

ENVIRONMENTAL PROTECTION AGENCY**[OPP-00745; FRL-6809-9]****Pesticides; Draft Guidance for Pesticide Registrants on False or Misleading Pesticide Product Brand Names****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice of availability.

SUMMARY: The Agency is announcing the availability of and seeking public comment on a draft Pesticide Registration (PR) Notice entitled "False or Misleading Pesticide Product Brand Names." PR Notices are issued by the Office of Pesticide Programs (OPP) to inform pesticide registrants and other interested persons about important policies, procedures, and registration related decisions, and serve to provide guidance to pesticide registrants and OPP personnel. This particular draft PR Notice provides guidance to registrants, applicants and the public as to what product brand names may be false or misleading, either by themselves or in association with company names or trademarks.

DATES: Comments, identified by docket control number OPP-00745, must be received on or before May 28, 2002.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit V.A. of the

SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-00745 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: Jeff Kempter, Antimicrobial Division, (7510C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5448; fax number: (703) 308-6467; e-mail address: kempter.carlton@epa.gov.

SUPPLEMENTARY INFORMATION:**I. Does this Action Apply to Me?**

This action is directed to the public in general. Although this action may be of particular interest to those persons who are required to register pesticides. Since other entities may also 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 information in this notice,

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

II. What Guidance Does this PR Notice Provide?

This draft PR Notice provides guidance to registrants and distributors concerning pesticide product brand names that may be false or misleading, either by themselves or in association with particular company names or trademarks. Occasionally, some registrants and distributors have considered or adopted product brand names (or placed company names or trademarks within or in close proximity to product brand names) that conflict with current Agency regulations concerning false or misleading claims [40 CFR 156.10(a)(5) and (b)(2)] and with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) sections 12(a)(1)(e) and 2(q)(1)(A). Under these regulations, products with brand names (or any other statements) that state or imply safety, efficacy, or comparative claims, or are false or misleading in any particular, are considered to be misbranded. To address this problem as it specifically relates to pesticide product brand names, the Agency is proposing to clarify the applicability of its regulations as follows:

- These regulations (40 CFR 156.10(a)(5) and 156.10(b)(2)) require that a pesticide product brand name, either by itself or containing or located in close proximity to a company name or trademark, not be false or misleading. Examples of potentially false or misleading product brand names are provided in Table 1 in the draft PR Notice. In addition, the guidance provided by Section III.4. of PR Notice 93-6 (pertaining to the use of "Brand" to qualify superlative terms) would be superseded by this notice.

- When the draft PR Notice is formally issued, following this notice and comment, the Agency would be applying these regulations as clarified in the notice when evaluating applications for new products or brand names, or notifications for alternate or changed brand names, for registration or reregistration. Registrants would review their product names in light of the notice, and, if warranted, take corrective action before October 1, 2003. It is proposed that as of that date, EPA would use this guidance when determining whether a product is misbranded under FIFRA section 12.

Because of the growing potential for product brand names (either by themselves or in association with company names or trademarks) that appear not to comply with FIFRA and the regulations, the Agency believes that

additional guidance is needed so that registrants can better understand the circumstances under which product brand names are potentially false or misleading and what kinds of corrective actions are needed for registered products already bearing such brand names.

The Agency's policy as set forth in the draft PR Notice concludes that a pesticide product brand name, either by itself or in connection with a company name or trademark must not be false or misleading in any particular. EPA's regulations (40 CFR 156.10(a)(5) and (b)(2)) and FIFRA give the regulatory foundation for this position.

The draft PR notice is intended to aid registrants in bringing their product brand names into compliance with those regulatory requirements. Specifically, that draft document provides clarifying guidance to help registrants determine whether their product brand names, alone or through association with their company names or trademarks, comply with the regulations cited above. To ensure that a product's name is consistent with those regulations, a registrant would review the brand names of its products in light of the regulations and guidance in this notice and take corrective action, if warranted. Examples of words, terms, or phrases that might cause product brand names to be false or misleading are listed in the draft PR Notice. By examining these examples as well as other terms listed in the regulations cited above, registrants could determine whether they need to take corrective steps.

If a Federal registrant or distributor of a product were to have a product bearing a false or misleading product brand name, then the draft PR Notice would provide two basic options for bringing that product label into compliance, depending on the specific circumstances:

- (1) Change or delete words, phrases, company names or trademarks in the product brand name, and/or
- (2) use an appropriate qualifier or disclaimer.

