



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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SEP 30 1981

PR Notice 81-4

NOTICE TO PRODUCERS, REGISTRANTS AND FORMULATORS

Attention: Persons Responsible for Federal Registration of Pesticides

Subject: Label Improvement Program: Label Revisions to Accommodate
New AOAC Methods of Chemical Analysis

This Notice describes procedures that will be used to ensure that pesticides label ingredients statements reflect percentages of ingredients determined by the most specific chemical analytical techniques approved by the Association of Official Analytical Chemists (AOAC). These procedures potentially affect all registrants since AOAC methods for a wide range of chemicals are continually being reviewed and modified. This Notice is a statement of policy. NO SPECIFIC ACTION IS REQUIRED UNTIL REGISTRANTS ARE NOTIFIED INDIVIDUALLY.

I. BACKGROUND

All pesticide products are required to bear a label ingredients statement, including the identification and percentage of each active ingredient and the total percentage of inert ingredients. Methods for pesticide chemical analysis are refined and standardized by the AOAC on a continuing basis. Consequently, pesticide labels that are revised infrequently do not always reflect analyses by the most definitive AOAC methodology. This situation can lead to difficulties in pesticide enforcement, in label consistency, and in coordination between state and Federal programs.

Certain older methods of analysis (such as the total chlorine and acid methods) determine the amount of label-declared active ingredients as including any related compounds that are not separately identified in the ingredients statement. Newer, more specific AOAC methods (such as high pressure liquid chromatography) are more discriminating and are able to distinguish between the intended active component and the related compounds that were previously indistinguishable. Use of more specific methods of analysis for enforcement purposes without modifying label ingredients statements would indicate that the active ingredient content is less than the current label declaration. The product therefore would appear deficient and might be subject to the misbranding provisions of FIFRA. Several states in their pesticide enforcement programs have already set deadlines for product/labeling compliance using newly approved AOAC methodology.

The purpose of this notice is to delineate a uniform policy and procedure for resolution of these problems.

II. APPROACH

The Agency is clearly in favor of greater accuracy in definition and declaration of pesticide ingredients. When AOAC methods are changed the Agency must consider either requiring the registrant to change pesticide labeling and confidential statements of formula or allowing changes in the chemical composition of the pesticide itself. The Agency considers unacceptable the "spiking" or overformulation of the formulated product with additional active ingredient solely to compensate for apparent deficiencies resulting from new analytical techniques. Moreover, such an approach could significantly increase Agency review time by triggering evaluations for potential increased hazard to the environment unless label dosage rates were proportionally decreased.

For some chemicals, new methods do not exist or new methods of analysis will continue to evolve. In order to deal with this changing situation, a flexible regulatory approach is needed. Such an approach must accommodate this evolutionary process while supporting enforcement activities and resulting in minimum impact on the environment, on the regulatory review process, on pesticide use patterns and on registrants.

Samples collected by Federal inspectors pursuant to FIFRA or by State inspectors under the Pesticide Enforcement Grant Program are analyzed by official methods when such methods exist. As new methods are developed and evaluated, these may become official AOAC methods replacing the old methods. Superseded methods are no longer considered official. If old and new methods give the same results, both methods maintain official status and either may be used in the analysis of potentially violative samples. In other situations where the official AOAC analytical method represents improved definition of ingredients

and creates discrepancies between analytical results and existing label ingredients statements, the Agency will issue notifications to registrants to accommodate the new official AOAC method.

The Agency's approach entails an appropriately timed revision of label ingredients statements and revision of confidential statements of formula to reflect the minimum percentage of each active component as determined by newly accepted AOAC methods of chemical analysis and, as appropriate, the inclusion of related compounds in the inert ingredients.

III. POLICY

A. For purposes of this notice the term "label ingredients statement" includes not only the percentages of active and inert ingredient(s), but also, if applicable, associated acid or metallic equivalents and quantity of active ingredient(s) per volume of liquid formulation.

B. Related compounds no longer indistinguishable from the intended active ingredient(s) due to newer, more discriminating methods of analysis must be accounted for within the pesticide label ingredients statement. The active or inert status of each ingredient including these related compounds is determined according to 40 CFR 162.6(b)(2)(i)(C)(2). Such determination is the responsibility of the registrant. If one or more related compounds is isolated and found to be active, it must be specifically identified and quantified by percentage under the active ingredient heading of the label ingredients statement. Those related compounds whose active/inert status is not determined by the registrant must be included (without designation as related compounds or by name) within the total percentage of inerts in the label ingredients statement.

C. Unless declared as active ingredients, related compounds will not be included in expressing percent acid or metallic equivalents, nor in the declaration of pounds active ingredient or acid equivalent per gallon in the label ingredients statement.

D. On the other hand, references to weight of active ingredient per volume of liquid and references to percent of active ingredient found in the product name, such as 4L, 3AS, 80W, or 10G, need not be changed as a result of altering the method of analysis.

E. Confidential statements of formula must indicate the appropriate AOAC method number for each active component affected by this notice. Since the method numbers are periodically revised by the AOAC, the AOAC manual edition must be specified. Methods of analysis will not be considered confidential.

IV. PROCEDURES

Procedures established for the Label Improvement Program (45 FR 37884, June 5, 1980) will be followed, with the following modifications:

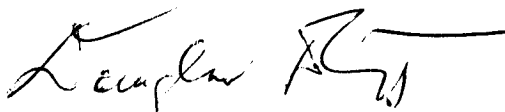
A. A Confidential Statement of Formula (EPA Form 8570-4) will be required for each product, and will be reviewed for compliance with Section III.E. of this Notice. This Notice does not negate any previous requirements relative to Confidential Statements of Formula.

B. Applications will be considered non-compensable, i.e., not subject to the provisions of FIFRA 3(c)(1)(D), provided no changes are made other than those required by this Notice. Therefore, no Offer to Pay or Certification Statements will be required to be submitted.

C. Because of the nature of the revisions resulting from analytical method changes, and in order to ensure that formulators and repackagers can reference Agency-accepted Confidential Statements of Formula, basic pesticide producers will be required to comply before formulators and repackagers of end-use products. Phased notification will allow producers to advise their formulators of Agency-accepted labeling and should provide a more orderly and efficient processing of information within the Agency.

REGISTRANTS OF AFFECTED PRODUCTS WILL BE NOTIFIED WHEN TO SUBMIT APPLICATIONS. THIS NOTICE DOES NOT REQUIRE ACTION BY REGISTRANTS UNTIL NOTIFIED. However, we encourage early submission of amended applications whenever registrants become aware of new AOAC official methods. A more rapid review can be done if applications are submitted on a phased basis by registrants rather than awaiting a notice requiring specific compliance times.

Questions concerning the policies or procedures in this Notice may be directed to Dr. Thomas Ellwanger, by telephone (703) 557-1650.



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