United States
Environmental Protection
Agency

Office of Prevention, Pesticides
And Toxic Substances
(7508W)

EPA 738-R-93-014 5
September 1993

EPA

Reregistration Eligibility Decision (RED)

Glyphosate

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.

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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 <u>**nominal concentration**</u> 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,

Peter Caulkins

Daniel Barolo, Director
Special Review and
Reregistration Division

Enclosures

United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA-738-F-93-011
September 1993

EPA R.E.D. FACTS

Glyphosate

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for glyphosate.

Use Profile

Glyphosate is a non-selective herbicide registered for use on many food and non-food field crops as well as non-crop areas where total vegetation control is desired. When applied at lower rates, glyphosate also is a plant growth regulator.

Glyphosate is among the most widely used pesticides by volume. It ranked eleventh among conventional pesticides used in the U.S. during 1990-91. In recent years, approximately 13 to 20 million acres were treated with 18.7 million pounds of glyphosate annually. The largest use sites include hay/pasture, soybeans and field corn.

Three salts of glyphosate are used as active ingredients in registered pesticide products. Two of these active ingredients, plus technical grade glyphosate, are contained in the 56 products that are subject to this RED.

The isopropylamine salt, an active ingredient in 53 registered products, is used as a herbicide to control broadleaf weeds and grasses in many food and non-food crops and a variety of other sites including ornamentals, lawns and turf, residential areas, greenhouses, forest plantings and industrial rights-of-way. It is formulated as a liquid, solid or pellet/tablet, and is applied using ground or aerial equipment.

The sodium salt of glyphosate, an active ingredient in two registered pesticide products, is used as a plant growth regulator for peanuts and sugarcane, to modify plant growth and hasten the ripening of fruit. It is applied as a ground spray to peanut fields and as an aerial spray to sugarcane. Preharvest intervals are established for both crops.

The monoammonium salt of glyphosate is an active ingredient in an additional seven herbicide/growth regulator products. This form of glyphosate was initially registered after November 1984, so it is not subject to reregistration or included in this RED. However, in reassessing the existing glyphosate tolerances (maximum residue limits in or on food and feed), EPA included those for the monoammonium salt.

Regulatory History

EPA issued a Registration Standard for glyphosate in June 1986 (NTIS PB87-103214). The Registration Standard required additional phytotoxicity, environmental fate, toxicology, product chemistry and residue chemistry studies. All of the data required have been submitted and reviewed, or were waived.

Human Health Assessment

Toxicity

Glyphosate is of relatively low oral and dermal acute toxicity. It has been placed in Toxicity Category III for these effects (Toxicity Category I indicates the highest degree of acute toxicity, and Category IV the lowest). The acute inhalation toxicity study was waived because glyphosate is non-volatile and because adequate inhalation studies with end-use products exist showing low toxicity.

A subchronic feeding study using rats showed blood and pancreatic effects. A similar study with mice showed reduced body weight gains in both sexes at the highest dose levels. A dermal study with rabbits showed slight reddening and swelling of the skin, decreased food consumption in males and decreased enzyme production, at the highest dose levels.

Several chronic toxicity/carcinogenicity studies using rats, mice and beagle dogs resulted in no effects based on the parameters examined, or resulted in findings that glyphosate was not carcinogenic in the study. In June 1991, EPA classified glyphosate as a Group E oncogen--one that shows evidence of non-carcinogenicity for humans--based on the lack of convincing evidence of carcinogenicity in adequate studies.

In developmental toxicity studies using pregnant rats and rabbits, glyphosate caused treatment-related effects in the high dose groups including diarrhea, decreased body weight gain, nasal discharge and death.

One reproductive toxicity study using rats showed kidney effects in the high dose male pups; another study showed digestive effects and decreased body weight gain. Glyphosate does not cause mutations.

In one metabolism study with rats, most of the glyphosate administered (97.5 percent) was excreted in urine and feces as the parent compound; less than one percent of the absorbed dose remained in tissues and organs, primarily in bone tissue. Aminomethyl phosphonic acid (AMPA) was the only metabolite excreted. A second study using rats showed that very little glyphosate reaches bone marrow, that it is rapidly eliminated from bone marrow, and that it is even more rapidly eliminated from plasma.

Dietary Exposure

The nature of glyphosate residue in plants and animals is adequately understood. Studies with a variety of plants indicate that uptake of glyphosate or AMPA from soil is limited. The material which is taken up is readily translocated throughout the plant and into its fruit. In animals, most glyphosate is eliminated in urine and feces. Enforcement methods are available to detect residues of glyphosate and AMPA in or on plant commodities, in water and in animal commodities.

85 tolerances have been established for residues of glyphosate and its metabolite, AMPA, in or on a wide variety of crops and crop groups, as well as in many processed foods, animal feed and animal tissues (please see 40 CFR 180.364, 40 CFR 185.3500 and 40 CFR 186.3500). EPA has reassessed the existing and proposed tolerances for glyphosate. Though some adjustments will be needed, no major changes in existing tolerances are required. EPA also has compared the U.S. tolerances with international Codex maximum residue limits (MRLs), and is recommending certain adjustments to achieve greater compatibility.

EPA conducted a dietary risk assessment for glyphosate based on a worst-case risk scenario, that is, assuming that 100 percent of all possible commodities/acreage were treated, and assuming that tolerance-level residues remained in/on all treated commodities. The Agency concluded that the chronic dietary risk posed by glyphosate food uses is minimal.

A reference dose (RfD), or estimate of daily exposure that would not cause adverse effects throughout a lifetime, of 2 mg/kg/day has been proposed for glyphosate, based on the developmental toxicity studies described above.

Occupational and Residential Exposure

Occupational and residential exposure to glyphosate can be expected based on its currently registered uses. However, due to glyphosate's low acute toxicity and the absence of other toxicological concerns (especially carcinogenicity), occupational and residential exposure data are not required for reregistration.

Some glyphosate end-use products are in Toxicity Categories I or II for primary eye irritation or skin irritation. In California, glyphosate ranks high among pesticides causing illness or injury to workers, who report numerous incidents of eye and skin irritation from splashes during mixing

and loading. EPA is not adding any personal protective equipment (PPE) requirements at this time, but any existing PPE label requirements must be retained.

The Worker Protection Standard (WPS) for Agricultural Pesticides (please see 40 CFR 156 and 170) established an interim restricted entry interval (REI) of 12 hours for glyphosate. The Agency has decided to retain this REI as a prudent measure to mitigate risks to workers. During the REI, workers may reenter areas treated with glyphosate only in the few, narrow exceptions allowed in the WPS. The REI applies only to glyphosate uses within the scope of the WPS, so homeowner and commercial uses are not included.

Human Risk Assessment

EPA's worst case risk assessment of glyphosate's many registered food uses concludes that human dietary exposure and risk are minimal. Existing and proposed tolerances have been reassessed, and no significant changes are needed to protect the public.

Exposure to workers and other applicators generally is not expected to pose undue risks, due to glyphosate's low acute toxicity. However, splashes during mixing and loading of some products can cause injury, primarily eye and skin irritation. EPA is continuing to recommend PPE, including protective eye wear, for workers using end-use products that are in Toxicity Categories I or II for eye and skin irritation. To mitigate potential risks associated with reentering treated agricultural areas, EPA is retaining the 12 hour REI set by the WPS.

Environmental Assessment

Environmental Fate

Glyphosate adsorbs strongly to soil and is not expected to move vertically below the six inch soil layer; residues are expected to be immobile in soil. Glyphosate is readily degraded by soil microbes to AMPA, which is degraded to carbon dioxide. Glyphosate and AMPA are not likely to move to ground water due to their strong adsorptive characteristics. However, glyphosate does have the potential to contaminate surface waters due to its aquatic use patterns and through erosion, as it adsorbs to soil particles suspended in runoff. If glyphosate reached surface water, it would not be broken down readily by water or sunlight.

Ecological Effects

Glyphosate is no more than slightly toxic to birds and is practically non-toxic to fish, aquatic invertebrates and honeybees. Due to the presence of a toxic inert ingredient, some glyphosate end-use products must be labeled, "Toxic to fish," if they may be applied directly to aquatic environments. Product labeling does not preclude off-target movement of

glyphosate by drift. EPA therefore is requiring three additional terrestrial plant studies to assess potential risks to nontarget plants.

EPA does not expect that most endangered terrestrial or aquatic organisms will be affected by the registered uses of glyphosate. However, many endangered plants as well as the Houston toad (due to its habitat) may be at risk. EPA is deferring any use modifications or labeling amendments until it has published the Endangered Species Protection Plan and has given registrants guidance regarding endangered species precautionary labeling.

Ecological Effects Risk Assessment

Based on current data, EPA has determined that the effects of glyphosate on birds, mammals, fish and invertebrates are minimal. Under certain use conditions, glyphosate may cause adverse effects to nontarget aquatic plants. Additional data are needed to fully evaluate the effects of glyphosate on nontarget terrestrial plants. Risk reduction measures will be developed if needed, once the data from these studies are submitted and evaluated.

Additional Data Required

EPA is requiring three generic studies (Tier II Vegetative Vigor, Droplet Size Spectrum, and Drift Field Evaluation) which are not part of the target data base and do not affect the reregistration eligibility of glyphosate. The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, as well as revised Confidential Statements of Formula and revised labeling.

Product Labeling Changes Required

All end-use glyphosate products must comply with EPA's current pesticide product labeling requirements. In addition:

- **Protection of Aquatic Organisms**

Non-Aquatic Uses - End-use products that are not registered for aquatic uses must bear the following label statement:

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters and rinsate.

Aquatic Uses - End-use products registered for aquatic uses must bear the following label statement:

Do not contaminate water when disposing of equipment washwaters and rinsate. Treatment of aquatic weeds can result in oxygen loss from decomposition for dead plants. This loss can cause fish kills.

- **Worker Protection Standard (WPS) Requirements**

Any product whose labeling permits use in the production of an agricultural plant on any farm, forest, nursery or greenhouse must comply with the labeling requirements of:

  - PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS)," and
  - PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7."

Unless specifically directed in the RED, all statements required by these two PR Notices must appear on product labeling exactly as instructed in the Notices. Labels must be revised by April 21, 1994, for products distributed or sold by the primary registrant or supplementally registered distributors, and by October 23, 1995, for products distributed or sold by anyone.

- **Personal Protective Equipment (PPE)**

No new PPE requirements must be added to glyphosate labels. However, any existing PPE requirements on labels must be retained.

- **Entry Restrictions**

Products Not Primarily Intended for Home Use:

- Uses Within the Scope of the WPS - A 12-hour restricted entry interval (REI) is required for all products with uses within the scope of the WPS, except products intended primarily for home use. The PPE for early entry should be that required for applicators of glyphosate, except any applicator requirement for an apron or respirator is waived. This REI and PPE should be inserted into the standardized statements required by PR Notice 93-7.

  - Sole Active Ingredient End-Use Products - Labels must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on current labeling must be removed.
  - Multiple Active Ingredient Products - Registrants must compare the entry restrictions set forth in this section to those on their current labeling and retain the more protective. A specific time period in hours or days is considered more protective than "until sprays have dried" or "dusts have settled."

- Uses Not Within the Scope of the WPS - No new entry restrictions must be added. However, any entry restrictions on current product labeling with these uses must be retained.

