

imidacloprid is not considered to present a hazard via the dermal route.

D. Cumulative Effects

Imidacloprid is a chloronicotinyl insecticide. At this time, EPA has not made a determination that imidacloprid and other substances that may have a common mechanism of toxicity would have cumulative effects. Therefore, for these tolerance petitions, it is assumed that imidacloprid does not have a common mechanism of toxicity with other substances and only the potential risks of imidacloprid in its aggregate exposure are considered.

E. Safety Determination

1. *U.S. population.* EPA has considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. These studies are discussed under section A (Toxicology Profile) above. The developmental toxicity data demonstrated no increased sensitivity of rats or rabbits to *in utero* exposure to imidacloprid. In addition, the multi-generation reproductive toxicity study did not identify any increased sensitivity of rats to *in utero* or postnatal exposure. Parental NOAELs were lower or equivalent to developmental or offspring NOAELs. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

Based on the exposure assessments described above and on the completeness and reliability of the toxicity data, it can be concluded that the dietary exposure estimates from all label and pending uses of imidacloprid are 7.8% of the aPAD at the 99.9th percentile and 0.5% of the cPAD for the U.S. population. Thus, it can be concluded that there is a reasonable certainty that no harm will result from aggregate exposure to imidacloprid residues.

2. *Infants and children.* Based on the exposure assessments described above for the safety determination of the U.S. population and on the completeness and reliability of the toxicity data, it can be concluded that the dietary exposure estimates from all label and pending uses of imidacloprid are 20.9% of the aPAD at the 99.9th percentile and 1.5% of the cPAD for the most sensitive population subgroup, children 1–2 years. Thus, it can be concluded that there is a reasonable certainty that no

harm will result from aggregate exposure to imidacloprid residues.

F. International Tolerances

No CODEX maximum residue levels have been established for residues of imidacloprid on soybean.

[FR Doc. 04–10103 Filed 5–4–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0063; FRL–7354–8]

Esfenvalerate; 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 ID number OPP–2004–0063, must be received on or before June 4, 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: 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 are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 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–2004–0063. 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.

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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-2004-0063. 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-2004-0063. 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-2004-0063.

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-2004-0063. 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: April 20, 2004.

Betty Shackleford,

Acting 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 Interregional Research Project Number 4 (IR-4) and represents the view of the petitioner. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position 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 (IR-4)

PP 0E3912, PP 9E3810, PP 9E3813, PP 9E5075, and PP 9E6061

EPA has received pesticide petitions PP 0E3912, PP 9E3810, PP 9E3813, PP 9E5075, and PP 9E6061 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 FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.533, by establishing tolerances for residues of the insecticide, esfenvalerate ((S)-cyano-(3-phenoxyphenyl)methyl(S)-4-chloro-alpha-(1-methylethyl)benzeneacetate) in or on the following raw agricultural commodities:

1. PP 0E3912 proposes the establishment of a tolerance for cardoon at 1.0 part per million (ppm). Registration will be limited to California based on the geographical representation of the residue data submitted to EPA.

2. PP 9E3810 proposes the establishment of tolerances for cabbage, chinese, bok choy at 1.0 ppm. Registration will be limited to areas east of the Mississippi River based on the geographical representation of the residue data submitted to EPA.

3. PP 9E3813 proposes the establishment of a tolerance for sweet potato at 0.05 ppm.

4. PP 9E5075 proposes the establishment of a tolerance for canola, seed at 0.3 ppm.

5. PP 9E6061 proposes the establishment of a tolerance for Brussels sprouts at 0.2 ppm for regional registration only.

EPA has determined that the petitions contain 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 petitions. Additional data may be needed before EPA rules on the petitions. This notice includes a summary of the petitions prepared by DuPont Crop Protection, (formerly DuPont Agricultural products) P.O. Box 30, Newark, DE 19714-0030.

A. Residue Chemistry

1. *Plant metabolism.* The metabolism and chemical nature of residues of fenvalerate in plants are adequately understood. The fate of fenvalerate has been extensively studied using radioactive tracers in plant metabolism/nature of the residue studies. These studies have demonstrated that the parent compound is the only residue of

toxicological significance. EPA has concluded that the qualitative nature of the residue is the same for both fenvalerate and esfenvalerate.

