Draft as of: October 16, 2007

PESTICIDE REGISTRATION (PR) NOTICE 2007-X

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

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products

SUBJECT: Label Statements Regarding Third-Party Endorsements & Cause Marketing Claims

This Notice contains a description of the Agency's framework for evaluating proposed statements and graphic material to appear on pesticide labeling regarding third-party endorsements or a relationship between the pesticide registrant and a charity ("cause marketing claims"). The Notice identifies factors EPA may consider in reviewing applications for registration or amended registration with labeling that contains either third-party endorsements or cause marketing claims. The Notice also identifies the types of discussion and information that applicants could provide to support EPA review of such applications.

I. SCOPE OF LABEL ADDITIONS POTENTIALLY AFFECTED BY THIS NOTICE

This Notice describes the framework EPA expects to use to review certain types of labeling statements, specifically third-party endorsements and cause marketing claims. An applicant could potentially propose to add such labeling statements to any type of pesticide product. For purposes of this Notice, EPA will use the term "label statement" to refer both to text and to any related graphical material, e.g., logos and pictures, which would appear on the pesticide product label or elsewhere in the product labeling. This framework addresses:

- Label statements containing a "third-party endorsement," e.g., an expression of approval or a recommendation to use a product made by a entity other than the applicant / registrant, and

- Label statements containing a "cause marketing claim," i.e., a statement describing a relationship (usually philanthropic) between the registrant of the pesticide product and another entity, usually a charity.

II. LEGAL FRAMEWORK

EPA regulates the sale, distribution, and use of pesticide products under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). With certain minor exceptions, every pesticide product must be "registered" by EPA before it may lawfully be sold or distributed in the United States. FIFRA sec. 3(a); 12(a)(1)(A). Under FIFRA sec. 3(c)(5), EPA may register a pesticide, i.e., approve a license authorizing the sale and distribution of the pesticide product, if EPA determines, among other things, that;

> (A) [the pesticide's] composition is such as to warrant the proposed claims made for it;
> (B) its labeling and other material required to be submitted comply with the requirements of [FIFRA; and]
> (C) it will perform its intended function without unreasonable adverse effects on the environment . . . .

The labeling of a pesticide plays a critical role in assuring the safe use of pesticide products. FIFRA 2(p)(1) defines the label of a pesticide as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers." FIFRA 2(p)(2) defines "labeling" to mean "all labels and all other written, printed or graphic matter (A) accompanying the pesticide or device at any time; or (B) to which reference is made on the label . . . ." Typically, the label of a pesticide contains the product name, brand, or trademark; an ingredients statement; a statement of net weight or contents; directions for use; and hazard and precautionary statements. See EPA regulations at 40 CFR part 156.

Two other sections of FIFRA relating to the labeling of pesticide products contain important provisions that establish the link between registration decisions and pesticide use. Under FIFRA section 12(a)(2)(G), it is unlawful for any person "to use any registered pesticide in a manner inconsistent with its labeling." To reinforce this authority, FIFRA sec. 12(a)(2)(A) also declares it unlawful for any person to "detach, alter, deface or destroy, in whole or in part, any labeling required under [FIFRA]" i.e., the labeling approved as part of EPA's registration decision. Thus, EPA's registration decisions regarding approved labeling become the primary vehicle by which EPA establishes enforceable requirements on the use of a pesticide.

In addition, FIFRA sec. 12(a)(1)(E) prohibits the sale or distribution of any pesticide or device which is "misbranded." FIFRA sec. 2 (q) contains a lengthy definition explaining when a pesticide should be considered misbranded, including when:

> (1)(A) its labeling bears any statement, design or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;
>
> . . .
>
> (E) any word, statement, or other information required by or under the authority of [FIFRA] to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;
>
> (F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, . . . are adequate to protect health and the environment.

The language in FIFRA sec. 3(c)(5)(B), in effect, makes the misbranding definition one of the criteria for determining the acceptability of a pesticide for registration.