Products Primarily Intended for Home Use:

- No new entry restrictions must be added. However, any entry restrictions on current product labeling must be retained.

Regulatory Conclusion

The use of currently registered pesticide products containing the isopropylamine and sodium salts of glyphosate in accordance with the labeling specified in this RED will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

These glyphosate products will be reregistered once the required product-specific data, revised Confidential Statements of Formula and revised labeling are received and accepted by EPA.

Products which contain active ingredients in addition to glyphosate will not be reregistered until all their other active ingredients also are eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for glyphosate during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Following the comment period, the glyphosate RED document will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the glyphosate RED, or reregistration of individual products containing glyphosate, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 6:00 pm Central Time, Monday through Friday.

REREGISTRATION ELIGIBILITY DECISION DOCUMENT

GLYPHOSATE

LIST A
CASE 0178

US Environmental Protection Agency
Office of Pesticide Programs
Special Review and Reregsitration Division

GLYPHOSATE REREGISTRATION ELIGIBILITY TEAM

Office of Pesticide Programs:

Special Review and Reregistration Division
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Health Effects Division
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GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
CAS	Chemical Abstracts Service
CFR	Code of Federal Regulations
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FR	Federal Register
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral or dermal). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
MATC	Maximum Allowable Toxicant Concentration: A range at which the pesticide causes no effect (NOEL) and the lowest dose at which an effect was observed (LOEL).

MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	Parts Per Million
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TC	Toxic Concentration. The dose at which a substance produces a toxic effect.
TMRC	Theoretical Maximum Residue Contribution.
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

This document addresses the reregistration eligibility of the pesticide glyphosate. There are 63 glyphosate-containing products registered for use in the United States. The isopropylamine salt of glyphosate, the active ingredient in 53 of these registrations, is used as a herbicide to control a number of broadleaf weeds and grasses. The principal food use sites include corn, wheat, sorghum, citrus and stone fruits, potatoes and onions, asparagus, coffee, peanuts, and pineapples. There are also a number of non-food use sites including ornamental, turf, forestry, and industrial rights-of-way. Two registrations contain the sodium salt of glyphosate and are used in sugarcane fields. In addition there are seven herbicide/plant regulation products containing the monoammonium salt of glyphosate which were registered subsequent to the development of List A and are not a subject of this RED. Except where explicitly noted otherwise, the term "glyphosate," when used in this document, refers to either the technical acid or the isoproplyamine and sodium salts of glyphosate. However, the monoammonium salt is included in the tolerance expression. Available data have been sufficient to allow re-assessment of existing tolerances, which includes the monoammonium salt of glyphosate.

In June 1986, the Agency issued the document "Registration Standard for Pesticide Products Containing Glyphosate as the Active Ingredient" (NTIS #PB87-103214). The Registration Standard required scientific studies in the areas of phytotoxicity, environmental fate, toxicology, product chemistry, and residue chemistry. With the exception of a few waived studies, all of the data required have been submitted. After completing its review for reregistration, the Agency now concludes that the data base on glyphosate is substantially complete.

Based on the results of its reregistration review, EPA has concluded that all registered uses of glyphosate are eligible for reregistration. The Agency has classified glyphosate as a Group E carcinogen (signifies evidence of non-carcinogenicity in humans). A Reference Dose of 2 mg/kg/day has been recommended. This proposal is based on a maternal NOEL of 175 mg/kg/day from a rabbit developmental toxicity study and an uncertainty factor of 100. The dietary risk assessment is based on a worst-case scenario, assuming treatment of 100% of acreage and highest legal residue values which likely result in an overestimation of exposure and risk. Even with these values, however, dietary exposure is expected to be minimal. There are 85 tolerances established for various crops and crop groups as well as Federal Food, Drug, and Cosmetic Act §409 tolerances for processed food and animal feed and animal tolerances. A re-assessment of tolerances is included in this document and there are no major changes in the previously-established tolerances. Studies show that glyphosate is no more than slightly toxic to birds and is practically non-toxic to fish and honeybees. However, a toxic inert in glyphosate end use products

necessitates the labelling of some products "toxic to fish" since some glyphosate products are applied directly to aquatic environments.

The Agency does have concerns regarding the potential hazard to endangered plant species and the Houston toad. However, the Agency is not requiring any modification of use or label changes in this document. A Federal Register Notice on the Endangered Species Protection Plan and subsequent guidance to registrants will impose appropriate exposure mitigation measures for areas where endangered plant species and the Houston toad may be encountered. In addition, there have been a number of reported incidents of spray drift damage to non-target crops. Spray drift studies are required as is a Tier II Vegetative Vigor study. These studies are not part of the target data base for reregistration of glyphosate.

Before reregistering each product, the Agency is requiring that product specific data in the areas of product chemistry and acute toxicology, revised Confidential Statements of Formula, and revised labeling be submitted within eight (8) months of the issuance of this document. In an effort to reduce the time, resources, and number of animals needed to fulfill the acute toxicology data requirements for glyphosate-containing end use products, the Agency has "batched" products considered to be similar with respect to acute toxicity testing requirements. After reviewing these data and the revised labels, the Agency will determine whether to re-register a product based on whether or not that product meets the requirements in Section 3(c)(5) of FIFRA. End use products containing glyphosate in combination with other active ingredients will not be re-registered until the Reregistration Eligibility Decisions for all active ingredients contained in that product are issued and all the active ingredients contained in the product are also eligible for reregistration. However, product specific data for these products are being called in at this time.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for registration" before calling in data on products and either re-registering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of the isopropylamine salt and the sodium salt formulations of glyphosate. Except where explicitly noted otherwise, the term "glyphosate," when used in this document, refers to either the technical acid or the isoproplyamine and sodium salts of glyphosate but does not cover the monoammonium salt products since the compound was not included in the Federal Register publication of List A. The document consists of six sections. Section I is the introduction. Section II describes glyphosate, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for glyphosate. Section V discusses the reregistration requirements for glyphosate. Finally, Section VI is the Appendices which support this Reregistration Eligibility Document. Additional details concerning the Agency's review of applicable data are available on request.[1]

[1] EPA's reviews of data on the set of registered uses considered for EPA's analysis may be obtained from the OPP Public Docket, Field Operations Division (H7506C), Office of Pesticide Programs, EPA, Washington, DC 20460.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient(s) are covered by this Reregistration Eligibility Document:

Common Name:	glyphosate
Chemical Name:	N-phosphonomethyl glycine
CAS Registry Number:	38641-94-0
OPP Chemical Codes:	103601 (isopropylamine salt) 103603 (sodium salt)
Empirical Formula:	$C_3H_8NO_5P$
Trade Names:	Roundup, Rodeo, Shackle
Basic Manufacturer:	Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167

B. Use Profile

The following is information on the current registered uses with an overview of use sites and application methods. A detailed table of the uses of glyphosate is given in Appendix A.

Chemical:	glyphosate, isopropylamine salt (103601)
Type of Chemical:	herbicide
Mechanism of Action:	not known at this time, but it appears to inhibit the aromatic amino acid biosynthesis pathway and may inhibit or repress chlorismate mutase and/or prephenate hydratase.

Use groups and sites:

AQUATIC FOOD CROP:
agricultural drainage systems, irrigation systems, lakes/ponds/reservoirs (with human or wildlife use), streams/rivers/channeled water.

AQUATIC NON-FOOD INDUSTRIAL:
aquatic areas/water, drainage systems, sewage systems.

AQUATIC NON-FOOD OUTDOOR:
aquatic areas/water

FORESTRY:
conifer release, forest plantings (reforestation programs), forest trees (all or unspecified).

GREENHOUSE FOOD CROP:
greenhouses-in use.

INDOOR NON-FOOD:
greenhouse-empty.

OUTDOOR RESIDENTIAL:
household/domestic dwellings outdoor premises.

TERRESTIAL FEED CROP:
alfalfa, barley, beans, buckwheat, corn, grass forage/fodder/hay, lentils, millet (proso), nongrass forage/fodder/straw/hay, oats, pastures, rye, sorghum, wheat.

TERRESTRIAL FOOD CROP:
acerola (West Indies Cherry), apricot, artichoke (Jerusalem), asparagus, atemoya, avocado, banana, beech nut, beets, blackberry, blueberry, boysenberry, brazil nut, breadfruit (breadnut), broccoli, brussels sprouts, butternut, cabbage, cabbage (Chinese), carambola (jalea), carrot (including tops), cashew, cauliflower, celery, chard (swiss), cherimoya, cherry, chestnut, chicory, cocoa, coffee, collards, cranberry, cress (water), cucumber, currant, date, dewberry, eggfruit tree (canistel), eggplant, elderberry, endive (escarole), fig, filbert (hazelnut), garlic, gooseberry, gourds, groundcherry (strawberry tomato/tomatillo), guava, hickory nut, horseradish, huckleberry, jaboticaba, jackfruit, kale, kitembilla (ceylon

gooseberry), kiwi fruit, kohlrabi, leek, lettuce, litchi nut, loganberry, longan, loquat, macadamia nut (bushnut), mamey (mammee apple), mango, marmaladebox (genipapo), mayhaw (hawthorn), melons, melons (cantaloupe), melons (honeydew), melons (mango), melons (musk), melons (water), melons winter (casaba/crenshaw/honeydew/persian), mustard, nectarine, okra, olive, onion, papaya, parsley, passion fruit, peach, pear, pecan, pepper, persimmon, pistachio, plantain, plum, pomegranate, prune, pumpkin, quince, radish, raspberry (black, red), rhubarb, rutabaga, sapodilla, sapota (white), soursop, spinach, squash (summer), squash (winter), sugar apple (custard apple), sweet potato, tamarind, taro, tea, walnut (English/black), yam.

TERRESTRIAL FOOD + FEED CROP:
agricultural fallow/idleland, almond, apple, barley, beans, beets (unspecified), buckwheat, calamondin, citron (citrus), citrus hybrids other than tangelo, corn (unspecified), corn (field), cotton (unspecified), grapefruit, grapes, kumquat, lemon, lentils, lime, millet proso (broomcorn), mustard, oats, orange, parsnip, peanuts (unspecified), peas (unspecified), pineapple, potato (white/irish), pummelo (shaddock), rape, rice, rice (wild), rye, sorghum, soybeans (unspecified), sugar beet, sugarcane, tangelo, tangerines, tomato, triticale, turnip, wheat.

TERRESTRIAL + GREENHOUSE NON-FOOD CROP:
ornamental and/or shade trees, ornamental woody shrubs and vines.

TERRESTRIAL NON-FOOD CROP:
agriculturalfallow/idleland,agriculturalrights-of-way/fencerows/hedgerows, agricultural uncultivated areas, airports/landing fields, christmas tree plantations, golf course turf, industrial areas (outdoor), nonagricultural outdoor buildings/structures, nonagricultural rights-of-way/fencerows/hedgerows, nonagricultural uncultivated areas/soils, ornamental and/or shade trees, ornamental lawns and turf, ornamental woody shubs and vines, paths/patios, paved areas (private roads/sidewalks), recreational areas, urban areas.

TERRESTRIAL NON-FOOD + OUTDOOR RESIDENTIAL:
ornamental and/or shade trees, ornamental herbaceous plants, ornamental lawns and turf, ornamental woody shubs and vines.

