

PESTICIDE REGISTRATION (PR) NOTICE 2003-1

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

ATTENTION: Persons Responsible for Registration of Pesticide Products

SUBJECT: Labeling of Pesticide Products under 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. This PR Notice provides an example of acceptable label language and the procedures for adding such identification to product labels. 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. According to USDA's rules, organic growers are required to rely on their certifier for compliance with the NOP (7 CFR Sections 205.400 - 406). Any label language on a pesticide product as described in this notice is to assist the grower and certifier. 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 and/or certifier ascertains meets the requirements of the NOP. Registrants of pesticide products are not required to add such NOP language to their products for the products to be used in organic agriculture. Use of products with NOP language does not modify the requirement that growers rely on their certifier for compliance with the NOP.

This notice provides guidance to pesticide registrants who may consider participation in this voluntary program.

II. BACKGROUND

On December 21, 2000 (65 FR 80548), 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. The rule became effective on October 21, 2002.

The National List is divided roughly into 3 categories, substances permitted in crop production (7 CFR 205.601), substances permitted in animal production (7 CFR 205.603), and substances permitted in food processing (7 CFR 205.605 & 606). Specific prohibitions are also included (7 CFR 205.602 & 604), as are procedures to amend the National List (7 CFR 205.607). The National List includes, among other things, substances that are pesticides or pesticide inert ingredients as defined and regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The Secretary of Agriculture determines, upon recommendation by the National Organic Standards Board (NOSB), which substances, including active ingredients and inert or other ingredients, are allowable for use in organic production and handling.

At present, the National List only specifies by name certain synthetic active ingredients which are allowed and non-synthetic materials which are prohibited. EPA intends to rely on the expertise of USDA in all determinations regarding whether an active ingredient qualifies under the approach set forth in the National List. Therefore, until USDA identifies for EPA those specific active ingredients that meet the conditions of the List, EPA may not be able to approve NOP labeling for products containing such ingredients. A list of all allowable non-synthetic materials can not be complete. Innovative individuals will continue to research pesticidal properties in plants and microbes and develop ways within the constraints of the National Organic Program to utilize them as pesticides. Therefore, EPA expects to have a continuous working relationship with USDA about which active ingredients meet the criteria.

Pesticide manufacturers and organic farmers have indicated to EPA that it would be useful to have some identification on pesticide labels regarding those pesticide products that are acceptable for organic production. In response to this request, EPA has consulted with USDA/AMS National Organic Program Staff and with the NOSB on the procedures for registrants of pesticide products submitting product registration amendments to EPA. These amendments will allow pesticide product labels to carry identification language denoting that the product meets the criteria allowable under the NOP. If the ingredients and label language meet the criteria for organic production and handling, and the product and its labeling meet the pesticide registration requirements, they will be accepted by EPA. USDA will provide EPA with a current version of the National List whenever it is updated.

III. PESTICIDE LABELING UNDER FIFRA

Under FIFRA, unless otherwise exempted, each pesticide product must be registered with EPA, and its labeling accepted before it may be distributed or sold for use. FIFRA establishes standards for pesticide labeling, among which is the requirement that labeling not be false or

misleading in any manner, and that products and use(s) not pose unreasonable adverse effects on the environment. Users are required to use a registered pesticide product only in accordance with its labeling, or face possible penalties under FIFRA.

EPA has generally regarded statements such as “organic” to be forms of false or misleading safety claims prohibited by statute and EPA’s labeling regulations. The Agency believed such claims could not be well defined, in part because there are a variety of definitions of organic. EPA has evaluated its policy in light of the Federal Organic Foods Production Act of 1990 and USDA’s associated NOP and has determined, for reasons explained below, that a statement “for organic production” is an acceptable labeling statement under certain conditions.

