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DRAFT PESTICIDE REGISTRATION (PR) NOTICE 2000 -XX

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for Federal Registration and Reregistration of Pesticide Products

SUBJECT: Bee Precautionary Labeling Statements

This Notice clarifies and updates EPA's policy on bee labeling statements for pesticide products which are toxic to bees, such as honey bees, alfalfa leaf-cutting bees, alkali bees, and other native and non-indigenous pollinating insects that are important to crop production. Although the labeling statements are focused primarily on the protection of honey bees, the Agency believes if honey bees are protected from the adverse effects of pesticides, then other bee species and other pollinators will also be protected.

I. BACKGROUND

To help determine whether pesticide products used outdoors pose risks of bee mortality, the Agency generally requires acute toxicity data on bees to be submitted with a registration application. See e.g., 40 CFR 158.590(a). Depending on the results of the acute study, EPA may require additional residual toxicity data. EPA pesticide labeling regulations require that "...pesticides toxic to pollinating insects must bear appropriate label cautions." 40 CFR 156.10(h)(2)(ii)(E). In the 1980s, the Agency published a policy which described a set of standard bee precautionary labeling statements it believed appropriate where results from the bee data indicated toxicity. These precautionary statements identified a product as either "toxic" or "highly toxic" to bees, and warned against application of a product if use would result in residues on blooming crops or weeds when bees were "visiting" or "actively visiting" the treatment area.

The current standard labeling statements were introduced in the early 1980s, but controversy has continued among beekeepers, growers, commercial applicators and state regulators about the adequacy of these statements. For example, many beekeepers believe that the labeling statements are not adequately protective, while many growers believe that the labeling statements are overly restrictive and prevent them from managing pests adequately during the bloom period. Commercial applicators are concerned about the risks to themselves from such practices as flying at night when bees are less active. State regulators believe that the labeling statements need to be clarified

regarding the obligations of applicators with respect to bees.

In response to these concerns, EPA has extensively reviewed and discussed these issues with interested groups (beekeepers, applicators, growers, pesticide registrants and state regulatory authorities). In particular, the Agency has received input from the State FIFRA Issues Research and Evaluation Group (SFIREG) and the Association of American Pesticide Control Officials (AAPCO) through the State Labeling Issues Panel which was composed of representatives from states, regions and beekeeper organizations. EPA has actively sought input from various representatives on this group and from others parties as well in a variety of other fora. EPA has also received formal resolutions from the American Beekeeping Federation and AAPCO.

After considering the comments and suggestions from many involved parties over the past several years, EPA has decided to revise its policy on bee precautionary labeling statements, and to develop new language which EPA believes is appropriate precautionary language for bee protection. EPA believes that these revisions will help to make the labeling clearer and more easily understood. Once implemented, these changes should help to improve bee protection and to resolve some significant concerns that have been raised. The revised policy and steps for its implementation are described below.

II. PRECAUTIONARY LABEL STATEMENT FOR BEES

The Agency believes that the following language constitutes an appropriate label caution for pesticides that are toxic to bees. All pesticide products that are registered for outdoor uses to which bees or other pollinating insects may be exposed, and that meet criteria of being toxic to bees, should bear the following labeling statements:

> *This product is toxic to bees exposed to treatment and for _X_ hours/days** following treatment. Do not apply this pesticide to blooming, pollen-shedding or nectar-producing parts of plants if bees may forage on the plants during this time period. The _X_ hour/day limitation does not apply if the applicator operates in a state with a formal, state-approved bee protection program, and the applicator follows all applicable requirements of the state-approved program designed to ensure that managed bees are not present in the treatment area during this time period.*

**The time period to be inserted is based on the bee residual toxicity data for the product submitted to the Agency. If no bee residual toxicity data are available, the time period should be at least 24 hours.

III. DISCUSSION

A. Goals of Revised Label Language

The Agency's general policy on bee protection in relation to pesticide products is to have precautionary labeling statements that are easy to interpret for both users and regulators, and,

because labeling statements on environmental hazards are intended to govern the use of pesticide products, they should be practical to enforce. In addition, the Agency wishes to encourage the development of effective bee protection programs, as well as development of residual toxicity data by registrants. More specifically, the revised bee precautionary language is intended to achieve the following goals:

1. Provide a clear identification of the hazard to bees and the means of avoiding it through the "X hours/days" toxicity statement.

