any applicable unsatisfied data requirements.

V. Proposed Existing Stocks Provision

Pursuant to section 6(f) of FIFRA, EPA proposes to grant the requests for voluntary amendment and cancellation during the appropriate time frames identified in Tables 1 and 2. For purposes of the cancellation order that the Agency proposes to issue at the close of the comment period for this announcement, the term ''existing stocks'' will be defined, pursuant to EPA's Existing Stocks Policy published in the **Federal Register** of June 26, 1991 (56 FR 29362), as those stocks of a registered pesticide product which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the amendment or cancellation. Any distribution, sale, or use of existing stocks after the effective date of the cancellation order that the Agency intends to issue that is not consistent with the terms of that order will be considered a violation of section 12(a)(2)(K) and/or 12(a)(1)(A) of FIFRA.

A. Distribution, Sale, and Use of Products with Deleted Uses by Registrants

If the requested use deletions are approved, the distribution, sale, or use of such stocks by the registrants of acephate products will not be lawful under FIFRA after the sale, distribution, and use dates listed in Tables 1 and 2, except for the purposes of returns and relabeling, shipping such stocks for export consistent with the requirements of section 17 of FIFRA, or for proper disposal.

B. Distribution, Sale, and Use of Products with Deleted Uses by Persons Other than Registrants

If the requested use deletions are approved, retailers, distributors, and end-users may sell, distribute, or use end-use products with previously approved labeling which have been released for shipment until such supplies are exhausted, as presented in Table 2.

C. Distribution, Sale, and Use of Canceled Products

If the requested voluntary product cancellations are approved, the effective date of cancellation will be the date of the cancellation order, which is projected to be December 31, 2001. The orders effecting these requested cancellations will generally permit a registrant to sell or distribute existing stocks for 1 year after the date the cancellation request was received by the Agency. In this case, registrants will also be subject to the time frames and proposed existing stocks provisions for products with deleted uses described above, as appropriate. Unless the provisions of an earlier order apply, existing stocks already in the hands of dealers or users can be distributed, sold or used legally until they are exhausted, provided that such further sale and use comply with the EPA-approved label and labeling of the affected product(s).

List of Subjects

Environmental protection, Pesticides and pests.

Dated: November 13, 2001.

Lois A. Rossi,

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

[FR Doc. 01–29556 Filed 11–27–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–34240; FRL–6811–8]

Amendment to the Rodenticide Cluster and Zinc Phosphide Reregistration Eligibility Decision (RED) Documents

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The August 1998, Reregistration Eligibility Decision (RED) documents issued for the rodenticide cluster (brodifacoum, bromadiolone, bromethalin, chlorophacinone, diphacinone, and pival) and zinc phosphide outlined requirements to lessen the probability and severity of exposure to children. The RED established short-term risk mitigation including the incorporation of a bittering agent and an indicator dye in formulations to reduce accidental exposures to children and pets. In addition, the RED established the Rodenticide Stakeholder Workgroup (RSW) to develop long-term risk mitigation measures. On February 5, 2001, after extensive discussions, meetings, and recommendations from the RSW, the Agency came to a mutual agreement with the rodenticide registrants to rescind the bittering agent and indicator dye requirements from the RED. This decision, which amends the Rodenticide Cluster and Zinc Phosphide RED, is summarized below.

DATES: Comments, identified by docket control number OPP–34240, must be received on or before December 28, 2001.

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–34240 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: John Pates, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8195; fax number: (703) 308–7042; e-mail address: pates.john@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to companies that formulate rodenticides for use by certified personnel and the general public. 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 applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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/*. In addition, related information can be accessed at: *http://www.epa.gov/pesticides.*

2. *In person*. The Agency has established an official record for this action under docket control number OPP–34240. 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.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative, that you identify docket control number OPP–34240, 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–34240. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI that I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person 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 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 or collection activity.

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.

