

considered a decision in the review reversing an adverse determination of patentability as that phrase is used in 35 U.S.C. 154(b)(2) as amended by section 532(a) of the Uruguay Round Agreements Act, Public Law 103-465, 108 Stat. 4809, 4983-85 (1994), and a final decision in favor of the applicant under paragraph (c)(3) of this section. A remand by a panel of the Board of Patent Appeals and Interferences shall not be considered a decision in the review reversing an adverse determination of patentability as provided in this paragraph if there is filed a request for continued examination under 35 U.S.C. 132(b) that was not first preceded by the mailing, after such remand, of at least one of an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151. A reopening of prosecution after a notice of appeal has been filed shall not be considered a decision in the review reversing an adverse determination as provided in this paragraph if appellant files a request to withdraw the appeal, an amendment pursuant to § 41.33 of this chapter canceling all of the claims on appeal, or a request for continued examination under 35 U.S.C. 132(b).

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3. Section 1.702 is proposed to be amended by revising paragraph (e) to read as follows:

§ 1.702 Grounds for adjustment of patent term due to examination delay under the Patent Term Guarantee Act of 1999 (original applications, other than designs, filed on or after May 29, 2000).

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(e) Delays caused by successful appellate review. Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to review by the Board of Patent Appeals and Interferences under 35 U.S.C. 134 or by a Federal court under 35 U.S.C. 141 or 145, if the patent was issued under a decision in the review reversing an adverse determination of patentability. If an application is remanded by a panel of the Board of Patent Appeals and Interferences and the remand is the last action by a panel of the Board of Patent Appeals and Interferences prior to the mailing of a notice of allowance under 35 U.S.C. 151 in the application or if the Office reopens prosecution after a notice of appeal has been filed but before any decision by the Board of Patent Appeals and Interferences and issues an Office action under 35 U.S.C. 132 or notice of allowance under 35 U.S.C. 151, the remand or issuance of an Office action under 35 U.S.C. 132 or notice of

allowance under 35 U.S.C. 151 shall be considered a decision in the review reversing an adverse determination of patentability as that phrase is used in 35 U.S.C. 154(b)(1)(C)(iii), and a final decision in favor of the applicant under § 1.703(e). A remand by a panel of the Board of Patent Appeals and Interferences shall not be considered a decision in the review reversing an adverse determination of patentability as provided in this paragraph if there is filed a request for continued examination under 35 U.S.C. 132(b) that was not first preceded by the mailing, after such remand, of at least one of an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151. A reopening of prosecution after a notice of appeal has been filed shall not be considered a decision in the review reversing an adverse determination as provided in this paragraph if appellant files a request to withdraw the appeal, an amendment pursuant to § 41.33 of this title canceling all of the claims on appeal, or a request for continued examination under 35 U.S.C. 132(b).

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4. Section 1.704 is amended by revising paragraph (d) to read as follows:

§ 1.704 Reduction of period of adjustment of patent term.

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(d)(1) A paper containing only an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraphs (c)(6), (c)(8), (c)(9), or (c)(10) of this section if it is accompanied by a statement that each item of information contained in the information disclosure statement:

(i) Was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement; or

(ii) Is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

(2) The thirty-day period set forth in paragraph (d)(1) of this section is not extendable.

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Teresa Stanek Rea,

Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office.

[FR Doc. 2011-8275 Filed 4-5-11; 8:45 am]

BILLING CODE 3510-16-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 168

[EPA-HQ-OPP-2009-0607; FRL-8862-2]

RIN 2070-AJ53

Pesticides; Regulation to Clarify Labeling of Pesticides for Export

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to revise the regulations on labeling of pesticides and devices intended for export. Internal review of the regulations revealed that the current regulations needed clarification and restructuring to increase understandability and ease of use.

DATES: Comments must be received on or before June 6, 2011.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2009-0607, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

Instructions: Direct your comments to docket ID number EPA-HQ-OPP-2009-0607. EPA's policy is that all comments received will be included in the docket without change and may be made

available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or e-mail. The [regulations.gov](http://www.regulations.gov) Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. 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. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Vera Au, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9069; fax number: (703) 305-5884; e-mail address: au.vera@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you export a pesticide product, a pesticide device, or an active ingredient used in producing a pesticide. Potentially affected entities may include, but are not limited to: Pesticide and other agricultural chemical manufacturing (NAICS code 325320), e.g., Pesticides manufacturing, Insecticides manufacturing, Herbicides manufacturing, Fungicides manufacturing, etc.