EPA regulations at 40 CFR 156.10(a)(5) contain a non-exhaustive list of 10 examples of potential false and misleading claims, upon which the proposed label statements can be judged. The following summarizes the examples in the regulations and elaborates on them with language from EPA's Label Review Manual:

(a) Product composition – Statements relating to the composition of a product must be consistent with the product's ingredient statement. Words or phrases implying that the product contains unique characteristics due to its composition are not acceptable.
(b) Product effectiveness – Claims as to the effectiveness of a product cannot be inaccurate or exaggerated.
(c) Statements relating to the non-pesticidal value of the product – A label cannot bear false or misleading statements unrelated to the pesticidal value of the product.
(d) Comparisons to other pesticide products.
(e) Statements implying endorsement by a Federal agency – Phrases such as "approved" or "recommended" used in connection with a reference to a Federal agency are not acceptable.
(f) Product names which suggest some, but not all of the active ingredients in a product.
(g) A true statement used in a misleading manner – A label statement which is true, but has the potential to mislead the purchaser, i.e., "contains all natural ingredients."

(h) Negating or detracting label disclaimers – an example is a claim of benefits that are negated or contradicted by other labeling information.
(i) Safety-related claims – Use of phrases such as "safe," "non-toxic," or "harmless" that purport the product to be safe.
(j) Comparative safety claims – such as, "Among the least toxic chemical known" or "pollution approved" or "nonpolluting".

Finally, FIFRA sec. 12(a)(2)(B) makes it unlawful for any person to sell or distribute a pesticide "if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration . . . ." Applicants should be aware that the Agency may consider collateral information that substantially differs from material submitted with an application as potentially subject to the "differing claims" provision of section 12(a)(1)(B). Applicants are reminded that any collateral information related to the graphic/text should be consistent with the information contained in the application and allowed on the label. OPP may periodically check such information to ensure that it does. Such collateral information includes, but is not limited to:

a) Television advertisements
b) Radio advertisements
c) Print advertisements
d) Website content
e) Other advertising or solicitation (such as direct mail campaign material or door-to-door material distribution).

In sum, to approve the addition to a pesticide label of text or graphics conveying a third-party endorsement or cause marketing claim, EPA must make a finding that the information is not false or misleading and does not detract from other valuable information on the label. If EPA cannot make such a finding, an application to add such information cannot be granted

III. DISCUSSION OF FACTORS AND RECOMMENDATIONS FOR SUPPORTING INFORMATION

As explained above, the Agency will independently review an application to add a cause marketing claim or a third party endorsement to a pesticide label. EPA will not approve a statement in the labeling of a pesticide product if the statement is false or misleading or if the presence of the statement detracts from other information required on the labeling. The statutory standards reflect the fundamental purpose of FIFRA, which is to prevent unacceptable risk from the use of pesticides. The labeling of a pesticide product is the primary way EPA informs users about the measures needed to prevent such risks. Thus, EPA believes it is important to consider whether label statements may confuse a consumer or create a distorted impression regarding the safety or efficacy of a pesticide.

The Agency identifies below information that EPA would find useful for its review of an application to add a cause marketing claim or third-party endorsement to a product label. Section A describes factors that EPA could consider in making its decision, in particular the potential impacts of the proposed label on consumers – and encourages applicants to consider these factors when preparing any submissions supporting such applications. The Agency notes that its recommendations do not constitute requirements. Should an applicant not provide some or all of the recommended information, EPA will review each submission and make a decision based on the information available, using the Agency's expertise in review of pesticide labeling. Ultimately, the applicant has the responsibility to provide the Agency with sufficient information to allow the Agency to make the necessary findings. See 40 CFR Part 158. If, upon initial review, the Agency finds that the applicant has not met its burden, EPA might request additional information from the applicant to facilitate further consideration of the proposal. 40 CFR 158.75. Failure to provide requested information could lead EPA to deny the application. Section B discusses circumstances in which EPA might approve the addition of a cause-marketing claim or third-party endorsement on a condition that the registrant provide data to assess the impact of adding such a claim.

A. Information to support application review.

The Agency recommends that applications proposing a label statement that is either a third-party endorsement or a cause marketing claim should include the following information.

Mock Label. The Agency strongly recommends that applicants submit a realistic looking, actual size, full color mock-up of the entire label (or labeling, if the statement does not appear on the label), containing the proposed label statement. EPA will review each submission on a case-by-case basis and will consider both the textual and graphical elements of any proposed label statement. Note that EPA's review may determine the graphics to be unacceptable but find the related text is acceptable, or vice versa.

The primary purpose of the mock label is to allow EPA to consider whether the proposed label statement would mislead the user or detract from the user's ability to use the product safely. For example, EPA may consider the location of any graphics and text, as well as the size, style, and color of the label text and graphics. Concerns could be raised if the graphics or text is more prominent than any other contents of the label.

