

Free and Secure Trade/Customs-Trade Partnership Against Terrorism (FAST/CTPAT) participants, 30 minutes;

- For arrival by land via rail at ports that are fully equipped to accommodate CBP's Advance Electronic Information Rule, no later than 2 hours prior to the arrival of the train at the border;

- For arrival by air, no later than the departure time ("wheels up") of the aircraft from any foreign port or place in North America, including locations in Mexico, Central America, South America (from north of the Equator only), the Caribbean, and Bermuda, and from other areas into ports that are fully equipped to accommodate CBP's Advance Electronic Information Rule no later than 4 hours prior to the arrival of the aircraft in the United States.

## II. Joint FDA-CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes

After consultation, FDA and CBP have developed a plan to increase integration and assess whether FDA can adopt reduced timeframes. As set out in the plan, the agencies intend to assess whether FDA can meet its statutory mandate under section 801(m)(2)(A) of the FD&C Act if prior notice is received and confirmed electronically by FDA for review with reduced timeframes, including those adopted by CBP by mode of transportation listed in the following paragraphs, no fewer than:

- 1 hour before arrival by land by road, or 30 minutes for participants in FAST/CTPAT;

- 2 hours before arrival by land by rail;

- By "wheels up" for flights originating in North and Central America, South America (north of the Equator only), the Caribbean, and Bermuda; otherwise 4 hours before arrival by air.

As noted previously, section 801(m)(2)(A) of the FD&C Act states that FDA shall by regulation prescribe the time of submission of the notification in advance of importation or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, and any timeframe FDA adopts in the final rule must be justified under this standard.

## III. Comments

Elsewhere in this issue of the **Federal Register**, we are reopening the comment period on the prior notice IFR. To be considered part of the rulemaking record, interested persons must submit to the Division of Dockets Management

(see **ADDRESSES**) written or electronic comments on the plan as indicated in the **DATES** section of this document. Two copies of any mailed comments are to be submitted by commenting entities; individuals may submit one copy.

Comments are to be identified with the docket number found in brackets in the heading of this document. The plan and comments FDA has received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Interested persons who wish to submit general comments on the prior notice IFR should consult the document reopening the comment period that is published elsewhere in this issue of the **Federal Register**.

## IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/oc/bioterrorism/bioact.html>.

Dated: March 24, 2004.

**Lester M. Crawford,**

*Acting Commissioner for Food and Drugs.*

Dated: April 6, 2004.

**Robert C. Bonner,**

*Commissioner, Customs and Border Protection.*

[FR Doc. 04-8515 Filed 4-9-04; 4:51 pm]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 1 and 20

[Docket No. 2002N-0276]

#### Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Reopening of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Interim final rule; reopening of comment period

**SUMMARY:** The Food and Drug Administration (FDA) is reopening for 30 days, on a limited set of issues, the comment period on the registration of food facilities interim final rule (IFR) that appeared in the **Federal Register** of October 10, 2003 (68 FR 58894). The IFR requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003. FDA is taking this action consistent with its

statement in the IFR that it would reopen the comment period for 30 days in March 2004 to ensure that those commenting on the IFR have had the benefit of FDA's outreach and educational efforts and have had experience with the systems, timeframes, and data elements of the registration program.

**DATES:** Submit written or electronic comments on the identified set of issues for the IFR by May 14, 2004.

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

#### FOR FURTHER INFORMATION CONTACT:

Melissa S. Scales, Center for Food Safety and Applied Nutrition (HFS-24), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2378.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of October 10, 2003 (68 FR 58894), FDA issued an IFR to implement section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). The registration regulation requires facilities that manufacture/process, pack, or hold food (including animal feed) for consumption in the United States to register with FDA by December 12, 2003. In the "Request for Comments" section of the IFR, FDA requested comments on specific issues in order to improve the assumptions used in its economic analysis. The IFR stated that its comment period would coincide with that of the prior notice IFR, given the relatedness of the two rules. Therefore, the registration IFR was open for comments for 75 days following the publication of the IFR. The IFR also stated that "to ensure that those commenting on this interim final rule have had the benefit of FDA's outreach and educational efforts and have had experience with the systems, timeframes, and data elements of this interim final rule," FDA would reopen the comment period for an additional 30 days in March 2004.

