

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

August 13, 1993

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

PR NOTICE 93-11

NOTICE TO MANUFACTURERS, FORMULATORS, PRODUCERS, AND REGISTRANTS OF AGRICULTURAL PESTICIDES

Attention:

Persons Responsible for Registration of Pesticide

Products

Subject:

SUPPLEMENTAL GUIDANCE FOR PR NOTICE 93-7 --

LABELING REVISIONS REQUIRED BY THE WORKER

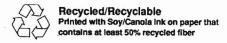
PROTECTION STANDARD (WPS)

PR Notice 93-7, issued on April 20, 1993, provided guidance to pesticide registrants on amending product labeling in compliance with the labeling requirements for the revised Worker Protection Standard (WPS) for agricultural pesticides (40 CFR part 156, subpart K) that was issued August 21, 1992. Since issuance of PR Notice 93-7, EPA has received many comments and inquiries about situations not covered in that notice and about the difficulties registrants are having meeting the regulation-specified deadlines for incorporating WPS labeling onto products. This notice identifies options that you may choose to allow efficient production and distribution of products that comply with PR Notice 93-7. It will also direct you to appropriate detailed guidance about the various options.

I. APPLICABILITY OF THIS NOTICE

This notice applies to all registrants of pesticide products determined to be within the scope of PR Notice 93-7, as determined by application of the criteria included in that notice.

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NOTE: When this Notice uses the phrase "PRN-complying labeling," such complying labeling may be one of the following:

- final labeling or interim product-specific replacement labeling that fully complies with the guidance in PR Notice 93-7 for adding WPS-related statements,
- final labeling or interim product-specific replacement labeling that only deviates from the guidance in PR Notice 93-7 under specific instructions from the WPS Label Information Line,
- final labeling or interim product-specific replacement labeling that fully complies with the guidance in PR Notice 93-7 and this notice for removing the product from the scope of PR Notice 93-7 by deleting uses or by adding pre-approved exclusionary statements,
- final labeling or interim product-specific replacement labeling that EPA has stamped as accepted in response to an amendment request submitted by the registrant to comply with PR Notice 93-7.

II. WHAT IS IN THIS PACKAGE?

If you hold no registrations for crop, forestry, nursery, or ornamental use (as determined by EPA records), EPA has sent you only this PR Notice, which contains an overview of the additional guidance and options available to registrants with products within the scope of PR Notice 93-7. If you want the supplements to this notice (listed below), call the WPS Label Information Line (1-800-777-2185).

If you hold one or more registrations for crop, forestry, nursery, or ornamental use, you are being sent, in addition to this PR Notice, the following supplemental materials:

Supplement A:

"Additional Guidance on Label Approval and Pre-Approved Deviations from PR Notice 93-7." This supplement describes the registrants' option of selfverifying that revised labeling complies with PRN 93-7. It also contains guidance for registrants with deviations from PR Notice 93-7 that are pre-approved by EPA.

Supplement B:

"Guidance for Timing of Amendment Submissions." This supplement recommends that registrants wishing to have 3 months to incorporate stamped-accepted labeling onto products should submit PRN-complying amendments to EPA no later than September 21, 1993. It also contains guidance about dormant products.

Supplement C:

"What Can Be Done with Stock with Non-PRN-Complying Labeling?" This supplement describes the Release-For-Shipment by January 1, 1994, option.

Supplement D:

"What Type of Revised Labeling Can Be Used By Registrants?" This supplement describes the option of interim replacement labeling ("stickering" option)

Supplement E:

"Where May Relabeling Occur?" This supplement describes the option of relabeling by distributors and dealers and the option, in very narrow circumstances, of stickering by end-users.

Supplement F:

"Additional Guidance for Removing Products from Scope." This supplement offers further guidance about the scope tests for products "primarily intended for home use." It also offers guidance on the use of exclusionary statements to remove a product from the scope of PR Notice 93-7 and lists several pre-approved exclusionary statements.

Supplement G:

"WPS Statements on Sublabels with No In-Scope Uses." This supplement offers guidance for determining whether a sublabel bears directions for any use within the scope of PR Notice 93-7, and which statements placed on the "master" labeling through compliance with PR Notice 93-7 must be retained on sublabels that bear no in-scope uses.

III. USE OF THE SUPPLEMENTS

The guidance and options in each of the supplements are, unless otherwise specified, independent of one another. You may choose -- either at the same time or at various times during the implementation process -- to use various combinations of the options listed in this notice, provided you follow the requirements listed for each option. Several examples of available combinations are listed below.

- Registrants may select the registrant-verification option for (1) fully complying WPS labeling, (2) WPS labeling with only involuntary, preapproved deviations, (3) labeling taken out of scope through usedeletions, or (4) labeling taken out of scope through the addition of preapproved exclusionary statements.
- Registrants may choose the Release-For-Shipment option for non-complying inventory released for shipment by January 1, 1994, and the interim replacement labeling ("stickering") option for non-complying inventory released for shipment after January 1, 1994.
- Registrants choosing the Interim Replacement Labeling ("stickering") option may:
 - -- use final approved labeling or registrant-verified labeling as the replacement labeling.
 - use the replacement labeling to (1) add WPS statements, (2) delete all WPS uses, or (3) add exclusionary statements to remove the product from scope.
 - -- choose to add the sticker at (1) establishments under registrant control, (2) dealers or distributors, or (3) (under very narrow circumstances) end users.
- Registrants choosing to add pre-approved exclusionary statements may:
 - -- self-verify compliance of the labeling, and ship without waiting for EPA acceptance,
 - -- choose the release-for-shipment option for non-complying inventory,

- -- choose to add a sticker containing the exclusionary statements or choose the interim replacement labeling option with its "generic" sticker and full replacement labeling,
- choose to add the sticker at (1) establishments under registrant control, (2) dealers or distributors, or (3) (under very narrow circumstances) end users.