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. What should I consider as I prepare my comments for EPA?

1. **Submitting CBI.** Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, 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 claimed as CBI. In addition to one complete version of the comment that includes 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. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. **Tips for preparing your comments.** When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What action is the agency taking?

Section 17(a)(1) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires that unregistered pesticides and devices intended for export be subject to several provisions that include labeling, production reports, inspection of establishments, and reporting and recordkeeping. These provisions are contained in 40 CFR 168.65 and 168.85. FIFRA section 17(a) further requires that exporters obtain a purchaser acknowledgement statement (PAS) before exporting an unregistered pesticide (but not a device). The requirements related to PAS are contained in 40 CFR 168.75.

On February 18, 1993, regulations interpreting the FIFRA requirements about the export of unregistered pesticides and devices were published in the **Federal Register** (58 FR 9085) as subpart D of 40 CFR part 168. Subpart D implements FIFRA sections 17(a) and 17(b).

The current regulations in subpart D have not been changed since 1993. Recently, an EPA internal review determined that the 1993 regulations are not as clear as EPA intended and that the resulting ambiguity might have led to uncertainty in compliance. To clarify the regulations in order to aid compliance, EPA decided to propose adding a more specific labeling requirement. In addition, EPA is restructuring the regulations to increase ease of use. Clarification and restructuring of the current regulations are administrative actions with no significant policy issues.

This proposed rule will supplement the requirements of 40 CFR 168.65 *Pesticide export label and labeling requirements*.

B. What is the agency's authority for taking this action?

EPA is authorized under FIFRA to regulate the sale, distribution, and use

of pesticide products and devices through a licensing (registration) scheme. This action is issued under the authority of section 17 of FIFRA (7 U.S.C. 136–136y).

Executive Order 12988, entitled Civil Justice Reform (61 FR 4729, February 7, 1996), requires agencies that are reviewing existing regulations take the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct.

III. Purpose and Scope of Proposal

EPA is proposing to clarify, restructure, and add specificity to labeling regulations for the export of unregistered pesticide products and devices according to Executive Order 12988 to eliminate ambiguity and simplify EPA regulations. This action is discretionary and is not subject to a statutory, judicial, or administrative deadline. Clarification, restructuring, and adding specificity will not change the substance of the current requirements.

EPA is also proposing to include a specific indication that these requirements also pertain to unregistered export pesticide products and devices shipped between registered establishments operated by the same producer pursuant to 40 CFR 152.30(a). Section 152.30(a) states that an unregistered pesticide product transferred between registered establishments operated by the same producer must be labeled according to 40 CFR part 156. However, there are additional label requirements at § 168.65 that also apply to a subset of the products covered by § 152.30(a), specifically, unregistered export pesticide products. For example, part 156 does not require that the label indicate that the pesticide product or device is not registered for use in the United States, while § 168.65 requires the statement “Not Registered for Use in the United States” to appear on the label of any unregistered export pesticide product or device. This statement may be further amplified by adding the reason for the unregistered status. For example:

1. Not Registered for Use in the United States of America because the product is exempt from registration;
2. Not Registered for Use in the United States of America because pesticide devices are not required to be registered;
3. Not Registered for Use in the United States of America because [insert crop name] is not grown in the United States.

EPA believes that including the information required by § 168.65 on the label while an export product moves within the United States prior to its actual export further protects public health and the environment by contributing to safer and more appropriate handling and distribution of unregistered pesticide products and devices. EPA also believes that unregistered pesticide products and devices intended for export must be clearly marked with the labeling according to § 168.65 to prevent them from inadvertently entering the U.S. market. EPA requests comment on the amplifications of the phrase “Not Registered for Use in the United States.”

IV. Overview of Proposed Changes

A. Clarification and Restructuring of Current Regulations

The clarifications and added specificity are consistent with section 1(b)(12) of Executive Order 12866; this section requires each agency to draft its regulations to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty. Certainty can also contribute to increased compliance with the requirements.

B. Definitions

In order to clarify and distinguish between the labeling requirements for pesticide products from the requirements for pesticide devices, two definitions are proposed for 40 CFR part 168, subpart D: Export pesticide product, and export pesticide device. Export pesticide products include registered export pesticide products and unregistered export pesticide products. The requirements for registered export pesticide products, unregistered export pesticide products, and export pesticide devices are presented in separate categories. This way the producer and/or exporter can more easily determine the status of the product and follow the specific directions for its category.

