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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

January 2, 1992

PR NOTICE 92-1

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

ATTENTION: Persons responsible for Federal registration of pesticides

SUBJECT: Requirement to submit and identify adverse effects information

I. PURPOSE

The purpose of this notice is to clarify the Office of Pesticide Program's (OPP's) policy with regard to submission and identification of adverse effects information under Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 6(a)(2). The notice advises registrants of their obligation to submit adverse effects data, pursuant to FIFRA Section 6(a)(2), and clearly identify it as 6(a)(2) data, pursuant to 40 Code of Federal Regulations (CFR) 152.125. Registrants are also advised that studies for certain toxicology guidelines with potential adverse effects flagged under 40 CFR 158.34 are considered to be Section 6(a)(2) information, and are subject to this notice. The notice informs registrants of EPA's intention to enforce aggressively the Section 6(a)(2) submission obligation and the 40 CFR 152.125 identification requirement. The notice also advises registrants of a proposed rule on Section 6(a)(2) implementation that will be published soon. Finally, the notice describes EPA's improved tracking procedures for handling Section 6(a)(2) information.

II. APPLICABILITY

This notice applies to all current and former registrants of pesticide products, and to applicants for amended registrations or registration of new products. Although Section 6(a)(2) does not directly address applicants, 40 CFR 152.50(f)(3) requires

applicants for registration to submit with their applications any factual information regarding unreasonable adverse effects of the pesticide that would be required to be submitted by registrants under Section 6(a)(2) if the product were registered.

III. REQUIREMENTS

As discussed more fully in Section IV, FIFRA Section 6(a)(2) requires registrants and applicants to inform the Agency of any new, factual information on adverse effects of their pesticides. This notice explains how registrants must comply with the 40 CFR 152.125 requirement to identify clearly all submissions under Section 6(a)(2). Section 152.125 reads as follows:

> If at any time the registrant receives or becomes aware of any factual information regarding unreasonable adverse effects of the pesticide on the environment that has not previously been submitted to the Agency, he shall, in accordance with FIFRA sec. 6(a)(2) and subpart D of part 153 of this chapter, provide such information to the Agency, clearly identified as FIFRA 6(a)(2) data.

At a minimum, registrants must satisfy this requirement by highlighting the submission under Section 6(a)(2) in the transmittal letter accompanying the data submission, and submitting the data to one of the following addresses:

Via the U.S. Postal Service:

Document Processing Desk -- 6(a)(2)
Office of Pesticide Programs - H7504C
U.S. Environmental Protection Agency
401 M Street SW
Washington, D.C. 20460-0001

Via Personal or Courier Delivery:

Office of Pesticide Programs
Document Processing Desk -- 6(a)(2)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Section 6(a)(2) submissions should be limited to Section 6(a)(2) information, and not mixed with data that is not submitted under Section 6(a)(2). The cover letter should note if the Section 6(a)(2) submission is in response to any Agency request (e.g., a Data Call-In, or DCI), in addition to being a Section 6(a)(2) submission.

If the Section 6(a)(2) submission relates to a larger package of related information (e.g. response to a DCI), the transmittal letter for the larger package should reference the Section

6(a)(2) information submitted under separate cover.

Toxicology studies flagged under 40 CFR 158.34 are considered to be Section 6(a)(2) information and must be submitted as described above. The above requirements are in addition to the flagging requirements specified in 40 CFR 158.34.

In order to encourage prompt reporting of adverse effects information, Section 6(a)(2) data submissions will not be rejected for failure to conform with 40 CFR 158.32 and PR Notice 86-5, which specify formatting requirements for all data submissions. However, these requirements must be met before the submission will be accepted as a response to other program requirements (e.g. as a valid response to a DCI).

Any claims of confidentiality for Section 6(a)(2) submissions must be made at the time of submission, by the procedure and under the authorities defined at 40 CFR 158.33. No other opportunity will be provided to assert claims of confidentiality, and if no claims are asserted at the time of submission the information may be publicly released by the Agency without further notice to the submitter. The Agency further defines all 6(a)(2) submissions as "health and safety data" subject to the automatic presumption of releasability under FIFRA Section 10(d)(1), except to the extent they are among the exceptions to this presumption identified in Sections 10(d)(1)(A),(B), or (C).

Registrant compliance with this guidance will ensure compliance with the Section 152.125 requirement to identify clearly all Section 6(a)(2) submissions.

IV. BACKGROUND

This section provides background on the Section 6(a)(2) submission and identification requirements.

A. What the Act Requires. Section 6(a)(2) of FIFRA contains the following requirement:

> If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator.

EPA interprets this broadly worded requirement to cover a wide range of information. For example, it may include interim test results, raw test data, and other information from on-going, full, or incomplete studies, as well as incident reports.

B. Previous EPA policy statements describing information to be submitted. EPA has issued the following interpretive policy statements on Section 6(a)(2). The purpose of each policy statement is briefly stated; registrants should refer to the actual statements to determine the applicability of Section 6(a)(2) requirements to particular situations.