IV. RELATIONSHIP WITH PR NOTICE 93-7

A. General Relationship With PR Notice 93-7

Most of the instructions in this notice supplement the instructions and guidance in PR Notice 93-7. The instructions in PR Notice 93-7 remain applicable except where specific instructions in this notice modify or supersede them.

B. Relationship With Registrant Verification

Once you have submitted to EPA a WPS amendment request that complies exactly with the instructions in PR Notice 93-7 or complies with the instructions in PR Notice 93-7 except for deviations that have been pre-approved by EPA or the WPS Label Information Line, you may self-verify without further correspondence with EPA.

Section V-B in Supplement Two of PR Notice 93-7 states:

"Most label changes require Agency approval before product may be sold or distributed bearing the new label. If any changes to your label are neither reviewed nor accepted, sale or distribution of product bearing a label including such changes will probably be in violation of FIFRA, and could subject you to enforcement action."

These statements refer to nonWPS changes (such as adding a new crop or use-site) made to a label through a WPS amendment, and do not invalidate the registrant-verification process.

V. FOR FURTHER INFORMATION AND ASSISTANCE

The Agency maintains a toll-free WPS Label Information Line to help registrants understand and implement the required labeling changes. If after reading this notice and any relevant supplements you have questions about what you must do to bring your label into compliance, you are encouraged to call the WPS Label Information Line (1-800-777-2185) for help. It is attended during normal business hours; at other times you may leave a message for a return call.

Douglas D. Campt, Director Office of Pesticide Programs

SUPPLEMENT -A-

ADDITIONAL GUIDANCE ON LABEL APPROVAL AND PRE-APPROVED DEVIATIONS FROM PR NOTICE 93-7

I. WHAT APPROVAL MUST REVISED LABELING RECEIVE?

A. EPA Acceptance Option

Under this option a registrant would wait to sell or distribute product with revised labeling until after EPA notifies the registrant of acceptance.

Registrants must use the EPA-acceptance option for products:

- for which voluntary deviations (described in section II of this supplement) are being requested, and
- for which exclusionary statements other than pre-approved exclusionary statements (described in section III of Supplement F of this notice) are being requested.

Registrants may choose this option for other products because it involves the least uncertainty about compliance with PR Notice 93-7 requirements.

B. Registrant-Verification Option

Under certain conditions, EPA will allow registrants to self-verify revised labeling and, on the basis of the registrant-verification, to sell or distribute product with revised labeling that has not yet been stamped as accepted by EPA.

1. What labeling qualifies for the registrant-verification?

The option of registrant-verification is available for the following types of amended labeling:

Complete and exact compliance — labeling for which the registrant certifies in the WPS amendment application submitted to EPA that the labeling instructions in PR Notice 93-7 are followed exactly. (See instructions starting on page 3 in Supplement Two of PR Notice 93-7 —

Amending a Section 3 Registration to Comply with WPS Requirements.)

- Involuntary deviations labeling for which the registrant certifies in the WPS amendment application submitted to EPA that the labeling instructions in PR Notice 93-7 are followed exactly, except for involuntary deviations. (See instructions in section II of this supplement, Guidance about Pre-Approved "Involuntary" Deviations.)
- Deletion of all WPS uses labeling for which the registrant submits to EPA a WPS amendment application to delete all in-scope uses or other statements or directions for use that cause the current labeling to fall within the scope of the WPS. (See instructions starting on page 9 in Supplement Two of PR Notice 93-7 Amending a Section 3 Registration to Take the Product Out of Scope of the WPS.)
- Adding pre-approved exclusionary statements -- labeling for which the registrant submits to EPA a WPS amendment application to remove the product from the scope of the WPS by adding one or more pre-approved exclusionary statements to the labeling. (See instructions in section II-B-2 of Supplement F of this notice -- Procedure for Adding Pre-Approved Exclusionary Statements.)

2. What labeling does not qualify for the registrant-verification?

The option of registrant-verification is NOT available for the following types of amended labeling:

- voluntary deviations labeling for which the registrant indicates in the WPS amendment application submitted to EPA that the labeling instructions in PR Notice 93-7 are NOT followed exactly and EPA preapproval has not been obtained.
- mon-approved exclusionary statements -- labeling for which the registrant submits to EPA a WPS amendment application to remove the product from the scope of the WPS by adding one or more exclusionary statements to the labeling that EPA has not listed in Supplement F of this notice.

Due to the tight schedule for labeling to be amended to comply with PR Notice 93-7, registrants who submit amendments requesting voluntary deviations from the guidance

in PR Notice 93-7 are strongly encouraged to also develop and submit fall-back labeling that is registrant-verifiable as described in section I-B-1 of this supplement.

3. What process should be used for registrant-verification?

Once you have submitted to EPA a complete application to amend your registration, you may sell or distribute products using the registrant-verifiable labeling that you submitted with the amendment application. When you receive from EPA a copy of the stamped-accepted labeling, check the comments in the accompanying acceptance letter for any EPA-required alterations to your registrant-verified labeling. The EPA acceptance letter will probably not require corrections until the next label printing.

