DRAFT of JANUARY 19, 2001FOR COMMENT

PESTICIDE REGISTRATION (PR) NOTICE 2001-X

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

ATTENTION: Persons Responsible for Registration of Pesticide Products

SUBJECT: Pesticide Label Identification for Pesticide Products Meeting the Requirements of the National Organic Program

I. PURPOSE

This notice describes how registrants can obtain Environmental Protection Agency (EPA) approval of label language indicating that all ingredients (active and inert) in a pesticide product and all uses of that pesticide meet the criteria defined in the United States Department of Agriculture's (USDA) National Organic Program (NOP) Rule. The information on the pesticide label will assist organic growers and those persons certifying organic production methods in knowing which pesticide products meet the requirements of the NOP Rule for use in organic agriculture. Label language on a pesticide product stating that the pesticide meets the NOP Rule criteria is not required for an organic producer to utilize a pesticide product which the producer ascertains meets the requirements of the NOP.

II. BACKGROUND

On December 21, 2000 (65 FR 80547-80684), the USDA's Agricultural Marketing Service (AMS) published its final rule for the National Organic Program. The final rule establishes national standards for the production and handling of organically produced products, including a National List of substances approved and prohibited for use in organic production and handling (7 CFR 205.600-205.606). Procedures for amending the National List are also established in this rule (7 CFR 205.607). The National List includes pesticide products regulated by the EPA.

Pesticide manufacturers and organic farmers have indicated that it would be useful to have some identification on pesticide labels to indicate which pesticide products are acceptable for organic production. This PR Notice provides examples of acceptable label language and the procedures for adding such identification to product labels. The Secretary of Agriculture determines, upon recommendation by the National Organic Standards Board (NOSB), which active ingredients and inert or other ingredients are acceptable for use in organic production and handling. EPA has consulted with USDA/AMS and with the NOSB on the procedures for registrants of pesticide products submitting product registration amendments to EPA. These amendments will allow for pesticide products to carry identification language denoting NOP approval on the EPA accepted label if the ingredients meet the criteria for organic production and

handling. USDA will provide EPA with a current version of the National List on an annual basis.

The National Organic Program Rule provides for an 18 month implementation period to give organic producers and suppliers time to make necessary changes. EPA plans to expedite amendment requests which are solely for adding the approved language.

EPA has generally regarded statements such as "organic" and other similar claims to be forms of false or misleading safety claims prohibited by EPA's labeling regulations at 40 CFR 156.10(a)(5). Such claims cannot be well defined and may be misinterpreted as a claim of safety. EPA has reevaluated its policy and has determined, for reasons explained below, that a claim that a pesticide product meets the requirement of the USDA National Organic Program is an acceptable labeling statement under certain conditions. An example of an acceptable claim is set forth in section G. of this notice.

EPA's concern with safety claims is the overall effect such claims have on consumers of pesticides. If a claim leads users to believe that a product is safe for humans and the environment to the extent that the label directions and precaution may be disregarded, the EPA considers the claim to be misleading. Examples of such claims are "safe," "harmless," "contains all natural ingredients" and "among the least toxic chemicals known". Furthermore, prior to USDA's promulgation of its national rule, terms such as "organic" were often misleading because there was not necessarily a standard to which they clearly referred.

Although NOP-related claims are essentially safety-related claims, EPA believes that these claims can be narrowly stated so that their potential to mislead or confuse the public is limited. The claim "The ingredients in this product meet the requirements of the USDA National Organic Program" as well as the presence of an NOP symbol neither broadly imply complete safety for the product nor should they lead users to ignore labeling precautions. The use of the term "organic" in the context of the name of an official government program would not be considered false or misleading under FIFRA, in that the term is used in a very narrow context for a specific purpose; and not used in any broad sense of safety. Further, EPA believes that the minimal potential for such claims to mislead consumers is outweighed by the benefit to consumers and the regulated community in making EPA's policy consistent with the regulations, policies, and programs of other regulatory agencies such as USDA. Additionally, this policy will allow organic producers and handlers to make an informed choice when selecting pesticide products that may be used under the Federal Organic Foods Production Act of 1990 and the associated NOP Rule.

III. PROCEDURES FOR LABEL CHANGES

EPA will begin processing applications for review of new or amended product labels bearing statements indicating that the pesticide meets the NOP Rule criteria (see example statement in Section G. below) when this PR Notice goes into effect and EPA has received a list of acceptable active and inert ingredients from USDA. This section also lays out procedures for new products that are currently being reviewed at EPA or would be submitted to EPA in the future. These are as follows:

A. Amendments to Currently Registered Pesticide Products

Registrants of existing products who wish to gain EPA acceptance to add a NOP statement and symbol may submit an application for amended registration if the product meets all of the following requirements:

1. Each active and other (inert) ingredient in the product must be included on the current National List for the use approved under the NOP. The National List is contained in 7CFR 205.600 et seq. Thus, a product containing one or more ingredients not on the National List may not bear labeling statements indicating that the product complies with the NOP. Such a statement would be false and misleading, and the pesticide misbranded, within the meaning of FIFRA section 2(q). See also 40 CFR 156.10(a)(5).

a. A product's use instructions must be consistent with the use instructions specified by the NOP Rule in order to claim compliance with the NOP on its label. Thus, to be permitted to bear the NOP statement and symbol, the product may bear only NOP approved uses. Therefore, a product that has multiple uses, some of which are acceptable under the NOP and others which are not, may not bear labeling statements indicating that the product complies with the NOP nor should the registrant of such a product apply to use the NOP statement and symbol. Such a label would be misleading. In such a case, a registrant may choose to register a separate product to bear the NOP statement and symbol (see G. below)

b. A product that has alternate formulations permitted under EPA regulations (40 CFR 142.43) must ensure that each alternate formulation meets the requirements of the NOP above. If an alternate formulation does not meet the requirements of the NOP and the registrant is interested in adding language to the product label stating that the product meets the NOP Rule criteria, the registrant must request and agree that the formulation that is out of compliance with the NOP Rule criteria be removed from EPA's accepted alternate formulations for the registered product.