Pests: many broadleaf and grass weeds

Formulation types registered:

SINGLE ACTIVE INGREDIENT:

Form Not Identified/Liquid
- 53.50 % glyphosate, isopropylamine salt
- 41.00 % glyphosate, isopropylamine salt

Form Not Identified/Solid
- 76.00 % glyphosate, isopropylamine salt

Liquid-Ready to Use
- 19.70 % glyphosate, isopropylamine salt
- 18.30 % glyphosate, isopropylamine salt
- 15.80 % glyphosate, isopropylamine salt
- 1.00 % glyphosate, isopropylamine salt
- 0.96 % glyphosate, isopropylamine salt
- 0.50 % glyphosate, isopropylamine salt

Manufacturing Use
- 94.00 % glyphosate, isopropylamine salt

Pelleted/Tableted
- 83.50 % glyphosate, isopropylamine salt
- 60.00 % glyphosate, isopropylamine salt

Pressurized Liquid
- 0.96 % glyphosate, isopropylamine salt
- 0.75 % glyphosate, isopropylamine salt

Soluble Concentrate/Liquid
- 62.00 % glyphosate, isopropylamine salt
- 53.80 % glyphosate, isopropylamine salt
- 41.50 % glyphosate, isopropylamine salt
- 41.00 % glyphosate, isopropylamine salt
- 28.60 % glyphosate, isopropylamine salt
- 25.10 % glyphosate, isopropylamine salt
- 18.00 % glyphosate, isopropylamine salt
- 10.00 % glyphosate, isopropylamine salt
- 8.20 % glyphosate, isopropylamine salt
- 7.00 % glyphosate, isopropylamine salt
- 5.00 % glyphosate, isopropylamine salt

Soluble Concentrate/Solid
- 93.96 % glyphosate, isopropylamine salt

MULTIPLE ACTIVE INGREDIENT:
Liquid-Ready to Use
12.40 % glyphosate, isopropylamine salt + 1 other A.I.
7.70 % glyphosate, isopropylamine salt + 1 other A.I.
0.50 % glyphosate, isopropylamine salt + 1 other A.I.
0.25 % glyphosate, isopropylamine salt + 1 other A.I.
Soluble Concentrate/Liquid
16.50 % glyphosate, isopropylamine salt + 1 other A.I.
14.80 % glyphosate, isopropylamine salt + 1 other A.I.
13.30 % glyphosate, isopropylamine salt + 1 other A.I.
12.90 % glyphosate, isopropylamine salt + 1 other A.I.

Methods and rates of application (Given in maximum active (acid equivalent (ae)) rates, except as otherwise noted):

Broadcast or spray; for example as needed:

Form Not Identified/Liquid - rates were not specified in Appendix A dated 8/12/93;

Form Not Identified/Solid - rates were not specified in Appendix A dated 8/12/93;

Liquid-Ready to Use - applied at rate of 3.08 lb ae/A;

Pelleted/Tableted - applied as a spot treatment, for example from a hand held sprayer;

Pressurized Liquid - applied as a spot treatment, for example from an aerosol can;

Soluble Concentrate/Liquid - applied at rate of 7.5 lb ae/A;

Soluble Concentrate/Solid - applied at rates of 0.09 gal ae/A;

Chemical:	glyphosate, sodium salt (103603)
Type of Chemical:	plant regulator
Mechanism of Action:	modifies plant growth; hastens fruit ripening

Use Groups and Sites:

TERRESTRIAL FOOD + FEED CROP:
peanuts (unspecified); sugarcane

Formulation Types Registered:

SINGLE ACTIVE INGREDIENT:
soluble concentrate/solid
75.0% glyphosate, sodium salt

Methods and Rates of Application:

soluble concentrate/solid - applied as ground spray at peanut bloom stage at 0.0375 lb a.i./A in 10 gal water;

soluble concentrate/solid - applied as aerial spray at sugarcane ratoon stage at 0.525 lb a.i./A in 5 gal water.

Use Limitations:
sugarcane - 21 days preharvest interval; peanuts - 84 days preharvest interval. Do not apply this product through any type of irrigation system.

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of glyphosate. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

The table below summarizes glyphosate useage by site.

Glyphosate Usage		
Site	Multiple Acres Treated (x1000)	Pounds AI (x1000)
non-ag areas	unknown	3000-7000
almonds	350-390	500-550
apples	75-275	65-200

barley	550-600	275-325
cherries	15-95	20-125
corn, field	1,300-1,700	1,100-1,200
cotton	300-1,000	225-375
hay/pasture	3,000-3,500	1,500-1,700
dry edible beans/peas	50	20
grapefruit	70-140	183-375
grapes	45-550	25-265
lemons	5-75	10-70
other ag sites	3,000-3,500	1,000-1,500
oranges	300-600	650-1,300
peaches	10-150	10-110
peanuts	10-30	5-10
pears	15-50	15-65
pecans	5-300	5-150
plums/prunes	5-80	5-40
rice	30-55	25-30
sorghum	450-550	100-150
soybeans	2,600-4,800	2,200-2,400
spring wheat	200-225	50-60
sugarcane	10-70	5-35
potatoes	20-40	25-30
sunflowers	60-70	25-40
sweet corn	10-30	5-15
tomatoes	30-40	15-30
green beans/peas	20-40	5-20
walnuts	150-175	100-125
winter wheat	350-1,150	250-450
TOTAL	**12,985-20,280**	**11,398-18,745**

In a typical year between 1989 and 1991, approximately 13-20 million acre treatments were made with 18.7 million pounds active ingredient. Hay/pasture (20%), soybeans (20%), field corn (9%), and other agricultural areas (20%) comprise 71% of the total acreage treated with glyphosate. Non-agricultural areas (33%), soybeans (15%), hay/pasture (11%), and corn (8%) comprise 67% of the total pounds of active ingredient applied.

D. Data Requirements

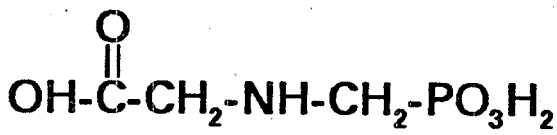
Data required in the June 1986 Registration Standard for glyphosate include studies on product chemistry, ecological effects, environmental fate, toxicology, and residue chemistry. These data were required to support the uses listed in the Registration Standard. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

Glyphosate is registered in the United States for use as a herbicide. The June 1986 Registration Standard evaluated the studies currently on file at the Agency and required submission of further data. This Reregistration Eligibility Document reflects an assessment of all data which were submitted in response to the Registration Standard.

III. SCIENCE ASSESSMENT

A. Product Chemistry



MOLECULAR STRUCTURE OF GLYPHOSATE

Empirical Formula: $C_3H_8NO_5P$
Molecular Weight: 169.07

CAS Registry No.: 38641-94-0
Shaughnessy No.: 103601 (isopropylamine salt, IPA)
103603 (sodium salt)

The glyphosate (N-phosphonomethyl glycine) salts are nonselective herbicides and plant growth regulators. The technical isopropylamine salt (IPA) is a white crystalline solid with a melting point of 200°C and a bulk density of 1.74 lb/ft^3. It is 1% soluble in water at 25°C and insoluble in ethanol, acetone, or benzene. The technical sodium salt is a white crystalline solid which decomposes at 140°C with a bulk density of 30 lb/ft^3.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base on glyphosate is adequate and will support reregistration eligibility.

a. Acute Toxicity

The table below summarizes the toxicity results and categories for technical grade glyphosate. The acute inhalation study was waived by the Agency since glyphosate technical is a nonvolatile solid and adequate inhalation studies were conducted on the end-use product formulations.

Acute Toxicity		
Test	Result	Category
Acute Oral (rat) (1)	> 4320 mg/kg	III
Acute Dermal (rabbit)(1)	> 2 g/kg	III
Acute Inhalation (1)	Not Required	N/A
1 - MRID 00067039		

The following table is derived from MPs considered toxicologically similar to glyphosate technical.

Acute Toxicity		
Test	**Result**	**Category**
Eye Irritation (1)	mild irritation, clears in 7 days	III
Dermal Irritation (2)	slight irritation	IV
Skin Sensitization (3)	negative	N/A

1 - MRID 41400603
2 - MRID 41400604
3 - MRIDs 00137137, 00137138, 00137139, 00137140

Other studies submitted to the Agency give similar results. They are acceptable for reregistration (MRIDs 41400601, and 41400602)

b. Subchronic Toxicity

In a 90-day feeding study Sprague-Dawley rats were fed diets containing 0, 1000, 5000 or 20000 ppm of glyphosate for three months. These doses were equivalent to 0, 63, 317 and 1267 mg/kg/day, respectively (males) and 0, 84, 404 and 1623 mg/kg/day, respectively (females). The following findings were regarded as possibly treatment-related: (1) increased serum phosphorus and potassium in all treated groups, males and females; (2) increased serum glucose in the mid-dose and high-dose males; (3) increased blood urea nitrogen (BUN) and serum alkaline phosphatase in the high-dose males; and (4) occurrence of pancreatic lesions in the high-dose males (pancreas was not examined in the low-dose and mid-dose groups). Based on these findings, the systemic NOEL is < 1000 ppm (not determined definitively) for both sexes. (MRIDs 40559401, and 00093879)

In a second 90-day feeding study CD-1 mice were fed diets containing 0, 250, 500 or 2500 mg/kg/day of glyphosate for three months. Body weight gains of the high-dose males and females were about 24% and 18% lower, respectively, than those of the controls. Body weight gains of the low-dose and mid-dose groups were comparable to those of the controls.