4. What if registrant-verified labels contain errors?

Registrants electing to sell or distribute products bearing registrant-verified revised labeling run some risk that the proposed labeling is incorrect and must be revised. It is difficult to be precise about likely enforcement response to all of the wide variety of errors that could occur. However, it is clear that some types would be serious, possibly requiring such enforcement responses as stop-sale orders, recalls, or civil penalties. Other errors would be regarded by EPA as minor, requiring only such response as correction at the next printing of the label. In general, errors will be regarded by EPA as serious when they create a potential for harm to workers, handlers, other persons, or the environment, or when the errors prevent achievement of basic goals of the WPS or FIFRA. EPA has listed examples of each class of errors below:

a. Serious errors:

- Statements that would render all or part of WPS unenforceable because they either contradict WPS or fail to make it clear that compliance with WPS in use of the product is required.
- REI's that are shorter than required, are misleading, or allow early entry other than that allowed in the WPS or in product-specific statements pre-approved in PR Notice 93-7.
- PPE that is missing, or is incorrect and judged by EPA to be significantly underprotective or risk-inducing.

Major changes outside WPS statements, such as addition of a crop for which EPA approval had not been obtained.

b. Minor errors:

- Spelling, placement, or format (e.g. boxing, shading, etc.) errors that are unlikely to mislead users about their WPS responsibilities.
- Errors, such as mistakes or deletions that are unlikely to threaten handler or worker safety, in optional statements (e.g. engineering control statements, soil-injection or soil-incorporation statements, or user safety recommendations.)

II. GUIDANCE ABOUT PRE-APPROVED "INVOLUNTARY" DEVIATIONS

PR Notice 93-7 contains instructions at several places in Supplement Three "Main Labeling Guidance" and Supplement Three-A "Addendum to Main Labeling Guidance" where certain registrants are requested to call the WPS Label Information Line for assistance. Usually the directions to call involve situations for which there are no instructions in the Guidance. For example, registrants are instructed to call EPA if the product contains:

- a solvent or solvent combinations for which no chemical-resistance category is assigned,
- a requirement for an air-supplying respirator or other unusual respirator type,
- a complex closed system or enclosed cab requirement, or
- reentry statements that explicitly prohibit entrance by any person.

In addition, registrants are instructed to call EPA if they believe that applying the Main Labeling Guidance to their current product label would lead to a label that is not protective enough, unreasonably overprotective, or otherwise unreasonable for the product.

When registrants call EPA in response to instructions in the Supplements to PR Notice 93-7, they will receive instructions for making labeling modifications to

deal with their specific situation. Since these modifications are not in the Main Labeling Guidance, these modifications are "deviations" and, as such, prevent the registrant from signing the "Certification when Supplement Three is followed exactly." Instead, such registrants will sign the "Certification when deviations are proposed."

EPA offers the following additional guidance to registrants of products whose ONLY deviation from the Main Labeling Guidance is one or more deviations preapproved by EPA as described above.

A. Amendment Submissions

Registrants with only pre-approved deviations should do the following:

- Sign the "Certification when deviations are proposed,"
- Highlight the deviations in a way that distinguishes them from the label changes that use the exact language or location specified in the PR Notice, and
- In Section II on EPA Form 8570-1 "Application for Pesticide Amendment" in the block labeled "explanation" enter "Amendment to meet WPS requirements; additional certification statements are attached; all deviations are pre-approved by EPA through the WPS Label Information Line."

B. Processing of Submissions

Amendment applications for labels whose only deviations are pre-approved will be reviewed quickly by the Agency using an accelerated process similar to the process used to review labels for which the certification that Supplement Three was followed exactly was signed.

SUPPLEMENT -B-

GUIDANCE FOR TIMING OF AMENDMENT SUBMISSIONS

GUIDANCE FOR ACTIVELY MARKETED PRODUCTS.

Based on its best understanding of the EPA review workload involved, the Agency advises registrants wishing to have a reasonable expectation of receiving EPA's acceptance of revised labeling by January 21, 1994, (three months before the April 21, 1994, compliance date for registrants) to submit correct and complete amendment requests responding to PR Notice 93-7 as early as possible, but no later than September 21, 1993. In setting priorities for review, EPA intends to give particular attention to applications received by September 21, 1993. Other applications will still, however, be reviewed through the special WPS process.

The Agency is unlikely to make a decision by January 21, 1994, on proposed labeling that deviates significantly from the guidance, especially if supporting data must be reviewed.

II. GUIDANCE FOR "DORMANT" PRODUCTS.

The Agency offers the following additional guidance for registrants of products that are not being actively marketed:

- Registrants choosing not to cancel registrations for products that are within the scope of PR Notice 93-7, but for which the registrant has no current plans to sell or distribute after April 21, 1994, are encouraged not to submit amendment requests for such products, if at all, until shortly after that date at the earliest.
- Registrants with non-PRN-complying products that are no longer actively marketed but which are likely to remain in significant supply in channels of trade after October 23, 1995, are encouraged to submit amendment requests well before April 21, 1994, even if they plan no future sales of the product.
- Registrants submitting amendment requests for dormant products should identify them as dormant so their review can be deferred until reviews of more urgent applications are completed. Place the phrase "DORMANT PRODUCT" in the "explanation" block of Section II of EPA Form 8570-1, Application for Pesticide Amendment.

- Regardless of whether or when amendment requests for dormant products are submitted to EPA, such products may not be sold or distributed by registrants after April 21, 1994, (or by any person after October 23, 1995), unless they are brought into compliance with PR Notice 93-7 or this notice.
- The stickering, release-for-shipment, and other options described in this Notice are not available for a product for which no labeling amendment responding to PR Notice 93-7 is submitted to EPA by April 21, 1994.
- Registrants are advised that EPA has established an expedited process for reviewing and approving PRN-complying labels. EPA plans call for this process to be discontinued in 1994. Labeling amendments responding to PR Notice 93-7 submitted after the expedited process is discontinued will be processed by the EPA Product Manager for the product. At that time, such amendments will receive no special priority.

