

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

March 24, 1993

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Pesticide Regulation (PR) NOTICE 93-5

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

ATTENTION:

Persons Responsible for Federal Registration of

Pesticide Products

SUBJECT:

LABELING REQUIREMENTS OF THE CLEAN AIR ACT

This notice alerts pesticide registrants to a recently issued rule under the Clean Air Act (CAA) requiring a warning statement on products (including pesticide products) manufactured with or containing Class I ozone depleting substances, including chlorofluorocarbons (CFCs), methyl chloroform and carbon tetrachloride. Products containing Class II hydrochlorofluorocarbons (HCFCs) and methyl bromide are not required to bear the statement at this time.

Because alternative placement options are provided, the warning statement is not necessarily required to appear on the pesticide label or labeling itself, but it must be available at the point of purchase. Pesticide registrants may place it on the label or labeling in accordance with this notice.

NO SUBMISSION TO THE AGENCY UNDER FIFRA IS REQUIRED. Registrants may add the warning statement without amendment of registration or notification.

All products produced after May 15, 1993, must display the warning statement. Products produced before May 15 are not subject to the requirement.

The labeling rule contains a number of exceptions that are not product-specific. Registrants should familiarize themselves with the rule before deciding whether and how they must add the warning statement. Refer to Unit III.

EPA expects to issue additional PR Notices as needed to keep registrants informed of new events under the CAA that may require action under FIFRA. PR Notice 93-4, issued concurrently with

this notice, contains information on the ban of certain products under the Clean Air Act.

I. BACKGROUND

On March 19, 1992, EPA issued PR Notice 92-3, which described provisions under Title VI of the Clean Air Act for the protection of stratospheric ozone. That notice discussed major provisions of the Clean Air Act that may affect pesticide products, including the required addition of a label warning statement (see Unit V of PR Notice 92-3).

Briefly, CAA sec. 611 requires that products manufactured with or containing Class I and Class II ozone depleting substances display a warning statement to alert purchasers that it contains a substance that may harm the ozone layer. The purpose of the warning is to allow purchasers an informed choice, so that they may select a product that does not contain an ozone-depleting substance if desired. This action will complement the phaseout of ozone depleting substances scheduled to occur by the end of 1995.

On February 11, 1993, EPA issued a final rule (58 FR 8136) setting out the warning statement requirements under the Clean Air Act. A copy of the rule is appended to this notice.

III. APPLICABILITY OF THE WARNING STATEMENT

- A. Products containing CFCs and methyl chloroform. The rule requires a warning statement for all products containing or manufactured with a Class I ozone-depleting substance (ODS), including those CFC aerosol and pressurized products that will be banned in January 1994 (refer to PR Notice 93-4). More than 850 pesticide products contain CFCs or methyl chloroform.
- B. Products containing HCFCs. The rule applies to products containing or manufactured with HCFCs, but does not become effective for such products until 2015. Fewer than 100 pesticide products contain HCFCs.
- C. Carbon tetrachloride. The rule applies to products containing or manufactured with carbon tetrachloride. No currently registered products contain carbon tetrachloride. Some technical grade active ingredients (TGAIs) are manufactured with carbon tetrachloride (but refer to Unit III.A. for an exception which may apply).
- D. Methyl bromide. Methyl bromide is NOT required to be labeled at this time. When methyl bromide is listed as a Class I ODS, the warning statement will be required no later than one year after listing. EPA has proposed to list methyl bromide; registrants of methyl bromide products are advised to familiarize

themselves with the warning statement requirements. Products treated with methyl bromide would not be required to be labeled.

E. Packaging. If you manufacture your own packaging for the pesticide product and use an ODS in its manufacture, you must label the packaged pesticide product, even if the pesticide formulation does not contain an ODS. If you purchase packaging from another source, you are not required to "pass through" any ODS warning statement on the packaging material.

III. KEY EXCEPTIONS

The labeling rule contains a number of exceptions, some of which are product-specific and others of which depend upon broader criteria. Moreover, a petition process has been established in the Office of Air Programs for those seeking a temporary exemption from the requirement. Registrants should read the rule carefully to determine if any of these exceptions apply to their products. Some of the key exceptions that may apply to pesticide products are as follows:

- A. Trace quantities of ODS (such as impurities or unreacted feedstock chemicals) may remain after transforming the ODS into another product without triggering the warning statement requirement. Thus pesticide technical grade active ingredients (TGAIs) which are produced using an ODS which is transformed (except for trace amounts as an impurity) are not required to bear the warning statement.
- B. Export. Products produced solely for export are not required to bear the warning statement, provided they are clearly identifiable as intended for export only. Such identification does not have to be a label statement on the product itself, but may be on warehouse or shipping records that identify the product's export status.
- C. Usage reduction. A limited exception is provided for products containing methyl chloroform or CFC-113, where the registrant can demonstrate and certify a 95% reduction in overall usage (based on 1990 usage) for the year preceding the certification. A registrant wishing to avail himself of this exception should carefully read the rule for specific procedures. Refer to ^U 82.122 of the rule in the Appendix.
- D. Research and development products which have not been introduced into commerce are not required to bear the warning statement. Products distributed under a FIFRA experimental use permit must bear the warning statement because such products have been introduced into interstate commerce.

A. What is Required. The following warning statement is required:

WARNING: Contains (or, Manufactured with) [name of substance],

a substance which harms public health and environment by destroying ozone in the upper atmosphere.

- B. Points to Note for Pesticide Registrants
- 1. The wording must be used exactly, including the word WARNING (in all caps), regardless of the signal word of your pesticide product. Do NOT change the signal word to correspond to that of your product.
- 2. Pesticide products will likely "contain" rather than be "manufactured with" the ODS, unless the warning statement refers to packaging material manufactured by the registrant using an ODS, as noted in Unit II.E. of this notice.
- 3. Insert the name of the Class I substance in the blank. Use "CFC-xxx" or "methyl chloroform" as appropriate. If more than one, list all Class I substances.

V. WARNING STATEMENT PLACEMENT

- A. Placement options. The rule provides several alternative placements for the warning statement. The basic rule of thumb in determining acceptable placement is that the statement should be "clearly legible and conspicuous" to consumers purchasing the product at the time of purchase. With this guiding principle in mind, the following are acceptable placements for the statement:
 - 1. Any panel of the immediate container, or the outer container, whichever will be seen by the consumer at the time of purchase. The statement is required on only one of these. It may appear on the front panel of the label or another panel that will be seen by the consumer, such as the back or side panel. A warning statement on a shipping container does not comply if that is not the container that will be viewed by the consumer.
 - 2. Supplemental labeling that is securely attached to the container or which accompanies the product through sale and distribution to the consumer, and that is visible to the consumer at the time of purchase. Hang tags, stickers, cards, brochures, leaflets, etc., are acceptable for this purpose. Supplemental labeling that is not visible to the consumer (such as package inserts containing Use Directions) does not comply.
 - Printed material available at the point of purchase.

The registrant may provide the warning statement separately to be displayed at the point of purchase, by shelf stickers, cards or leaflets that are available to the consumer at the time of purchase.

- B. Advertising, catalogues, and other promotional material that does not accompany the product must bear the statement when the product itself is not normally viewed by the consumer at the time of sale. In this case, the statement is not required on the product itself.
- C. Placement on pesticide labeling. Pesticide registrants who choose to place the statement on the label or labeling regulated under FIFRA (V.A.1. or 2. above) must ensure that it does not obscure, detract from or interfere with labeling statements required under FIFRA. For this purpose:
 - 1. If the statement is on the front panel, it should NOT appear at the top center in the area where a Restricted Use Statement is or would be located.
 - 2. If on the front panel, it should NOT precede the front panel signal word/practical treatment statements.
 - 3. The statement should NOT be part of the Precautionary Statements section of the label unless it is separated and clearly distinguishable from the Hazards to Humans, Environmental Hazards and Physical/Chemical Hazards statements. It may appear as a separate statement within the Precautionary Statements.
 - 4. Suggested (but not required) locations for purposes of FIFRA labeling are:
 - "The bottom of the front panel (after the front panel hazard/practical treatment statements). In no case should the statement precede human hazard warnings or assume such prominence that it detracts from such warnings.
 - °At the end of the side/back panel Precautionary Statements, after the Physical/Chemical Hazards section.
 - °At the end of a Directions for Use section on a side or back panel (but not if the Directions for Use appear only in supplemental labeling that is not visible to the consumer at the time of purchase).
 - As a substatement to the ingredients statement, if the ingredients statement does not appear on the front panel.

VI. FORMAT OF STATEMENT

The rule establishes similar requirements for format of the statement as are required under FIFRA, including the following:

- A. Conspicuousness and contrast requirements.
- B. Blocking of the statement with borders or white space.
- C. Parallel placement with surrounding text.
- D. Type size requirements for both the word WARNING and the text that depend upon the area of the display panel.

Pesticide registrants should note that the minimum type sizes for this statement are smaller than those required under FIFRA for the same size display panel. Consequently, the statement will generally be smaller than the rest of the pesticide label text.

