III. What is the Agency Authority for Taking This Action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be amended to delete one or more uses. The Act further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, the Administrator may approve such a request.

IV. How and to Whom Do I Submit Withdrawal Requests?

1. *By mail*: Registrants who choose to withdraw a request for use deletion must submit such withdrawal in writing to James A. Hollins, at the address given above, postmarked July 6, 2001

2. *In Person or by courier*: Deliver your withdrawal request to: Document Processing Desk (DPD), Information Services Branch, Office of Pesticide Programs (OPP), Environmental Protection Agency, Room 266A, Crystal Mall 2, 1921 Jefferson Davis Highway, Arlington, VA. The DPD is open from 8:00 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The DPD telephone number is (703) 305–5263.

3. *Electronically*. You may submit your withdrawal request electronically by e-mail to: hollins.james@epa.gov. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0 or ASCII file format.

V. Provisions for Disposition of Existing Stocks

The Agency has authorized the registrants to sell or distribute product under the previously approved labeling for a period of 18 months after approval of the revision, unless other restrictions have been imposed, as in special review actions.

List of Subjects

Environmental protection, Pesticides and pests, Product registrations.

Dated: May 14, 2001.

Richard D. Schmitt,

Associate Director, Information Resources and Services Division, Office of Pesticide Programs.

[FR Doc. 01–13950 Filed 6–5–01; 8:45 a.m.]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1025; FRL–6785–1]

Notice of Filing Pesticide Petitions to Establish Tolerances 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 control number PF–1025, must be received on or before July 6, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1025 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; 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 affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number PF–1025. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1013 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division

(7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–1025. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI 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. 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified 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 control 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 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 the petitions.

List of Subjects

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

Dated: May 23, 2001.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petitions

The petitioner summary of the pesticide petitions is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petitions was prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. 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 (IR-4)

0E6173, 0E6217, 1E6230, 1E6236, 1E6245, 1E6255, 1E6256, and 1E6260

EPA has received pesticide petitions from the Interregional Research Project Number 4 (IR-4), P.O. Box 231, Rutgers University, New Brunswick, NJ 08903 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of the insecticide, spinosad (spinosyn A and spinosyn D) in or on the following raw agricultural commodities (RACs):

1. 0E6173 proposes the establishment of tolerances for the pome fruit group at 0.2 parts per million (ppm), and foilage of legume vegetables at 8.0 ppm.

2. 0E6217 proposes the establishment of a tolerance for asparagus at 0.02.

3. 1E6230 proposes the establishment of tolerances for tree nut group, and pistachio at 0.02 ppm.

4. 1E6236 proposes the establishment of a tolerance for okra at 0.4 ppm.

5. 1E6245 proposes the establishment of tolerances for beet (garden) roots and beet (sugar) roots at 0.1 ppm, cranberry at 0.01 ppm, and the leaves of root and tuber vegetable group at 10 ppm.

6. 1E6255 proposes the establishment of tolerances for the bushberry group, juneberry, lingonberry, and salal at 0.25 ppm.

7. 1E6256 proposes the establishment of a tolerance for globe artichoke at 0.3 ppm.

8. 1E6260 proposes the establishment of a tolerance for strawberry at 0.75 ppm.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of spinosad in plants and animals are adequately understood for the purposes of these tolerances.

2. *Analytical method*. There is a practical method (immun. assay) for detecting (0.005 ppm) and measuring (0.01 ppm) levels of spinosad in or on food with a limit of detection that allows monitoring of food with residues at or above the level set for these tolerances. The method has had a successful method tryout in EPA's laboratories.

3. *Magnitude of residues*. The magnitude of residues are adequately understood for the purposes of these tolerances.

B. Toxicological Profile

1. *Acute toxicity*. Spinosad has low acute toxicity. The rat oral lethal dose $(LD)_{50}$ is 3,738 milligrams/kilograms (mg/kg) (males) and > 5,000 mg/kg (females); mouse oral LD_{50} is >5,000 mg/

kg; rabbit dermal LD_{50} is >5,000 mg/kg; and rat inhalation lethal concentration $(LC)_{50}$ is >5.18 mg/L air. In addition, spinosad is not a skin sensitizer in guinea pigs and does not produce significant dermal or ocular irritation in rabbits.

2. *Genotoxicity*. Short-term assays for genotoxicity consisting of a bacterial reverse mutation assay (Ames test), *in vitro* assay for cytogenetic damage using the Chinese hamster ovary cells, mammalian gene mutation assay using mouse lymphoma cells, 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 highest dose tested (HDT). This was not accompanied by either embryo, fetal, or developmental toxicity. The no observed adverse effect level (NOAEL) for maternal and fetal toxicity in rats were 50 and 200 mg/kg/day, respectively. A developmental study in rabbits showed that spinosad caused decreased body weight gain and a few abortions in maternal rabbits given 50 mg/kg/day HDT. Maternal toxicity was not accompanied by either embryo, fetal, or developmental toxicity. The NOAEL for maternal and fetal toxicity in rabbits were 10 and 50 mg/kg/day, respectively. In a 2-generation reproduction study in rats, parental toxicity was observed in both males and females given 100 mg/kg/day HDT. 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 the following NOAELs: 4.89 and 5.38 mg/kg/day, respectively for male/female dogs; 6 and 8 mg/kg/day, respectively for male/female mice; and 33.9 and 38.8 mg/kg/day, respectively for male/female 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, 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 intraspecies 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. 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 HDT 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.