Based on the reduced body weight gains in both sexes, the NOEL for systemic toxicity is 500 mg/kg and the LOEL is 2500 mg/kg. (MRID 00036803)

In a 21-day dermal study glyphosate was applied to the skin of New Zealand white rabbits using 10 rabbits/sex/dose (5 with intact and 5 with abraded skin). The levels of glyphosate tested were 10, 1000 or 5000 mg/kg/day. The rabbits were exposed for three consecutive weeks, 6 hours/day, 5 days/week. Treatment-related effects observed only in the high dose groups included: (1) very slight erythema and edema in intact and abraded skin of both sexes; (2) decreased food consumption in males; and (3) decreased serum lactic dehydrogenase in both sexes. Based on these effects, the NOEL for males and females is 1000 mg/kg/day and the LOEL is 5000 mg/kg/day. (MRID 00098460)

The required 90-day feeding study in dogs is satisfied by the one-year dog feeding study. (MRID 00153374)

c. Chronic Toxicity

A chronic feeding/carcinogenicity study was conducted using male and female Sprague-Dawley rats which were fed diets containing 0, 30, 100 or 300 ppm of glyphosate for 26 months. These levels were equivalent to 0, 3, 10 and 31 mg of glyphosate/kg/day, respectively, for the males and 0, 3, 11 and 34 mg of glyphosate/kg/day, respectively, for the females. There were no effects based on any of the parameters examined (toxic signs, mortality, body weights, food consumption, hematology, clinical chemistry, urinalysis, organ weights and organ/tissue pathology). Therefore, the NOEL for systemic toxicity is ≥ 300 ppm (HDT; males: 31 mg/kg/day and females: 34 mg/kg/day). (MRID 00093879)

A second chronic feeding/carcinogenicity study was conducted using male and female Sprague-Dawley rats which were fed diets containing 0, 2000, 8000 or 20000 ppm of glyphosate for 2 years. These levels were equivalent to 0, 89, 362 or 940 mg/kg/day, respectively, for the males and 0, 113, 457 or 1183 mg/kg/day, respectively, for the females. Treatment-related effects observed only in the high-dose group

included: (1) In the females: decreased body weight gains; and (2) In the males: increased incidence of cataracts and lens abnormalities, decreased urinary pH, increased absolute liver weight and increased liver weight/brain weight ratio (relative liver weight). No significant systemic effects were observed in the low-dose and mid-dose male and female groups. Therefore, the NOEL for systemic toxicity is 8000 ppm (males: 362 mg/kg/day and females: 457 mg/kg/day) and the LOEL is 20000 ppm (HDT; males: 940 mg/kg/day and females: 1183 mg/kg/day). (MRID 41643801)

A chronic study was conducted using male and female beagle dogs which were given glyphosate in gelatin capsules containing 0, 20, 100 or 500 mg/kg/day for one year. There were no effects based on all parameters examined, in all groups. Therefore, the NOEL for systemic toxicity is ≥ 500 mg/kg/day, for both sexes. (MRID 00153374)

d. Carcinogenicity

A chronic feeding/carcinogenicity study was conducted using Sprague-Dawley rats which were fed diets containing glyphosate (males: 0, 3, 10 or 31 mg/kg/day and females: 0, 3, 11 or 34 mg/kg/day) for 26 months. The following findings were observed in the high-dose groups when compared with the concurrent controls: (1) increased incidence of thyroid C-cell carcinomas in females; and (2) increased incidence of interstitial cell (Leydig cell) testicular tumors. However, the Agency concluded that these neoplasms were not treatment-related and glyphosate was not considered to be carcinogenic in this study because the incidence of thyroid carcinomas was not statistically significant and the incidence of testicular tumors was within the historical incidence. The Agency also concluded that this study was not conducted at high enough dose levels for an adequate negative carcinogenicity. (MRID 00093879)

A chronic feeding/carcinogenicity study was conducted using Sprague-Dawley rats fed diets containing glyphosate (males: 0, 89, 362 or 940 mg/kg/day and females: 0, 113, 457 or 1183 mg/kg/day) for 2 years. The study showed a slightly increased incidence of (1) pancreatic islet cells

adenomas in the low-dose and high-dose males; (2) hepatocellular (liver) adenomas in the low-dose and high-dose males; and (3) thyroid C-cells adenomas in the mid-dose and high-dose males and females. The Agency concluded that these adenomas were not treatment-related and glyphosate was not considered to be carcinogenic in this study. With respect to pancreatic islet cells adenomas, there was no statistically significant positive dose-related trend in their occurrence; there was no progression to carcinomas; and the incidence of pancreatic hyperplasia (non-neoplastic lesion) was not dose-related. With respect to hepatocellular adenomas, the increased incidence of these neoplasms was not statistically significant in comparison with the controls; the incidence was within the historical control range; there was no progression to carcinomas; and the incidence of hyperplasia was not compound-related. With respect to thyroid C-cell adenomas, there was no statistically significant dose-related trend in their occurrence; the increased incidence was not statistically significant; there was no progression to carcinomas; and there was no significant dose-related increase in severity or incidence of hyperplasia in either sex. (MRID 41643801)

A carcinogenicity study in mice was conducted with CD-1 mice fed diets containing 0, 150, 750 or 4500 mg/kg/day of glyphosate for 18 months. No effects were observed in the low-dose and mid-dose groups. The following findings were observed in the high-dose group: (1) decreased body weight gain in males and females; (2) increased incidence of hepatocellular hypertrophy, hepatocellular necrosis and interstitial nephritis in males; (3) increased incidence of proximal tubule epithelial basophilia and hypertrophy in females; and (4) slightly increased incidence of renal tubular adenomas, a rare tumor, in males. Based on these effects, the systemic NOEL and LOEL were 750 mg/kg/day and 4500 mg/kg/day, respectively. The Agency concluded that the occurrence of these adenomas was spontaneous rather than compound-induced because the incidence of renal tubular adenomas in males was not statistically significant when compared with the concurrent controls. An independent group of pathologists and biometricians also conducted extensive evaluations of these adenomas and reached the same

conclusion. Therefore, glyphosate was not considered to be carcinogenic in this study. (MRIDs 00130406, and 00150564)

On June 26, 1991, the Agency classified glyphosate in Group E (evidence of non-carcinogenicity for humans), based on a lack of convincing evidence of carcinogenicity in adequate studies with two animal species, rat and mouse.

e. Developmental Toxicity

A developmental toxicity study was conducted with pregnant Charles River COBS CD rats which were administered 0, 300, 1000 or 3500 mg/kg/day of glyphosate by gavage during gestation days 6 through 19. Treatment-related effects observed only in the high-dose dams included: (1) diarrhea; (2) decreased mean body weight gain; (3) breathing rattles; (4) inactivity; (5) red matter around the nose and mouth, and on forelimbs and dorsal head; (6) decreases in total implantations/dam and inviable fetuses/dam; and (7) deaths (6/25 or 24% of the group). Treatment-related developmental effects observed only in the high-dose group included: (1) increased number of litters and fetuses with unossified sternebrae; and (2) decreased mean fetal body weights. Therefore, the NOEL and LOEL for maternal toxicity are 1000 mg/kg/day and 3500 mg/kg/day, respectively. The NOEL and LOEL for developmental toxicity are 1000 mg/kg/day and 3500 mg/kg/day, respectively. (MRID 00046362)

In a second study, pregnant Dutch Belted rabbits were administered 0, 75, 175 or 350 mg/kg/day of glyphosate by gavage during gestation days 6 through 27. Treatment-related findings were observed only in the high-dose group and included: (1) diarrhea; (2) nasal discharge; and (3) death (10/16 or 62.5% of does died by gestation day 21). Developmental toxicity was not observed at any dose tested. Therefore, the NOEL and LOEL for maternal toxicity are 175 mg/kg/day and 350 mg/kg/day, respectively. The NOEL for developmental toxicity is ≥ 175 mg/kg/day. Due to high maternal mortality at the 350 mg/kg/day dose level, too few litters (only 6) were available to assess adequately developmental toxicity at that level. (MRID 00046363)

f. Reproductive Toxicity

A reproduction study was conducted with male and female Sprague-Dawley rats which were administered 0, 3, 10 or 30 mg/kg/day of glyphosate continuously in the diet for three successive generations. The only effect observed was an increased incidence of focal tubular dilation of the kidney (both unilateral and bilateral combined) in the high-dose male F_{3b} pups. Therefore, the NOEL for systemic and reproductive toxicity is ≥ 30 mg/kg/day (HDT). The NOEL and LOEL for developmental toxicity are 10 mg/kg/day and 30 mg/kg/day, respectively. (MRID 00105995)

Another reproduction study was conducted with Sprague-Dawley rats which were administered 0, 100, 500 or 1500 mg/kg/day of glyphosate continuously in the diet for two successive generations. Treatment-related effects observed only in the high-dose group included: (1) soft stools, very frequent, in the F_0 and F_1 males and females; (2) decreased food consumption and body weight gain of the F_0 and F_1 males and females during the growth (premating) period; and (3) decreased body weight gain of the F_{1a}, F_{2a} and F_{2b} male and female pups during the second and third weeks of lactation. Focal tubular dilation of the kidneys, observed in the previous study (00105995), was not observed at any dose level in this study. Based on the above findings, the systemic NOEL and LOEL are 10000 ppm (500 mg/kg/day) and 30000 ppm (1500 mg/kg/day), respectively. The reproductive NOEL is 30000 ppm (1500 mg/kg/day; HDT); and the developmental NOEL and LOEL are 10000 ppm (500 mg/kg/day) and 30000 ppm (1500 mg/kg/day), respectively. (MRID 41621501)

Since the focal tubular dilation of the kidneys was not observed at the 1500 mg/kg/day level (HDT) in the 2-generation rat reproduction study but was observed at the 30 mg/kg/day level (HDT) in the 3-generation rat reproduction study (00105995), the Agency concluded that the latter was a spurious rather than glyphosate-related effect.

g. Mutagenicity

A Gene mutation assay in an Ames Test was conducted using glyphosate, both with and without metabolic activation. The strains of *Salmonella typhimurium* used were TA98, TA100, TA1535 and TA1537. No increases in reverse mutations were observed at any concentration. (MRID 00078620)

A gene mutation assay in mammalian cells was conducted using glyphosate in the Chinese hamster ovary (CHO) cells/hypoxanthine - guanine -phosphoribosyl transferase (HGPRT) assay, with and without metabolic activation. No mutagenic response was observed either with or without metabolic activation up to the limit of cytotoxicity (10 mg/Ml). (MRID 00132681)

A Structural Chromosomal Aberration Assay was conducted using a single dose of glyphosate administered intraperitoneally (i.p.) to male and female Sprague-Dawley rats. The dose used was 1 g/kg of body weight and the bone marrow cells were examined for clastogenic (chromosome-damaging) effect. No significant clastogenic effects were observed. (MRID 00132683)

In a fourth study, glyphosate was tested in two assays: the rec-assay using *B. subtilis* H17 (rec^+) and M45 (rec^-); and the reverse mutation assays using *E. coli* WP2 hcr and *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538, with and without metabolic activation. No increases in mutations were observed in either study. (MRID 00078619)

h. Metabolism

Two metabolism studies with rats are available. In the first study, single or repeated doses of radiolabeled ^{14}C-glyphosate were administered orally to male and female Sprague-Dawley rats. Following a single oral dose of ^{14}C-glyphosate, 30 to 36% of the dose was absorbed and less than 0.27% of the dose was eliminated as CO_2. Ninety-seven point five percent of the administered dose was excreted in the

urine and feces as the parent compound, glyphosate. Amino methyl phosphonic acid (AMPA) was the only metabolite found in urine (0.2-0.3% of the administered dose) and feces (0.2-0.4% of the administered dose). Less than 1.0% of the absorbed dose remained in tissues and organs, primarily in bone tissue. Repeated dosing at 10 mg/kg did not significantly change the metabolism, distribution or excretion of glyphosate. (MRIDs 40767101, and 40767102)

In a second study, male and female Sprague-Dawley rats received single intraperitoneal injections of radiolabeled ^{14}C-glyphosate. The dose level of glyphosate used for male and female rats was 1150 mg/kg. Blood samples were collected 0.25, 0.50, 1, 2, 4, 6 and 10 hours after injection. Femoral bone marrow samples were collected from one third of the male and female rats sacrificed at 0.5, 4, or 10 hours after injection. Thirty minutes after injection of glyphosate, the concentration of radioactivity in the bone marrow of male and female rats was equivalent to 0.0044% and 0.0072%, respectively, of the administered dose. Assuming first order kinetics, the decrease in radioactivity in bone marrow occurred with a half-life of 7.6 and 4.2 hours for males and females, respectively. Similarly, the half-lives of the radioactivity in plasma were approximately 1 hour for both sexes. These findings indicate that very little glyphosate reaches bone marrow, that it is rapidly eliminated from bone marrow and that it is even more rapidly eliminated from plasma. (MRID 00132685)

i. Neurotoxicity

The acute and 90-day neurotoxicity screening battery in the rat (guidelines 81-8-SS, 82-7) is not being required since there was no evidence of neurotoxicity seen in any of the existing studies at very high doses and this chemical lacks a leaving group; therefore, it would not seem likely to inhibit esterases (the presumptive neurotoxic mechanism of concern for all organophosphates).

j. Other Toxicological Endpoints

A dermal penetration study (guideline 85-2) with technical grade glyphosate is not being required because there are no toxicological endpoints to indicate this study is necessary.