SUPPLEMENT -C-

WHAT CAN BE DONE WITH STOCK WITH NON-PRN-COMPLYING LABELING?

I. FULL COMPLIANCE (NO SALE OR DISTRIBUTION) OPTION

Registrants who have under their ownership, custody or control existing stock of in-scope product that does not bear PRN-complying labeling may fully comply with the WPS by:

- only selling or distributing the product before April 21, 1994, or
- relabeling the product with final PRN-complying labeling or relabeling with interim PRN-complying labeling (as described in Supplement D of this notice) before selling or further distributing it, except for distribution necessary to relabel the product.

II. RELEASED-FOR-SHIPMENT BY JANUARY 1, 1994 OPTION

A. Products Released for Shipment Before January 1, 1994

Product within the scope of PR Notice 93-7 that is released for shipment in the United States before January 1, 1994, may be sold or distributed by the registrant after April 21, 1994, without bearing labeling that complies with PR Notice 93-7, provided all of the following conditions are met:

- Before the registrant sells or distributes after April 21, 1994, a product with non-PRN-complying labeling for which this January 1, 1994, option is being selected, the registrant submits to EPA in writing:
 - the product name and EPA registration number,
 - a statement that the "January 1, 1994, Released-For-Shipment Option" is being elected for that product, and

For the purposes of this notice, EPA is using an established definition of "packaged, labeled, and released for shipment" that is located at the end of this supplement. In this notice, this phrase is shortened to "released for shipment."

- the registrant's commitment to adhere to the requirements listed in this section.

The written notice must be submitted by mail or private courier to the following address:

US EPA Office of Compliance Monitoring Box 146 2101 Crystal Plaza Arcade Arlington, VA 22202

- The registrant notifies in writing every person (other than end users) to whom they sell the non-PRN-complying product after April 21, 1994, of the registrant's offer to relabel (using final or interim labeling) or recall, from anywhere in the channels of trade, any of the product (including distributor product) that does not bear PRN-complying labeling by October 23, 1995. The notice would allow all holders of the product (other than end users) until April 21, 1996, to notify the registrant of the non-complying inventory. (Registrants may wish to include in this notice recommendations on product inventory management to minimize the volume of such stocks.)
- Starting no later than April 21, 1994, the registrant makes available to every person to whom the registrant sells the non-PRN-complying product adequate supplies of Generic WPS Supplemental Labeling, and urges retailers and distributors to furnish the appropriate Generic WPS Supplemental Labeling to all end users at the time such product is sold or distributed to them. (See the final pages in this supplement for copies of the Generic WPS Supplemental Labeling.) One type of Generic WPS Supplemental Labeling should be furnished to purchasers of agricultural fumigants; the other type of Generic WPS Supplemental Labeling should be furnished to purchasers of all other agricultural pesticides, except ethyl parathion products. Registrants of ethyl parathion products who choose this Released-For-Shipment by January 1, 1994 option, are exempt from providing Generic WPS Supplemental Labeling since there is no such labeling applicable to ethyl parathion products.

B. Requests for Extension of the January 1, 1994 Release-For-Shipment Date

EPA will consider registrant requests for extension of the January 1, 1994, Release-For-Shipment date, but does not expect to grant many such extensions. The registrant must submit a written request for extension by September 21, 1993, to the address to which PR Notice 93-7 amendment applications are submitted. The request must propose a specific alternative release-for-shipment date between January 1, 1994, and April 21, 1994, and include a persuasive rationale for granting the request.

DEFINITION OF "RELEASED FOR SHIPMENT"

A product is "packaged, labeled, and released for shipment" by a producing establishment when the product has been produced, packaged, and labeled and it is the intent of the producer to introduce such product into commerce. Intent is considered to exist in any of the following situations:

- Previous experience with the pesticide industry in general or with a particular producer indicates that similarly situated products are intended for release.
- A product is stored in an area where finished products are held for shipment in the ordinary course of business (warehouse, loading docks, etc.). NOTE: Products that have not been released for shipment, but are stored in areas where finished products are held for shipment, must be physically separated and identified as not yet released for shipment.
- A producer asserts that the product is representative of what is actually sold.

The phrase "packaged, labeled, and released for shipment" is only relevant at the producing establishment level. Products at the distributor and retail level have previously been released for shipment by the producing establishment. Repackaging or relabeling are considered production and if such activities take place after April 21, 1994, the product must be relabeled with PRN-complying labeling.

AGRICULTURAL PESTICIDE GENERIC SUPPLEMENTAL LABELING

For compliance with the Worker Protection Standard (40 CFR part 170)

tTANT: This supplemental labeling does not apply (1) to soil or space fumigant products, (2) to products comming ethyl parathion, or (3) if elsewhere on the product labeling an Agricultural Use Requirements box requires compliance with the Worker Protection Standard (40 CFR Part 170).

When this product is used on an agricultural establishment (farm, forest, nursery, or greenhouse) for the commercial or research production of agricultural plants, users must comply with the instructions in this supplemental labeling. Users who must comply with these instructions include owners/operators of the agricultural establishment and owners/operators of commercial businesses that are hired to apply pesticides on the agricultural establishment or to perform crop-advising tasks on such establishments. Failure to comply with the requirements on this supplemental labeling and with the Worker Protection Standard (40 CFR part 170) is a violation of Federal law, since it is illegal to use a pesticide product in a manner inconsistent with its labeling.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements in this labeling about personal protective equipment, restricted-entry intervals, and notification to workers. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard (WPS).