II. Background

A. What Action is the Agency Taking?

In August 1998, EPA issued two reregistration eligibility decision (RED) documents on seven rodenticide active ingredients. The Rodenticide Cluster RED included brodifacoum, bromadiolone, bromethalin, chlorophacinone, diphacinone, and pival. One stand-alone RED covered the active ingredient zinc phosphide. As a group, the seven active ingredients are registered for rodent control in both agricultural and residential settings. In these decision documents, EPA found the seven rodenticides eligible for reregistration, provided certain modifications were made to the terms and conditions of registration and use. The REDs proposed registration modifications and risk mitigation measures aimed at minimizing the potential risk to wildlife, non-target animals and humans, particularly children. Some of these modifications related to the finding that the use of these compounds in the residential setting was responsible for a disproportionate number of exposures to children (<6 years old). Over a 2–year period, the American Association of Poison Control Centers (AAPCC) collected data on over 18,000 exposures cases involving such young children.

Initial concerns centered around exposure to children in the residential setting. The Agency, recognizing the important public health benefits of rodenticides, pursued ways of minimizing potential exposure to children. In order to mitigate the risk from the use of rodenticides and maintain the benefits, the Agency developed a two-phased approach. Phase one centered on short-term risk mitigation measures, namely, the incorporation of a bittering agent and indicator dye in rodenticide formulations. Another requirement for registrants was to submit to the Agency annual reports on incidents of exposure. It was perceived that this information would enable the Agency to determine whether the imposed risk mitigation measures were reducing exposures to humans, particularly children. Phase two involved formation of a stakeholder group (the RSW) whose task was to find technologies or other measures to preclude such incidents from occurring in the future.

The RSW was formed in 1999 as a subcommittee under the federally-chartered advisory body, the Pesticide Program Dialogue Committee (PPDC), and met 5 times over an 8–month period in 1999. In forming the RSW, EPA's goal was to generate a stakeholder process that would explore creative ways of improving the management and/or regulation of rodenticides labeled for use in the home. The RSW was to consider evidence of the problem and develop potential measures to reduce exposures involving young children while being mindful of the following factors: Public health benefits of rodenticides; avoiding the creation or aggravation of other human health ''hazards'' equity among those who bear the cost and regulatory burden; and considering the overall economy and efficacy of the recommendations.

The Rodenticide Cluster and Zinc Phosphide REDs concluded that the rodenticide bait would not be eligible

for reregistration without including an indicator dye and bittering agent into the formulations of all rodenticide baits. These indicator dyes were expected to show whether a child had come into contact with the bait by leaving a stain on a child's mouth or hands. By staining the hands, mouth, etc., of an exposed child, EPA believed that such an indicator dye would confirm whether a child ingested or handled any rodenticide bait. The recommendation of the RSW was to drop this requirement from the RED due to the lack of suitable dye. Other issues of concern included: (1) There are no data on indicator dyes as an adequate marker; (2) the dye's effect on the overall efficacy of the product; (3) potential cost of new efficacy testing; (4) distinguishing between stains on a child from food products and stains from indicator dyes; (5) finding a dye that was temporary; and (6) contending with inevitable property damage resulting from contacted surfaces. Some members of the RSW felt that if technology was available, indicator dyes might have merit in managing potential exposure cases. Additional research and development, however, is needed before implementing such a requirement.

The REDs also concluded that a bittering agent be incorporated into the formulations of all rodenticide baits with the intention of minimizing the amount of bait accidentally ingested. In theory, a bittering agent would prevent a child from taking more than one mouthful, thereby possibly limiting the magnitude and severity of the exposure. The RSW recommended dropping the bittering agents as a mandatory requirement. Rodents have the ability to taste bittering agents raising the potential for bait acceptance problems. RSW members associated with urban rat control programs strongly believed that bittering agents adversely affect the efficacy of rodenticide baits. Another point of contention was EPA's reluctance to allow registrants of products containing bittering agents to make representations on the labeling about the bittering agent as a safety feature. Federal regulations prohibit making safety claims on pesticide labeling. (See 40 CFR 156.10(a)(5)(ix)). Also, inclusion of the bittering agent does not make the bait less toxic nor does it provide absolute protection for children.

