

## 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.

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#### 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.

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#### FOR FURTHER INFORMATION AND ASSISTANCE ٧.

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