Domestic Animal Safety Studies (86-1) are not being required for the use patterns of glyphosate (a plant growth regulator and herbicide).

Technical grade glyphosate contains N-nitrosoglyphosate (NNG) as a contaminant. Carcinogenicity testing of nitroso contaminants is normally required only in those cases in which the level of nitroso compounds exceeds 1.0 ppm. Analyses showed that greater than 92% of the individual technical glyphosate samples contained less than 1.0 ppm NNG. The Agency concluded that the NNG content of glyphosate was not toxicologically significant.

k. Reference Dose

On August 27, 1992, the Agency's Office of Pesticide Programs Reference Dose (RfD) Peer Review Committee recommended that the RfD for glyphosate be established at 2 mg/kg/day. This value was based on the maternal NOEL of 175 mg/kg/day from the rabbit developmental toxicity study (00046363) and an uncertainty factor (UF) of 100. This RfD has not yet been confirmed by the Agency RfD Work Group.

In September of 1986, the Joint Food and Agricultural Organization of the United Nations (FAO)/World Health Organization (WHO) on Pesticides Residues [JMPR] proposed an Allowable Daily Intake (ADI) of 0.3 mg/kg body weight for glyphosate *per se*. The ADI was based on a 26-month feeding study in the rat yielding a NOEL of > 31 mg/kg body weight per day and and uncertainty factor of 100. The Agency places more importance on the developmental rabbit study since no effect was observed in the 26-month study whereas maternal mortality was observed in the developmental rabbit study in

the high dose group. JMPR acknowledged that there is no effect at the highest dose tested in the 26-month rat study.

2. Exposure Assessment

a. Dietary Exposure

The qualitative nature of the residue in plants is adequately understood. Studies with a variety of plants including corn, cotton, soybeans, and wheat indicate that the uptake of glyphosate or its metabolite, aminomethyl phosphonic acid (AMPA), from soil is limited. The material which is taken up is readily translocated. Foliarly applied glyphosate is readily absorbed and translocated throughout the trees or vines to the fruit of apples, coffee, dwarf citrus (calamondin), pears and grapes. Metabolism via N-methylation yields N-methylated glycines and phosphonic acids. For the most part, the ratio of glyphosate to AMPA is 9 to 1 but can approach 1 to 1 in a few cases (e.g., soybeans and carrots). Much of the residue data for crops reflects a detectable residue of parent (0.05 - 0.15 ppm) along with residues below the level of detection (<0.05 ppm) of AMPA. The terminal residue to be regulated in plants is glyphosate *per se*.

The qualitative nature of the residue in animals is adequately understood. Studies with lactating goats and laying hens fed a mixture of glyphosate and AMPA indicate that the primary route of elimination was by excretion (urine and feces). These results are consistent with metabolism studies in rats, rabbits, and cows. The terminal residues in eggs, milk, and animal tissues are glyphosate and its metabolite AMPA; there was no evidence of further metabolism. The terminal residue to be regulated in livestock is glyphosate *per se*.

An adequate enforcement method is available for analysis of residues of glyphosate and its metabolite AMPA in or on plant commodities and in water. This method utilizes GLC (Method I of PAM Vol. II; limit of detection is 0.05 ppm). For enforcement of tolerances in animal commodities, an HPLC method with fluorescence detection is available; the reported limits of detection are 0.01 ppm for glyphosate and 0.012 ppm for AMPA.

The available storage stability data indicate that residues of glyphosate and its metabolite AMPA are stable under frozen ~~storage conditions (-20°C)~~: in or on plant commodities for a period of 1 year, in animal commodities for 2 years, and in water for 1 year. No additional storage stability data are needed.

All data requirements for magnitude of the residue in plants have been evaluated and deemed adequate. Additional potato processing data are being generated. All data requirements for magnitude of the residue in plants as a result of irrigation with glyphosate-treated water have also been submitted and are adequate to support registered use and applicable tolerances. No additional data are required for magnitude of the residue in animals, potable water, and fish. A list of residue chemistry study references is provided on page 24.

b. Occupational and Residential

Occupational and residential exposure can be expected based on the currently registered uses of products containing glyphosate. However, due to the low toxicity (acute category III) of glyphosate and the lack of other toxicological concerns (i.e carcinogenicity) occupational and residential exposure data are not required. Glyphosate is a non-selective herbicide applied to terrestrial food and non-food crops, turf, greenhouse crops, and non-crop areas where total vegetation control is desired. Glyphosate, when applied at lower rates, is also a plant growth regulator.

Although glyphosate meets the Agency's exposure criteria for post-application/reentry and/or mixer/loader/applicator exposure monitoring data, glyphosate does not meet the Agency's toxicity criteria for these data requirements. Acute oral and dermal toxicity data for the technical material are in Toxicity Category III and IV. In addition, glyphosate is poorly absorbed dermally. The acute inhalation toxicity study for the technical material was waived because glyphosate is non-volatile and because there were adequate inhalation studies with end-use products showing low

toxicity. Therefore, occupational and residential exposure data are not required to support the reregistration of glyphosate. (For these same reasons, these data were not required in the 1986 Registration Standard.)

The following information is product-specific related, but is presented here for informational purposes. Some glyphosate end-use products are in Toxicity Category I and II based on primary eye irritation or dermal irritation. In California, where physicians are required to report pesticide poisonings, glyphosate was ranked third out of the 25 leading causes of illnesses or injury due to pesticides used between 1980 and 1984. These mixer/loader/applicator reported incidents consisted of eye and skin irritation. In reports issued by California since then (1987 and 1988), glyphosate continued to be a leading cause of illnesses or injuries (primarily eye and skin irritation). In the 1986 Registration Standard, the Agency recommended personal protective equipment, including protective eyewear for mixer/loader/applicators using end-use products that could cause eye or skin irritation. At that time, it was determined that mixer/loaders were at risk of eye or skin injury from splashes during mixing and loading. The Agency did not require personal protective equipment for users of "homeowner" products (containing up to 10% glyphosate) because of the low concentration of glyphosate and because the products are "ready-to-use", requiring no mixing; therefore, the potential for eye or dermal exposure is minimized.

The Agency, at this time, is not adding any additional personal protective equipment requirements to the labels of end-use products; however, any existing personal protective equipment on those labels must be retained.

The Worker Protection Standard (WPS) for Agricultural Pesticides -- 40 CFR Parts 156 and 170 -- established an interim restricted entry interval (REI) of 12 hours for glyphosate because the acute toxicity categories of glyphosate for acute dermal toxicity, skin irritation potential, and eye irritation potential are Toxicity Category III or IV. The Agency has determined that the 12-hour REI for all WPS sites should be retained as a prudent measure to mitigate risk to workers

entering treated areas after application. Furthermore, given the known irritation-effects concerns for glyphosate, the Agency considers the additional protections offered by the requirements in the WPS essential to its decision that a 12-hour REI for this chemical will offer sufficient risk mitigation to workers. Therefore, during the REI the Agency will allow workers to enter areas treated with glyphosate during the REI only in the few narrow exceptions allowed in the WPS.

The Agency has determined that, at this time, the entry restrictions discussed in this section need not apply to uses of glyphosate ouside the scope of the Worker Protection Standard for Agricultural Chemicals, including out-of-scope commercial uses and homeowner uses. The predicted frequency, duration, and degree of exposure due to post-application as the result of such uses should not warrant the risk mitigation measures being required for persons engaged in the production of agricultural plants for commercial or research purposes.

3. Risk Assessment

a. Dietary

The chronic dietary risk analysis used tolerance level residues and assumed all acreage, of the crops considered, was treated with glyphosate to estimate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. These exposures (TMRCs) were then compared to the RfD for glyphosate to estimate chronic dietary risk.

The calculated TMRC for the overall U.S. population from food uses of glyphosate is 0.025 mg/kg bwt/day, which represents 1.2% of the RfD. The subgroup most highly exposed, non-nursing infants less than one year old, has a TMRC of 0.058 mg/kg bwt/day, or 2.9% of the RfD. Over one third of the dietary exposure and risk from glyphosate is due to the proposed tolerances on wheat.

This analysis was meant to be a "worst case" scenario of risk. The inclusion of recommended tolerances for reregistration as well as tolerances recommended for

revocation; the use of the highest existing, pending, or recommended residue value for each commodity; and the assumptions of tolerance level residues and treatment of 100 percent of the crops for every commodity considered result in an overestimation of exposure and risk values for glyphosate (though there is some underestimation due to the lack of consumption information for some of the commodities to which glyphosate is expected to be applied). Nonetheless, given the risk values arrived at by this analysis, EPA concludes that the chronic dietary risk posed by this pesticide on these food uses is minimal.

b. Occupational and Residential

As discussed above in the occupational exposure assessment, exposure to humans from proper application of glyphosate to terrestrial food and non-food crops as well as greenhouses, turf, and non-crop areas can result in injury (primarily eye and skin irritation) from splashes during mixing and loading. The Agency continues to recommend protective clothing (including protective eye wear) for mixer/loader/applicators using end-use products that may be in toxicity category I or II for primary eye and dermal irritation.

c. Dietary Exposure References

This table references the residue data used to support the reregistration of glyphosate and includes the commodities eligible for reregistration.

