

name, date, and **Federal Register** citation.

## II. Registration Application

EPA received an application as follows to register a pesticide product containing an active ingredient not included in any previously registered products pursuant to the provision of section 3(c)(4) of FIFRA. Notice of receipt of the application does not imply a decision by the Agency on the application.

### *Product Containing an Active Ingredient Not Included in Any Previously Registered Products*

#### *EPA File Symbol 524-LEI*

In the **Federal Register** of March 19, 2001 (66 FR 15435) (FRL-6771-5), EPA announced receipt of a seed increase registration application from Monsanto Company, 700 Chesterfield Parkway N., St. Louis, MO 63198 to register the product Event MON 863: Corn Rootworm Protected Corn (ZMIR13L) containing the plant-pesticide *Bacillus thuringiensis* Cry3Bb protein and the genetic material (Vector ZMIR13L) necessary for its production in corn. Monsanto subsequently modified their application for full commercial use and EPA announced receipt of the application on March 13, 2001 (67 FR 11330) (FRL-6828-1). The original comment period ended on April 12, 2002. The comment period is being extended to May 31, 2002. Proposed Classification/Use: None. For full commercial use.

#### List of Subjects

Environmental protection, Pesticides and pest.

Dated: April 19, 2002.

**Janet L. Andersen,**

*Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.*

[FR Doc. 02-10627 Filed 4-30-02; 8:45 am]

BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0012; FRL-6833-4]

### 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 control number OPP-2002-0012, must be received on or before May 31, 2002.

**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 OPP-2002-0012 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Shaja R. Brothers, Registration Support Branch, Registration Division (7505C), 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 OPP-2002-0012. 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 OPP-2002-0012 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 OPP-2002-0012. 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 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 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 15, 2002.

### **Debra Edwards,**

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

### **Summary of Petitions**

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioners. 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.

*2E6359, 2E6365, 2E6377, and 2E6393*

EPA has received pesticide petitions (PP) 2E6359, 2E6365, 2E6377, and 2E6393 from the Interregional Research Project Number 4 (IR-4), New Jersey Agricultural Experiment Station, 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 180.516 by establishing tolerances for residues of fludioxonil (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile) in or on the following raw agricultural commodities (RACs) with the respective tolerance levels in parts per million (ppm): PP 2E6359 proposes the establishment of a tolerance for the bushberry subgroup, lingonberry, juneberry, and salal at 2.0 ppm, PP 2E6365 proposes the establishment of a tolerance for watercress at 7.0 ppm, PP 2E6377 proposes the establishment of a tolerance for pistachio at 0.10 ppm and PP 2E6393 proposes the establishment of a tolerance for the caneberry subgroup at 5.0 ppm.

This notice includes a summary of petitions prepared by Syngenta Crop Protection Inc., Greensboro, North Carolina, 27409. 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 these petitions.

### *A. Residue Chemistry*

1. *Plant metabolism.* The plant metabolism of fludioxonil is adequately understood for the purpose of the proposed tolerances.

2. *Analytical method.* Syngenta has developed and validated analytical methodology for enforcement purposes. This method (Syngenta Crop Protection Method AG-597B) has passed an Agency petition method validation for several commodities and is currently the enforcement method for fludioxonil. This method has also been forwarded to FDA for inclusion into PAM II. An extensive database of method validation data using this method on various crop commodities is available.

3. *Magnitude of residues.* Complete residue data for caneberry subgroup, bushberry subgroup, lingonberry, juneberry, salal, pistachio and watercress have been submitted. The requested tolerances are adequately supported.

### *B. Toxicological Profile*

The nature of the toxic effects caused by fludioxonil are discussed in unit II.B of the **Federal Register** on December 29, 2000 (65 FR 82927) (FRL-6760-9).

1. *Animal metabolism.* The metabolism of fludioxonil in rats is adequately understood.

2. *Metabolite toxicology.* The residues of concern for tolerance setting purposes is the parent compound. Consequently,

there is no additional concern for toxicity of metabolites.

3. *Endocrine disruption.* Fludioxonil does not belong to a class of chemicals known for having adverse effects on the endocrine system. No estrogenic effects have been observed in the various short- and long-term studies conducted with various mammalian species.

