transformed by monoamine oxidases, through a variety of pathways. These include: deamination, methylation , N-dealkylation, N-oxidation, N-acetylation, cyclization, N-hydroxylation, and nitrosation.

7. *Metabolite toxicology*. Secondary amines are prone to react with nitrite, depending on the pH of the media, to form nitrosamines, some of which are potent animal carcinogens. Some studies have suggested the possibility of *in vivo* formation of carcinogenic nitrosamines within the acidic environment of the stomach following ingestion of secondary amines. The major human intake of nitrates (≈50 mg/day) comes from vegetables, water supplies, or additives in the meat and fish curing process (Ellen et al. 1990. *Food Additives Contaminants* 7(2) :207–221). Nitrates are converted to nitrites in the upper part of the gastrointestinal tract by nitroreductase bacteria normally present in the lower bowel.

Amines or amine precursors are present in vegetables, wine, spirits, beer, tea, fish, food flavoring agents, and some drugs. As indicated above, at least 10 mg of amine nitrogen is excreted per day; the intake of amines or their precursors is therefore probably in the 100 mg/day range. Thus there exists the required elements for the *in vivo* formation of carcinogenic nitrosamines from amine ingestion. Despite this theoretical possibility, epidemiologic studies have not provided evidence for a causal association between nitrite exposure and human cancer. Nor has a causal link been shown between N-nitroso compounds preformed in the diet or endogenously synthesized and the incidence of human cancer (Gangilli., S.D., 1999, ''Nitrate, nitrite and N-nitroso compounds'', In Ballintine, B., Marrs, T., and Turner, P., *General and Applied Toxicology*, Stockton Press, New York, p. 2111, 2143). It has been demonstrated in animals that nitrosation of diethylamine and dimethyamine *in vivo* is a very slow process. When these substances were fed to rats together with nitrite for over two years no tumors typical of treatment of rats with nitrosodiethylamine were observed Druckery et al, 1963 Cited by Benya et al., *Patty's*, 4th Ed. Vol II, Part B , page 1097). In any event, the addition to the diet of nanogram levels of amines from the proposed used of amine based surfactants is insignificant compared to normal endogenous levels and to those naturally occurring in food.

8. *Endocrine disruption*. There is no evidence to suggest that the alkyl amines have an effect on any endocrine system. In developmental and two-generation reproduction toxicity tests systemic toxicity was noted but no developmental or reproductive effects were found.

*C. Aggregate Exposure*

1. *Dietary exposure*. Exposure through both food and drinking water were estimated using data and methods more commonly applied to pesticide active ingredients. The methods for estimating dietary exposure are discussed above under residues. Drinking water exposures were estimated using EPA's combined Pesticide Root Zone Model/Exposure Assessment Modeling System (PRZM/EXAMS) and the 1 ha pond scenario.

i. *Food*. Both Tier 1 and Tier 2, acute and chronic dietary assessments were constructed in several different ways and in general margin of exposures (MOEs) >100 were found. Tier 1 acute assessments did yield MOEs <100, but the Tier 2 analysis gave an MOE = 1,500 for the lowest Tier 1 scenario.

ii. *Drinking water*. Using the average peak value from PRZM/EXAMS modeling for acute exposure, the average 60–day concentration for chronic exposure and the standard estimates of water consumption, acute and chronic margins of exposure for drinking water all MOEs were greater than 460. In using the model, maximum application rates and number of applications were assumed and the alkoxylated surfactants were assumed not to degrade in water or the environment. The modeling provides an extreme worst-case estimate of exposure in that the peak values simulated accumulation (i.e., no degradation) of the surfactants in water during a 30 years period of application.

2. *Non-dietary exposure*. For non-dietary exposure and risk analysis outdoor lawn care with broadcast application via hose-end sprayer was selected as the worst case. Dermal absorption was assumed to be 10%. Applicators were assumed to have dermal and inhalation exposures, while re-entry exposures were dermal and oral, the oral via hand-to-mouth activities by children. MOE's >100 were estimated by Tier 1 analyses, indicating reasonable certainty of no harm for the worst-case bounding scenario evaluated.