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

Entry-Restrictions: Do not enter or allow worker entry during the restricted-entry interval (REI). The restricted-entry erval for this product is:

the specific number of hours or days (if any) listed elsewhere on the product labeling as the reentry interval or entry restriction for the crop or site, if 12 hours or more;

12 hours, if no specific number of hours or days is listed elsewhere on the product labeling as the reentry interval or entry restriction for the crop or site;

The restricted-entry interval for this product must be at least 12 hours.

Notification Instructions: Follow the rules in the WPS for notifying workers of the application. Exception: If the instructions about notification (if any) listed elsewhere on the product labeling require posting of treated areas (rather than offering a choice), you must notify workers of the application by warning them orally AND by posting signs at entrances to treated areas, following the rules in the WPS.

Personal Protective Equipment (PPE) Requirements:

Handler PPE: Pesticide handlers must wear the PPE listed elsewhere in the product labeling for applicators. If specific PPE is required elsewhere on the product label for specific handling tasks (such as mixing or loading), it must be worn while performing such tasks. In any case, any handler using this product must wear no less than: long-sleeved shirt, long pants, shoes, socks, and chemical-resistant or waterproof gloves.

Early Entry PPE: PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is the same PPE as required elsewhere on this product label for applicators, except that any respirator requirement is waived. In any case, the minimum PPE required for any early entry worker exposed to this product is no less than: coveralls, shoes, socks, and chemical-resistant or waterproof

Conflicting Instructions: If the requirements of the WPS conflict with instructions listed elsewhere on this product label, ers must obey the more protective requirements.

AGRICULTURAL FUMIGANT GENERIC SUPPLEMENTAL LABELING

For compliance with the Worker Protection Standard (40 CFR part 170)

IMPORTANT: This supplemental labeling applies ONLY to soil or space furnigant products used in the production of agricultural plants. It does not apply if elsewhere on the product labeling an Agricultural Use Requirements box requires compliance with the Worker Protection Standard (40 CFR Part 170).

When this product is used on an agricultural establishment (farm, forest, nursery, or greenhouse) for the commercial or research production of agricultural plants, users must comply with the instructions in this supplemental labeling. Users who must comply with these instructions include owners/operators of the agricultural establishment and owners/operators of commercial businesses that are hired to apply pesticides on the agricultural establishment or to perform crop-advising tasks on such establishments. Failure to comply with the requirements on this supplemental labeling and with the Worker Protection Standard (40 CFR part 170) is a violation of Federal law, since it is illegal to use a pesticide product in a manner inconsistent with its labeling.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements in this labeling about personal protective equipment, restricted-entry intervals, and notification to workers. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard (WPS).

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

Entry-Restrictions: Follow the applicable entry restrictions listed elsewhere on the product labeling.

Notification Instructions: Follow the rules in the WPS for notifying workers of the application. Exception: If there are instructions listed elsewhere on the product labeling that requires the posting of specific signs at treated areas, you must notify workers of the application by warning them orally AND by posting the signs specified on the labeling.

Personal Protective Equipment (PPE) Requirements: Follow the applicable PPE instructions (if any) listed elsewhere on the labeling.

Conflicting Instructions: If the requirements of the WPS conflict with instructions listed elsewhere on this product label, users must obey the more protective requirements.

SUPPLEMENT -D-

WHAT TYPE OF REVISED LABELING CAN BE USED BY REGISTRANTS?

Registrants may employ revised labeling as either final or interim labeling (sticker plus replacement labeling), subject to the restrictions on each discussed below. The final or interim labeling may be EPA-accepted labeling or registrant-verified labeling (when permitted -- see Supplement A) and may include labeling amended to (1) add WPS statements, (2) delete all WPS uses, or (3) add exclusionary statements to exclude all WPS uses.

I. FINAL-LABELING OPTION

Registrants may comply by ensuring that all product within the scope of PR Notice 93-7 and this notice that they sell or distribute after April 21, 1994, bears full and final (EPA-approved or registrant-verified) labeling complying with PR Notice 93-7.

II. INTERIM LABELING ("STICKERING") OPTION

EPA will allow registrants to exercise the option of interim labeling. Acceptable interim labeling for PR Notice 93-7 compliance consists of:

- a sticker or similar modification to an existing label, and
- product-specific replacement labeling referenced by the sticker that meets the specifications and conditions of use listed below.

Interim labeling may be particularly appropriate for product that entered channels of trade without any PRN-complying labeling. Once a product has been correctly interim-labeled, it may be sold or distributed by anyone without time limit.

A. Sticker Specifications

Prominence — must be legible and prominent on product package through use of contrasting colors or other graphic devices, and placement on the label of each product.

- Location must be printed or affixed onto product package. If affixed, must be difficult to remove without residue or damage to underlying packaging or labeling and must not be located on the bottom or any other place that will not readily be noticed by users. If the product bears labeling on both outer packaging and immediate container, the sticker must be affixed to both. (Exception: Inner water soluble packages need not be modified under the interim labeling approach.)
- Obscuring Existing Language if replacement labeling does not accompany the product at each point of sale or distribution by the registrant after the sticker is affixed to the product, the sticker must not obscure any information on the existing label. If the replacement labeling does accompany the product, the sticker must not obscure on the existing label the product name, EPA registration number, signal word, statement of practical treatment (if any), active ingredient statement, or restricted-use statement (if any).
- Required Text "STOP! The label on this pesticide is no longer in effect. Follow replacement labeling received at sale. If you do not have the replacement labeling for this product, contact the seller or registrant or call (_______ __ ___ ___ ___ to obtain it before using this product. The Worker Protection Standard, 40 CFR Part 170, must be followed when this product is used."

