US Environmental Protection Agency
Office of Pesticide Programs

Pesticide Registration (PR) Notice 1988-6
Change in Registration Procedures - Agency Approval not Required for Certain Amendments

August 12, 1988

PR NOTICE 88-06

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[Note: On August 17, 1989, a draft of "PR NOTICE 89- " was circulated which proposed the revision of PR Notice 88-06. It appears that everyone who was given a copy of the draft notice concurred without comments, but there is no evidence that this revisionary notice was ever issued.]

The Notice states:

"This notice describes changes in Agency policies and procedures with respect to applications for amended registration of pesticide products. In accordance with new regulations promulgated on May 4, 1988 (53 FR 15952):

1. The Agency will permit certain types of amendments to registration to be accomplished by notification to the Agency ("Notifications") instead of by application for amended registration.

2. EPA is identifying certain minor actions that may be taken by registrants entirely on their own initiative, without notice to the Agency ("Non-notifications").

3. Finally, EPA is stating its intention to use certification of compliance as a preferred mechanism for monitoring registrant compliance with Agency-directed label changes involving straightforward or exact revisions.

This notice describes the revised policies for these new actions, and sets out procedures for registrants and the Agency to accomplish them.

This change in procedure is effective immediately.

I. BACKGROUND

On May 4, 1988, EPA published in the Federal Register a final rule revising its procedures for registration and amended registration. 40 CFR 152.44 provides that, with certain exceptions set out in §§ 152.44(b) and 152.46, an applicant must apply for, and obtain approval of, each modification of his registration. The registrant may not sell or distribute the new product (including release for shipment as defined in § 152.3(j)), as modified, until the application is approved. Moreover, the Agency's policy is that a registrant must submit a copy of his final printed labeling prior to sale or distribution if the revision involves labeling.

The rule provides, in § 152.46, that certain types of modifications to registration no longer require an application to the Agency or approval by the Agency. This differs from previous procedure, under which any change in registration may be accomplished by simply notifying the Agency: these are termed "notifications" to distinguish them from "amendments." Under § 152.46(b), other changes, of lesser significance, are entirely within the discretion of the registrant and may be accomplished without any notification to the Agency: these are termed "non-notifications."

In addition, § 152.44(b) provides that the Agency may permit a registrant to certify that he has complied with an Agency requirement instead of submitting an amendment.

II. ACTIONS THAT ARE NOTIFICATIONS

In accordance with § 152.46(a), the actions listed below may be accomplished by notification to the Agency. Refer to Section III. for information on how to submit a notification.

A. Product Chemistry Changes

1. Active ingredient.

A registrant may change the source of an active ingredient by

notification to the Agency, provided that the alternate source(s) is an EPA-registered product. This applies whether the alternate source is purchased by the registrant from another company, or is part of an integrated system used by the registrant himself.

The following actions are not acceptable as notifications; EPA approval must be obtained prior to sale and distribution:

a. A change in the source of the active ingredient which necessitates changing the nominal concentration of an inert ingredient so that it would exceed its certified limits. This would result in an alternate formulation, which is considered an amendment.

b. A change to an unregistered source of active ingredient; this requires an application for amended registration.

c. Addition, deletion or substitution of active ingredients; this results in a new formulation which requires an application for new registration.

d. A change in the stated nominal concentration of any active ingredient; this requires an application for amended registration.

2. Inert ingredients.

a. If the Agency has required for any reason that a registrant identify the source of an individual inert ingredient, whose identity is known to the registrant, the registrant may change the source of that inert ingredient by notification to the Agency. If the Agency has not required identification of the source of an inert ingredient, the registrant may change sources freely, without notification to the Agency.

b. A registrant may change the stated nominal concentration of any particular inert ingredient by notification to the Agency, provided that (1) the certified limits for that ingredient are not exceeded and (2) that the composition of the ingredient is known to the registrant.

Note particularly that both of the above changes are limited to inert ingredients whose complete identity or specific composition are known to the registrant, such as specific solvents or common commodity diluents. Changes in proprietary ingredients, which generally are composed of a mixture of ingredients and whose composition is not disclosed to the registrant, may not be made by notification but must be accomplished by application for amendment. Since the registrant does not know the composition of such an inert ingredient, the Agency must determine its acceptability based upon information on its composition supplied by its producer.

