Commodity	Parts per million	Expiration/Revocation date
* * *		
Corn, sweet, forage .....	0.6	06/20/01
Corn, sweet, kernel, plus cob with husk removed .....	0.02	06/20/01
Corn, sweet, stover .....	1.0	06/20/01
* * *		
Tuberous and corm vegetables (crop subgroup 1C)	0.02	None
* * *		

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