B. Replacement Labeling Specifications

- Location need not be attached to container.
- Format may be in draft form, provided all text is legible and any required skull-and-crossbones symbol is included. The User Safety Recommendations and Agricultural Use Requirements must each be in a clearly separate box with lines or other graphic indicators to separate them from the surrounding text.
- Content must contain the complete text of the PRN-complying labeling (as EPA-accepted or registrant-verified) including the full text of the current labeling, except for changes/deletions made to comply with PR Notice 93-7 or this Notice.

Title -- must prominently bear the words "REPLACEMENT LABELING" at the top of the first page.

C. Use of Interim Labeling

Products may be stickered, or bear a label containing a facsimile of a sticker, provided:

- The sticker or facsimile is applied before sale or distribution to end user. (See exception in supplement E for end users who purchase product on intact pallets or in unopened shipping containers.)
- The registrant takes steps to ensure that the replacement labeling accompanies the product at the time of sale to any end users.

 Whenever feasible, such replacement labeling should accompany the stickered product at every stage of distribution.
- Before the product is sold or distributed with replacement labeling, the registrant submits to EPA a labeling amendment in accordance with the instructions in PR Notice 93-7 and this notice.
- No later than 90 days from the date of EPA acceptance of product labeling amended to comply with PR Notice 93-7, all newly released-for-shipment product bears that EPA-accepted (final or interim) labeling.

SUPPLEMENT -E-

WHERE MAY RELABELING OCCUR?

REGISTRANT CUSTODY OR CONTROL

WPS-related stickering, provision of replacement labeling, or full relabeling may occur at sites where product is under registrant custody or control at any time.

II. DISTRIBUTION OR RETAIL SITES

WPS-related stickering, provision of replacement labeling, or full relabeling may occur at sites where product is not under direct registrant control (such as distribution or retail sites), by any person the registrant designates, and without registration of the site as a pesticide producing establishment. The registrant, however, retains full responsibility for ensuring that such labeling modifications are carried out correctly except as provided below.

III. END-USER SITE

Product may be distributed or sold to end users in unopened shipping pallets or other unopened outer shipping containers without a WPS-related sticker affixed to the inner pesticide containers provided the registrant:

- ensures that the end user is supplied at delivery (e.g. by attaching an envelope containing such supplies to the outside of the pallet load or other outer container) with sufficient quantity of stickers for each inner container (other than inner water-soluble packages).
- ensures that the pallet load or other container prominently bears the following statement: "IMPORTANT NOTICE: It is a violation of Federal law to use any pesticide inside this outer container until the provided sticker has been applied to its container."
- takes steps (in the case of interim labeling) to ensure that sufficient quantity of replacement labeling for each inner container accompanies the product at the time of delivery to the end user.

SUPPLEMENT -F-

ADDITIONAL GUIDANCE FOR REMOVING PRODUCTS FROM SCOPE

I. ADDITIONAL SCOPE GUIDANCE FOR PRODUCTS "PRIMARILY INTENDED FOR HOME USE"

A. Additional Guidance On Scope Criteria

For registrants who wish to remove their products from the scope of PR Notice 93-7 through the "primarily intended for home use" tests (Question E in section IV "Scope Criteria" in PR Notice 93-7), EPA provides the following additional guidance regarding scope criteria.

If the product meets all the tests in question E except that it bears directions for tankmixing with fertilizer or other pesticides, OR it contains the word "crop" in the Directions for Use, OR it contains directions for use of a surfactant, buffer, or adjuvant without using the words "surfactant," "buffer," or "adjuvant," STOP! This product is NOT within the scope of PR Notice 93-7 and its labeling need not be changed.

B. Appealing to EPA About Products Intended Primarily for Home Use

If your product fails to meet the "primarily intended for home use" test (Question E in section IV "Scope Criteria" in PR Notice 93-7 and the preceding section of this supplement), but you believe the product is nonetheless "intended primarily for home use," call the WPS Label Information Line at 1-800-777-2185 and be prepared to do the following:

- identify all statements on the product labeling that cause the product to fail the tests in question E,
- identify any other characteristics of the product such as container size that cause it to fail the tests in question E, and
- explain why you believe the product is nonetheless "intended primarily for home use or is otherwise limited to use on plants grown for other than commercial or research purposes."

EPA will review the product labeling and notify you of its finding. If EPA concludes that the product appears to be primarily intended for home use, it is NOT within the scope of PR Notice 93-7, and its labeling need not be changed.

If EPA concludes that the product is NOT primarily intended for home use, you may chose any of the response options listed in Supplement Two: "Procedures for Responding to PR Notice 93-7" OR you may request an amendment to the registration to add an appropriate exclusionary statement as described immediately below.

II. PRE-APPROVED EXCLUSIONARY STATEMENTS FOR REMOVING PRODUCTS FROM THE SCOPE OF PR NOTICE 93-7

EPA has pre-approved statements for registrants to use to remove products from the scope of PR Notice 93-7.

When these exclusionary statements are correctly used, registrants may:

- submit an amendment application as described PR Notice 93-7
 Supplement Two, section VII "Amending a Section 3 Registration to
 Take the Product Out of Scope of the WPS" except in the block
 labeled "explanation" on EPA Form 8570-1, enter "Amendment to add
 pre-approved exclusionary statements to remove product from scope of
 WPS."
- submit with the amendment application the certification statement "Certification when deviations are proposed" that is in PR Notice 93-7 Supplement Two, section V. (NOTE: these are considered "involuntary" deviations as described in section II of Supplement A of this notice), and
- choose the registrant-verification option (described in section I-B of Supplement A of this notice).