*D. Cumulative Effects*

Other alkoxylated amine compounds may be used in pesticide formulations. However, the assessment of this class of compounds assumes 100% of the pesticide products applied to crops will use one member of this class of alkoxylated amines. Therefore, the cumulative risk for this class of compound is covered by the assessments in this submission.

*E. Safety Determination*

1. *U.S. population*. As a general rule in any pesticide assessments, exposures of children are the highest of any subpopulation. This pattern was found to hold true for the alkoxylated surfactants and lead to simplifications in the assessment procedure. When exposures to children were found to be acceptable, e.g., acute and chronic Tier 2 estimated dietary exposures to children yielded large MOEs, separate estimates for other subpopulations were not deemed necessary. In the risk assessment we ultimately have adopted the dietary exposures for children for all subpopulations. Exposures for females 13–49 were calculated in certain instances and found to be comparable to each other and less than for children. Hence, exposure estimates for the latter were not formally completed. Rather the exposure numbers for females were assumed for the full U.S. population.

2. *Infants and children*. Except when using acute Tier 1 dietary exposure estimates and the most conservative toxicity endpoint, 3 mg/kg-bw/day, all MOEs were found to be comfortably greater than 100. Given the worst-case conservatism built into all the analyses, the results support a conclusion that Tomah[3]'s alkoxylated surfactants may be used safely in pesticide formulations without concerns for dietary and non-occupational exposures.

[FR Doc. 05–13978 Filed 7–19–05; 8:45 am]
**BILLING CODE 6560–50–S**

## ENVIRONMENTAL PROTECTION AGENCY

**[OPP–2005–0180; FRL–7721–6]**

## Spinosad; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

**DATES:** Comments, identified by docket identification (ID) number OPP–2005–0180, must be received on or before August 19, 2005.

**ADDRESSES:** Comments may be submitted electronically, by mail, or

through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: *brothers.shaja@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

## I. General Information

### *A. Does this Action Apply to Me?*

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

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

### *B. How Can I Get Copies of this Document and Other Related Information?*

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2005–0180. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although, a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or on paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

### *C. How and to Whom Do I Submit Comments?*

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also, include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets

at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2005–0180. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to *opp-docket@epa.gov*, Attention: Docket ID number OPP–2005–0180. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID number OPP–2005–0180.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID number OPP–2005–0180. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

*D. How Should I Submit CBI to the Agency?*

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*E. What Should I Consider as I Prepare My Comments for EPA?*

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

## II. What Action is the Agency Taking?

EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on these petitions.

**List of Subjects**

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 30, 2005.

**Lois Rossi,**

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

**Summary of Petition**

The petitioner's summary of the pesticide petitions is printed below as required by FFDCA section 408(d)(3). The summary of the petitions was prepared by the Interregional Research Project Number 4, and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

**Interregional Research Project Number 4**

*PP 3E6699, PP 3E6780, PP 3E6782, PP 3E6802, PP 3E6804, PP 4E6811*

EPA has received pesticide petitions (PP 3E6699, PP 3E6780, PP 3E6782, PP 3E6802, PP 3E6804, and PP 4E6811) from Interregional Research Project Number 4 (IR–4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180.495 by establishing tolerances for residues of spinosad in or on the following raw agricultural commodities:

PP 3E6699 proposes to establish tolerances for banana and plantain at 0.25 parts per million (ppm).

PP 3E6780 proposes to establish tolerances for food commodities at 0.02 ppm.

PP 3E6782 proposes to establish tolerances for spearmint, tops at 5.0 ppm and peppermint, tops at 5.0 ppm.

PP 3E6802 proposes to establish tolerances for animal feed, nongrass, group 18, forage at 20 ppm; animal feed, nongrass, group 18 hay at 25 ppm; and peanut, hay at 25 ppm.

PP 3E6804 proposes to establish tolerances for vegetable, bulb, except green onion, group 3 at 0.1 ppm and onion, green at 2.0 ppm.

PP 4E6811 proposes to establish tolerances for:

- Grass, forage, fodder and hay, group 17, forage at 1.5 ppm.
- Grass, forage, fodder and hay, group 17, hay at 5 ppm.
- Corn, field, stover; corn, pop, stover; and corn, sweet, stover at 5.0 ppm.