C. Labeling Export Shipments of Unregistered Pesticides and Devices Between Establishments Operated by Same Producer

EPA believes the minimal identity and safety information required for export labeling in FIFRA section 17(a)(1) is important in ensuring unregistered pesticide products and devices are properly identified during transportation both within the United States and upon arrival in the importing country. The current regulations in 40 CFR 152.30(a) allow the transfer of

unregistered pesticide products between registered establishments operated by the same producer. The notification of identity and safety measures of products intended for export is not only important between the time the unregistered pesticide product or device leaves a U.S. port and the time it arrives in the importing country; this labeling is equally important while the unregistered pesticide product or device is shipped between registered establishments operated by the same producer within the United States.

EPA intended that the labeling requirements in § 168.65 be followed for each unregistered export pesticide product as it makes its way towards the importing country. However, the regulations promulgated in 1993 inadvertently failed to explicitly state that the § 168.65 labeling requirements applied to unregistered pesticide products and devices intended for export as they move between registered establishments operated by the same producer in the United States, including transfers authorized by § 152.30(a).

If the producer exports an unregistered pesticide product or device directly, then it is clear that the label that must accompany the unregistered pesticide product or device when it leaves the production facility must comply with § 168.65.

The requirement to label the unregistered pesticide product and pesticide device as it begins to move between registered establishments operated by the same producer may transfer the responsibility for the label to the producer from the exporter/reformulator/repackager if the latter was primarily responsible for the label before export.

Therefore, EPA is proposing to explicitly require labeling as prescribed by § 168.65 to accompany the unregistered export pesticide product or device at all times, even when they are being shipped between registered establishments operated by the same producer. Section 168.65 has been replaced by a proposed new numbering of sections to accommodate the new categories of products and accompanying regulations. EPA invites public comment on the requirement for labeling unregistered pesticide products and devices being shipped between establishments operated by the same producer.

V. Implementation

This proposal addresses the future labeling of unregistered pesticide products and devices shipped between establishments operated by the same producer. The proposed labeling

requirements, once final, would apply to all pesticide products and devices intended for export that are produced after the effective date of the rule. The Agency believes that producers do not frequently redesign the labels they use on unregistered pesticide products and devices, so producers will have time to plan and implement any changes to their current products or practices.

Therefore, the Agency is proposing an effective date of 1 year after the date of publication of the final rule. The Agency requests comment on the proposed effective date.

VI. FIFRA Review Requirements

In accordance with FIFRA section 25(a), EPA submitted a draft of the proposed rule to the FIFRA Scientific Advisory Panel (SAP), the Secretary of Agriculture (USDA), and appropriate Congressional Committees. The FIFRA SAP waived its review of this proposal on December 8, 2010, because this proposal does not raise scientific issues. USDA waived the opportunity to review the draft proposal on November 29, 2010, because clarification and restructuring of the current regulations are administrative actions with no scientific or policy issues.

VII. Statutory and Executive Order Reviews

A. Regulatory Planning and Review

This action is not a “significant regulatory action” subject to review by the Office of Management and Budget (OMB) under the terms of Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993).

EPA has determined that the cost is minimal to comply with the new requirement that the unregistered pesticide product or device shipped between registered establishments operated by the same producer be labeled with the statement “Not Registered for Use in the United States.” This determination was made given that labeling is already in place under existing requirements and the burden of adding the additional statement to unregistered products or devices shipped between establishments would be negligible. EPA believes that this labeling change may be easily accomplished using commonly available word processing software; in addition, this label change does not require label submission to or approval by EPA, and shall be phased in as part of normal business operations. EPA concludes that the per firm and industry level impact of the rule is not significant.

B. Information Collection Burdens

This action does not impose any new information collection burden that would require additional review or approval by OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* OMB previously approved the information collection requirements contained in the existing regulations, 40 CFR 168.65, and has assigned OMB control number 2070–0027 (EPA ICR No. 0161). Burden is defined at 5 CFR 1320.3(b). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA’s regulations in 40 CFR are displayed in the **Federal Register** and are listed in 40 CFR part 9.

C. Small Entity Impacts

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, the Agency hereby certifies that this action will not have a significant adverse economic impact on a substantial number of small entities.

