

questions, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

## II. What Action is EPA Taking?

This document reopens the public comment period established in the **Federal Register** of August 3, 2005 (70 FR 44632) (FRL-7729-2). In that document, EPA made available the human health risk assessment for ethylene oxide (ETO). ETO is a fumigant/sterilant used to sterilize medical or laboratory equipment, pharmaceuticals, and aseptic packaging, or to reduce microbial load on cosmetics, whole and ground spices or other seasoning materials, and artifacts, archival material or library objects. The Agency developed this risk assessment as part of its public process for making pesticide reregistration eligibility and tolerance reassessment decisions. Through these programs, EPA is ensuring that pesticides meet current standards under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The Agency received a request by a stakeholder to extend the comment period. EPA is hereby reopening the comment period, which ended on October 3, 2005; comments must now be received on or before *[insert date 30 days after date of publication in the Federal Register]*. This extension is being given based on the request to have additional time to review the extensive amount of information provided and the nature of the issues involved.

### List of Subjects

Environmental protection, Pesticides and pests.

Dated: October 5, 2005.

**Peter Caulkins,**

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

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## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2005-0229; FRL 7740-4]

### Flumiclorac pentyl; Tolerance Reassessment Decision for Low Risk Pesticide; Notice of Availability

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the availability of EPA's Tolerance

Reassessment Decision (TRED) for the pesticide flumiclorac pentyl, and opens a public comment period on this document, related risk assessments, and other support documents. EPA has reviewed the low risk pesticide flumiclorac pentyl through a modified, streamlined version of the public participation process that the Agency uses to involve the public in developing pesticide tolerance reassessment and reregistration decisions. Through the tolerance reassessment program, EPA is ensuring that all pesticides meet current health and food safety standards.

**DATES:** Comments must be received on or before November 18, 2005.

**ADDRESSES:** Comments, identified by docket identification (ID) number OPP-2005-0229 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:

Tawanda Spears, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; telephone number: (703) 308-8050; fax number: (703) 308-8005; e-mail address: [spears.tawanda@epa.gov](mailto:spears.tawanda@epa.gov).

#### SUPPLEMENTARY INFORMATION:

### I. General Information

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

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, 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 applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP-2005-0229. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information

whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

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

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket ID number.

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

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA

identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

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

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

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

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

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket/>, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPP-2005-0229. 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 [toopp-docket@epa.gov](mailto:toopp-docket@epa.gov), Attention: Docket ID Number OPP-2005-0229. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

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

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID Number OPP-2005-0229.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP-2005-0229. 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 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 your estimate.
5. Provide specific examples to illustrate your concerns.
6. Offer alternatives.
7. Make sure to submit your comments by the comment period deadline identified.
8. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

## **II. Background**

#### *A. What Action is the Agency Taking?*

EPA completed its evaluation of the uses of flumiclorac pentyl, reassessed five (5) existing tolerances or legal residue limits, and reached a tolerance reassessment decision for this low risk pesticide on August 23, 2005. Flumiclorac pentyl is a post-emergence herbicide used on field corn, soybeans and non-crop areas, such as: industrial sites, airports, military installations, roadsides and associated rights-of-way,

and other similar areas to control a selected group of broadleaf weeds, specifically morning-glory and velvet leaf. Although there are no labeled residential homeowner uses, there is potential risk for non-occupational exposure from other treated areas, such as golf courses, athletic fields, recreational areas, schools, apartment buildings, etc. The Agency is now issuing for comment the resulting Report on Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision for flumiclorac pentyl, known as a TRED, as well as related risk assessments and technical support documents.

EPA developed the flumiclorac pentyl TRED through a modified, streamlined version of its public process for making tolerance reassessment and reregistration eligibility decisions. Through these programs, the Agency is ensuring that pesticides meet current standards under the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by FQPA. EPA must review tolerances and tolerance exemptions that were in effect when the FQPA was enacted, to ensure that these existing pesticide residue limits for food and feed commodities meet the safety standard established by the new law. Tolerances are considered reassessed once the safety finding has been made or a revocation occurs. EPA has reviewed and made the requisite safety finding for the flumiclorac pentyl tolerances included in this notice.

The flumiclorac pentyl TRED presents the Agency's tolerance reassessment conclusions for flumiclorac pentyl alone; however, section 408(b)(2)(D)(v) of the FFDCA directs the Agency also to consider available information on the cumulative risk from substances sharing a common mechanism of toxicity. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to flumiclorac pentyl and any other substances, and flumiclorac pentyl 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 flumiclorac pentyl has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by

EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

EPA is applying the principles of public participation to all pesticides undergoing reregistration and tolerance reassessment. The Agency's Pesticide Tolerance Reassessment and Reregistration; Public Participation Process, published in the **Federal Register** of May 14, 2004 (69 FR 26819) (FRL-7357-9), explains that in conducting these programs, the Agency is tailoring its public participation process to be commensurate with the level of risk, extent of use, complexity of issues, and degree of public concern associated with each pesticide. EPA can expeditiously reach decisions for pesticides like flumiclorac pentyl, which pose no risk concerns, have low use, affect few if any stakeholders, and require no risk mitigation. Once EPA assesses uses and risks for such low risk pesticides, the Agency may go directly to a decision and prepare a document summarizing its findings, such as the flumiclorac pentyl TRED.

The tolerance reassessment program is being conducted under Congressionally mandated time frames, and EPA recognizes the need both to make timely decisions and to involve the public in finding ways to effectively mitigate pesticide risks. Flumiclorac pentyl, however, poses no risks that require mitigation. The Agency therefore is issuing the flumiclorac pentyl TRED, its risk assessments, and related support documents simultaneously for public comment. The comment period is intended to provide an opportunity for public input and a mechanism for initiating any necessary amendments to the TRED. All comments should be submitted using the methods in Unit I. of the **SUPPLEMENTARY INFORMATION**, and must be received by EPA on or before the closing date. These comments will become part of the Agency Docket for flumiclorac pentyl. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

EPA will consider all comments received by the closing date and will provide a Response to Comments Memorandum in the Docket and electronic EDOCKET. If any comment significantly affects the document, EPA also will publish an amendment to the TRED in the **Federal Register**. In the absence of substantive comments

requiring changes, the decisions reflected in the TRED will be implemented as presented. These decisions may be supplemented by risk mitigation measures when EPA considers its cumulative assessment of pesticides.

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

Section 408(q) of the FFDCA, 21 U.S.C. 346a(q), requires EPA to review tolerances and exemptions for pesticide residues in effect as of August 2, 1996, to determine whether the tolerance or exemption meets the requirements of section 408(b)(2) or (c)(2) of FFDCA. This review is to be completed by August 3, 2006.

#### **List of Subjects**

Environmental protection, Pesticides, and pests.

Dated: October 5, 2005.

**Peter Caulkins,**

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

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## **ENVIRONMENTAL PROTECTION AGENCY**

[OPP-2004-0182; FRL-7727-6]

### **Pesticide Product Registrations; Conditional Approval**

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

**ACTION:** Notice.

**SUMMARY:** This notice announces Agency approval of applications submitted by Monsanto Company, to conditionally register the pesticide products, Event MON 863: Corn Rootworm Protected Corn (ZMIR13L) and YieldGard Plus containing a new active ingredient not included in any previously registered products pursuant to the provisions of section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

**FOR FURTHER INFORMATION CONTACT:** Mike Mendelsohn, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8715; e-mail address: [mendelsohn.mike@epa.gov](mailto:mendelsohn.mike@epa.gov).

**SUPPLEMENTARY INFORMATION:**