2. *Analytical method.* There is a practical analytical method utilizing electron-capture gas chromatography with nitrogen phosphorous detection available for enforcement with a limit of detection that allows monitoring of food with residues at or above tolerance levels. The limit of detection for updated method is the same as that of the current Pesticide Analytical Manual (PAM) II, which is 0.01 ppm.

3. *Magnitude of residues.* Fenvalerate is a racemic mixture of four isomers about 25% each. Technical Asana the S,S-isomer enriched formulation, esfenvalerate, has been the only fenvalerate formulation sold in the U.S. for agricultural use. Since the S,S-isomer is the insecticidally active isomer, the use rate for Asana is 4 times lower than that for pydrin. A petition is pending (PP 4F4329), to convert tolerances still to be expressed as the sum of all isomers based on the use rates for Asana. Bridging residue studies have shown Asana residues to be 3-4 times lower than pydrin residues.

Field trials were conducted on each commodity (cardoon; cabbage, Chinese, bok choy; sweet potato; canola, seed; and brussels sprouts) in the requested geographical regions. Results from these trials support the proposed tolerances.

B. Toxicological Profile

An assessment of the toxic effects caused by esfenvalerate is discussed in Unit III.A. and Unit III.B. of the **Federal Register** dated March 1, 2001 (66 FR 16926) (FRL-6774-5).

1. *Animal metabolism.* In animal studies, after oral dosing with radioactive fenvalerate, the majority of the administered radioactivity was eliminated in the initial 24-hours. The metabolic pathway involved cleavage of the ester linkage followed by hydroxylation, oxidation, and conjugation of the acid and alcohol moieties.

2. *Metabolite toxicology.* The parent molecule is the only moiety of toxicological significance appropriate for regulation in plant and animal commodities.

C. Aggregate Exposure

1. *Dietary exposure.* Tolerances have been established for the residues of fenvalerate/esfenvalerate, in or on a variety of agricultural commodities. For purposes of assessing dietary exposure, chronic and acute dietary assessments have been conducted using all existing tolerances for esfenvalerate. The

following crops with pending petitions have been included in the assessment: Brussels sprouts; cabbage, Chinese, bok choy; canola; cardoon; sweet potato, and pistachio. In addition, previously pending or intended uses that have been withdrawn leaf lettuce, kale, passion fruit are also, included in the dietary exposure assessment.

i. *Food—a. Chronic.* A chronic dietary exposure assessment was conducted using Novigen's Dietary Exposure Estimate Model (DEEM™). Anticipated residues and adjustment for percent crop treated were used in the chronic dietary risk assessment. The percentages of the reference dose (RfD) utilized by the most sensitive subpopulation, children 1–6 years, was 2.0% based on a daily dietary exposure of 0.000134 milligrams/kilogram body weight/day (mg/kg bwt/day). Chronic exposure for the overall U.S. population was 0.9% of the RfD based on a dietary exposure of 0.000058 mg/kg bwt/day. EPA 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.

b. *Acute exposure.* Potential acute exposures from food commodities were estimated using a Tier 3 (Monte Carlo) Analysis, appropriate processing factors for processed food, and distribution analysis. This analysis used data from field trial studies and pesticide monitoring programs to estimate exposure, and federal and market survey information to derive the percent of crop treated. These data are considered reliable, and used the upper end estimate of percent crop treated in order to not underestimate any significant subpopulation. Regional consumption information was taken into account.

ii. *Drinking water.* Esfenvalerate is immobile in soil, and will not leach into ground water. Due to the insolubility and lipophilic nature of esfenvalerate, any residues in surface water will rapidly and tightly bind to soil particles and remain with sediment, therefore, not contributing to potential dietary exposure from drinking water.

Surface water concentrations for pyrethroids were estimated using PRZM3, and Exposure Analysis Modeling System (EXAMS) using standard EPA cotton runoff and Mississippi pond scenarios. The maximum concentration predicted in the simulated pond was 0.052 parts per billion (ppb). Concentrations in actual drinking water would be much lower than the levels predicted in the hypothetical, small, stagnant farm pond model since drinking water derived

from surface water would be treated before consumption.