Any exclusionary statements differing from those listed in section II-C of this supplement are considered "voluntary deviations" and registrants must:

submit an amendment application as described PR Notice 93-7
Supplement Two, section VII "Amending a Section 3 Registration to
Take the Product Out of Scope of the WPS" — except in the block
labeled "explanation" on EPA Form 8570-1, enter "Amendment to add
exclusionary statements to remove product from scope of WPS."

- submit with the amendment application the certification statement "Certification when deviations are proposed" that is in PR Notice 93-7 Supplement Two, section V.
- await EPA-acceptance before selling or distributing product with the revised labeling.

A. Need for Exclusionary Statements

EPA offers the following additional guidance on the need for exclusionary statements:

- Products that are primarily intended for home use do not need special exclusionary statements on their labeling to be out of scope.
- Products that are primarily intended for application in areas other than around the home or are intended for application by a professional applicator (i.e., rights-of-way, professional turf or ornamental products, and forestry products) will need special statements on their labeling to remove the product from scope, unless all WPS uses are deleted. If you answered "NO" to question B or C in the Scope Criteria (section IV) in PR Notice 93-7, but fully satisfied the tests in question E, exclusionary statements, use-deletions, or both generally will be needed to take the product out of scope.

B. Adding Pre-Approved Exclusionary Statements

- 1. Correct Use of Exclusionary Statements
- a. Exclusionary Statements for Ambiguous Use Sites

Exclusionary statements should be used when the directions for use on the current product label are ambiguous as to whether the label allows uses within the scope of PR Notice 93-7. For example, the current label contains directions for use on turf, ornamentals, seeds, and/or forests, or is vague as to the use site. Exclusionary statements are necessary and appropriate for these labels to clarify that WPS uses are not allowed.

b. Use-Deletions for Removing Explicit Use Sites

When the directions for use on the current product labeling contain explicit statements or instructions for a WPS use, exclusionary statements cannot be used by themselves to remove that product from the scope of PR Notice 93-7. You must request one or more use-deletions (possibly along with the addition of one or more exclusionary statements) to remove the product from the scope of PR Notice 93-7. You must not add exclusionary statements to a label where they directly contradict explicit use directions contained elsewhere on the product labeling. Examples of explicit use directions that must be deleted to take a product out of the scope of PR Notice 93-7 include:

- Directions for use on "sod farms," in "sod production" for "turfgrass research," or on "turf grown for seed."
- Directions for use in "commercial" nurseries or greenhouses, for "commercial" production of ornamentals, on "ornamentals grown for sale," or on "ornamentals grown for seed."
- Directions for use in "commercial" forests, on "trees grown for timber," on "trees grown to produce seed," or on "trees grown for research."
- Directions for use as a seed treatment "at planting," in "hopper boxes," "planter boxes," or "slurry boxes," in "tractor-mounted treaters," or "just before planting."

Procedure for Adding Pre-Approved Exclusionary Statements

Use the following procedure to add pre-approved exclusionary statements to a product label.

- a. Registrant Procedure:
- Unless otherwise directed below, use the exact language of the appropriate exclusionary statement(s).
- Place the statement(s) (1) on the front panel of the label in association with the product name or (2) near the beginning of the Directions For Use section.

- Follow the instructions in section VII, "Amending a Section 3
 Registration to Take the Product Out of Scope of the WPS," of
 Supplement Two in PR Notice 93-7, except in Section II of EPA Form
 8570-1, in the block labeled "explanation," enter "Adding pre-approved
 exclusionary statement to remove product from scope of PR Notice
 93-7."
- Highlight the exclusionary statements on the proposed labeling that you submit to the Agency for review.
- Sign and include with the complete application the statement in section V of Supplement Two in PR Notice 93-7 titled "Certification when deviations are proposed:"

b. EPA Process

EPA will process the amendment application as described in section VII of Supplement Two in PR Notice 93-7: "Amending a Section 3 Registration to Take the Product Out of Scope of the WPS."

- 3. How can exclusionary statements be added to product labeling?
- a. Printed on labeling

The exclusionary statements be may printed on the labeling.

b. Sticker on labeling

The exclusionary statements may be permanently affixed to the product container through the use of a sticker. The sticker must meet the following conditions:

- Prominence must be legible and prominent on product package through use of contrasting colors or other graphic devices, and placement on the label of each product.
- Location must be printed or affixed onto product package. Must be difficult to remove without residue or damage to underlying packaging or labeling and must not be located on the bottom or any other place that will not readily be noticed by users. If the product bears labeling on both outer packaging and immediate container, the sticker must be

affixed to both. (Exception: Inner water soluble packages need not be modified under this labeling approach.)

- Existing Language Not Obscured must not obscure any existing language on the existing labeling.
- Required Text must use the exact text of the pre-approved exclusionary statements.
- When Applied must be applied before sale or distribution to end user, except for stickering by end users as provided in supplement E of this notice.
- Location Sticker Applied may be applied at the locations described in supplement E of this notice, provided all of the conditions listed for each location are met.

c. Interim labeling

The registrant may choose to add the exclusionary statements through the use of the interim labeling option described in Supplement D of this notice.

C. Pre-Approved Exclusionary Statements

EPA has pre-approved the following statements for registrants to use to remove products from the scope of PR Notice 93-7. Choose the statement(s) listed below that will exclude your product from the scope of PR Notice 93-7.

If your product is labeled for use on turf, add the statement:

"Not for use on turf being grown for sale or other commercial use as sod, or for commercial seed production, or for research purposes."