Approximate equivalents to pesticide requirements are given in the table below. If the CAA signal word and text are at least the point sizes given, they will comply with the CAA requirement (1 pt = 1/72 inch). Larger type sizes equivalent to those used on your product for the FIFRA signal word and Child Hazard Warning will always comply with the CAA requirement.

Display Panel ar	rea (in2)	WARNING	Text
0 - 2		4	4
2 - 5	100	5	4
5 - 10		7	5
10 - 15		8	7
15 - 30		9	7
Greater than 30		12	8

VI. WHAT REGISTRANTS SHOULD DO

- A. Determine whether you need to comply. Determine which of your products are subject to the warning statement requirements because they are manufactured with or contain an ODS (CFC, methyl chloroform, or carbon tetrachloride).
 - 1. A TGAI producer who uses an ODS in the manufacturing process which is entirely consumed or transformed except for trace amounts generally is not subject to the warning requirement for that product. The Agency is aware that a number of TGAI products are produced using carbon tetrachloride as a feedstock chemical. These TGAIs may meet this criterion, and would not be required to bear the statement when sold or distributed.
 - 2. If, however, that producer further formulates the TGAI

into a Manufacturing Use Product (MUP), Formulation Intermediate (FI) or an End Use Product (EP) by adding an ODS as an inert ingredient, the product must bear a "contains" warning statement when sold or distributed.

3. A formulator who purchases a product (TGAI, FI, EP or inert ingredient) may rely on the information provided (or not provided) in determining whether his formulated product produced from those ingredients must display the warning statement. In general:

"If any purchased product bears a "contains" statement, the formulated product must also bear a "contains" statement.

'If a purchased product bears a "manufactured with" statement, the formulated product is not required to bear a "manufactured with" statement. [Formulators are not required to pass through "manufactured with" statements.]

- B. Determine which method of compliance you will use. For each product that is subject, determine which means of providing the required warning statement (refer to options in Unit V) you will use.
- C. Comply by May 15, 1993. Ensure that all products produced on or after May 15, 1993, display the warning statement, either on labeling or by other means that comply. Maintain sufficient records to verify the date of production.
- D. Do not submit anything to the Registration Division. No submission of amendment, notification, or labeling to the Office of Pesticide Programs is required. The Clean Air Act prohibits an approval process for the addition of the warning statement. This PR Notice provides guidance for addition of the statement to FIFRA labeling to avoid obscuring, detracting from or interfering with required FIFRA labeling.
- E. Optional petition process. The Agency has established a petition process by which registrants or others may seek to extend the labeling requirement to additional products or temporarily exempt a product from the warning requirement. This procedure is set out in ^U 82.120 of the rule. The basis for an exemption petition is a lack of currently or potentially available alternatives. Note that submission of a petition does not extend the compliance date beyond May 15, 1993: products must bear the warning statement while the Agency evaluates the petition.

The petition process is under the Clean Air Act, not FIFRA. A submission address is given in ^U 82.120.

VII. INTERIM LABELING OF BANNED CFC AEROSOL PRODUCTS

In a companion action under the Clean Air Act, EPA has banned the sale or distribution of aerosol and pressurized products containing CFCs, effective January 17, 1994. These products are required to comply with the requirement for a warning statement for products produced after May 15, 1993. PR Notice 93-4, issued concurrently with this notice, explains the ban in detail.

Registrants of these products may avoid the labeling requirement by ceasing production of these products prior to May 15, 1993.

VIII. ENFORCEMENT

It is the Agency's policy to take no enforcement action for matters occurring during the first nine months following publication (until November 11, 1993). Such enforcement discretion recognizes the short time frame allotted for compliance (May 15, 1993), which the Agency cannot extend, and the complexity in implementing the requirement for a large number of products.

ENFORCEMENT DISCRETION APPLIES ONLY TO THE CLEAN AIR ACT WARNING STATEMENT REQUIREMENTS, AND DOES NOT AFFECT ENFORCEMENT OF LABELING REQUIREMENTS UNDER FIFRA.

IX. FOR FURTHER INFORMATION

Further information on this notice may be obtained from Jean Frane, Policy and Special Projects Staff, OPP, at 703-305-5944. Please do not call Product Managers in the Registration Division.

More detailed information on Clean Air Act requirements in general, and specific provisions of the rule such as the petition process may be obtained from the Stratospheric Ozone Hotline, at 1-800-296-1996.

Douglas D. Campt Director Office of Pesticide Programs

Appendix: 40 CFR 82 rule text [not included]