3. Starting materials for integrated system products. A registrant who produces a product by an integrated system (i.e., using an unregistered active ingredient) is required to supply the Agency with the sources of the staring materials for each such ingredient. If he proposes to change the source of his starting materials, he may do so by notification to the Agency if the change will not result in (1) a significant increase in the level of any existing impurity or toxicological concern (to exceed the upper certified limit of that impurity) or (2) the formation of any new impurity at a level greater than 0.1 percent by weight of the technical grade active ingredient.

4. Change in formulation process. A registrant may modify a formulation process (a blending or dilution process involving no chemical reactions -- distinguished from a production process) by a notification, provided that the certified limits of the active and inert ingredients would not change as a result.

B. Labeling changes

The following label revisions may be accomplished by notification:

1. Addition or substitution of brand names. A registrant is permitted to

market his products under separate brand names provided he notifies the Agency of the names he intends to use. The registrant should continue to refer to the product by its official name of record in correspondence with the Agency. The addition of brand names for use by the registrant is not the same as supplemental registration by a different company under agreement with the registrant. Procedures for supplemental registration have not changed.

2. Use of bilingual labeling when such labeling is not required by the Agency. Implicit in a notification of bilingual labeling is an assurance that the bilingual text will be an accurate translation of the label text.

3. Use of symbols in conjunction with label text. Symbols may not be substituted for label text, but must be used in conjunction with and in close proximity to existing explanatory label text.

4. Combination of labeling statements to remove redundancy, provided all required information is maintained.

5. Deletion of use patterns, pests, claims or sites of use.
[Handwritten here is: "No longer Notification -- see FIFRA 6(f) -- and Part C of the Worksheet." See attached page]

6. Changes in warranty or warranty disclaimer statements.

7. Any other revision of label language consistent with 40 CFR Part 156, which involves no change in the ingredients statement, precautionary statements or directions for use.

III. HOW TO SUBMIT NOTIFICATIONS

To submit a notification, registrants should use the current application form (EPA Form 8570-1). Although not currently designed for notifications, the form will make it easier for EPA to identify incoming notifications and to acknowledge receipt.

All actions under this PR Notice are non-fee items. No fees are required to be submitted with qualified notifications or certifications. For this reason, non-fee notifications and fee amendments may not be submitted on the same form.

The registrant should submit an application form, and write the word NOTIFICATION prominently in the explanation part of Section II. If a product chemistry notification is being made, a Statement of Formula (EPA Form 8570-4) should accompany the notification form if changes in product composition are being made. If a labeling change is being made, the revised label text should be included as an attachment, including "before" and "after" text for easy comparison. A final printed label may be used for this purpose.

The Agency will not review all notifications for compliance, but will screen notifications for accuracy and compliance. If an unqualified notification is received, the Agency will require that it be resubmitted in the proper form (and with the proper fee).

IV. NON-NOTIFICATIONS

The following types of actions may be accomplished by a registrant without notification to the Agency:

A. Correction of typographical and printing errors in labeling.

B. Changes in the new contents necessary to accommodate changing package sizes or contents variability, provided such changes would not affect any requirement for child-resistant packaging under 40 CFR Part 157, or other Agency requirements pertaining to size.

C. Use of metric units in addition to standard U.S. units for new contents, dosages and other numeric expressions.

D. Routing changes in the name or address of the registrant on the label. A registrant is required to keep the Agency current on his address of record: therefore an address change necessitates notifying the Agency. However, such changes may be made on labeling as soon as they occur, with separate

notification to the Agency.

E. Revision, addition, or deletion of non-mandatory label elements, such as the following:

1. Inclusion of the DOT hazard diamond when a shipping container is also the immediate container offered for sale.

2. Addition of State-required analysis of a fertilizer product.

3. Inclusion of lot or batch codes, or other production identifiers.

4. Date of manufacture or label approval.

F. Redesign of label format that does not modify approved label text, consistent with the format requirements of § 156.10. These may include, among other things, changes in color, type size or style, use of space, configuration or placement of label elements.

V. CERTIFICATION OF COMPLIANCE

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Under § 152.44, the Agency may allow certification of compliance with its instructions instead of application for amendment. Because of resource constraints for review of applications, certification of compliance, with spot-checking and enforcement, is a preferred alternative to review of each Agency-initiated action. EPA intends to use the certification approach routinely when it prescribes the exact wording or exact instructions for labeling changes such that registrants can be expected to understand and comply easily.