2. Each application for amendment must include:

- a completed EPA form 8570-1, which includes the purpose of the request in the narrative section,
- three copies of the revised pesticide label with the proposed wording,
- a completed, signed and up-to-date Confidential Statement of Formula.

B. Changes to Currently Registered Pesticide Products to Meet the NOP Rule

If a registrant wants to reformulate a product to meet the requirements of the NOP rule, the registrant has three options:

1. If the product remains substantially similar to the current formula, the registrant would

submit an amendment request with a revised Confidential Statement of Formulation, needed label modifications to meet the criteria set forth in the National List and any other required information for a non-expedited amendment, or

2. If the other (non-active) ingredients (inerts) in the product would be substantially changed, the registrant would submit an application for an amended formulation and include supporting required data (product chemistry, toxicity and, if applicable, efficacy data)

3. If the product's active ingredient(s) are changed, the registrant would have to submit an application for the registration of a new product.

C. Modifications to Registered Uses or Use Directions

Registrants may also wish to change allowed use practices for their product so that such product meets the NOP Rule criteria and can be labeled as such. These changes would be made in the form of an amendment or a new product. Typically changes in use practices would be more restrictive than the current EPA accepted label and could be made by fast track amendment or "me too" new products.

D. Pending Products

A company with a pending application for a new product, which qualifies under the final NOP rule, may submit a request to modify the pending application to add the NOP statement and symbol language to the appropriate product manager through the Document Processing Desk addresses list below.

E. New Products

A new product may be registered that contains label language indicating that it meets the criteria of the NOP Rule if such product does in fact meet the criteria of the NOP.

F. Exempted Products

EPA will only review labeling submissions for pesticide products that are registered or proposed to be registered. There are pesticide products which are exempted from regulation under 25(b) of FIFRA. EPA does not, however, review product labels of pesticides exempt under 25(b) and, therefore, EPA cannot approve the use of this NOP language on 25(b) product labels. Products exempted under FIFRA section 25(b) are not precluded from identifying whether they meet the requirements of the National Organic Program. However, producers of such products are reminded that it is their responsibility to ensure that the products contain only ingredients permitted under the NOP and that they conform in all respects with the criteria of the National List. Such products may be in violation of FIFRA if they misrepresent on the label their status under the NOP. See 40 CFR 152.25(g)(3)(iii).

G. Acceptable Labeling Statement

The Agency has determined that an example of a labeling statement that would be acceptable under Part 156 labeling requirements for those pesticide products containing active and inert (other) ingredients, all of which, meet the requirements of the National Organic Program is:

NOP

The ingredients in this product meet the requirements of the USDA National Organic Program.

The wording and logo may be placed on the front panel or on another panel, provided that it does not detract from FIFRA-required labeling, and is not given prominence by placement, format, type size or highlighting. See 40 CFR Part 156. The statement/symbol should not appear at the top of the front panel of the label. See 40 CFR 156.10(j)(2).

EPA has worked with USDA and NOSB to develop this suggested labeling language. The Agency believes that it would be useful for registrants to use a consistent labeling statement to avoid any confusion on the part of individuals wishing to use products for organic crop production. The language was also developed to avoid creating label language which could be viewed as false and misleading. See 40 CFR 156.10(a)(5).

H. Delisting.

USDA may on occasion prohibit use of allowed materials. If USDA prohibits use of an allowed material, use of this material after the delisting is final may endanger the organic producers organic certification. Such prohibitions would be made as amendments to the National List through rule making with public comment. It is the intention of EPA to notify registrants of pesticide products containing materials which have been proposed for prohibition. If a material is prohibited by a final USDA rule, for any pesticide containing such a material and labeled as meeting the NOP criteria, USDA's action would have the effect of rendering such NOP statements false or misleading statements under the statutory definitions of misbranding. Such a product would then be subject to enforcement actions under FIFRA. The registrant may submit an amendment to either remove any reference to the NOP from the label or change the formulation by removing the ingredient to be prohibited. EPA regulations for these situations are covered under 40 CFR Part 152.130.

IV. WHERE SHOULD REGISTRANTS SUBMIT AN APPLICATION

A. Registrants must send applications for a label amendment as described above to the appropriate following address:

U.S. Postal Service Deliveries

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

Document Processing Desk (AMEND) or (APPL)
Office of Pesticide Programs (7504-C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Ave., NW
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 (APPL)
Office of Pesticide Programs (7504-C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

V. FOR FURTHER INFORMATION

For information on this notice, contact:

- Robert Torla, Biopesticides and Pollution Prevention Division, at 703-308-8098, or by e-mail to: torla.robert@epa.gov.
- Linda Arrington, Registration Division, at 703-305-5446, or by email to: arrington.linda@epa.gov.
- Michael Hardy, Antimicrobial Division, at 703-308-6432, or by email to: hardy.michael@epa.gov.

Marcia E. Mulkey
Director