- Corn, field, forage; corn, sweet, forage; and corn, pop, forage at 1.5 ppm.
- Teosinte, forage at 1.5 ppm.
- Millet, pearl, forage; and millet, proso, forage at 1.5 ppm.
- Millet, pearl, hay; millet, proso, hay; millet proso, straw at 5.0 ppm.
- Sorghum, forage, forage and sorghum, grain, forage at 1.5 ppm.
- Sorghum, forage, hay; and sorghum, grain, stover at 5.0 ppm.
- Wheat, forage at 1.5 ppm.
- Wheat, hay and wheat, straw at 5.0 ppm.
- Barley, straw and barley, hay at 5.0 ppm.
- Rye, forage at 1.5 ppm.
- Rye, straw at 5 ppm.
- Oat, forage at 1.5 ppm.
- Oat, hay and oat, straw at 5.0 ppm.
- Triticale, forage at 1.5 ppm.
- Triticale, hay and 5.0 ppm.

These petitions were prepared by Dow AgroSciences LLC, Indianapolis IN, 46268. EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petitions. Additional data may be needed before EPA rules on the petitions.

*A. Residue Chemistry*

1. *Plant metabolism*. The nature of the residue of spinosad in plants is adequately understood for the purpose of these tolerances. A rotational crop study showed no carryover of measurable spinosad related residues in representative test crops.

2. *Analytical method*. There is a practical method (immunoassay) for detecting and measuring levels of spinosad in or on food with a limit of detection 0.005 ppm that allows monitoring of food with residues at or above the level set for these tolerances. The method had undergone successful EPA laboratory validation.

3. *Magnitude of residues*. Five field trials were conducted for bananas and showed residues of 0.02–0.20 ppm. Three field trials were conducted for mint and showed residues in mint tops of 0.25–3.25 ppm. No residue was found in mint oil. Three field trials were conducted for onions (representative for bulb vegetable, group 3). Residues were 1 ppm in onion, dry (bulb) and 2 ppm in green onion. A magnitude of residue study was conducted at 7 sites on grass. Residues were 1.4–6.9 ppm for forage and 0.57–4.2 ppm in hay. Residue data generated from this study were used in support of the proposed tolerances for group 17 (grass forage, fodder and hay) and group 16 (forage, fodder and straw of cereal grains). A magnitude of residue study was conducted at 5 sites each for alfalfa and clover. Residues were 1.8–20 ppm in alfalfa forage and 1.6–5.3 ppm in clover forage. In hay, residues were 0.7–24.8 ppm for alfalfa and 1.3–9.5 ppm for clover. Residue data generated from this study were used in support of the proposed tolerances for peanut hay and group 18 (non-grass animal feeds, forage, fodder, straw and hay).

*B. Toxicological Profile*

1. *Acute toxicity*. Spinosad has low acute toxicity. The rat oral $LD_{50}$ is 3,738 milligrams/kilogram (mg/kg) for males and >5,000 mg/kg for females, whereas the mouse oral $LD_{50}$ is >5,000 mg/kg. The rabbit dermal $LD_{50}$ is >5,000 mg/kg and the rat inhalation $LC_{50}$ 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. *Genotoxicty*. Short-term assays for genotoxicity consisting of a bacterial reverse mutation assay (Ames test), and *in vitro* assay for cytogenetic damage using the Chinese hamster ovary cells, an *in vitro* mammalian gene mutation assay using 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 and developmental toxicity*. Spinosad caused decreased body weights in maternal rats given 200 mg/kg/day by gavage in a teratology study (highest dose tested). This was not accompanied by either embryotoxicity, fetal toxicity, or teratogenicity. The no-observed-adverse-effect levels (NOAELs) for maternal and fetal toxicity in rats were 50 and 200 mg/kg/day, respectively. A teratology study in rabbits showed that spinosad caused decreased body weight gain and a few abortions in maternal rabbits given 50 mg/kg/day (highest dose tested). Maternal toxicity was not accompanied by either embryotoxicity, fetal toxicity, or teratogenicity. The NOAELs for maternal and fetal effects in rabbits were 10 and 50 mg/kg/day, respectively. In a two-generation reproduction study in rats, parental toxicity was observed in both males and females given 100 mg/kg/day (highest dose tested). Perinatal effects (decreased litter size and pup weight) at 100 mg/kg/day were attributed to maternal toxicity. The NOAEL for maternal and pup effects was 10 mg/kg/day.