Under the RFA, small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this proposed rule on small entities, small entity is defined in accordance with section 601 of the RFA as:

1. A small business as defined by the Small Business Administration’s (SBA) regulations at 13 CFR 121.201. A small business that manufactures pesticides and other agricultural chemicals as defined by NAICS code 325320, has 500 or fewer employees based on the SBA standards.

2. A small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000.

3. A small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

The small entities directly regulated by this proposed rule are small manufacturers of pesticides which export unregistered pesticide products or devices.

EPA has determined that the cost is minimal to comply with the new requirements that the unregistered pesticide product or device be labeled with “Not Registered for Use in the United States.” This is because the labeling is already in place under existing requirements and the burden of adding the additional statement to unregistered pesticide products or devices shipped between establishments

operated by the same producer would be negligible. EPA believes this labeling change may be easily accomplished using commonly available word processing software; in addition, this label change does not require label submission to or approval by EPA, and shall be phased in as part of normal business operations. EPA concludes that the per firm and industry level impact of the proposed rule is insignificant.

Although this proposed rule will not have a significant economic impact on a substantial number of small entities, EPA believes that increasing the specificity of the current regulations will minimally affect all manufacturers of export pesticide products and devices, not just small entities. The more specific indication that “Not Registered for Use in the United States” will be required while unregistered pesticides products and devices are shipped between establishments operated by the same manufacturer; this is the identical information that is required before the unregistered pesticide product or device is exported to another country.

The Agency continues to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates

This rule does not contain a Federal mandate as described in the Unfunded Mandates Reform Act (UMRA), 2 U.S.C. 1531–1538, that may result in expenditures of \$100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. This action is expected to only affect producers, transporters, formulators, packagers, and exporters of unregistered pesticide products and devices but not resulting in expenditures of \$100 million or more. Since no State, local, or tribal government is known to produce, transport, formulate, package, or export unregistered pesticide products or devices, this rule is not expected to affect State, local, and tribal governments individually, much less in the aggregate. Thus, this rule is not subject to the requirements of sections 202 or 205 of UMRA.

This rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. Since no small government is known to produce, transport, formulate, package, or export unregistered pesticide products or devices, this rule is not

subject to the requirements of section 203 of UMRA.

E. Federalism

This action does not have federalism implications because it is not expected to have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). This action is expected to only affect producers, transporters, formulators, packagers, and exporters of unregistered pesticide products and devices. Since no State or local government is known to produce, transport, formulate, package, or export unregistered pesticide products or devices, there is no effect on a State, the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Thus, Executive Order 13132 does not apply to this action.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed action from State and local officials.

F. Indian Tribal Implications

This action does not have tribal implications, as specified in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000). This action is expected to only affect producers, transporters, formulators, packagers, and exporters of unregistered pesticide products and devices. Since no Indian tribal government is known to produce, transport, formulate, package, or export unregistered pesticide products or devices, this action has no tribal implications. Thus, Executive Order 13175 does not apply to this action.

EPA specifically solicits additional comment on this proposed action from tribal officials.

G. Children's Health Protection

EPA interprets Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5-501 of the Executive Order has the potential to

influence the regulation. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks, nor is it an "economically significant regulatory action" as defined in Executive Order 12866. The clarification and restructuring of current regulations for the export of unregistered pesticide products and devices do not present a disproportionate risk to children. Requiring that such unregistered pesticide products and devices shipped between establishments operated by the same producer be labeled according to the current regulations in § 168.65 prevents them from inadvertently entering the U.S. market and provides compliance assistance. This requirement further protects public health and the environment by ensuring safe and appropriate handling and distribution without presenting a disproportionate risk to children.

H. Effect on Energy Supply, Distribution or Use

This action is not a "significant energy action" as defined in Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because this action is not likely to have any effect on the supply, distribution, or use of energy.

I. Technical Standards

Because this action does not involve any technical standards, section 12(d) of The National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note), does not apply to this action.

J. Environmental Justice

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994). EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. This rule is proposing to clarify, restructure, and add specificity to the current regulations and thus add an

extra margin of safety for all affected populations as shipments of unregistered pesticides and devices move between establishments operated by the same producer. Labeling regulations at 40 CFR 152.30(a) currently require that an unregistered pesticide transferred between establishments operated by the same producer must follow labeling requirements in 40 CFR part 156. EPA believes that requiring the registration status information from 40 CFR 168.65 on the label further protects public health and the environment by contributing to safer and more appropriate handling and distribution of unregistered pesticide products and devices. EPA believes that unregistered pesticide products and devices intended for export must be clearly marked with the labeling according to § 168.65 to prevent them from inadvertently entering the U.S. market.

