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

FEB 16 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency (the "Agency") has completed its reregistration eligibility decision on the pesticide active ingredient glyphosate.

Enclosed is a Reregistration Eligibility Decision (RED) Document for the pesticide active ingredients isopropylamine salt of glyphosate and sodium salt of glyphosate, hereafter referred to as glyphosate. The RED is the Agency's evaluation of the glyphosate data base, its conclusions regarding human and environmental risks associated with the current product uses, and its decisions and conditions under which uses and products will be eligible for rereregistration. Also enclosed is the EPA RED facts and the Pesticide Reregistration Handbook which provides instructions to registrants on how to respond to any labeling and data requirements specified in the RED and how to reregister products.

The RED identifies outstanding product specific data requirements for end-use products and manufacturing-use products. These requirements are listed on the Requirements Status and Registrant's Response Form, which, along with the Data Call-In Response Form listing all of your company's products subject to the RED, is included as an Attachment. Instructions for completing both forms are contained in the RED package. All product specific data must be submitted and found acceptable by the Agency before a product can be reregistered.

Generic data requirements usually will have been fulfilled prior to making a reregistration eligibility decision. However, there may be some instances where additional generic data are required. If generic data requirements need to be fulfilled, all registrants must complete the appropriate Data Call-In Response Form and Requirements Status and Registrant's Response Form. These forms are in the appendices to the RED.

The RED identifies any specific labeling requirements such as restricted use classification, groundwater hazard statements, endangered species precautions, etc., necessary for reregistration based on a review of the generic data for the active ingredient. In addition, in order to be reregistered, all product labeling must be in compliance with format and content labeling as described in 40 CFR §156.10 and all labeling changes imposed by Pesticide Regulation (PR) Notices, and any label changes imposed by this RED.

The Pesticide Reregistration Handbook contains detailed instructions for compliance with the RED and must be followed carefully. There are several key points to remember in preparing your response to the RED:

Within 90 Days of Your Receipt of this Letter

1. For each product which is subject to this RED, you must complete, sign and submit the data call-in (DCI) response forms attached to the RED [Appendix F, Attachments B and D, has forms for product specific data]. Follow the instructions in Attachments B and D for completing those forms and submit the forms to the appropriate address specified in the Data Call-Ins. Note that the DCI forms are to be sent to the Special Review and Reregistration Division (use the mailing distribution code RED-SRRD-0178 for your generic response).

2. No time extensions will be granted for submitting the 90-day responses. If the Agency does not receive a response for a product, it may issue a Notice of Intent to Suspend (NOIS) for that product.

3. Any requests for data waivers or time extensions to the 8-month deadline must be submitted as part of your 90-day response. Such requests will generally not be considered if submitted later than the 90-day response.

Within 8 Months of the Date of this Letter

1. For each product, you must submit a completed Application for Reregistration (EPA Form 8570-1), five copies of the label and labeling revised as specified by the RED and in accordance with current requirements, two completed copies of the Confidential Statement of Formula (CSF) (EPA Form 8570-4), a completed Certification with Respect to Citation of Data (EPA Form 8570-31), and data or references to data (see item 2 below).

2. You must submit or cite the required product specific data as part of your commit-ment for reregistration. For most products, you will probably be citing data which have already been submitted to the Agency. In these cases, you must submit a list of the studies and the corresponding EPA identifier numbers (i.e., ACCESSION or MRID numbers). Before citing these studies, you must make sure that they meet the

Agency's current acceptance criteria (Appendix F, Attachment E). Be sure to follow data formatting requirements in P.R. Notice 86-5. Failure to adequately comply with the data requirements specified in this RED may result in the Notice of Intent to Suspend your product.

3. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 (Appendix D). That Notice requires that the amount of active ingredient declared in the ingredient statement must be stated as the nominal concentration rather than the lower certified limit. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e).

4. Send your Application for Registration to the Registration Division Product Manager who is assigned to the product, PM #25 Robert Taylor. Use the correct address shown on page 6 of the enclosed Product Reregistration Handbook (Appendix E). Note that the mailing distribution code for your response is RED-RD-PM25.

Questions on product specific data requirements and labeling (for both End-use and Manufacturing-use products) should be directed to the Special Review and Registration Division Planning and Reregistration Review Manager for glyphosate, Frank Rubis at (703) 308-8184. Questions on the generic data requirements should be directed to Eric Feris, the Chemical Review Manager in the Special Review and Reregistration Division at (703) 308-8048 (call via the Virginia Relay: 1-800-828-1140).

The Agency is prepared to meet with any registrants who have questions about responding to the glyphosate RED. If you wish to meet with the Agency, you must contact Eric Feris within two weeks of your receipt of the RED. The Agency intends to have one combined meeting with interested registrants. If there are any requests for such a meeting, the Agency will notify all registrants who requested a meeting of the date, location and time. Requests for a meeting will not extend the 90-day or 8-month response deadlines.

Sincerely yours,

Daniel Barolo, Director
Special Review and
Reregistration Division

Enclosures

① Enregistrement le 16.02.1994 par EPA (United States environmental protection agency.) de l'ingredient actif d'isopropylamine de glyphosate et du sel de sodium de glyphosate, tous deux se référant comme GLYPHOSATE.

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