Guideline/Commodity	References[1]
§171-4 (a): Plant Metabolism	00038771, 00039141, 00051983, 00065753, 00108097, 00108129, 00108133, 00108140, 00108151, 00111945
§171-4 (b): Animal Metabolism	00094971, 00108098, 00108099, 00108100, 00108101, 00108116, 00108099, 00108200, 40541301-40541304

Guideline/Commodity	References[1]
§171-4 (c) and (d): Residue Analytical Methods	00028853, 00036222, 00036223, 00036231, 00037688, 00038770, 00038979, 00044423, 00051982, 00053002, 00053005, 00060108, 00061559, 00063714, 00065751, 00065752, 00067425, 00076805, 00078823, 00078824, 00108133, 00108144, 00108149, 00108151, 00108175, 00108176, 00108186, 00108231, 00111945, 00111949, 00122715, 00159419, 00164729, 40502601, 40541304
§171-4 (e): Storage Stability	00039142, 00040083, 00051980, 00053002, 00061553, 00061555, 00108129, 00108132, 40502605, 40532004, 41940701
§171-4 (k) (l): Magnitude of the Residue in Plants	
Root and Tuber Vegetables Group	
- Artichokes, Jerusalem	N/A
- Beets, garden	00108159
- Carrots	00108159
- Chicory	N/A
- Horseradish	N/A
- Parsnips	N/A
- Potatoes	00108151, 41947001
- Radish	00108159
- Rutabagas	N/A
- Salsify	N/A
- Sugar beets	00039381, 00108151
- Sweet potato	00108151
- Turnips	40835201
Leaves of Root and Tuber Vegetables Group	
- Beets, greens	N/A
- Chicory leaves	N/A
- Sugar beet tops	00039381, 00108151

Guideline/Commodity	References[1]
- Turnip tops	40835201
Bulb Vegetables Group	
- Garlic	N/A
- Onions (green and dry bulb)	40783101
Leafy Vegetables (except Brassica) Group	
- Celery	N/A
- Lettuce (head and leaf)	00108159
- Spinach	N/A
Brassica Leafy Vegetables Group	
- Broccoli	40802801, 40802801
- Cabbage	00108159
- Cauliflower	N/A
- Kale	N/A
- Mustard greens	40802801, 40802801
Legume Vegetables (Succulent/Dried) Group	
- Beans (succulent and dried)	00108159
- Lentils	00108159
- Peas (succulent and dried)	00108159
- Soybeans	00015759, 00015760, 00015761, 00015762, 00015763, 00015764, 00015765, 00015766, 00015767, 00024503, 00033954, 00038908, 00040084, 00061555, 00108153, 00108203
(processed commodities)	00061555, 00108153, 00156793
Foliage of Legume Vegetables (Succulent/Dried) Group	
- Bean vines and hay	00108159
- Lentil forage and hay	00108159
- Pea vines and straw	

Guideline/Commodity	References[1]
- Soybean forage and hay	00015759, 00015760, 00015761, 00015762, 00015763, 00015764, 00015765, 00015766, 00015767, 00033954, 00038908, 00040084, 00061555, 00108153, 00108203
Fruiting Vegetables Group	
Cucurbit Vegetables Group	
Citrus Fruits Group	00039142
(processed commodities)	40159401
Pome Fruits Group	00108129
Stone Fruits Group	00111949
- Plums (fresh prunes)	00111949
Small Fruits and Berries Group	
- Blackberries	
- Blueberries	
- Cranberries	00053002
- Grapes	00038770, 00108132
(processed commodities)	40785303
- Raspberries	
Tree Nuts Group	00111945
- Almond hulls	00111945
Cereal Grains Group	
- Barley	00038908, 00040087, 00044422, 00108203
(processed commodities)	N/A
- Corn (field and fresh)	00023336, 00023512, 00037687, 00038908, 00040085, 00048284, 00108203, 40502602
(processed commodities)	40502604, 41478101
- Oats	00038908, 00040087, 00044422, 00108203
(processed commodities)	N/A

Guideline/Commodity	References[1]
- Rice	00038908, 00040087, 00044422
(processed commodities)	N/A
- Rye	N/A
(processed commodities)	N/A
- Sorghum	00038908, 00040087, 00044422, 00108203, 00109271, 40502601
(processed commodities)	40502603
- Wheat	00038908, 00040086, 00044426, 00108203, 00122715, 41484301
(processed commodities)	00150835
Forage, Fodder, and Straw of Cereal Grains Group	
- Barley forage, hay, and straw	00038908, 00040087, 00044422, 00108203
- Corn forage and fodder	00023336, 00023512, 00037687, 00038908, 00040085, 00048284, 00108203, 40502602
- Oat forage, hay, and straw	00038908, 00040087, 00044422, 00108203
- Rice straw	00038908, 00040087, 00044422
- Rye forage and straw	N/A
- Sorghum forage and fodder	00038908, 00040087, 00044422, 00108203, 00109271, 40502601
- Wheat forage and straw	00038908, 00040086, 00044426, 00108203, 00122715
Grass Forage, Fodder, and Hay Group	00076805, 00108147
Non-grass Animal Feeds (forage, fodder, straw, and hay) Group	00076805, 00108147
- Alfalfa seed	40541304
Miscellaneous Commodities	
- Acerola	
- Atemoya	
- Asparagus	00108144, 40642401
- Avocados	00108149
- Bananas	00108175
- Breadfruit	40149401
- Canistel	40149401
- Carambola	

Guideline/Commodity	References[1]
- Cherimoya	
- Cocoa beans	
- Coconut	
- Coffee beans	00051980, 00051981
- Cotton	00060103, 00061553, 00108176, 00108153, 00108203
(processed commodities)	00061553, 00108176, 00108153
- Dates	40149401
- Figs	
- Genip	
- Guavas	00059050
- Jaboticaba	40149401
- Jackfruit	40149401
- Kiwi fruit	
- Litchi Nut (Lychee)	
- Longan	
- Mamey Sapote (Mammee Apple)	
- Mangoes	40580401
- Okra	N/A
- Olives	00108175, 42398401
(processed commodities)	00108175, 42398401
- Palm oil	
- Papayas	00063713
- Passion Fruit	
- Peanuts	00144341, 00028852
(processed commodities)	00144341, 00028852
- Persimmons	40149401
- Pineapple	N/A
- Pistachio	00111945
- Sapodilla	
- Sapote (black and white)	40149401
- Soursop	40149401
- Sugar apple	

Guideline/Commodity	References[1]
- Sugarcane	00108140
(processed commodities)	00108168
- Tamarind	40149401
- Tea	00078823, 00078824
- Watercress	N/A
§171-4 (h): Magnitude of the Residue in Plants Resulting from the Use of Irrigation Water	00039381, 40541305
§171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs	00108115, 40532001-03
§171-4 (g): Magnitude of the Residue in Fish	00036229, 00076491, 00154311, 00155120
§171-4 (f): Nature and Magnitude the Residue in Drinking and Irrigation Water	00039377, 00039381, 00077227, 00077228, 00077229, 00077230, 00077231, 00077232, 00077233, 00077234, 00077235, 00077236, 00077237, 00077238, 00077301, 00108173,
§171-4 (i): Magnitude of the Residue in Food Handling Establishment	
§171-5. Reduction of Residues	

1 N/A means not available by MRID number. Those guidelines/commodities which do not list a MRID reference number, additional reference information can be provided from Table A in the Product and Residue Chemistry Chapters by R.B. Perfetti, Chemistry Branch Reregistration Support (CBRS# 10665) in the Health Effects Division dated 10/27/92 through FOI.

C. Environmental Assessment

1. Environmental Fate

a. Environmental Fate and Transport

(1) Hydrolysis

Glyphosate is stable at pH 3, 6, 9 at 5 and 35°C. (Accession 00108192)

(2) Photodegradation in Water

Glyphosate is stable to photodegradation in pH 5, 7, and 9 buffered solutions under natural sunlight. (MRID 41689101)

(3) Photodegradation on Soil

Glyphosate is stable to photodegradation on soil. (MRID 41335101)

(4) Aerobic Soil Metabolism

Data indicate half-life values of 1.85 and 2.06 days in Kickapoo sandy loam and Dupo silt loam respectively. Aminomethyl phosphonic acid (AMPA) was the major degradate. (MRID 42372501)

(5) Anaerobic Aquatic Metabolism

Glyphosate has a half-life of 8.1 days in anaerobic (flooded plus nitrogen atmosphere) silty clay loam sediment. AMPA was the major degradate. (MRID 42372502)

(6) Aerobic Aquatic Metabolism

Glyphosate has a half-life of 7 days in flooded silty clay loam sediment that was incubated in the dark at 24.6 ± 0.57 C for 30 days. AMPA was the major degradate. (MRID 42372503)

(7) Leaching/Adsorption/Desorption

K_d values of 62, 90, 70, 22, and 175 were reported for Drummer silty clay loam, Ray silt, Spinks sandy loam, Lintonia sandy loam, and Cattail Swamp sediment respectively. After (aged) leaching 7 soils with 20" of water, the recovered radioactivity in the soils

was 93-100% of the applied material. (Accessions 00108192, 00076493, 00108140)

(8) Terrestrial Field Dissipation

The Agency has received an interim report on a terrestrial field dissipation study in progress by Monsanto Company. (MRID 42607501)

This report contains data from eight different field sites. Some of the data from the individual field sites are deficient; however, the Agency may use the data from the eight field sites together to satisfy the terrestrial field dissipation 164-1 data requirement.

The interim report results from the first 12 months of bareground field dissipation trials from eight sites show that the median half-life (DT_{50}) for glyphosate applied at maximum annual use rates (7.95 lb a.e./acre, 10.7 lb a.i./acre) was 13.9 days with a range of 2.6 (Texas) to 140.6 (Iowa) days. Acceptable aerobic soil, aerobic aquatic and anaerobic aquatic metabolism studies demonstrate that under those conditions at 25°C in the laboratory glyphosate degrades rapidly with half-lives of approximately 2, 7 and 8 days respectively. The reported half-lives (DT_{50}) from the field studies conducted in the coldest climates, ie. Minnesota, New York and Iowa, were the longest at 28.7, 127.8, and 140.6 days respectively indicating that glyphosate residues in the field are somewhat more persistent in cooler climates as opposed to milder ones (Georgia, California, Arizona, Ohio, and Texas).

Glyphosate (as well as AMPA) was shown to remain predominantly in the 0-6 inch soil layer throughout the duration of the study at all field sites. Iowa was the individual test site to have average glyphosate residues, at all sampling times, greater than 0.01 ppm in the 6-12 inch depth. There were a number of detections from 0.01 to 0.09 ppm in the 6-12 inch layer in Minnesota, New York and Texas, and

glyphosate was detected at generally <0.05 ppm at the other 5 field sites (6-12 inch depth).

Glyphosate was detected at three different sites below 12 inches. In California, at 0 DAT, average glyphosate residues were 0.21 ppm and 0.10 ppm in the 12-18 and 18-24 inch soil horizons respectively. Soil core contamination was attributed to these detections since movement of residues to this depth on the first day of sampling is unlikely. In Arizona at 21 DAT the average glyphosate residues were 0.06, in the 18-24 inch soil layer. There were no glyphosate residues in the 6-12 or 12-18 inch soil layer in Arizona on 21 DAT and in subsequent samples below 12 inches which may indicate a problem with sampling technique. In Iowa at 190 DAT the average glyphosate residues were 0.05 ppm in the 12-18 inch soil layer. Since there were no glyphosate residues detected in the 6-12 inch soil layer at 190 DAT, and the lack of a significant amount of rainfall between sampling intervals in combination with the amount of time between sampling intervals and the high adsorptive characteristics of glyphosate give an indication that there may have been a problem with sampling technique.

AMPA was also shown to remain predominantly in the 0-6 inch soil layer. AMPA was found at every test site on Day 0 samples indicating the rapid degradation of parent glyphosate. The AMPA levels generally reached a maximum between day 14 and day 30. Where the field half-lives were longer (Iowa, Minnesota, New York), the maximum average AMPA levels occurred between 62 and 95 DAT. The maximum average AMPA levels found in the 0-6 inch soil layer were 0.6 ppm and occurred in Ohio and Georgia at 21 DAT and 61 DAT respectively. The AMPA levels at those sites had decreased to 0.12 and 0.44 ppm at 12 months after treatment.

In all samples but three, AMPA residue levels were <0.05 ppm in the 6-12 inch soil layer. In New York at 14 and 30 DAT average residues were detected

at 0.06 ppm. In Iowa at the 92 DAT sample average AMPA residues were 0.08 ppm. Iowa and New York also exhibited 50% dissipation times of 140.6 and 127.8 days respectively.