List of Subjects in 40 CFR Part 168

Environmental protection, Exports, Labeling, Pesticides and pests.

Dated: March 25, 2011.

Lisa P. Jackson,
Administrator.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 168—STATEMENTS OF ENFORCEMENT POLICIES AND INTERPRETATION

1. The authority citation for part 168 continues to read as follows:

Authority: 7 U.S.C. 136–136y.

§ 168.65 [Removed and Reserved].

2. Remove and reserve § 168.65.

3. Add §§ 168.66 through 168.71 to read as follows:

*	*	*	*	*
Sec.	168.66	Labeling of pesticide products and devices for export.		
	168.67	Definitions.		
	168.68	Applicability.		
	168.69	Registered export pesticide products.		
	168.70	Unregistered export pesticide products.		
	168.71	Export pesticide devices.		
	*	*	*	*

§ 168.66 Labeling of pesticide products and devices for export.

(a) This subpart describes the labeling requirements applicable to pesticide products and devices that are intended solely for export from the United States under the provisions of FIFRA sec. 17(a). The requirements for pesticide production reporting, recordkeeping and inspection and purchaser

acknowledgement provisions can be found in the following parts:

(1) Pesticide production reporting requirements under FIFRA sec. 7 are located in part 167 of this chapter (or § 168.85(b));

(2) Recordkeeping and inspection requirements under FIFRA sec. 8 are located in part 169 of this chapter (or § 168.85(a));

(3) Purchaser acknowledgement statement provisions under FIFRA sec. 17(a) are located in § 168.75.

(b) The required label information may be fully met by:

(1) The product label attached to the immediate product;

(2) The product label and supplemental labeling; or

(3) Supplemental labeling that must be:

(i) Attached at all times during shipping or while being held for shipping; or

(ii) Attached to the immediate product container or to the shipping container.

§ 168.67 Definitions.

Terms used in this subpart have the same meaning as in the Act. The definitions of terms in § 152.3 of this chapter apply to this subpart unless defined in this section.

Export pesticide device means a device, as defined in FIFRA sec. 2(h), that is intended solely for export from the United States to another country.

Export pesticide product means a pesticide product, as defined in § 152.3 of this chapter, that is intended solely for export from the United States to another country.

§ 168.68 Applicability.

This subpart applies to all export pesticide products and export pesticide devices regardless of the purpose of the export.

§ 168.69 Registered export pesticide products.

(a) Each export pesticide product that is registered under FIFRA sec. 3 or FIFRA sec. 24(c) must bear a label or be accompanied by labeling approved by EPA for its registration.

(b) For the purposes of this subpart, a registered export pesticide product is considered to be any of the following:

(1) A pesticide product of composition, packaging and labeling as described in its registration under FIFRA sec. 3;

(2) A pesticide product that has been modified in compliance with the notification or non-notification provisions of § 152.46 of this chapter, and any associated procedures issued

under § 156.10(e) of this chapter, regardless of whether such modification has been made for the pesticide product's registration under FIFRA sec. 3;

(3) A pesticide product initially registered by a State under FIFRA sec. 24(c), and whose Federal registration has not been disapproved by EPA under § 162.164 of this chapter.

(c) The text of the label or supplemental labeling of the registered pesticide product must be provided in one of the following languages besides English:

(1) The language of the country of final destination, if known;

(2) The language predominantly used in the importing country; or

(3) The language in which official government business is conducted in the importing country.

§ 168.70 Unregistered export pesticide products.

(a) Any export pesticide product that does not meet the terms of § 168.69 is an unregistered export pesticide for purposes of this subpart.

(b) Each unregistered export pesticide product must bear a label or be accompanied by supplemental labeling that complies with all requirements of this section and § 168.66(b).

(1) The label or supplemental labeling must comply with all of the prominence and legibility requirements of § 156.10(a)(2) of this chapter.

(2) The label or supplemental labeling must comply with all the language requirements in § 168.69(c) and § 156.10(a)(3) of this chapter.