While the RSW recommended dropping indicator dyes and bittering agents as mandatory requirements, members also recommended that EPA allow industry to retain the option of including such ingredients in rodenticide bait products on a voluntary basis.

Therefore, based on the findings presented to the PPDC by the RSW, EPA has determined that the rodenticide bait products are eligible for reregistration without indicator dyes and bittering agents. Although indicator dyes and bittering agents may not be necessary in all cases, EPA supports voluntary incorporation of these ingredients in rodenticide formulations.

B. Next Steps

EPA plans to move forward with a series of steps to implement the other recommendations of the RSW. These include modifying label language for rodenticide products, examining the potential value of reducing the amount of bait per placement to reduce a child's potential maximum exposure, considering the development of a website with educational and safety information for consumers, and improving the collection and quality of data on exposures. Additionally, as discussed in the 1998 Rodenticide Cluster RED, EPA is evaluating the comparative risk of secondary poisoning to birds and nontarget mammals associated with rodenticide products. Included in this comparative ecological risk assessment are three second-generation anticoagulants, three first-generation anticoagulants, and three non-anticoagulants. Through the findings of this comparative risk analysis, EPA hopes to bring forth a better understanding of the major differences in the potential risks of these compounds and their overall implications to birds and non-target mammals as well as develop any necessary risk mitigation measures that may be warranted to address these risks.

EPA has received comments and recommendations from stakeholders regarding label improvement. The Agency is in the process of reviewing these recommendations and expects to propose a strategy for label improvements within the next several months. EPA is also considering efficacy and other information to determine the feasibility of reducing the maximum quantity of bait per placement, and is also considering the content and presentation of consumer safety information that might be appropriate for a rodenticide website. The Agency has also obtained funds to purchase annual poisoning incident data directly from the American Association of Poison Control Centers (AAPCC). EPA will review these and other data, such as those submitted to the Agency under FIFRA section 6(a)(2), to explore the underlying causes of exposures, as well as, the adequacy of actions taken to reduce both the frequency and severity of incidents. The Agency will continue to monitor incident data in an effort to maintain awareness of reported exposures and to reduce the overall number of exposures to children.

Finally, the Agency plans to amend the 1998 RED to address the findings of the comparative ecological risk assessment, which is now near completion. EPA plans to use a public participation process to ensure transparency and stakeholder involvement in the development of the risk assessment and risk management documents and decisions. This will parallel the process currently in use for tolerance reassessment and reregistration of other pesticides, and will involve an error-only review by the registrants and federal agencies, public comment on the risk assessment and risk characterization, and public comment on EPA's risk-reduction proposal prior to EPA's final risk management decision. This process is expected to be completed in FY–2002.

Registrants are reminded that the date of publication of this **Federal Register** Notice will start the 8–month timetable for data submission as required per the Product Data Call-In (PDCI). Other time frames will also be imposed as required per the Generic Data Call-In as set forth in the Rodenticide Cluster RED; both of which had been temporarily put on hold, due to the RSW process.

C. What is the Agency's Authority for this Action?

EPA's legal authority for the RED documents issued for the rodenticide cluster (brodifacoum, bromadiolone, bromethalin, chlorophacinone, diphacinone, and pival) and zinc phosphide comes from section 4(g)(2)(A) of FIFRA. Section 4(g)(2)(A) directs that, after submission of all data concerning a pesticide active ingredient, ''the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration,'' before calling in product-specific data on individual end-use products, and either reregistering products or taking ''other appropriate regulatory action.''

List of Subjects

Environmental protection.

Dated: November 13, 2001.

Lois A. Rossi,

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

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