No specific items of certification are provided by this notice. The Agency will state in its notice to registrants when certification is permitted and will provide the form of a certification statement when it finds that certification is an acceptable means of monitoring compliance. A certification must be accompanied by a statement of the labeling language being certified to.

VI. FINAL PRINTED LABELING

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In the past, the Agency's policy has been that, after approval of an amendment based upon draft labeling, final printed labeling must be submitted before the product, as modified, is sold or distributed. This will continue to be the case. For all amendments, certifications, and notifications, final printed labeling must be submitted before the product, as revised, is sold or distributed. For a notification, final printed labeling may be submitted as the notification; two submissions are not required.

The Agency expects that final printed labeling for an amendment or a notification will include not-notification items. No submission of final printed labeling is required for non-notifications.

VII. PENDING APPLICATIONS

A number of applications for amendment that may be notifications are pending with the Agency. Since these bear no identification as notifications, the Agency cannot segregate them from amendments requiring full review and approval. EPA will continue to review pending applications for amendment by its normal review process, and registrants may not sell or distribute the product until Agency approval is received and final printed labeling submitted.

A registrant may, however, submit a qualifying notification, submit final printed labeling, and thereafter sell or distribute the product immediately, without awaiting Agency approval of the pending application for amendment. The Agency will attempt to link up such overlapping actions.

A registrant who does not submit a qualifying notification for a pending amendment must await action by the Agency's normal review process before selling and distributing the product as revised.

VIII. ENFORCEMENT

EPA reminds registrants that they are entirely responsible for the content and accuracy of labeling, and for compliance with labeling requirements, whether or not the Agency chooses to review and approve labeling changes. Any product that is misbranded under FIFRA sec. 2(g), or that is in violation of FIFRA sec. 12 may be the subject of an enforcement action.

Furthermore, registrants are responsible for ensuring that the labeling of distributor products is in compliance with FIFRA.

IX FUTURE NOTIFICATION ACTIONS

Actions not identified in this notice as notifications or non-notifications must be submitted as applications for amendment requiring Agency review and approval before sale and distribution.

The Agency intends to expand the notification process by including additional types of actions. If EPA determines in the future that additional types of registration amendments may be accomplished by notification or non-notification, it may choose to issue subsequent PR Notices to inform registrants, or may revise its regulations by publishing a final rule. Suggestions on additional actions that could be accomplished by notification are encouraged. However, until EPA implements such suggestions by issuance of a notice to registrants (or a revision of its regulations), no registrant should assume that submission of a suggested change constitutes permission to take such action by notification or non-notification rather than amendment.

X. FOR FURTHER INFORMATION

A copy of EPA's final regulation concerning notification and non-notification is available from Jean Frane, Registration Division (TS-767C), EPA, 401 M St., SW., Washington, D.C. 20640. Telephone: (703) 557-0944. Further information on this notice may also be obtained from Ms. Frane."

This Notice was signed:

Edwin R. Tinsworth, Director
Registration Division

[Handwritten above is: "See PR 88-06 pg. 4 deletion of use pattern -- no longer a Notification"]

PART C OF THE WORKSHEET

Part C of the Worksheet is provided for your use if you commit to supply generic data, but wish to amend the registration of one or more products to delete one or more uses to avoid the necessity of a commitment to generate data specific to that use. Note that the necessity to commit to supply data for a use category exists unless you delete all uses of the active ingredient that fall into that use category.

If you act as an agent for supplementally registered products derived from your basic registration and you indicate on Part C that you intend to drop certain uses from your registration, you must ensure that your distributor products also take that action.

On May 4, 1988, EPA issued in the Federal Register (53 FR 15952) revised Pesticide Registration Procedures. That regulation provided that registrants of pesticide products could make various changes to their product registration without going through the formal amendment process. In August of 1988, the Agency issued PR Notice 88-06 which explained in more detail the types of changes that did not require amendment. Among those changes which only required that the registrant notify the Agency prior to adoption, was "deletion of use patterns, pests, claims or sites of use".

Provisions of FIFRA which direct the Agency to publish notices of a registrant's intent to not seek reregistration, and notices of cancellation actions for failure to respond adequately, are intended to provide the public with knowledge of the potential loss of a product or a specific use of a product. To accomplish the objective of informing the public, the Agency must track the deletion of uses from product registrations as well as cancellations of products themselves. Therefore, the instruction in this package relating to the submission of requests for amendment to delete uses from a registration, supersede PR Notice 88-06 with respect to deletion of uses from a product registration.