##### II. Comments

Consistent with the intent expressed in the preamble to the IFR, we are seeking comments on the following issues in order to improve FDA's economic analysis:

1. The cost to foreign facilities of hiring and retaining a U.S. agent.

Specifically, FDA invites comment, and the submission of data or other information, on the following:

a. The costs to a foreign facility of hiring a U.S. agent;

b. The number of foreign facilities that have hired a U.S. agent or negotiated additional duties from someone with whom they have an existing relationship, in response to the IFR, instead of relying on an existing relationship with a person who qualifies as a U.S. agent;

c. The number of foreign facilities that have ceased exporting to the United States because they have decided not to hire/retain a U.S. agent for registration purposes;

d. The distribution of costs between submitting registrations and other services offered by the U.S. agent; and

e. The assumptions underlying FDA's estimates of the costs of hiring and retaining a U.S. agent.

2. The effects on domestic small businesses, if any, if some foreign facilities cease exporting to the United States due to the U.S. agent requirement for registration. Specifically, FDA invites comment, and the submission of data or other information, on the following:

a. The number of domestic small businesses that have been adversely affected by trading partners that have ceased exporting to the United States due to the U.S. agent requirement for foreign facility registration; and

b. The costs incurred by these domestic small businesses due to the loss of these trading partners.

To be timely, interested persons must submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the above issues as indicated in the **DATES** section of this document. Two copies of any comments are to be submitted by commenting entities; individuals may submit one copy. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

As noted, the IFR was effective on December 12, 2003. The agency will address comments on the identified set of issues that are received during this reopened comment period and were received during the previous comment period that closed on December 24, 2003, and will confirm or amend the IFR in a final rule. The agency, however, will not address any comments that

have been previously considered during this rulemaking.

Dated: March 24, 2004.

**Lester M. Crawford,**

*Acting Commissioner for Food and Drugs.*

Dated: April 6, 2004.

**Robert C. Bonner,**

*Commissioner, Customs and Border Protection.*

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[OPP-2004-0083; FRL-7351-9]

#### Thifensulfuron-methyl; Withdrawal of Tolerance Actions

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

**ACTION:** Withdrawal of direct final rule.

**SUMMARY:** Because EPA received relevant adverse comment, the Agency is withdrawing the direct final rule for the reinstatement of corn tolerances for the herbicide thifensulfuron-methyl. EPA published the direct final rule on February 13, 2004 which would have reinstated corn tolerances for the herbicide thifensulfuron-methyl that were previously established but inadvertently removed shortly thereafter. EPA stated in that direct final rule that if relevant adverse comment were received by April 13, 2004, the Agency would publish a timely withdrawal in the **Federal Register**. EPA subsequently received relevant adverse comment on that direct final rule. EPA will therefore publish a notice of proposed rulemaking in a future edition of the **Federal Register**. The Agency will address the comments on the direct final rule as part of that proposed rulemaking.

**DATES:** As of April 14, 2004, EPA withdraws the direct final rule published at 69 FR 7161, on February 13, 2004.

**FOR FURTHER INFORMATION CONTACT:**

Joseph Nevola, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8037; e-mail address: [nevola.joseph@epa.gov](mailto:nevola.joseph@epa.gov).

**SUPPLEMENTARY INFORMATION:** EPA received a relevant adverse comment during the comment period for the February 13, 2004 (69 FR 7161) (FRL-7338-6) direct final rule in which the

Agency stated that it would reinstate corn tolerances for residues of the herbicide thifensulfuron-methyl that were previously established by rulemaking in the **Federal Register** and that were inadvertently removed from 40 CFR 180.439. Because of a relevant adverse comment, EPA is withdrawing the direct final rule so that it will not take effect. EPA will publish a notice of proposed rulemaking in a future issue of the **Federal Register** and address the comments on the direct final rule as part of that notice of proposed rulemaking.

Currently, there are active products registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) which list corn as a use site for thifensulfuron-methyl application. These registrations have existed since 1994 with associated tolerances established in May 1994. In the direct final rule of February 13, 2004 (69 FR 7161), EPA stated that the deletion of the corn tolerances from the 40 CFR was both inadvertent and improper.

#### List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 26, 2004.

**James Jones,**

*Director, Office of Pesticide Programs.*

■ Accordingly, the direct final rule for thifensulfuron-methyl published in the **Federal Register** of February, 13, 2004 at 69 FR 7161 is withdrawn.

[FR Doc. 04-8103 Filed 4-13-04; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[OPP-2004-0075; FRL-7353-1]

#### Boscalid; Pesticide Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl) in or on certain commodities and establishes a tolerance for the residues of boscalid in or on pome fruit crop group, group 11 at 3.0 ppm, apple pomace, wet at 10.0 ppm, hops cones, dried at 35.0 ppm, soybean, vegetable at 2.0 ppm, soybean seed at 0.1 ppm, soybean hulls at 0.2 ppm and aspirated grain fractions at 3.0