Documentation of Third-Party Relationships. If the label statement contains a third-party endorsement, the Agency strongly recommends that an applicant provide information demonstrating that the third party has actually endorsed the product and that the label statement is consistent with the terms of the endorsement. For example, an applicant could provide a letter from the third party stating that it agrees to the proposed label statement.

Similarly, if the label statement contains a cause marketing claim, an applicant should provide information to substantiate the truthfulness of the claim. For example, if

the claim indicates that the registrant is making a donation to a charitable cause, an applicant should provide a letter from the charity confirming that the proposed label statement regarding the donation is accurate. The applicant should indicate the duration of the cause marketing campaign and its relationship to the length of time the cause marketing claim would appear on the product label.

In addition, EPA will consider whether label statements could be misleading. In the case of third-party endorsement, if the label statement indicates that it rests on the results of a survey or other type of study, EPA encourages the applicant to provide the data from the study. In the case of cause marketing claims, language stating that a donation to a charitable cause will be made for each purchase should not be misleading in any particular, for example with respect to the amount or specific benefits of such donation. Misleading language about the amount of a donation could potentially be resolved by including label text either identifying the exact amount of money that would be given to the charity or indicating that the donation plan is consistent with the Better Business Bureau, Truth in Advertising/Code of Advertising guidelines (http://www.bbb.org/) and complies with all federal, state and local charitable solicitation statutes, regulations, and ordinances that may affect or apply to the promotion.

Discussion of Potential Consumer Impacts. The applicant may also wish to consider including a discussion of the potential impact of the proposed label statement on the behavior of consumers – both people who would consider buying the product and people who would use the product. For example, might the label addition confuse a consumer thereby leading the consumer to purchase and use a product for which the consumer had no need? Could the proposed label statement distort the consumer's perception of the safety of the product thereby causing a change in the way the consumer uses the pesticide?

Such a discussion might also consider whether the proposed labeling could have different effects on various groups of consumers, such as consumers from different age groups, different cultural backgrounds, people with a limited understanding of English, and people of limited reading abilities. How could individuals from these groups interpret the significance of the graphics or text? For example, do graphics have the same meaning across cultures? Would any of the group's characteristics make its members more likely to be misled? For example, could a graphic have a special impact on a child (e.g., a cartoon), an individual for whom the English language is not the first language, or an older person with impaired sight?

The discussion could address possible ways in which a consumer might misunderstand the labeling and what consequences, if any, might flow from that misunderstanding. Could a third-party endorsement convey an unwarranted impression of greater efficacy? Could a reference to a relationship with a charity suggest that the charity endorses use of the pesticide? (Unless a charity explicitly wishes to endorse the product, applicants may want to add language specifically disclaiming any endorsement.) Could the label statement, particularly when it involves an endorsement by a charity, create a greater perception of safety for humans or the environment, leading the user to

ignore the product's label directions? What are the consequences of certain groups (e.g. children) of being misled?

The applicant may also wish to consider the addition of disclaimer language to minimize any adverse consequence that could result. If disclaimer language is proposed, then the discussion should also address how effectively the disclaimer mitigates the potential for misunderstandings. For example, it would be helpful to know whether there are acute or chronic effects that may reasonably result from the misinterpretation of the label and whether a disclaimer would mitigate the misinterpretations so that the effects would be less likely.

All sections of the Discussion of Potential Consumer Impacts will benefit from reference to (and potential submission of) studies, surveys, and research conducted by the registrant and other institutions.

Consumer Market Research and Other Supporting Information. The Agency expects that many of the potential impacts of a proposed label statement on different groups of consumers would be fairly obvious, and that the types of materials described above should provide adequate information on which EPA could make a decision. Nonetheless, in some cases, the information may not allow EPA to evaluate the potential for adverse impacts for some groups of consumers. In the case of those impacts, the applicant should consider providing additional data or information to support any conclusions reached in the discussion of consumer impacts regarding changes in purchasing or use behavior.

EPA may need information to assess the validity of the impression created by the proposed label statement. For example, if a third-party endorsement conveys to the user either increased efficacy or safety, EPA may request an explanation of the basis for the third-party's decision to endorse the product.