(Note: use the statement directly below if your product includes ornamentals as well as turf uses)

If your product is labeled for use on ornamentals or ornamentals and turf, add the statements:

"Not for use on plants being grown for sale or other commercial use, or for commercial seed production, or for research purposes. For use on plants intended for aesthetic purposes or climatic modification and being grown in interior plantscapes, ornamental gardens or parks, or on golf courses or lawns and grounds."

Note: if one or more of the sites in the second sentence — "interior plantscapes," "ornamental gardens or parks," "golf courses," or "lawns or grounds" — is not appropriate for your product, it need not be listed.

If your product is labeled for use on forests, add the statement:

"Not for use on trees being grown for sale or other commercial use, or for commercial seed production, or for the production of timber or wood products, or for research purposes."

If your product is intended for use on rangeland, rights-of-way, or other non-crop areas, add the statements:

"For use on plants in non-crop and non-timber areas only. Not for use on crops, timber, or other plants being grown for sale or other commercial use, or for commercial seed production, or for research purposes."

If your product is intended for use for seed treatment, add the statements:

"Not for use on agricultural establishments in hopper-box, planter-box, slurry-box, or other seed-treatment applications at or immediately before planting."

If none of these statements will completely remove the product from the scope of PR Notice 93-7, follow the instructions for filing for a use-deletion in Section VII in Supplement Two of PR Notice 93-7 or call the WPS Label Information Line (1-800-777-2185) for assistance.

SUPPLEMENT -G-

WPS STATEMENTS ON SUBLABELS WITH NO IN-SCOPE USES

Some registrants do not include on each product label all the product's registered uses. In addition, some registrants use (with notification to EPA) distributors to market their product and produce for such persons supplementally registered "distributor" labels that do not include use-directions for all the product's registered uses.

"SUBLABEL" is the term used in this supplement to mean:

- a registrant's product label that includes only a subset of the usedirections on the registrant's in-scope "master label" and/or
- a supplementally registered "distributor" label that includes only a subset of the use-directions on the basic registrant's in-scope "master label."

EPA offers below additional guidance on:

- determining whether a sublabel bears directions for any use within the scope of PRN 93-7, and
- which statements placed on the "master" labeling through compliance with PR Notice 93-7 must also be placed on sublabels that bear no inscope uses.

IMPORTANT: If you, as the basic registrant of a product within the scope of WPS, permit distributors to market products labeled for subsets of the registered uses of that product, you are responsible for ensuring that the distributor label complies with these requirements.

I. SCOPE CRITERIA FOR SUBLABELS

To determine whether any of your sublabels contain NO uses within the scope of PR Notice 93-7, use the Scope Criteria in section IV of PR Notice 93-7. If your product fails to meet one or more of the three tests in Question E ("primarily intended for home use") of the Scope Criteria tests, EPA provides the following additional guidance regarding scope criteria.

If the sublabel meets all the tests in question E except that it bears directions for tankmixing with fertilizer or other pesticides, OR it contains the word "crop" in the Directions for Use, OR it contains directions for use of a surfactant, buffer, or adjuvant without using the words "surfactant," "buffer," or "adjuvant," STOP! This sublabel is NOT within the scope of PR Notice 93-7. If the "master" labeling for this sublabel bears WPS statements to comply with PR Notice 93-7, follow the instructions in section III of this supplement for the WPS statements that must be added to this sublabel.

II. ADDING EXCLUSIONARY STATEMENTS TO REMOVE SUBLABELS FROM SCOPE OF PRN 93-7

If the registrant determines that a sublabel contains uses within the scope of PR Notice 93-7, the registrant may add to that label one or more of the pre-approved exclusionary statements described in supplement F of this notice if the addition of such statements would take the label out of scope. For guidance about the correct use of exclusionary statements, see Supplement F, section II-B-1 "Correct Use of Exclusionary Statements." The exclusionary statements must be added to the sublabel as follows:

- Unless otherwise directed in the directions with the exclusionary statements, use the exact language of the appropriate exclusionary statement(s) as specified in Exclusionary Statements."
- Place the statement(s) (1) on the front panel of the sublabel in association with the product name or (2) near the beginning of the Directions For Use section on the sublabel.

III. WPS STATEMENTS THAT MUST BE PLACED ON SUBLABELS WITH NO IN-SCOPE USES

Registrants may eliminate the "Agricultural Use Requirements" box and any optional statements appearing on the complete "master" labeling that allow reduced

PPE when closed systems, enclosed cabs, or aircraft are used, from any sublabel that contains NO uses within the scope of PR Notice 93-7, provided all precautionary statements on the "master" labeling are also contained on the sublabel, including WPS statements placed on the "master" labeling to comply with PR Notice 93-7. Such statements and precautions include:

- personal protective equipment requirements (in the circumstance that the "master" labeling distinguishes between WPS and nonWPS PPE requirements, the WPS PPE requirements may be dropped)
- user safety recommendations,
- statements that require the use of closed systems, enclosed cabs, or aircraft in a manner that meets the requirements of the WPS,
- Spanish language signal word and statement for products with signal word "Danger" or "Warning,"
- statements: "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application" (unless these statements are inside the Agricultural-Use Requirements box on the complete "master" labeling),
- State and Tribal referral statement, and
- identification, as applicable, of organophosphates, n-methyl carbamates and fumigants.

IMPORTANT: If placing any of the above required statements on a sublabel would result in labeling directions that you believe to be nonsensical or underprotective, call the WPS Label Information Line (1-800-777-2185) to express your concern and request further guidance.

IV. TIMING OF LABELING CHANGES FOR PARTIAL-USE LABELS

The labeling changes for sublabels with no uses within the scope of PR Notice 93-7 must be made at the next label printing.