4. *Subchronic toxicity*. Spinosad was evaluated in 13–week dietary studies and showed NOAELs of 4.9 mg/kg/day in dogs, 6 mg/kg/day in mice, and 8.6 mg/kg/day in rats. No dermal irritation or systemic toxicity occurred in a 21–day repeated dose dermal toxicity study in rabbits given 1,000 mg/kg/day.

5. *Chronic toxicity*. 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 interspecies and intra-species variation. The NOAELs in the chronic dog 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. 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 any dosages. The NOAELs in the mouse oncogenicity 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 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 was not performed. Spinosad did not cause neurotoxicity in rats in acute, subchronic, or chronic toxicity studies.

6. *Animal metabolism*. There were no major differences in the bioavailability, routes or rates of excretion or metabolism if spinosyn A and spinosyn D following oral administration in rates. Urine and fecal excretions were almost completed in 48–hours post-dosing. In addition, the routes and rates of excretion were not affected by repeated administration.

7. *Metabolite toxicology*. 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.

8. *Endocrine disruption*. There is no evidence to suggest that spinosad has an effect on any endocrine system.

*C. Aggregate Exposure*

1. *Dietary exposure—i. Food.* An acute dietary exposure was not performed because the Agency did not identify an acute dietary endpoint that was applicable to females (13+ years) or to the general U.S. population,

including infants and children. EPA has recently assessed the chronic dietary exposure to spinosad on existing crop uses and time-limited use on onions (**Federal Register** of August 6, 2003, (68 FR 46491) (FRL–7317–3). In conducting the chronic dietary assessment, EPA used the Dietary Exposure Evaluation Model-Trade Mark (DEEM™) software with the food commodity intake database which incorporates food consumption data as reported by respondents in the U.S. Department of Agriculture (USDA) 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII). The chronic dietary analysis represents a moderately refined estimate of dietary exposure using percent crop treated (PCT) estimates, anticipated residues for meat and milk, and default processing factors. EPA has concluded that exposure to spinosad from food will utilize 30% of the chronic population adjusted dose (cPAD) for the general U.S. population, 24% of the cPAD for females 13–49 years old, and 69% of the cPAD for children 1–2 years old, the sub-population at greatest exposure. When the calculated, anticipated residues from the new crop uses proposed in this notice are included in the risk assessment dietary exposure evaluation model food commodity intake data base (DEEM-FCID), the estimated exposure is increased by approximately 5% for the U.S. population, 4% for females 13–49 years old, and 19% for children 1–2 years old. Adverse effects are not expected for exposures utilizing less than 100% of the RfD, therefore, chronic dietary exposure and risk for the general U.S. population and children are well within the acceptable levels.

ii. *Drinking water*. Since the Agency lacks sufficient monitoring data to complete a comprehensive exposure and risk for spinosad in drinking water, drinking water concentration estimates are made on simulation taking into account data on the physical characteristics of spinosad.

Guidance from EPA has indicated that Tier 1 screening level models, such as the generic expected environmental concentration (GENEEC) and the screening concentration in ground water (SCI-GROW), maybe used to estimate upper-bound pesticide residues in surface water and ground water when assessing potential exposure through drinking water. Estimated environmental concentrations (EEC) of pesticide in surface water or ground water are then compared to a drinking water level of comparison (DWLOC). DWLOC is not a regulatory standard for drinking water but a theoretical upper limit on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and from residential uses. DWLOC determines how much of the acceptable exposure (PAD) is available for exposure through drinking water. In calculating DWLOC, default values for body weights and water consumption were used: 2L/70 kg adult male, 2L/60 kg adult female, and 1L/10 kg child.

In a recent assessment, published in the August 6, 2003 **Federal Register**, EPA used the first index reservoir screening tool (FIRST) and SCI-GROW models to estimate the EECs of spinosad in surface water and ground water. The EECs for chronic exposures are estimated to be 2.3 parts per billion (ppb) in surface water and 0.037 ppb in ground water.