Prior to the Federal Organic Foods Production Act of 1990 and USDA’s promulgation of the associated National Organic Program rule, EPA regarded the term “organic” as misleading because there was no specific standard to which “organic” clearly referred and a variety of “organic”- type standards existed. For example, using a dictionary, various definitions of the term “organic” could be found including “any chemical compound containing carbon;” “of, relating to, yielding or derived from living organisms;” and “grown only with animal or vegetable inputs, such as, manure, bone meal, compost, and various animal or vegetable pest management materials.” In addition, a number of organizations and States had their own (sometimes different) definitions of “organic.” Furthermore, partly because of the variety of definitions, EPA believed that the term “organic” could give users misleading impressions regarding safety of the product.

Under the Federal Organic Food Production Act (7 U.S.C. section 6501et seq.) and associated NOP Rule, consistent Federal standards for “organic” now exist so that confusion over the meaning of “organic” with respect to crop and animal production (or “food” production) has been minimized. Further the phrase “for organic production” provides information about the use of the product in USDA’s program and would not be likely to be perceived as safety information. EPA believes that the minimal potential for such claims to mislead consumers is outweighed by the benefit to the regulated community in adapting EPA’s policy to mesh with the regulations, policies, and programs of other regulatory agencies such as USDA. Identification of NOP allowed products should greatly assist organic producers and handlers in making 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. Therefore, EPA has concluded that using the phrase “for organic production” when referring to pesticide products that may be used for organic production would not be considered false and misleading.

IV. GUIDANCE FOR ACCEPTABILITY OF PRODUCTS FOR NOP LABELING UNDER FIFIRA

This section contains a discussion of existing requirements of: the Federal Organic Foods Protection Act of 1990, the National Organic Program, the Federal Insecticide, Rodenticide and

Fungicide Act, EPA regulations and the Federal Food, Drug and Cosmetic Act. In order to be acceptable for use under the NOP, the product must meet the following:

A. Product Composition

-In order for a product to meet the requirements of the NOP, each ingredient in the product, including active and inert ingredients, must be allowable under The National List of Allowed and Prohibited Substances (National List) contained in 7 CFR part 205.

- The National List does not specifically list each allowable material but rather criteria for allowable materials. (However, specific allowed synthetics are included on the National List.) The National List is available at: <http://www.ams.usda.gov/nop/NationalList/FinalRule.html>. Inert ingredients (including List 4) (specifically allowable for use in crop and livestock production in the National List) are available at: http://www.epa.gov/opprd001/inerts/inerts_list4.pdf. Both of these lists will change as new materials are added and materials are deleted.

B. Product Uses

1. A product with use instructions that are inconsistent with the instructions specified by the NOP cannot claim compliance with the NOP on its label. Thus, if the National List includes restrictions on the use of a substance, the pesticide product's uses and use directions must conform to those restrictions. If a product bears multiple uses, some of which are within the National List restrictions and others not, the product should not be labeled with a NOP statement. In this instance the registrant may consider applying to register a new product which is fully compliant with the NOP. (see Section V).

Example: EPA List 4 inert ingredients are permitted under the NOP rule at Part 205.601 and Part 205.603 for use in crop and animal production only, not processed food production. A disinfectant/sanitizer pesticide product containing a List 4 inert bears directions for use in sanitizing both in animal facilities and in food processing areas or which bears only non-specific instructions for disinfection/sanitizing is not eligible for a NOP statement as such a claim regarding the product as a whole would be false since its label language covers uses not allowed under the NOP.

2. There are NOP use restrictions where it is unclear how to comply. An example would be "...copper-based materials must be used in a manner that minimizes accumulation in the soil and shall not be used as herbicides" where, in order for EPA to determine whether the product is consistent with the NOP criteria, the Agency would need to have sufficient information from a registrant demonstrating that the product does in fact comply with the NOP.

C. Food Uses

All ingredients of pesticide products registered (or exempted from regulation under FIFRA) for use on foods must have either a tolerance or an exemption from the requirement of a

tolerance if residues of such ingredients result in or on the food from such use. If no tolerance or exemption has been granted, foods containing such residues may not be lawfully sold in commerce. (Title 21 U.S.C. Section 408).