The "X/hour/day" period should be based to the extent possible on available residual toxicity data for honeybees. The Agency has such data for many of the pesticides most frequently linked to bee mortality. In some cases, however, pesticides which meet the acute bee toxicity criterion have not had residual toxicity data submitted. [In an action separate from this Notice, the Agency may choose to call in residual toxicity data for such products where the Agency believes it necessary, under the authority of section 3(c)(2)(B) of FIFRA. The Agency will make the appropriate findings under FIFRA section 3(c)(2)(B) at the time that it issues any such notices.]

The Agency requires residual toxicity data to be generated by testing the maximum application rate of typical end-use products. EPA recognizes, however, that in some cases lower application rates can provide effective pest control for users and may have the advantage of reduced time limitations for bee protection compared to maximum rates. In cases where use of a product on blooming crops is important, registrants may want to consider registering reduced-rate formulations if data indicate that residual toxicity to bees would be reduced enough to make applications practical.

2. Simplify the bee precautionary labeling scheme.

The single set of revised labeling statements should be used in place of the four variations of label statements now in effect under the 1980s policy (see Appendix 1). The distinction between showing and not showing residual activity has been replaced by the more precise information of " X hours/days" of toxicity. The distinction between "toxic" and "highly toxic" has been eliminated under the new policy because it adds no useful information.

3. Establish clear and verifiable criteria for allowing or prohibiting use.

Use of the labeling statements recommended by the 1980s policy requires the pesticide user to judge whether bees are "visiting" or "actively visiting" the treatment area. If the revised language described in the new policy is used on a label, the user has to judge whether or not one of several condition applies that allows use. The Agency believes these conditions are easier for a pesticide user to discern, and that any of these conditions can be verified after the fact if an incident needs to be investigated. Use of a pesticide to treat a crop which is

blooming, shedding pollen or producing nectar would be allowable if:

(a) the period of toxicity stated on the label is short enough (e.g., less than 12 hours) to allow evening or night application when bees will not be foraging (and the application is made at night); or

(b) the application method (e.g., soil incorporation) does not result in residues on "blooming, pollen-shedding or nectar-producing parts of plants," so that bees are not exposed; or

(c) the user participates in a state-approved plan for the protection of managed bees.

4. Balance pest control needs with reasonable assurance that effective precautions to protect bees will be taken. The language providing for an alternative to a time-period limitation on use, i.e., participation in a state approved plans for bee protection, is intended to achieve this balanced result.

EPA recognizes that the period of toxicity specified in the new policy's revised labeling statements may effectively prohibit the use of certain pesticides on blooming crops. However, the new labeling language also provides the option for users to follow a state program that is designed and operated to prevent the exposure of managed bees to toxic residues of pesticides. Under this option, users may be able to apply some products safely that the label would not be permit otherwise.

The Agency also recognizes that as a practical matter only managed bees can be protected through programs that rely primarily on notification to beekeepers and opportunity for removal of colonies from pesticide use areas. However, other measures states may choose to include in bee protection programs, such as restrictions on application methods, timing or specific use sites, can help to protect wild (feral) bees as well as managed colonies.

B. State bee protection programs

A state bee protection program should be designed to prevent exposure of managed bees to toxic pesticide residues. EPA does not intend to set specific criteria or approve state bee protection programs. The Agency believes that there are both regulatory and non-regulatory ways that states can pursue the basic goal of bee protection, and recommends that states consider some or all or the following approaches, which are currently being used in one or more existing state programs.

In general, a state program should be proportionate to the level of bee protection problems being experienced, and particularly focused on pesticide/crop combinations with a recurring history of bee-kill incidents. Regulatory approaches to bee protection can include regulations requiring the registration of beekeepers, and in some cases of growers as well. In such systems,

notification of beekeepers may be mandatory, but the notification requirements may apply only to use patterns of particularly high risk to bees, for example, bloom periods for certain crops (e.g., citrus). Another regulatory approach is for the state to require permits for the use of pesticides that are toxic to bees. Such permits may specify application practices to reduce risks to bees and include notification requirements. Some states have worked with registrants to tailor Special Local Need (FIFRA section 24 (c)) labels to improve bee protection for certain pesticide/crop combinations.