Chronic drinking water exposure has been estimated to be 0.000001 mg/kg/day for both the U.S. general population, and for non-nursing infants. Therefore, DuPont believes that there is a reasonable certainty of no harm from drinking water.

2. *Non-dietary exposure.*

Esfenvalerate is registered for non-crop uses including spray treatments in and around commercial and residential areas, treatments for control of ectoparasites on pets, home care products including foggers, pressurized sprays, crack and crevice treatments, lawn and garden sprays, and pet and pet bedding sprays. For the non-agricultural products, the very low amounts of active ingredient they contain, combined with the low vapor pressure (1.5×10^{-9} mm Mercury at 25 °C) and low dermal penetration, would result in minimal inhalation and dermal exposure.

To assess risk from nonfood short-term and intermediate-term exposure, EPA has selected a toxicological endpoint of 2.0 mg/kg/day, the NOAEL from the rat and rabbit developmental studies. For dermal penetration/absorption, EPA selected 25% dermal absorption based on the weight-of-evidence available for structurally related pyrethroids. For inhalation exposure, EPA used the oral NOAEL of 2.0 mg/kg/day, and assumed 100% absorption by inhalation.

Individual non-dietary risk exposure analyses were conducted using a flea infestation scenario that included pet spray, carpet and room treatment, and lawn care, respectively. The total potential short-term and intermediate-term aggregate non-dietary exposure including lawn, carpet, and pet uses are: 0.000023 mg/kg/day for adults, 0.00129 mg/kg/day for children 1–6 years old, and 0.00138 mg/kg/day for infants less than 1-year old.

EPA concluded in a final rule published in the **Federal Register** of November 26, 1997 (62 FR 63019) (FRL-5754-6) that the potential non-dietary exposure for esfenvalerate is associated with substantial margins of safety, and that there was reasonable certainty that no harm will result from aggregate exposure to esfenvalerate residues.

D. *Cumulative Effects*

Section 408 (b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s

residues and “other substances that have a common mechanism of toxicity.”

EPA does not have at this time available data to determine whether esfenvalerate has a common method of toxicity with other substances, or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, esfenvalerate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that esfenvalerate has a common mechanism of toxicity with other substances.

E. *Safety Determination*

1. *U.S. population.* Based on the chronic dietary exposure assessment, it is concluded that exposure to esfenvalerate, including the proposed uses in food will utilize 0.9% of the RfD for the U.S. general population. There is generally 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 margin of exposure (MOE) for the general population was 472 at the 99.9th percentile of exposure, based on a daily exposure estimate of 0.004229 mg/kg bwt/day. Therefore, there is a reasonable certainty that no harm to the U.S. population will result from chronic dietary, acute dietary, non-dietary, or aggregate exposure to esfenvalerate residues.

2. *Infants and children.* FFDC 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 effects, and the completeness of the toxicity data base. An extra 3X safety factor has been assessed for esfenvalerate due to a data gap.

A chronic dietary exposure assessment found the percentages of the RfD utilized by the most sensitive subpopulation to be 2.0% for children 1–6 years old based on a dietary exposure of 0.000134 mg/kg bwt/day. The most sensitive subpopulation, children 1–6 years, had acute dietary MOE of 378 at the 99.9th percentile of exposure. Nursing infants had a MOE of 750 at the 99.9th percentile of exposure. Non-nursing infants had a MOE of 761 at the 99.9th percentile of exposure. Therefore, there is a reasonable certainty that no harm to infants and children will result from chronic dietary, acute

dietary, non-dietary, or aggregate exposure to esfenvalerate residues.

F. International Tolerances

Codex maximum residue levels (MRLs) have been established for residues of fenvalerate on a number of crops that also have U.S. tolerances. There are some minimal differences between the section 408 tolerances, and certain Codex MRL values for specific commodities. These differences could be caused by differences in methods to establish tolerances, calculate animal feed, dietary exposure, and as a result of different agricultural practices. Therefore, some harmonization of these maximum residue levels may be required.

[FR Doc. 04-9722 Filed 5-4-04; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2004-0064; FRL-7354-9]

Indoxacarb; 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-2004-0064, must be received on or before June 4, 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: 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.

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