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), Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202–4501, from 8:30 a.m. to 4:00 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. Electronic copies of the dinocap RED, the fact sheet and supporting documents are available on the Agency's website at *http://www.epa.gov/pesticides/*. The site provides background information for dinocap. Technical questions can be directed to the person listed under **FOR FURTHER INFORMATION CONTACT**.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may access EPA Dockets at *http://www.epa.gov/edocket/* to view public comments, to 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.

II. Background

A. What Action is the Agency Taking?

On September 17, 2003 (OPP–2003–0268) (FRL–7321–8), EPA published a notice in the **Federal Register** announcing the availability of the RED document for dinocap, thus concluding the reregistration. This notice constitutes and announces the closing of the 30–day public comment period for dinocap. Because EPA did not receive any comments, the Agency considers the RED for dinocap a final decision.

B. What is the Agency's Authority for Taking this Action?

The legal authority for this RED falls under FIFRA, as amended in 1988 and 1996. Section 4(g)(2)(A) of FIFRA directs that, after submission of all data concerning a pesticide active ingredient, ''the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration,'' before calling in product specific data on individual end-use products, and either reregistering products or taking ''other appropriate regulatory action.''

List of Subjects

Environmental protection, Dinocap.

Dated: June 7, 2004.

Debra Edwards,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 04–13689 Filed 6–22–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0042; FRL–7358–3]

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 a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2004–0042, must be received on or before July 23, 2004.

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: William G. Sproat, Jr., Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8587]; e-mail address:*sproat.william@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS codes 111)
- Animal production (NAICS codes 112)
- Food manufacturing (NAICS codes 311)
- Pesticide manufacturing (NAICS codes 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–2004–0042. 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, 1921 Jefferson Davis Hwy., 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. 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–2004–0042. 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–2004–0042. 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–2004–0042.

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, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID number OPP–2004–0042. 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 a pesticide petition 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 this petition contains 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 the petition.

List of Subjects

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

Dated: June 8, 2004.

Lois Rossi,

Director, Registration Division, Office of PesticidePrograms.

Summary of Petition

The petitioner's summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by Dow AgroScience LLC, 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.

AgroSciences LLC

PP 3F6754

EPA has received a pesticide petition PP 3F6754 from Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268 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, by establishing a tolerance for residues ofspinosad in or on the raw agricultural commodity stored grain (wheat, barley, corn, oats, rice, and sorghum/milo), soybean, sunflower, peanut, and cotton seed at 1 part per million (ppm) and birdseed at 3 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; 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 petition.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of spinosad in plants apples, cabbage, cotton, tomato, and turnip, and animals (goats and poultry) are adequately understood for the purposes 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 (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 the EPA laboratories.

3. *Magnitude of residues*. Tolerances as high as 22 ppm for dried herb, 10 ppm (Brassica) and 8 ppm (leafy vegetables) have been previously established for crop commodities treated with spinosad. Magnitude of residue studies were conducted at three sites for artichokes. Residues found in these studies ranged from 0.062 to 0.156 ppm. Magnitude of residue studies were conducted at three sites for asparagus. Residues found in these studies were all less than 0.009 ppm. Magnitude of residues studies were conducted at five sites for garden beet tops (one of the representative crops for the leaves of root and tuber vegetable crop group). Residues found in these studies ranged from 0.03 to 4.0 ppm. Previously submitted data used in support of the established residue tolerance on Brassica (cole) leafy vegetables are also to be used in support of the proposed residue tolerance for leaves of root and tuber vegetables. Magnitude of residue studies were conducted at six sites for pears (one of the representative crops for the pome fruit crop group). Residues found in these studies ranged from non-detectable to 0.08 ppm. Previously submitted data used in support of the established residue tolerance on apples are also to be used in support of the proposed residue tolerance for pome fruit. Magnitude of residue studies were conducted at 4 sites on pecans (one of the representative crops for the tree nut crop group). Residues found in these studies ranged from less than 0.0010 to 0.0076 ppm. Previously submitted data used in support of the established residue tolerance on almonds are to be used also, in support of the proposed residue tolerance for tree nuts and pistachio. A magnitude of residue study was conducted at 20 sites on tomatoes and peppers (two of the representative crops for the fruiting vegetables crop group). Residues found in this study ranged from less than 0.01 to 0.13 ppm in tomatoes, and 0.01 to 0.18 ppm in peppers. Previously submitted data used in support of the established residue tolerance on fruiting vegetables (except cucurbits) are to be used in support of the proposed residue tolerance for okra. Magnitude of residue studies were conducted at six sites for cranberry. No quantifiable residues >0.01 ppm were observed in any test sample. Magnitude of residue studies were conducted at five sites for garden beet roots (one of the representative crops for the root and tuber vegetable crop group) and tops (one of the representative crops for the leaves of root and tuber vegetable crop group). Residues found in beet tops ranged from 0.03 to 4.0 ppm. Previously submitted data used in support of the established residue tolerance on Brassica (cole) leafy vegetables are also to be used in support of the proposed residue tolerance for leaves of root and tuber vegetables. These data support tolerances of 0.1 ppm in garden and sugar beet roots and a 10.0 ppm tolerance for Crop Group 2.

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 milligrams per liter (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. 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), 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 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 toxicity, 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 HDT. Maternal toxicity was not accompanied by either embryo toxicity, fetal toxicity, or teratogenicity. The NOAELs for maternal and fetal toxicity 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 HDT. Perinatal effects (decreased litter size and pup weight) at 100 mg/kg/day were attributed to maternal toxicity. The NOEL for maternal and pup effects was 10 mg/kg/day.