(1) 1978 Interpretive Statement (FEDERAL REGISTER, VOL. 43, No. 164, August 23, 1978, pages 37610 to 37615). The Agency issued an interpretive statement in 1978 to express more clearly its view of the scope of the 6(a)(2) requirements. The 1978 statement set forth in detail the Agency's view that registrants are required to submit to EPA information on their pesticides when: (1) the information, if true, would be relevant to any EPA decision on risks and benefits of the pesticide, and (2) the information had not previously been submitted to EPA.

(2) 1979 Enforcement Policy (FEDERAL REGISTER, VOL. 44, No. 135, July 12, 1979, pages 40716 to 40723). In a further effort to interpret 6(a)(2) and give guidance to registrants on how to comply, EPA issued a statement of Enforcement Policy in 1979. The policy reaffirmed the very broad interpretation of 6(a)(2) and described specific types of incomplete and completed studies and incident information that were covered by the 6(a)(2) reporting requirement. The policy described a number of circumstances in which the Agency would not seek or recommend civil or criminal penalties against pesticide registrants who fail to report information concerning the risks or benefits of their registered products, despite the fact that reporting is required according to the Agency's interpretation of Section 6(a)(2). This policy constituted EPA's first statement regarding particular types of potential adverse effects information which were not needed by EPA in order to properly discharge its statutory responsibility under FIFRA.

(3) 1985 Interpretive Rule (40 CFR 153 Subpart D). In 1985, EPA combined its statements on the interpretation and enforcement of Section 6(a)(2) and codified them at 40 CFR Part 153 Subpart D. The 1985 rule largely incorporated the 1978 Interpretive Statement and 1979 Enforcement Policy. However, it was not made effective by the Agency. It has remained in 40 CFR as general guidance on Section 6(a)(2) policy.

C. Agency Policy Statements concerning identification of Section 6(a)(2) information. While the policy statements described in the previous section defined the obligation of registrants to submit new data showing potential adverse effects, they did not impose any requirement to identify clearly the submissions as falling under 6(a)(2). The requirement to identify adverse effects information was first addressed in 1988, as described in the following sections. Again, registrants should refer to the actual statements in determining the applicability of Section

6(a)(2) requirements.

(1) 1988 Flagging Criteria for Certain Toxicology Studies (40 CFR 158.34). In 1988, EPA promulgated a final rule which requires flagging of certain toxicology studies meeting specific criteria (40 CFR 158.34). This rule requires applicants seeking new or amended registrations, or registrants responding to data call-ins, to flag certain toxicology studies that show statistically significant potential adverse effects. As stated previously, submissions that are flagged under 40 CFR 158.34 are considered Section 6(a)(2) submissions and must adhere to the procedures in this notice.

(2) 1988 Identification Requirement for Section 6(a)(2) Submissions (40 CFR 152.125). At the same time the flagging criteria were promulgated, EPA promulgated an additional regulation that contained a requirement to identify clearly Section 6(a)(2) submissions (40 CFR 152.125). The provision was quoted and explained previously in Section III of this notice.

D. Planned Proposed Rule on Section 6(a)(2). A proposed rule will soon be issued that will modify and formally codify the 1985 rule. When promulgated in final form, this will provide registrants with codified guidance as to their obligations under the law. The proposed regulation would require clear identification of information as a 6(a)(2) submission and would require submission to a specified address. All subsequent studies or incident reports that are submitted and are related to an original 6(a)(2) submission would also have to be identified as 6(a)(2) submissions. Once this proposed rule is issued, EPA will move quickly to address comments and promulgate a final rule. Registrants are encouraged to use the proposed rule as a comprehensive guide to Section 6(a)(2) requirements.

V. AGENCY ACTION

The Agency is implementing improved procedures for processing, reviewing and making decisions on Section 6(a)(2) information to ensure these submissions are handled properly and promptly. The revised procedures for studies identified as 6(a)(2), or otherwise identified as data related to adverse effects, may require review of the full studies on an expedited schedule. The revised procedures cover both studies and incident reports.

Coordinating the review and regulatory decisions for Section 6(a)(2) submissions is the responsibility of a special team of scientific reviewers and program managers. The special team oversees the handling of all 6(a)(2) and 40 CFR 158.34 flagged data, and it has the following principal functions:

(1) expedited screening of all potential adverse effects

study submissions to determine what priority the full science review should be given;

(2) screening reports of incidents to decide whether an immediate full science review is warranted;

(3) determining when a series of reported incidents constitutes a significant trend that may warrant science review and regulatory action;

(4) overseeing the timeliness of science reviews, and the timeliness, consistency, and appropriateness of follow-up regulatory actions; and

(5) tracking the status of all potential adverse effects data from date of submission to the Agency to final disposition, and providing regular reports on the status of adverse effects submissions to senior managers.

The intent of these procedures is to ensure thorough and timely consideration of all potential adverse effects data, and enforcement action when necessary.

VI. EFFECTIVE DATE

This notice is effective immediately because it clarifies and reiterates existing requirements to submit and identify Section 6(a)(2) information. Registrants must follow the guidelines in this notice for clearly identifying information submitted under Section 6(a)(2).

VII. FOR FURTHER INFORMATION

Registrants may contact Kennan Garvey for information or questions concerning this notice on (703) 305-7102.

Douglas D. Campt, Director
Office of Pesticide Programs
Environmental Protection Agency