AMPA levels were detected at 0.06 ppm in the 18-24 inch soil layer on 21 DAT in Arizona and 0.04 and 0.03 ppm in the 12-18 inch soil layer at 90 and 180 DAT respectively in New York.

A final report on the terrestrial field dissipation study showed the median half-life (DT_{50}) (of eight sites) of AMPA was 240 days with a range of 119 (Ohio) to 958 (California) days. The half-lives for the dissipation of AMPA for seven of the eight test sites were:

- Arizona 142 days
- California 958 days
- Georgia 896 days
- Minnesota 302 days
- New York 240 days
- Ohio 119 days
- Texas 131 days

Iowa was not calculated because recharging of AMPA residues was greater than degradation. AMPA was shown to remain predominantly in the 0-6 inch soil layer throughout the duration of the study at all eight field sites. AMPA was detected three times (at a concentration greater than 0.05 ppm) at depths greater than 12 inches. The three detections were attributed to contamination during sampling rather than vertical mobility.

(9) Aquatic Field Dissipation

Glyphosate dissipated from water (irrigation source) with a calculated half-life of 7.5 days and 120 days from the sediment of the farm pond in Missouri. (MRID 40881601)

In Michigan, Georgia and Oregon pond and stream water, the maximum glyphosate concentrations were measured immediately posttreatment and dissipated rapidly. Glyphosate accumulated in the pond sediment, and to a lesser extent in the stream sediments; glyphosate was present in pond sediment at ≥1 ppm in Michigan and Oregon at approximately 1 year posttreatment. (MRID 41552801)

(10) Forestry Dissipation

When aerially applied at 3.75 lb/A to forested sites in Michigan, Oregon, and Georgia, glyphosate averaged 652-1273 ppm in tree foliage immediately posttreatment. It then declined rapidly with half-lives of <1 day at the Michigan and Georgia sites and <14 days at the Oregon site.

The forestry dissipation study results demonstrate that when used under normal silviculture practices according to label directions, the maximum combined glyphosate and AMPA residue level in soil is less than 5 ppm. Glyphosate and AMPA residues in soil dissipate with time. The average half-life for the dissipation of glyphosate was 100 days, and ranged from 35 to 158 days. The average half-life for the dissipation of AMPA was 118 days, and ranged from 71 days to 165 days. (MRID 41552801)

(11) Accumulation in Confined Rotational Crops

Glyphosate residues (expressed as fresh weight) accumulated in lettuce, carrots, and barley planted 30, 119, and 364 days after sandy loam soil was treated with glyphosate at 3.71 lb ai/A. Accumulation decreased as the length of the rotation increased. In crops planted at 30 days, posttreatment, [^{14}C]residues at harvest were 0.097 ppm in lettuce, 0.051 and 0.037 ppm in carrot tops and roots, respectively, and 0.188 and 0.175 ppm in barley grain and straw, respectively. In immature lettuce harvested at 40 and 60 days postplanting, [^{14}C]residues were 0.108 and 0.048 ppm,

respectively. In crops planted at 119 days posttreatment, [^{14}C]residues at harvest were 0.037 ppm in lettuce, 0.028 and 0.017 ppm in carrot tops and roots, respectively, and 0.078 and 0.056 ppm in barley grain and straw, respectively. In immature lettuce harvested at 28 and 48 days postplanting, [^{14}C]residues were 0.059 and 0.055 ppm, respectively. In crops planted at 364 days posttreatment, [^{14}C]residues at harvest were 0.028 ppm in lettuce, 0.018 and 0.0096 ppm in carrot tops and roots, respectively, and 0.047 and 0.061 ppm in barley grain and straw, respectively. In immature lettuce harvested at 35 and 61 days postplanting, [^{14}C]residues were 0.057 and 0.043 ppm, respectively; in barley forage harvested at 48 days postplanting, [^{14}C]residues were 0.056 ppm. (MRID 41543201 and 41543202)

(12) Accumulation in Irrigated Crops

Alfalfa, corn (grain and forage), grass (fescue or sudan) and lettuce were irrigated five to eight times during the 1987 growing season with glyphosate treated water containing a maximum of 21.3 ppm (on treatment day then fell to 0.46 ppm by 1 day after treatment) of glyphosate. Residues in the sediment beneath the treated water reached a maximum of 3.5 ppm at 14 days after treatment. Residues of glyphosate in the sprinkler water at the pond site were the highest 7 days after treatment at 0.12 ppm. One lettuce sample from the Missouri location (the pond site) at 29 days after treatment (of water source) and 5 irrigation events was found to contain 0.06 ppm glyphosate. (MRID 40541305)

(13) Bioaccumulation in Fish

Maximum bioconcentration factors were 0.38X for edible tissues, 0.63X for nonedible tissues, and 0.52X for whole fish. (MRID 41228301)

(14) Laboratory and Field Volatility

The requirement of these studies was waived based on the low vapor pressure of glyphosate.

b. Environmental Fate and Groundwater Assessment

In general, the available field and laboratory data indicate glyphosate adsorbs strongly to soil and would not be expected to move vertically below the 6 inch soil layer. Based on unaged batch equilibrium studies glyphosate and glyphosate residues are expected to be immobile with $Kd_{(ads)}$ values ranging from 62 to 175. The mechanism of adsorption is unclear; however, it is speculated that it may be associated with vacant phosphate sorption sites or high levels of metallic soil cations. The data indicate that chemical and photochemical decomposition is not a significant pathway of degradation of glyphosate in soil and water. However, glyphosate is readily degraded by soil microbes to aminomethyl phosphonic acid (AMPA), which is degraded to CO_2, although at a slower rate than parent glyphosate. Even though glyphosate is highly water soluble it appears that parent glyphosate and AMPA have a low potential to move to groundwater due to their strong adsorptive characteristics demonstrated in the laboratory and field studies. However, glyphosate does have the potential to contaminate surface waters due to its aquatic use patterns and erosion via transport of residues adsorbed to soil particles suspended in runoff water. If glyphosate were to reach surface water it would be resistant to hydrolysis and aqueous photolysis.

Based on the low vapor pressure of glyphosate, volatilization from soils will not be an important dissipation mechanism. The low octanol/water coefficient suggests that glyphosate will have a low tendency to accumulate in fish.

2. Ecological Effects

a. Ecological Hazard

(1) Effects to Nontarget Birds

To establish the toxicity of glyphosate to birds, tests were required using the technical grade material.

(a) Avian Single-Dose Oral LD_{50} - Technical

Acute Oral Toxicity Findings			
Species	% AI	LD_{50} (95% CL)	Conclusions
Bobwhite quail	83%	> 2000 mg/kg	practically non-toxic to upland game birds

One avian single-dose oral study on either a waterfowl species (preferably mallard duck) or an upland species (preferably bobwhite quail) was required. These data indicate that technical glyphosate is practically non-toxic to an upland bird species on an acute oral basis. The guideline requirement for an avian acute oral study is fulfilled. (Study ID 234395)

(b) Avian Dietary - Technical

Avian Subacute Dietary Toxicity Findings			
Species	% AI	Reproductive Impairment	Conclusions
Mallard duck	98.5% Tech	> 4640 ppm	no more than slightly toxic to upland game birds and waterfowl
Bobwhite quail	98.% Tech	> 4640 ppm	

Two subacute dietary studies, one study on a species of waterfowl (preferably mallard duck) and one on an upland game bird species (preferably a bobwhite quail), were required. These data indicate that the technical glyphosate is no more than slightly toxic to birds on a dietary basis. The guideline requirement is fulfilled for both studies. (Study IDs 94171 and 00086492)

(c) Avian Reproduction

Avian Reproduction Findings			
Species	**% AI**	**Reproductive Impairment**	**Conclusions**
Mallard duck	83% Tech	No effects up to 1000 ppm	not expected to cause reproductive impairment
Mallard duck	90.4% Tech	No effects up to 30 ppm	
Bobwhite quail	83% Tech	No effects up to 1000 ppm	

An avian reproduction test was required to support registration of the end-use products of glyphosate since the following guideline criteria have been exceeded. The labeling for several use patterns contains directions for use under which birds may be subject to repeated exposure to glyphosate. The labeling allows repeat application for certain uses, such as alfalfa, barley, oats, apples, cherries, and oranges. These data indicate that technical glyphosate is not expected to cause reproductive impairment. The guideline requirements for an avian reproduction study on both upland game bird and waterfowl are fulfilled. (Study IDs 235924, 00036328, and 235924)

(d) Summary of Findings

Glyphosate is practically non-toxic to bobwhite quail on the basis of acute oral toxicity. An LD_{50} greater than 2000 mg/kg was determined for bobwhite quail given a single oral dose of technical glyphosate. Studies indicate that the 8-day dietary LC_{50} of the chemical is greater than 4000 ppm for both mallard ducks and bobwhite quail. These data indicate that the chemical is slightly toxic to birds. Avian reproduction studies indicate reproductive impairment would not be expected at a dietary level of up to 1000 ppm. The available acute toxicity data do not indicate a requirement of precautionary labeling for birds on products containing glyphosate.

(2) Effects on Non-Target Fish

(a) Acute Toxicity to Freshwater Fish

Acute Toxicity to Freshwater Fish Findings			
Species	**% AI**	**48-hr LC_{50} (95%CL)**	**Conclusions**
Bluegill sunfish	96.5%	> 24 mg/l	ranges in toxicity from slightly non-toxic to practically non-toxic to both cold water and warm water fish
Fathead Minnow	87.3%	84.9 mg/l (72.9-99.3)	
Bluegill sunfish	83%	120 mg/l (111-130)	
Rainbow Trout	83%	86 mg/l (70-106)	
Rainbow Trout	96.7%	140 mg/l (120-170)	
Fathead minnow	96.7%	97 mg/l (79-120)	
Channel catfish	96.7%	130 mg/l (110-160)	
Bluegill sunfish	96.7%	140 mg/l (110-160)	

The minimum data required for establishing the acute toxicity of glyphosate to freshwater fish are the results of two 96-hour studies with the technical grade product. One study was to be performed on a cold water fish species (preferably rainbow trout) and one study was to be performed using a warm water species (preferably bluegill sunfish). The results of these eight studies indicate that technical glyphosate is slightly to practically nontoxic to both cold water and warm water fish. The guidelines requirement for acute toxicity testing of the technical on freshwater fish is fulfilled. (Study IDs 00108112, 00108171, 234395, 097661, and 249160)

(b) Chronic Toxicity to Freshwater Fish

Chronic Toxicity to Freshwater Fish Findings			
Species	% AI	Results	Conclusions
Fathead Minnow	87.3% tech	MATC > 25.7 mg/l	no effects at or below this level

Due to the aquatic use of the chemical, its presence in water is likely to be continuous or recurrent regardless of toxicity; therefore, chronic testing was required. This fish full life cycle study satisfies the generic guideline requirement for chronic freshwater fish testing. (Study ID 00108171)