As shown in the table in this unit, the EECs in surface water and ground water are substantially below the chronic DWLOC, therefore, aggregate chronic exposure is not expected to exceed 100% of the cPAD.

| Population Subgroup | cPAD milligrams/ kilogram/day (mg/ kg/day) | %cPAD | Surface Water parts per billion (ppb) | Ground Water ppb | DWLOC ppb |
|---|---|---|---|---|---|
| U.S. population | 0.027 | 35 | 2.3 | 0.037 | 615 |
| Children 1–2 years old | 0.027 | 88 | 2.3 | 0.037 | 35 |
| Females 13–49 years old | 0.027 | 28 | 2.3 | 0.037 | 615 |

2. *Non-dietary exposure*. Spinosad is also currently registered for outdoor use on turf and ornamentals at low rates of application 0.04–0.54 lb active ingredient/Acre (a.i./A) that could result in short-term residential exposure. Intermediate-term residential exposure is considered negligible because residues on turf after 30 days were insignificant. Since dermal post-application exposure is not of concern (no identified toxicological end-point), only hand-to-mouth, object-to-mouth, and incidental ingestion of soil exposures for turf and ornamental uses were considered for exposure. The Agency has developed exposure formulas and estimated doses to theoretically assess residential incidental oral exposure. The resulting incidental oral ingestion margin of exposures (MOEs) from the residential use of spinosad calculated by the Agency are all below EPA's level of concern. The combined incidental oral MOE is 640, as published in the August 6, 2003 **Federal Register**.

*D. Cumulative Effects*

The potential for cumulative effects of spinosad and other substances that have a common mechanism of toxicity is also considered. In terms of insect control, spinosad causes excitation of the insect nervous system, leading to involuntary muscle contractions, prostration with tremors, and finally paralysis. These effects are consistent with the activation of nicotinic acetylcholine receptors by a mechanism that is clearly novel and unique among known insecticidal compounds. Spinosad also has effects on the gamma aminobatopic acid (GABA) receptor function that may contribute further to its insecticidal activity. Based on results found in tests with various mammalian species, spinosad appears to have a mechanism of toxicity like that of many amphiphilic cationic compounds. There is no reliable information to indicate that toxic effects produced by spinosad would be cumulative with those of any other pesticide chemical. Thus, it is appropriate to consider only the potential risks of spinosad in an aggregate exposure assessment. Spinosad is classified in a mechanism-of-action group of its own for the purpose of resistance management in insects and for rotation with other crop protection products.

*E. Safety Determination*

1. *U.S. population*. Chronic dietary exposures for the general U.S. population and females (13–49 years old) to residues of spinosad from the new uses proposed in this notice were estimated to increase the recent EPA risk estimate (see the August 6, 2003 **Federal Register** by approximately 5% of the cPAD. After calculating the chronic DWLOCs and comparing them to the EECs for surface water and

ground water, the aggregate exposure is not expected to exceed 100% of the cPAD. Additionally, all MOEs for short-term risk are below the level of concern. Thus, based on the completeness and reliability of the toxicity data and the moderately refined exposure assessment, it is concluded that there is a reasonable certainty that no harm will result to the U.S. population from short-term or chronic aggregate exposures to spinosad residues from current and proposed uses.

2. *Infants and children.* FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base. Based on the current toxicological data requirements, the data base for spinosad relative to prenatal and postnatal effects for children is complete. Furthermore, the NOAELs in the dog chronic feeding study which were used to calculate the RfD of 0.027 mg/kg/day are already lower than the NOAELs from the developmental studies in rats and rabbits by a factor of more than 10–fold. In the reproductive study in rats, the pup effects shown at the highest dose tested were attributed to the maternal toxicity. Also, no neurotoxic signs have been observed in any of the standard required studies conducted. Therefore, it is concluded that there is no indication of increased sensitivity of infants and children relative to adults and that an additional Food Quality Protection Act (FQPA) safety factor is not required.

Chronic dietary exposure to residues of spinosad from the new uses proposed in this notice was estimated to increase the EPA risk estimate by approximately 19% for children 1–2 years old, the population subgroup predicted to be most highly exposed. After calculating the chronic DWLOCs and comparing them to the EECs for surface water and ground water, the aggregate exposure is not expected to exceed 100% of the cPAD.

