UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 1, 1996

PESTICIDE REGULATION (PR) NOTICE 96-6

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

ATTENTION: Persons Responsible for Registration of Pesticide Products

SUBJECT: Pet Pesticide Product Label Statements

This notice specifies statements that should be added to the labels of pesticide products which are registered for use on dogs and/or cats. The label statements outlined in this notice will help to ensure that products bear labeling that will reduce the potential for misuse of pet pesticide products and protect pet and human health.

I. BACKGROUND

The Environmental Protection Agency (the Agency) has received reports of adverse reactions as a result of the application of various types of pesticide products registered for use on dogs and/or cats. While most of the reports involve exposure to cats, some involve exposure to dogs and humans. Many of the reported adverse reactions appear to be the result of product misuse or accidental exposure to animals. More specifically, some animal and human adverse reactions appear to be due to overdose or repeated applications at too frequent intervals, or simultaneous application of multiple pesticide products to pets and their environment.

Some adverse effects cited in the reports include neurological, general systemic, respiratory or gastrointestinal. Some reports claim animal deaths that mostly involve cats. The number and similarity of the adverse effects have led the Agency to conclude that the label changes set out in this notice should minimize misuse and thus reduce the potential risk of adverse effects to dogs, cats and humans from the use of pet pesticide products.

II. POLICY

Based on the adverse effects information currently available to the Agency concerning dog, cat and human health risks associated with the use of pesticide products for dogs and/or cats, the Agency believes that registrants should revise the product labels for such products to include additional use

directions and other statements described in this notice. The Agency believes that by including the statements outlined in this notice on pet pesticide product labels, registrants should significantly reduce misuse and the related risks of adverse effects to cats, dogs and humans, which should result in a reduction of the number of incidents associated with such products. The Agency also believes that the incremental cost of such label changes is outweighed by the health benefits of having comprehensive and appropriate label use directions and other statements which assure the proper use of pet pesticide products.

III. SCOPE

This notice applies to labeling for pesticide products registered for use directly on dogs and/or cats.

IV. LABEL STATEMENTS

Labels for all end-use pesticide products registered for use directly on dogs and/or cats should be amended to include the following types of statements as necessary in addition to statements that are currently required on labels. **Note that this notice does not replace more restrictive statements or information currently required on labels.**

1. **Direct User to Read Entire Label Before Each Use.**

   Direct user to read entire label by inserting the following statement at the top of the rear or side panel in bold, all caps.

   "READ ENTIRE LABEL BEFORE EACH USE."

2. **Clearly Indicate Registered Species.**

   The statement "Read Entire Label Before Each Use" should be followed immediately by the following statement in bold and caps:

   "USE ONLY ON (DOGS, CATS, or DOGS OR CATS)."

   In the case of a large number of misuse incidents regarding an unregistered use or incidents regarding specific breeds, then the product label should include:

   "Do not use on __(specific breed)__."

3. **Clarify Reapplication Limitation.**

   The reapplication statement needs to be product specific; and the statement should be one of the following:

(a) "Do not Reapply Product For _____ _____. (Insert number of day(s), week(s) or month(s).)"

(b) "Reapply every _____ _____." (Insert number of day(s), week(s), or month(s).)

(c) "Do Not Repeat Treatment For _____ _____." (Insert number of day(s), week(s), or month(s).)

(d) "Repeat every _____ _____." (Insert number of day(s), week(s) or month(s).)

Note: Efficacy and/or domestic animal safety data should be taken into consideration in determining the reapplication limitation.

4. **Clearly Indicate Minimum Age Of Animals.**

Every product label should have:

"Do Not Use On _____ Under _____ Weeks."

The minimum age may not be less than 12 weeks unless accepted domestic animal safety data are on file at the Agency to support use on younger animals.

Note: There are only a few products with data that would support a younger age than 12 weeks.