4. *Subchronic toxicity.* Spinosad was evaluated in 13–week dietary studies and showed NOELs/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. 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 NOELs found in the chronic dog study to account for inter-specoes and intra-species variation. The NOELs shown in the dog chronic study were 2.68 and 2.72 mg/kg/day, respectively for male and female dogs. The NOELs (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 all dosages tested. The NOELs shown 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 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.

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 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, 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*. For purposes of assessing the potential dietary exposure from use of spinosad on the raw agricultural commodities listed in this notice as well as from other existing spinosad crop uses, a conservative estimate of aggregate exposure is determined by basing the theoretical maximum residue contribution (TMRC) on the proposed tolerance level for spinosad and assuming that 100% of these proposed new crops and other existing (registered for use) crops grown in the U.S. were treated with spinosad. The TMRC is obtained by multiplying the tolerance residue levels by the consumption data which estimates the amount of crops and related foodstuffs consumed by various population subgroups. The use of a tolerance level and 100% of crop treated clearly results in an overestimate of 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. In addition for the use of dermal application of spinosad to cattle, the risk assessment applies a conservative (overestimate) 35% percent of market share for the dermal application to cattle to the tolerance levels for animal commodities based on existing crop uses.

Drinking water. Another potential source of dietary exposure is residues in drinking water. Based on the available environmental studies conducted with spinosad wherein it's properties show little or no mobility in soil, there is no anticipated exposure to residues of spinosad in drinking water. In addition, there is no established maximum concentration level for residues of spinosad in drinking water.

2. *Non-dietary exposure*. Spinosad is currently registered for use on a number of crops including cotton, fruits, and vegetables in the agriculture environment. Spinosad is also currently registered for outdoor use on turf and ornamentals at low rates of application (0.04 to 0.54 lb active ingredents (a.i.,) per acre and indoor use for drywood termite control (extremely low application rates used with no occupant exposure expected). Thus, the potential for non-dietary exposure to the general population is considered negligible.

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*. Using the conservative exposure assumptions and the RfD described above, the aggregate exposure to spinosad use on existing crop uses utilizes 30% of the RfD for the U.S. population from a previous EPA assessment based on the chronic population adjusted dose (cPAD) (as posted in the **Federal Register** of September 27, 2002) (FRL–7199–5). 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 in this notice are minor ones and are expected to contribute only a negligible impact to the RfD. 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 NOELs in the dog chronic feeding study which was used to calculate the RfD (0.027 mg/kg/day) are already lower than the NOELs 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 highest dose tested 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:

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 two-generation reproduction in rats, effects in the offspring were observed only at or below treatment levels that 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.

iv. Exposure data are complete or are estimated based on data that reasonably account for potential exposure.

Using the conservative exposure assumptions previously described (tolerance level residues), the percent RfD utilized by the aggregate exposure to residues of spinosad on existing crop uses is 69% for children 1–6 years old, the most sensitive population subgroup from an EPA assessment based on the chronic population adjusted dose (cPAD) (as posted in the **Federal Register** May 3, 2000. Additional refinements to the dietary exposure based on market share information would reduce the exposure of children 1–6 years old to less than 50% the cPAD. Grain treated under a tolerance is expected to have only a slight impact to the RfD since the vast majority of grain is untreated. Thus, based on the completeness and reliability of the toxicity data and the conservative 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 above proposed uses including existing crop uses.

F. International Tolerances

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

[FR Doc. 04–13857 Filed 6–22–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7778–6]

Air Quality Criteria for Particulate Matter (External Review Draft)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of drafts of chapters for public review and comment.

SUMMARY: On or about June 21, 2004, the National Center for Environmental Assessment (NCEA), within EPA's Office of Research and Development, will make available for public review and comment revised drafts of Chapters 7, 8, and 9 of EPA's document *Air Quality Criteria for Particulate Matter,* which incorporate revisions made in response to earlier external review of those chapters. Under sections 108 and 109 of the Clean Air Act, the purpose of this document is to provide an assessment of the latest scientific information on the effects of airborne particulate matter (PM) on the public health and welfare for use in EPA's current review of the National Ambient Air Quality Standards (NAAQS) for PM.

DATES: Comments on the draft chapters must be submitted in writing no later than July 20, 2004. Send the written comments to the Project Manager for Particulate Matter, National Center for Environmental Assessment—RTP (B243–01), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711.

ADDRESSES: The revised Chapters 7, 8, and 9 of the *Air Quality Criteria for Particulate Matter* will be available on CD ROM from NCEA–RTP. Contact Ms. Diane Ray by phone (919–541–3637), fax (919–541–1818), or e-mail (*ray.diane@epa.gov*) to request these chapters. Please provide the document's title, *Air Quality Criteria for Particulate Matter,* and the EPA numbers for each of the three revised chapters (EPA/600/P–99/002aE, EPA/600/P–99/002bE), as well as your name and address, to properly process your request. Internet users will be able to download a copy from the NCEA home page. The URL is *http://www.epa.gov/ncea/*. Hard copies of the revised chapters can also be made available upon request.

FOR FURTHER INFORMATION CONTACT: Dr. Robert Elias, National Center for Environmental Assessment—RTP (B243–01), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; telephone: 919–541–4167; fax: 919–541–1818; e-mail: *elias.robert@epa.gov*.

SUPPLEMENTARY INFORMATION: EPA is in the process of updating and revising, where appropriate, its *Air Quality Criteria for Particulate Matter* as issued in 1996 (usually referred to as the ''Criteria Document''). Sections 108 and 109 of the Clean Air Act require that EPA carry out a periodic review and revision, where appropriate, of the air quality criteria and national ambient air