EPA may also need information to assess how consumers would perceive the proposed label statement. While there may be a number of ways of developing such information, one likely possibility would be the conduct of consumer market research to ascertain how typical consumers, perhaps from a particular subgroup, would view or respond to a proposed label statement.

To avoid delays in processing a label statement containing a third-party endorsement or cause marketing claim, an applicant may wish to consider in appropriate circumstances submitting the results of consumer market research with the initial application. To maximize the usefulness of such marketing research and to increase the likelihood that it would provide the Agency with sufficient information to assess the requested label statement, EPA recommends that the applicant submit the proposed research design for independent peer review. Such peer review could be conducted by experts in academia or at a reputable/widely-recognized market research firm or similar organization. The peer review should address whether the proposed research design, including sampling strategy, sample size, and survey questions, is appropriate for

measuring the specific impact of the label statement on consumers. If the applicant chooses to conduct a survey, the Agency would like to review not only the results of the survey, but also a description of the survey design and the results of any independent peer review.

B. Data conditionally required to assess the impact of approved claims.

EPA anticipates that it may occasionally face a situation in which a proposed label statement appears to meet the statutory standard, but still causes EPA some residual concern. In such a situation, EPA could approve a proposed label statement but conditionally require the registrant to provide additional information to assess whether adverse consequences resulted from the addition of the label statement. While there may be a number of ways of developing such information, one possibility would be requiring the registrant to survey purchasers/users of the product bearing the approved label statement to assess how (if at all) their behavior changes with the pesticide containing the new label statement.

IV. WHAT APPLICANTS SHOULD DO

Addition of any graphic/text (except as described in PR Notice 98-10) must only be done by a label amendment. See 40 CFR 152.44 - .46. Addition of such language **cannot** be accomplished by notification or non-notification.

V. EFFECTIVE DATES

[To be determined.]

VI. ADDRESSES TO USE

Registrants should send applications to one of the following addresses:

U.S. Postal Service Deliveries

The following official mailing address should be used for all correspondence or data submissions sent to OPP by U.S. mail:
Document Processing Desk (AMEND)
(Distribution Code as identified in PR Notice 2006-1)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Ariel Rios Building1200 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 (Distribution Code as identified in PR Notice 2006-1) (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency

Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

VII. SCOPE OF POLICY

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

VIII. PAPERWORK REDUCTION ACT NOTICE

Under the Paperwork Reduction Act (PRA), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations codified in Chapter 40 of the CFR, after appearing in the preamble of the final rule, are listed in 40 CFR part 9, are displayed either by publication in the Federal Register or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9. For the ICR activity contained in this PR Notice, EPA is displaying the applicable OMB control number in the PR Notice above, and the applicable OMB control number also appears on the pesticide application.

The information collection activities associated with the activities described in this PR Notice are already approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq*. The corresponding Information Collection Request (ICR) document for pesticide applications, including the labeling requirements for pesticides and devices, has been assigned EPA ICR number 0277 and is approved under OMB control number 2070-0060. The annual average reporting and recordkeeping burden for a registration applicant respondent are estimated to range from 14 hours to 646 hours, depending upon the type of activity. For "Type A" activities, which include new active ingredients and new uses, the estimated annual applicant burden average is 194 hours per application. For "Type B" activities, which

include amendments and notifications, the estimated annual applicant burden average is 14 hours per application. The respondent burden estimate for "Type C" reduced risk products is an average of 646 hours per product.

Under the PRA, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection, it is the time reading the regulations, planning the necessary data collection activities, conducting tests, analyzing data, generating reports and completing other required paperwork, and storing, filing, and maintaining the data.

In addition to commenting on the substance of this PR Notice, EPA welcomes your comments on the information collected related activities and the provided burden estimates, as well as any suggested methods for minimizing respondent burden, including the use of automated collection techniques.

IX. FOR FURTHER INFORMATION

If you wish to obtain further information on this notice, please contact the appropriate division ombudsman for your product. Division contacts, including ombudsmen, can be found by visiting http://www.epa.gov/pesticides/contacts/index.htm. At the release date of this Notice, the ombudsmen are:

Biopesticides and Pollution Prevention Division (BPPD):
Brian Steinwand steinwand.brian@epa.gov 703-305-7973

Registration Division (RD):
Linda Arrington arrington.linda@epa.gov 703-305-5446

Antimicrobials Division (AD):
Michael Hardy hardy.michael@epa.gov 703-308-6432

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