5. **Include Statement Concerning Debilitated, Aged, Pregnant or Nursing Animals.**

The registrant should adopt the statement below or submit, cite data/information indicating this statement (or portion of it) is not needed.

"Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals."

6. **Include Adverse Reaction Information.**

All products should have the following precautionary statements.

"Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately."

Note: In the case of a collar, registrants should replace the second sentence with:

"If signs of sensitivity occur remove collar and bathe your pet with mild soap and rinse with large amounts of water."

7. **Include Information for Medicated Animals.**

The registrant should adopt the statement below unless the Agency's evaluation of the data indicates this statement is not needed.

(a) "Certain medications can interact with pesticides. Consult a veterinarian before using on medicated animals."; -OR-

(b) Add the following to the label statement under # 5:

"medicated"; or

"animals on medication."

8. **Include A Statement Pertaining to Cholinesterase Inhibitors.**

Products which inhibit cholinesterase should have the following Precautionary and Practical Treatment (or First Aid) Statement on label.

(a) "Do not use this product on animals simultaneously or within 30 days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides or chemicals. However, flea and tick collars may be immediately replaced."; and

(b) Under the First Aid statement, expand the "Note to Physicians" to include "and veterinarians"; and include information for veterinarians.

9. **Replace The Label Section Header "Statement of Practical Treatment" With The Header "First Aid."**

Registrants may use either "Statement of Practical Treatment" or "First Aid."

Note: "First Aid" is preferable for consumer product labels.

10. **Include Telephone Number on Label.**

Every product label should have a company or Animal Poison Control Center, or other telephone number that consumers may call for the purpose of receiving information concerning proper use of the product and specific actions to take in case of emergencies.

V. IMPLEMENTATION OF POLICY

In order to remain in compliance with FIFRA registrants of products subject to this notice should take either of the following actions:

(a) Registrants adopting the exact (word for word) label statements specified in this notice should submit a **notification** for each product with a completed Application for Registration (EPA Form 8570-1). A photocopy of the EPA application form is acceptable; an original form is not needed. The application should bear the following statements:

"Notification of label change per PR Notice 96-6. This notification is consistent with the provisions of PR Notice 96-6 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or 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 96-6 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 wish to modify the label statements specified in this PR Notice should submit an application for **amended** registration. This application should include the following items: EPA application form 8570-1 (filled in), five copies of the draft label, and a description on the application, such as, "Amended in accordance with PR Notice 96-6."

Registrants should send notifications and applications for amendment to the appropriate following address:

U.S. Postal Service Deliveries

The following official mailing address should be used for all correspondence or data submissions sent to OPP by mail:

Document Processing Desk (AMEND) or (NOTIF) [as applicable]
Office of Pesticide Programs (7504-C)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

Personal/Courier Service Deliveries

The following address should be used for all correspondence or data submissions that are hand-carried or sent by courier service Monday through Friday, from 8:00 AM to 4:30 PM, excluding Federal holidays:

Document Processing Desk (AMEND) or (NOTIF) [as applicable]
Office of Pesticide Programs (7504-C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

As stated above, the Agency believes that the statements outlined in this notice should reduce adverse effects to pets and humans. For this reason all products released for shipment by registrants after **October 1, 1998** should bear labeling that is consistent with this notice. It is the responsibility of registrants to submit applications or notification in a timely manner. After these dates, the Agency may either issue a notice of Intent to Cancel or bring enforcement action against products not bearing labeling necessary to prevent potential for possible misuse of pet products and protect pet and human health.

Registrants should submit label changes in a timely manner so as to meet the October 1st deadline. Adequate review time should be allowed for amendments that require Agency review and approval. If only a notification of a labeling change is submitted, the registrant may send in the notification near the compliance deadline. If an application for label amendment is submitted, the registrant will need to allow several months for EPA's review and additional time for states' reviews.

VI. FOR FURTHER INFORMATION

If you have questions regarding this notice, contact the Labeling Unit (703-308-8641).

Stephen L. Johnson, Director
Registration Division