D. Alternate Formulations

All formulations of a pesticide product which have the NOP allowed wording must comply with the requirements of the NOP. We would not allow alternate formulations for products which are not fully compliant with the NOP requirements where the basic formulation has NOP labeling language (40 CFR 152.43 (b)(3)).

V. PRODUCTS EXEMPTED FROM REGULATION UNDER FIFRA.

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 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 the products contain only ingredients permitted under the National List (7 CFR 205.600-607)

Ensure that they conform in all respects with the criteria of the National List

Ensure they conform in all respects with the criteria for exemption from regulation under FIFRA [40 CFR 152.25 (a) - (f)] .

Be aware that certain exempted products may be in violation of FIFRA if they misrepresent on the label their status under the NOP. [See for example 40 CFR 152.25(f)(3)(iii).]

Also note that some of the active and inert ingredients exempted from regulation currently do not have a tolerance or exemption from the requirement of a tolerance for residues of these pesticide chemicals on food.

VI. ACCEPTABLE FORMS OF LABELING STATEMENT

The phrase, “For Organic Production,” located on the front panel of the label in close proximity to the product name is an example of an acceptable labeling statement. The phrase should not appear above the product name (in the location normally reserved for a Restricted Use Statement). For example, the following would be acceptable:

Sam's Insecticide



For Organic Production

The Agency has determined that this label statement would be acceptable under Part 156 labeling requirements. To avoid being misleading, this statement should be in a font size comparable to that of other type and not highlighted by size, color, contrast or placement.

EPA has worked with USDA and the 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 an endorsement by a Federal agency; such statements are generally considered false and misleading. See 40 CFR 156.10(a)(5)(v).

The Agency is aware that other groups may have reviewed materials proposed for use in organic agriculture for a number of years and have determined that they meet the requirements of USDA's NOP rule. This Agency will also consider accepting use of label language and/or logo of the other groups for use on pesticide products in lieu of the phrase "for organic production" providing the registrant submits a letter from that group stating that the product does, in the opinion of such group, meet the NOP requirements, and the Agency concurs with the opinion. EPA will also consider whether such labeling could be false or misleading.

VII. HOW REGISTRANTS MAY APPLY FOR APPROVAL OF A NOP STATEMENT

A. Currently registered products that conform fully to NOP criteria

Submit an application for amended registration that should include:

An application for Amended Registration (EPA Form 8570-1).

Draft labeling, bearing the proposed changes, and including an acceptable NOP phrase or statement (see Section VI).

In order to substantially shorten the time for EPA approval of the new label language, registrants should consider also submitting a new Confidential Statement of Formula (EPA Form 8570-4), which includes a brief annotation describing how each product ingredient is consistent with the NOP; the brief description could include references to listed ingredients or categories in the National List. The registrant could also cite the EPA List of Other (Inert) Pesticide Ingredients Inert - List 4, for each ingredient in the product, where applicable.

In order to further expedite EPA approval, registrants should also submit a request to amend their registration to add the following term and condition: “This registrant acknowledges that its product will be misbranded if one or more of this product’s ingredients, active and/or inert, is removed (delisted) from the National List. If one or more of the ingredients in this pesticide product are removed (delisted) from the National List, the registrant will submit a label amendment to the Agency within 30 days requesting deletion of the NOP related labeling language. If the registrant does not submit such a request within 30 days of delisting, EPA may cancel or suspend this product pursuant to procedures in or similar to those in FIFRA Section 6(e).”

B. Currently registered products that do not fully conform to NOP criteria.

Submit a completed Application for Registration (EPA Form 8570-1) of a new product which fully complies with the requirements of the National List along with all forms and data requirements for a pesticide product registration. Additional data may be required if active or inert ingredients in the product change. If the new product merely contains more restrictive label language to have all label uses fully conform with the NOP requirements, no additional data will likely be required. Once you have received your fully conforming NOP label, you may wish to continue to market the currently registered product for the non-organic market or you may decide to cancel the registration of the currently registered product.

Include draft labeling, bearing the proposed label language, and including an acceptable NOP phrase (see Section VI).