6. *Animal metabolism*. There were no major differences in the bioavailability routes, rates of excretion, or metabolism of spinosyn A and spinosyn D following oral administration in rats. 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, metabolite toxicity is not applicable.

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*. Previously for the purposes of assessing potential dietary exposure from use of spinosad on RACs proposed within this petition as well as from other existing spinosad crop uses, a Tier I assessment was conducted using 100% crop treated and use of tolerance values within the residue file. However, with the proposal of several new uses including proposals from IR-4, a refined and more realistic assessment is needed. Information on average residues, market share and when available processing factors (specific to spinosad and commodities) has been used to estimate dietary burden of individual commodities. The theoretical maximum residue contribution (TMRC) is obtained by multiplying estimated residue levels by the consumption data which estimates the amount of crops and related food consumed by various population subgroups. The use of average residues and market share results in a refinement of the human exposure and a safety determination for the use of spinosad on crops cited in this summary that is based on a conservative exposure assessment.

ii. *Drinking water*. Based on the available environmental studies conducted with spinosad, its properties show little or no mobility in soil. Therefore, no anticipated exposure to residues of spinosad in drinking water is expected. In addition, no Maximum Concentration Level (MCL) has been established.

2. *Non-dietary exposure*. Spinosad is currently registered for outdoor use on turf and ornamentals at low rates of application (0.04 to 0.54 lb active ingredient per acre) and indoor use for drywood termite control (extremely low application rates used with no occupant exposure expected). Localized baits for fire ants again at low rates are also available. Thus, the potential for non-dietary exposure to the general population is considered negligible.

D. Cumulative Effects

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.

E. Safety Determination

1. *U.S. population*. Using the refined exposure assumptions and the RfD, the aggregate exposure to spinosad use on existing crop uses utilizes 5.5% of the RfD for the U.S. population. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The new crop uses proposed have been included in this refined dietary assessment. Thus, it is clear that there is reasonable certainty that no harm will result from aggregate exposure to spinosad residues on existing and all pending crop uses listed in this notice.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of spinosad, data from developmental toxicity studies in rats and rabbits and a 2–generation reproduction study in the rat are considered. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability and potential systemic toxicity of mating animals and on various parameters associated with the well-being of pups.

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. Further, for spinosad, the NOAELs in the dog chronic feeding study which was used to calculate the RfD (0.027 mg/kg/day) are considerably lower than the NOAELs from the developmental studies in rats and rabbits by a factor of more than 10–fold.

Concerning the reproduction study in rats, the pup effects shown at the HDT were attributed to maternal toxicity. Therefore, it is concluded that an additional uncertainty factor is not needed and that the RfD at 0.027 mg/kg/day is appropriate for assessing risk to infants and children.

In addition, the EPA has determined that the 10X factor to account for enhanced sensitivity of infants and children is not needed because: (1) The data provided no indication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to spinosad; (2) no neurotoxic signs have been observed in any of the standard required studies conducted; (3) the toxicology data base is complete and there are no data gaps; and (4) exposure data are complete or are estimated based on data that reasonably account for potential exposure.

Using the exposure assumptions, the percent dietary RfD utilized by the aggregate exposure to residues of spinosad on existing crop utilizes 15% of the chronic population adjusted dose (cPAD) for children 1 to 6 years old, the most sensitive population subgroup. The new crop uses have been included in this assessment. Thus, based on the completeness and reliability of the toxicity data and the exposure assessment, it is concluded that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to spinosad residues on the proposed uses including existing crop uses.

F. International Tolerances

There is no Codex maximum residue levels established for residues of spinosad at this time.

[FR Doc. 01–14253 Filed 06–05–01; 8:45 am]

BILLING CODE 6560–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–50879A; FRL–6784–2]

Issuance of an Experimental Use Permit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted an experimental use permit (EUP) to the following pesticide applicant. An EUP permits use of a pesticide for experimental or research purposes only in accordance with the limitations in the permit.

FOR FURTHER INFORMATION CONTACT: By mail: Alan Reynolds, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Office location, telephone number, and e-mail address: 1921 Jefferson Davis Hwy., Rm. 9010, Crystal Mall #2, Arlington, VA; (703) 605–0515; e-mail address: reynolds.alan@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who conduct or sponsor research on pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the information in this action, consult the designated contact person listed for the individual EUP.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–50879A. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. EUP

EPA has issued the following EUP:

524–EUP–91. Extension. Monsanto Company, 700 Chesterfield Parkway North, St. Louis, MO 63198. This EUP allows the use of 181.5 grams of the plant pesticide *Bacillus thuringiensis* Cry1Ac protein and the genetic material necessary for its production (vector PV–GMBT02) in soybean on 199.7 acres of soybean to evaluate the control of soybean looper, stem borer, and velvetbean caterpillar. The program is authorized only in the States of Alabama, Arkansas, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Louisiana, Maryland, Mississippi, Missouri, North Carolina, Pennsylvania, Puerto Rico, and Tennessee. The EUP is effective from May 1, 2001 to April 30, 2002. This permit is issued with the limitation that all treated crops will be destroyed or used for research purposes only.

Persons wishing to review this EUP are referred to the designated contact person. Inquiries concerning this permit should be directed to the person cited above. It is suggested that interested persons call before visiting the EPA office, so that the appropriate file may be made available for inspection purposes from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Experimental use permits.