(3) The label or supplemental labeling must bear the following information:

(i) The name and address of the producer, in accordance with the requirements of § 156.10(c) of this chapter;

(ii) The net weight or measure of contents, in accordance with the requirements of § 156.10(d) of this chapter;

(iii) The pesticide producing establishment number, in accordance with the requirements of § 156.10(f) of this chapter;

(iv) An ingredients statement, in accordance with the requirements of § 156.10(g) of this chapter, except that: (A) The ingredients statement need not appear in a second language besides English if the English language version is likely to be understood by the ordinary individual in the importing country; and

(B) An export pesticide product intended solely for research and development purposes, (and which bears the statement "For research and

development purposes only. Not for distribution, sale or use," or similar language) may bear coded ingredient information to protect confidentiality.

(v) Human health and precautionary statements in accordance with the requirements of subpart D of part 156 of this chapter. If a translated U.S. precautionary statement is inappropriate in the importing country, an equivalent statement appropriate to the importing country must be substituted;

(vi) The statement "Not Registered for Use in the United States of America," which may be amplified by additional statements describing the reason(s) why the export pesticide product is not registered in the United States, or is not registered for particular uses.

(c) This section also applies to all unregistered pesticide products and devices that are transferred, distributed, or sold between registered establishments operated by the same producer under the exemptions provided by § 152.30(a) of this chapter if:

(1) The transfer, distribution or sale occurs between a point in the United States and a point outside the United States, or

(2) The transfer occurs within the United States solely for the purpose of export from the United States.

§ 168.71 Export pesticide devices.

(a) Each export pesticide device sold or distributed anywhere in the United States must bear a label or be accompanied by supplemental labeling that complies with all requirements of this section and § 168.66(b).

(b) The label or supplemental labeling of each export pesticide device must meet all of the prominence and legibility requirements of § 156.10(a)(2) of this chapter.

(c) The label or supplemental labeling must also comply with all the language requirements in § 168.69(c) and § 156.10(a)(3) of this chapter.

(d) The label or supplemental labeling must bear the following information:

(1) The name and address of the producer, meeting the requirements of § 156.10(c) of this chapter;

(2) The producing establishment number, meeting the requirements of § 156.10(f) of this chapter;

(3) The statement "Not Registered for Use in the United States of America," which may be amplified by additional statements describing the reason why the export pesticide device is not registered in the United States.

(e) An export pesticide device is not required to bear an ingredients statement.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2005-0174; FRL-8867-9]

Sulfuryl Fluoride; Addendum to Proposed Order Granting Objections to Tolerances and Denying Request for a Stay; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed order and extension of comment period.

SUMMARY: In this document, EPA is supplementing its proposed order published January 19, 2011, regarding sulfuryl fluoride and fluoride tolerances promulgated under the Federal Food, Drug, and Cosmetic Act (FFDCA) to include proposed effective dates for the termination of tolerances for rice commodities. In order to provide a 90-day comment period on the proposed effective date for terminating the rice tolerances, while also maintaining a consistent closing date for all comments on the proposed sulfuryl fluoride actions and accommodating several comment period extension requests, the Agency will accept comment on both the proposed order and this addendum for 90 days following publication of this notice in the **Federal Register**. In addition, EPA is clarifying that all tolerances for sulfuryl fluoride and the associated fluoride tolerances were intended to be covered by the proposed order despite discrepancies in the way those tolerances are described in EPA's regulations.

DATES: Comments must be received on or before July 5, 2011.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2005-0174, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S.

Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

Instructions: Direct your comments to docket ID number EPA-HQ-OPP-2005-0174. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or e-mail. The www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. 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. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal

holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Meredith Laws, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-7038; e-mail address: laws.meredith@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, pesticide manufacturer, or consumer. Potentially affected entities may include, but are not limited to:

- Food manufacturing (NAICS code 311), e.g., grain and oilseed milling; animal food manufacturing; flour milling; bread and bakery product manufacturing; cookie, cracker, and pasta manufacturing; snack food manufacturing.
- Pesticide manufacturing (NAICS code 32532), e.g., pesticide manufacturers; commercial applicators.
- Community Food Services (NAICS code 624210), e.g., food banks.
- Farm Product Warehousing and Storage (NAICS 493130), e.g., grain elevators, private and public food warehousing and storage.

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. What should I consider as I prepare my comments for EPA?

1. **Submitting CBI.** Do not submit this information to EPA through www.regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, 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 claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not