In order to substantially shorten the time for EPA approval of the new label language, registrants should consider also submitting a brief annotation describing how each product ingredient is consistent with the NOP; the brief description could include references to listed ingredients or categories in the National List. The registrant could also cite the EPA List of Other (Inert) Pesticide Ingredients Inert - List 4, for each ingredient in the product, where applicable.

In order to further expedite EPA approval, registrants should also submit a request to amend their registration to add the following term and condition: “Registrant acknowledges that its product will be misbranded if one or more of this product’s ingredients, active and/or inert, is removed (delisted) from the National List. If one or more of the ingredients in this pesticide product are removed (delisted) from the National List, the registrant will submit a label amendment to the Agency within 30 days requesting deletion of the NOP related labeling language. If the registrant does not submit such a request within 30 days of delisting, EPA may cancel or suspend this product pursuant to procedures in or similar to those in FIFRA Section 6(e).”

C. Pending Applications

Resubmit an application for registration which notifies EPA of changes in your application to conform to the NOP. If the amendment involves changes in the ingredients of the pesticide product, any required additional data as discussed above may involve a delay in the Agency's decision regarding registration.

Provide draft labeling, bearing the proposed changes, including an acceptable NOP phrase or logo (see Section VI).

Follow the above procedures suggested in Section B.

D. New Product Registrations

Submit an application for registration of a pesticide product including all required EPA forms and supporting information.

Provide draft labeling, including an acceptable NOP phrase or statement (see Section VI).

In order to substantially shorten the time for EPA approval of the new label language, registrants should also consider submitting a brief annotation describing how each product ingredient is consistent with the NOP; the brief description could include references to listed ingredients or categories in the National List. The registrant could also cite the EPA List of Other (Inert) Pesticide Ingredients Inert - List 4, for each ingredient in the product, where applicable.

In order to further expedite EPA approval, registrants should also submit a request to amend their registration to add the following term and condition: "Registrant acknowledges that its product will be misbranded if one or more of this product's ingredients, active and/or inert, is removed (delisted) from the National List. If one or more of the ingredients in this pesticide product are removed (delisted) from the National List, the registrant will submit a label amendment to the Agency within 30 days requesting deletion of the NOP related labeling language. If the registrant does not submit such a request within 30 days of delisting, EPA may cancel or suspend this product pursuant to procedures in or similar to those in FIFRA Section 6(e)."

E. When to Make Submission

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 VI) when this PR Notice goes into effect. EPA is working with USDA to develop this list of active ingredients which are allowable under the National List. EPA will post this list on the Office of Pesticide Programs Web site (<http://www.epa.gov/pesticides/>) in the What's New section when this list of allowable active ingredients is available. Until this list is

developed, registrants may experience delays in Agency approval of pesticide labels with this language until this list is completed.

VIII. DISTRIBUTOR PRODUCTS

It is a registrant's responsibility to ensure that his distributor products (supplemental distribution) continue to conform to Agency requirements. A registrant who amends his product and product labeling would be obligated to ensure that any distributor products under the basic registration are also amended (40 CFR 152.132).

EPA believes it likely that distributor products will be eligible for NOP labeling if the underlying registered product is eligible. Under EPA requirements, a distributor product may vary from the underlying registered product only in minor ways. The composition may not vary, so that the NOP composition criteria should be met. Uses may vary only by omission of uses (the distributor product is not required to include all uses on the basic registered product), so that the use criteria should also be met. Note: The acceptable label statement must be on the basic registered product if it is on a distributor product (40 CFR 152.132). A distributor may not add an NOP statement independently.

IX. REGISTRANT/APPLICANT RESPONSIBILITIES

It is the registrant's/applicant's responsibility to demonstrate to the Agency that their product conforms fully with all requirements of the NOP and that their NOP labeling statements are therefore true. EPA will not be able to approve an application that fails to provide sufficient information to allow the Agency to make this determination. It should be pointed out that certain types of restrictions under the NOP are difficult to verify, and the Agency may not be able to approve the application for NOP labeling without additional justification provided by the applicant.