The draft PR notice proposes implementation steps for assuring that all products are brought into compliance with the applicable regulations. When the PR Notice is signed and formally issued, EPA would review all applications for new pesticide product registrations, for amendments to registered products, and for reregistration of registered products using this guidance. It is proposed that as of October 1, 2003, the Agency would monitor registered products using this guidance to determine whether their

labeling is consistent with (40 CFR 156.10(a)(5) and 156.10(b)(2)) and FIFRA. Pesticide products that are released for shipment by registrants or distributors on or after that date and that bear product brand names or trademarks that EPA determines are false or misleading would risk being considered in violation of FIFRA.

To give sufficient time for pesticide products in the channels of trade to be distributed or sold to users or otherwise disposed of, the Agency would provide a period of time for companies to comply with those labeling elements that have been clarified by this notice. Therefore, pesticide products released for shipment prior to October 1, 2003, would be considered existing stocks in the channels of trade that may be sold, used or otherwise disposed of until exhausted. Registrants and distributors would need to take corrective measures as soon as possible to assure that their product brand names are in compliance with FIFRA and its implementing regulations. Registrants who would want to modify their product labels to ensure compliance with FIFRA would submit revised labeling using the notification or amendment application process, as applicable.

The Agency is aware of certain Constitutional considerations that are applicable to commercial speech such as use of a corporate or product name or other statements in connection with a product's features or claims. It is the Agency's intent to address such considerations in this proposed PR Notice so as to promote the exercise of commercial speech in a way that does not run afoul of statutory and regulatory prohibitions against false or misleading statements in connection with sale or distribution of pesticide products. This proposed PR Notice deals with inherently false or misleading statements or claims and potentially false or misleading statements or claims—in particular, those that occur in names that appear on products. Rather than attempting to prohibit product names or claims where they may seemingly be false or misleading, the PR Notice incorporates an approach where the remedy is tailored to the situation. As such, the Agency recognizes that there may be instances where full prohibition may not be warranted and that some remedy short of prohibition might be employed such as the use of qualifiers or different placement of the statement or name on the product label. This proposed PR Notice seeks to employ such an approach.

III. Do PR Notices Contain Binding Requirements?

The PR Notice discussed in this notice is intended to provide guidance to EPA personnel and decision-makers and to pesticide registrants. While the requirements in the statutes and Agency regulations described here are binding on EPA and the applicants, this PR Notice itself is not binding on either EPA or pesticide registrants, and EPA may depart from the guidance where circumstances warrant and without prior notice. Likewise, pesticide registrants may assert that the guidance is not appropriate generally or not applicable to a specific pesticide or situation.

IV. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain an electronic copy of this **Federal Register** document using the date of publication from the listing of EPA **Federal Register** documents at <http://www.epa.gov/fedrgstr/>. You may obtain an electronic copy of this PR-Notice, as well as other PR-Notices, both final and draft, at http://www.epa.gov/PR_Notices/.

2. *Fax-on-demand.* You may request a faxed copy of the draft Pesticide Registration (PR) Notice entitled "False or Misleading Pesticide Product Brand Names," by using a faxphone to call (202) 401-0527 and selecting item 6146. You may also follow the automated menu.

3. *In person.* The Agency has established an official record for this action under docket control number OPP-00745. 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 Hwy., 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.

V. How Do I Submit Comments?

A. 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-00745 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 Hwy., 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-00745. Electronic comments may also be filed online at many Federal Depository Libraries.

B. 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**.

C. 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. Offer alternative ways to improve the notice.
7. Make sure to submit your comments by the deadline in this notice.
8. 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.

D. Issues for Comment

Following are several key issues that you may wish to comment on. While the Agency has identified these three issues, it does not intend to limit the issues upon which you may provide comments should you believe the Agency needs to consider other issues.

1. Does the draft PR Notice provide a reasonable approach to qualifying or disclaiming product names that might otherwise appear to conflict with EPA's regulations concerning false or misleading claims?
2. Could some claims in product names be so egregious that they could not be adequately qualified or disclaimed (e.g., "Safe As Water Insecticide")?
3. Does the Agency's proposed approach adequately balance commercial speech considerations and protection of the public against false or misleading claims in connection with the sale or distribution of pesticide products?

List of Subjects

Environmental protection,
Administrative practice and procedure,

Agricultural commodities, Pesticides and pests.

Dated: March 14, 2002.

Marcia E. Mulkey,

Director, Office of Pesticide Programs.

[FR Doc 02-7495 Filed 3-27-02; 8:45 a.m.]

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-30524; FRL-6827-7]

Pesticide Product; Registration Applications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of an application to register a pesticide product containing new active ingredients not included in any previously registered products pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

DATES: Written comments, identified by the docket control number OPP-30524, must be received on or before April 29, 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. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-30524 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By Mail: Andrew Bryceland, Regulatory Action Leader, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-6928 and e-mail address: bryceland.andrew@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

Categories	NAICS codes	Examples of potentially affected entities
	112 311 32532	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-30524. 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 Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m.,