#### C. Aggregate Exposure

1. *Dietary exposure.* The dietary exposure evaluation was made using the Dietary Exposure Evaluation Model (DEEM<sup>®</sup>, version 7.76) from Novigen Sciences, Inc. DEEM<sup>®</sup> default processing factors were used along with USDA's Continuing Survey of Food Intake by Individuals (CSFII) with the 1994–96 consumption database and the Supplemental CSFII children's survey (1998) consumption database. DEEM<sup>®</sup> inputs for all currently registered uses, pending uses, and proposed uses. Secondary residues in animal commodities were not considered in this evaluation since calculations showed that residue transfers from fed items to livestock and milk were minimal and resulted in negligible exposures.

i. *Food.* This chronic assessment utilized established tolerance values for the current uses and proposed tolerance values for the added proposed uses. This assessment assumes 100% crop treated for all commodities except strawberries and bulb vegetables. For strawberries and bulb vegetables, projected percent crop treated values of 50% and 28%, respectively, were calculated as a percent of base acres divided by the total planted acres.

ii. *Drinking water.* Estimated Environmental Concentrations (EEC's) of fludioxonil in drinking water were determined for the highest use rate of fludioxonil, which is turfgrass. SCI-GROW (Version 2.1) was used to determine acute and chronic estimated environmental concentrations in ground water. FIRST (Version 1.0) was used to determine acute and chronic estimated environmental concentrations in surface water.

Based on model outputs, the estimated environmental concentrations of fludioxonil are 0.0553 parts per billion (ppb) for acute and chronic exposure to ground water and 70 ppb and 33 ppb for acute and chronic exposure, respectively, to surface water.

2. *Non-dietary exposure.* There is a potential residential post-application exposure to adults and children entering residential areas treated with fludioxonil. Since the Agency did not select a short-term endpoint for dermal exposure, only intermediate-term

dermal exposures were considered. Based on the residential use pattern, no long-term post-application residential exposure is expected.

#### D. Cumulative Effects

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

#### E. Safety Determination

1. *U.S. population.* The chronic dietary exposure analysis showed that exposure from the established tolerances and proposed new tolerances for the general U.S. population would be 8% of the RfD. Chronic exposures to the U.S. population resulted in a margin of exposure (MOE) of 1445. The benchmark MOE for this assessment is 100. Therefore, results from the %RfD based risk analysis showed acceptable safety margins with respect to chronic exposures incurred by the dietary consumption of fludioxonil-treated commodities.

2. *Infants and children.* The chronic reference dose (RfD) for fludioxonil is 0.03 milligrams/kilograms (mg/kg) body weight/day and is based on a one year dog study with a no observed adverse effect level (NOAEL) of 3.3 mg/kg body weight/day and a safety factor of 100X. No additional FQPA safety factor was applied. The chronic dietary exposure analysis showed that exposure from the established tolerances and proposed new tolerances for Non-Nursing Infants <1 years old (the subgroup with the highest exposure) would be 34% of the RfD. The most sensitive subpopulation in the chronic assessment was non-nursing infants (<1 year old) with a MOE of 329. The benchmark MOE for this assessment is 100. Therefore, the estimates of dietary exposure clearly indicate adequate safety margins for the overall U.S. population.

Chronic Drinking Water Levels of Comparison (DWLOC) were calculated based on a chronic RfD of 0.03 mg/kg/day. For the chronic assessment, the non-nursing infant subpopulation generated the lowest chronic DWLOC of approximately 200 ppb. This gave a corresponding MOE value of 1,000. The

chronic DWLOC of 200 ppb is considerably higher than the chronic EEC of 33 ppb and the MOE far exceeds the benchmark MOE of 100.

#### F. International Tolerances

There are no Codex Maximum Residue Levels established for fludioxonil.

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## ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0015; FRL–6833–7]

### Notice of Filing Pesticide Petitions to Establish a Tolerance for Certain Pesticide Chemicals 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 certain pesticide chemicals in or on various food commodities.

**DATES:** Comments, identified by docket control number OPP–2002–0015, must be received on or before May 31, 2002.

**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 OPP–2002–0015 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–7610; e-mail address: jackson.sidney@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	Crop production