The majority of state bee protection programs are based on voluntary participation in notification programs. The Agency recognizes that notification of pending pesticide applications does not necessarily ensure bee protection since beekeepers may not be able to move vulnerable colonies for a variety of reasons. Some state agencies have found it useful to facilitate meetings between grower groups and beekeepers to improve mutual awareness of issues and encourage participation in the programs. In addition, most experts in this field agree that educating pesticide users and crop consultants about pesticide hazards to bees and the availability of less toxic alternatives is an important part of any bee protection program. Placing a specific period of toxicity on the label should also make outreach efforts more effective by making it very clear when a product may be applied safely with respect to bees.

IV. IMPLEMENTATION

In each individual licensing proceeding, EPA will expect that each applicant for registration of new products request adoption of the labeling statements in this Notice, if appropriate.

Registrants of currently-registered products to which this Notice is applicable should take one of the following actions, as appropriate:

(a) Registrants who have not submitted and do not intend to submit or cite bee residual toxicity data, but are willing to adopt the exact wording of the label language recommended in this Notice (including a statement that the product is toxic for up to 24 hours after application) may submit a notification for each product with a completed Application for Registration (EPA form 8570-1). A photocopy of the application form is acceptable. A copy of the label with the bee precautionary statement highlighted must be included. The application should bear the following statement:

"Notification of label change per PR Notice 2000-xx. This notification is consistent with the provisions of PR Notice 2000-xx, and includes a label statement that the product is toxic to bees for up to 24 hours after application. This notification is also consistent with EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or to the confidential statement of formula of this product. I

understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 2000-xx and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

(b) Registrants who have previously submitted or cited bee residual toxicity data that have been reviewed and accepted by the Agency, and who are willing to adopt the exact wording of the label language in this Notice, based on these previously submitted bee toxicity data, should submit an application for amended registration for each product. The application should include the following items: EPA application form 8570-1 (filled in), five copies of the draft label, a description on the application, such as, "Amended consistent with PR Notice 2000-xx", and appropriate citation of any data in support of the amendment.

(c) Registrants of products who intend to rely on bee residual toxicity data that have been submitted but not yet reviewed or accepted by the Agency to establish a stated period of residual toxicity on the label should submit an application for amended registration for each product. The application should include the following items: EPA application form 8570-1 (filled in), five copies of the draft label, a description on the application, such as, "Amended consistent with PR Notice 2000-xx", and appropriate citation of any data in support of the amendment.

The Agency requests that all products released for shipment by registrants after **October 1, 2002** bear labeling that is consistent with this notice. After October 1, 2002, EPA will begin monitoring pesticide products to determine whether they are labeled in accordance with the regulation at 40 CFR 156.10(h)(2)(ii)(E). It is the responsibility of registrants to submit applications in a timely manner. Registrants should allow adequate review time for acceptance of amendments, which could be several months for EPA's review and additional time for states' reviews. After receiving approval for amended labeling of each product, registrants should submit final printed labeling in accordance with PR Notice 82-2, before distributing the product in commerce.

V. ADDRESSES

For US Postal Service Submissions:

Document Processing Desk (AMEND) or (NOTIF) [as applicable]
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.

Washington, D.C. 20460-0001

For Courier Deliveries:

Office of Pesticide Programs
Document Processing Desk (AMEND) or (NOTIF) [as applicable]
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

VI. SCOPE OF POLICY

This Notice is intended to provide guidance to EPA personnel, pesticide registrants and applicants, and the public. As a guidance document, this policy is not binding on either EPA or any outside parties, and EPA may depart from the guidance where circumstances warrant and without prior notice. Registrants and applicants may propose alternatives to the recommended labeling statements described in this Notice and the Agency will assess them for appropriateness on a case-by-case basis. If a product does not meet the requirements of 40 CFR Part 156, the Agency may find the product to be misbranded. As stated above, the Agency believes that the statements outlined in this Notice should reduce the potential for adverse effects to the environment and are "appropriate" within the meaning of 40 CFR 156.10(h)(2)(ii)(E).

VII. FOR FURTHER INFORMATION

If you have questions regarding this Notice, contact Jim Roelofs, Field and External Affairs Division, at (703) 308-2964 or by electronic mail at roelofs.jim@epa.gov.

Marcia E. Mulkey, Director
Office of Pesticide Programs