Thus, based on the completeness and reliability of the toxicity data and the moderately refined exposure assessment, it is concluded that there is a reasonable certainty that no harm will result to infants and children from short-term and chronic aggregate exposures to spinosad residues from current and proposed uses.

*F. International Tolerances*

In 2003, Codex Alimentarius Commission adopted 29 new maximum residue levels (MRLs) for spinosad and included cotton, almonds, corn, and several fruits and vegetables, as well as animal commodities.

[FR Doc. 05–13977 Filed 7–19–05; 8:45 am]

BILLING CODE 6560–50–S

## FEDERAL COMMUNICATIONS COMMISSION

### Public Information Collections Approved by Office of Management and Budget

July 5, 2005.

**SUMMARY:** The Federal Communications Commission (FCC) has received Office of Management and Budget (OMB) approval for the following public information collections pursuant to the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid control number.

**FOR FURTHER INFORMATION CONTACT:** Dana Jackson, Federal Communications Commission, 445 12th Street, SW., Washington DC 20554, (202) 418–2247 or via the Internet at *Dana.Jackson@fcc.gov.*

**SUPPLEMENTARY INFORMATION:**

*OMB Control No.:* 3060–0717.

*OMB Approval date:* 6/28/2005.

*Expiration Date:* 6/30/2008.

*Title:* Billed Party Preference for InterLATA 0+ Calls, CC Docket No. 92–77, 47 CFR 64.703(a), 64.709, and 64.710.

*Form No.:* N/A.

*Estimated Annual Burden:* 54,375,330 responses; 30 seconds to 50 hours average per response; 477,185 hours.

*Total Annual Cost:* $216,150.

*Needs and Uses:* Pursuant to 47 CFR 64.703(a), Operator Service Providers (OSPs) are required to disclose, audibly and distinctly to the consumer, at no charge and before connecting any interstate call, how to obtain rate quotations, including any applicable surcharges. 47 CFR 64.709 codifies the requirements for OSP's to file informational tariffs with the Commission. 47 CFR 64.710, among other things, requires providers of interstate operator services to inmates at correctional institutions to identify themselves, audibly and distinctly, to the party to be billed.

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary.*

[FR Doc. 05–13862 Filed 7–19–05; 8:45 am]

BILLING CODE 6712–01–P

## FEDERAL COMMUNICATIONS COMMISSION

### Public Information Collection Approved By the Office of Management and Budget

July 11, 2005.

**SUMMARY:** The Federal Communications Commissions (FCC) has received Office of Management and Budget (OMB) approval for the following public information collection pursuant to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13, 109 Stat 163 (1995). An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. Notwithstanding any other provisions of law, no person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid control number.

**FOR FURTHER INFORMATION CONTACT:** For additional information or questions concerning the OMB control number and expiration date should be directed to Evan Baranoff, Kenneth Lewis or Eloise Gore, Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554, (202) 418–2120 or via the Internet to *Evan.Baranoff@fcc.gov, Kenneth.Lewis@fcc.gov* or *Eloise.Gore@fcc.gov.*

*OMB Control Number:* 3060–0311.

*OMB Approval Date:* 5/25/05.

*OMB Expiration Date:* 5/31/08.

*Title:* 47 CFR 76.54, Significantly Viewed Signals; Method to be followed for Special Showings.

*Form Number:* Not applicable.

*Respondents:* Business or other for-profit entities.

*Number of Respondents:* 500.

*Estimated Time Per Response:* 1–15 hours.

*Total Annual Burden:* 20,610 hours.

*Total Annual Costs:* $200,000.

*Needs and Uses:* 47 CFR 76.54(b) provides for cable operators and broadcast stations seeking cable carriage of ''significantly viewed'' signals to use the Section 76.7 petition process to demonstrate ''significantly viewed'' status on a community basis by independent professional audience surveys. The proposed rule changes, if adopted, would require satellite carriers or broadcast stations seeking satellite carriage of ''significantly viewed'' signals to use the same petition process now in place for cable operators, as required by 47 CFR sections 76.5, 76.7 and 76.54 of the FCC's rules.

47 CFR 76.54(c) is used to notify interested parties, including licensees or permittees of television broadcast