Example 1: Under 7 CFR 205.601, certain copper products are permitted provided that materials are used in a manner that "minimizes accumulation in the soil." This criterion is non-quantified. An applicant must justify how the use directions for the product will minimize accumulation in the soil.

Example 2: Certain chlorine-containing products are approved for use as disinfectants and sanitizing agents in agricultural, animal and food processing production, provided that residual chlorine at the use level does not exceed limits set under the Safe Drinking Water Act. An applicant who seeks an NOP label for a chlorine product must ensure that the use directions are adequate so that the user who follows label instructions will remain within the Safe Drinking Water limit.

X. RELATIONSHIP OF THE NATIONAL LIST TO EPA PESTICIDE INGREDIENTS

Inclusion of an ingredient on the National List is independent of approval of ingredients for use in pesticide products under FIFRA or FFDCA. The National List may include substances that are not currently found in any registered pesticide product.

For example, inclusion on the EPA List 4 Inerts list is sufficient to identify a pesticide inert ingredient as NOP-allowed, but the opposite is not true. Inclusion on the National List does not allow an applicant to presume that an ingredient (active or inert) is acceptable to EPA for use in a pesticide product.

Each ingredient in a pesticide product must be approved by the Agency, and, if for food use, must have a tolerance or exemption from the requirement of a tolerance for residues on food under the Federal Food, Drug and Cosmetic Act. Applicants who wish to obtain clearance for an ingredient on the National List for use in pesticide products are advised to consult with the Agency.

XI. DELISTING

USDA may on occasion prohibit use of previously allowed materials. If USDA prohibits use of a previously allowed material, use of this material after the delisting may endanger an organic producer's organic certification. Such prohibitions would be made as amendments to the National List through rule making with public comment. Organic certifiers normally provide for a period of time where a producer can use up existing stocks of a delisted material. Registrants and users are advised to keep abreast of any such delistings, and not to rely solely on the pesticide label for approval status under the NOP.

A. EPA cannot unilaterally modify registrations to keep abreast of changes in the National List and EPA List 4 inerts which could have the effect of making continued use of the NOP language unacceptable. Further, there may be delays in the revision of pesticide labeling. Thus product(s) in channels of trade and in the hands of users may not accurately reflect NOP status if an ingredient is delisted. Therefore, use of the product, though not in violation under FIFRA's misuse provisions, may jeopardize the user's organic production certification.

B. If delisting results in the loss of NOP approval for a pesticide product, EPA will permit the removal of the NOP statement by notification according to PR Notice 98-10, so that product labels can be revised rapidly. Registrants should submit such notifications and make label changes as soon as possible, to avoid having the product label deemed to be false and misleading under FIFRA.

C. If the registrant wishes thereafter to continue to market a product for the organic market, he should submit an application for a new product which is compliant with the NOP.

D. If a registrant does not take actions to remove information on a product label indicating a product meets the requirements of the NOP, the Agency may take action pursuant to

FIFRA Section 2(q), 6(e), 40 CFR 156.10(a)(5) and/or any other appropriate provision of FIFRA and the associated regulations.

XII. OTHER INFORMATION

We encourage registrants who want their pesticide products to be marketed for organic production to list all product ingredients on the pesticide label, including inert or other ingredients. This will make it easier for an organic farmer or the farmer's certifier to verify that the product is allowable for use in organic production, especially where changes to the NOP are made.

XIII. WHERE SHOULD REGISTRANTS SUBMIT AN APPLICATION

A. In order to properly process applications, registrants should 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

XIV. NON-BINDING STATEMENT

This PR Notice provides guidance to EPA and to pesticide registrants. This notice is not binding on either EPA or pesticide registrants, and EPA may depart from the guidance provided in individual circumstances. Likewise, pesticide registrants may assert that the guidance is not appropriate for a specific pesticide or situation.

XV. FOR FURTHER INFORMATION

For information on this notice, contact:

- Robert Torla, Biopesticides and Pollution Prevention Division, at 703-308-8098, or by email 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
Office of Pesticide Programs, (7501C)