Acute Toxicity to Freshwater Fish Findings from Studies using Formulated Products			
Species	% AI (IPA salt)	96-hr LC_{50} (95% CL)	Conclusions
Bluegill sunfish	41.8%	5.8 mg/l (4.4-8.3)	ranges in toxicity from moderately toxic to practically non-toxic to both warmwater and coldwater fish
Rainbow Trout	41.8%	8.2 mg/l (6.4-9.0)	
Channel catfish	41.36%	16 mg/l (9.4-26)	
Rainbow Trout	41.36	11 mg/l (8.7-14)	
Bluegill sunfish	41.36%	14 mg/l (8.7-24)	
Fathead Minnow	41.36%	9.4 mg/l (5.6-16)	
Rainbow Trout	62.4%	>1000 mg/l	
Bluegill sunfish	62.4%	>1000 mg/l	

Acute Toxicity to Freshwater Fish
Findings from Studies using Formulated Products

Rainbow Trout	*41.2% + 15.3 "AA" surfactant	120 mg/l (56-180)
Rainbow Trout	*40.7% + 15% "W" surfactant	150 mg/l (100-320)
Bluegill sunfish	*40.7% + 15% "W" surfactant	>100 mg/l
Bluegill sunfish	*41.2% + 15.3% "AA" surfactant	>180 mg/l
Rainbow Trout	7.03% + 0.5% "X-77"	240 mg/l (180-320 mg/l)
Bluegill sunfish	7.03% + 0.5% "X-77"	830 mg/l (620-1600)
Rainbow Trout	51%	8.3 mg/l (7.0-9.9)
Fathead minnows	41%	2.3 mg/l (1.9-2.8)
Rainbow Trout	41%	9.0 mg/l (7.5-11)
Bluegill sunfish	41%	4.3 mg/l (3.4-5.5)
Channel catfish	41%	13 mg/l (11-16)
Bluegill sunfish	41%	5 mg/l (3.8-6.6)
Rainbow Trout	41%	1.3 mg/l (1.1-16)

Testing of an end-use product is required if the pesticide will be introduced directly into an aquatic environment when used as directed by the label. Drainage systems would be included in such a category. Therefore, formulated product testing was required. According to the surfactant selected, the formulated product toxicity ranges from moderately toxic to practically non-toxic. (Study ID 249159, 00070894, 00070895, 00070897, 00070896, 00078661, 00078662, 00078658, 00078655, 00078656, 00078659, 00078664, 00078665, 249160)

Surfactant Test Findings			
Species	**% AI**	**96-hour LC_{50} (95% CL)**	**Conclusions**
Fathead minnow	MONO818 Tech 100%	1.0 mg/l (1.2-1.7)	ranges in toxicity from highly toxic to slightly toxic to warmwater and coldwater fish
Rainbow trout	MONO818 Tech 100%	2.0 mg/l (1.5-2.7)	
Rainbow Trout	MONO818	0.65 mg/l (.54-.78)	
Channel Catfish	MONO818 Tech 100%	13 mg/l (10-17)	
Bluegill sunfish	MONO818 Tech 100%	3.0 (2.5-3.7)	
Bluegill sunfish	MONO818 Tech 100%	1 mg/l (.72-1.4)	

Testing of the surfactant may be required under unusual circumstances. When inerts are likely to be toxic, testing can be required. These data indicate that MONO818 ranges from moderately toxic to very highly toxic to both cold and warm water fish after 96 hour exposure. (Study ID 249160)

(c) Summary of Findings

Three tests on warm water species, one bluegill and two with fathead minnow, produced the 96-hour LC_{50}s of 120 ppm, 84.9 ppm, and 97 ppm, respectively (McAllister and Forbis 1978, ID #234395; EG & G Bionomics 1975, ID #00108171 and Folmar, Sanders, and Julin 1979, ID #249160). Two rainbow trout 96-hour LC_{50}s provided values of 86 ppm and 140 ppm. Based on these tests, technical glyphosate ranges

from slightly to practically non-toxic to freshwater fish species.

Surfactant testing was performed with both cold water and warm water fish. In this case, the initial formulation demonstrated an application rate much lower than technical glyphosate. The LC_{50} for rainbow trout was 1.3 mg/l or moderately toxic. The surfactant (MON0818) when tested alone produced an LC_{50} value of 0.65 mg/l for rainbow trout indicating a highly toxic category (Folmar et al. 1979, ID #249160). In contrast, the formulation of 41.2 percent isopropylamine salt and 15.3 percent "AA" surfactant provided a rainbow trout LC_{50} of 120 mg/l, indicating a practically non-toxic compound (Thompson and Griffen 1980, ID #00078658). Bluegill are in the same category of toxicity with an even higher LC_{50} of greater than 180 mg/l (Thompson and Griffen 1980, ID #00078659). The bluegill and rainbow trout were similar in sensitivity to the formulation containing the "W" surfactant with LC_{50} values of 150 and >100 mg/l, respectively. Also, neither rainbow trout (LC_{50} 240 mg/l) nor bluegill (LC_{50} 830 mg/l) were very sensitive to the x-77(.5) surfactant and glyphosate(7.03%).

The surfactant MON0818 has been tested separately, producing an LC_{50} of 13 mg/l on *Chironomous* indicating it is a slightly toxic material. For fish, the catfish appears to be the most tolerant with an LC_{50} value of 13 mg/l, and rainbow trout the most sensitive with an LC_{50} value of 0.65 mg/l. Based upon available data products containing MON0818 must include the statement, "This pesticide is toxic to fish."

(3) Effects on Aquatic Invertebrates

(a) Acute Toxicity to Freshwater Invertebrates

Acute Toxicity to Freshwater Invertebrates Findings			
Species	% AI	48-hr LC_{50} (ppm)	Conclusions
Daphnia magna	83% tech	780	ranges in toxicity from slightly toxic to practically non-toxic to freshwater invertebrates
Chironomus plumosus	96.7% tech	55 (31-97)	

The minimum data requirement to establish the acute toxicity of glyphosate to freshwater invertebrates is a 48-hour acute study using the technical material. Test organisms should be first instar *Daphnia magna* or early instar amphipods, stone flies or mayflies. The results of these studies indicate that technical glyphosate is slightly toxic to *Chironomus plumosus* and is practically non toxic to *Daphnia magna*. The guideline requirement for acute testing on a freshwater invertebrate has been fulfilled. (Study ID 00108172, and 249160)

(b) Chronic Toxicity to Freshwater Invertebrates

Chronic Toxicity to Freshwater Invertebrates Findings			
Species	% AI	Results	Conclusions
Daphnia magna	99.7% tech	MATC > 50 - < 96 mg/L	caused reduced reproductive capacity

Due to the aquatic use of the chemical its presence in water is likely to be continuous or recurrent regardless of toxicity; therefore, chronic testing was required. This study satisfies the guideline requirement for chronic freshwater invertebrate testing. (Study ID 249160)

Acute Toxicity to Freshwater Invertebrates Findings from Studies using Formulated Products			
Species	% AI (IPA salt)	48-hr LC_{50} (ppm)	Conclusions
Daphnia magna	62.4%	869 (703-1019)	ranges in toxicity from moderately toxic to practically non-toxic to freshwater invertebrates

Acute Toxicity to Freshwater Invertebrates
Findings from Studies using Formulated Products

Daphnia magna	7.03% + X-77 surfactant @0.5%	>1000
Daphnia magna	41.2% + "AA" surfactant @ 15.3%	310 (250-400)
Daphnia magna	40.7% MON2139 + 15% "W" surfactant	72 (62-83)
Daphnia magna	41%	3 (2.6-3.4)
Gammarus pseudolimnaeus	41%	62 (40-98)
Chironomus plumosus	41%	18 (9.4-32)
Daphnia pulex	51% MON 2139	242(224-261.5)
Daphnia magna	41.36%	5.3 (4.4-6.3)
Gammarus pseudolimnaeus	41.83%	41.9 (30.7-62)
		Other results
Ephemerella walkeri	41%	Mayfly nymphs avoided glyphosate at concentrations of 10 mg/L but not at 1.0 mg/l.

Acute Toxicity to Freshwater Invertebrates Findings from Studies using Formulated Products			
Chironomus plumosus	41%	Significant increases in stream drift of midge larvae was observed after the 2.0 mg/l, but not at the 0.02 or 0.2 mg/l level.	

Testing of an end-use product is required if the pesticide will be introduced directly into an aquatic environment when used as directed by the label. Drainage systems (wet and dry) would be included in such a category. Therefore, formulated product testing was required. According to the surfactant selected, the formulated product toxicity ranges from moderately toxic to practically non-toxic. (Study ID 00078663, 00078666, 00078660, 00078657, 249160, 00108109, 00070893, and 249159)

Surfactant Test Findings			
Species	% AI	48-hr LC_{50} (95%CL)	Conclusions
Daphnia magna	100% MONO818 surfactant	13 mg/L (7.1-24)	slightly toxic to freshwater invertebrates

Testing of the surfactant may be required under unusual circumstances. One test on the surfactant was received and determined as acceptable for use in a risk assessment. (Study ID 249160)

(d) Summary of Findings

A 48-hour LC_{50} of 780 ppm (mg/l) was found for *Daphnia magna* exposed to technical glyphosate (McAllister and Forbis 1978, ID #00108172). The results of this study indicate that the chemical is practically non-toxic to aquatic invertebrates.

In addition to these acute studies, a fish life-cycle study indicates technical glyphosate has a MATC greater than 25.7 ppm. No effect was observed at the highest level tested. A *Daphnia magna* life cycle study with an MATC of >50 - <96 ppm reported reduced reproductive capacity, the most sensitive parameter.

The available acute toxicity data indicate that precautionary labeling for freshwater intervertebrates is not required for products containing glyphosate.

In order to determine the effect of the three surfactants ("W", "AA", and "X-77") on invertebrates, additional *Daphnia* studies were conducted. The 7.03 percent isopropylamine salt of glyphosate with a surfactant at 0.5 percent identified as X-77 resulted in an LC_{50} of greater than 1000 mg/l or practically non-toxic category for *Daphnia*. The second combination was 41.2 percent isopropylamine and 15.3 percent of a surfactant identified as "AA." This LC_{50} was 310 ppm which would indicate it is practically non-toxic to *Daphnia*. The third combination consisted of 40.7 percent isopropylamine and 15 percent of a surfactant identified as "W." The resultant LC_{50} of 72 ppm reveals that this material is slightly toxic to *Daphnia*.

A glyphosate formulation was tested several times with different invertebrates. The LC_{50} values ranged from 3 mg/l for *Daphnia* to 62 mg/l for *Gammarus* indicating a moderately toxic material for *Daphnia* and no more than slightly toxic for *Gammarus*.

(4) Effects on Marine/Estuarine Organisms

(a) Acute Toxicity

Acute toxicity testing for estuarine and marine organisms on technical glyphosate is required. The guidelines require estuarine and marine studies when exposure of such waters is likely. Crops, such as cotton, corn, sugarcane, turf, citrus, berries, forestry, sorghum, watermelon, etc. would allow this type of exposure to occur.

Acute toxicity testing for estuarine and marine organisms on formulated glyphosate may be required when exposure to estuarine and marine water is expected. The use in drainage systems (wet or dry) would allow this type of exposure. Minimum requirements are results from testing the technical on one estuarine fish (96 hrs LC_{50}) and either a 48 hrs oyster larvae study or a 96 hrs shell deposition study. Again, since there is such an extensive data set for this chemical, the Agency can determine that glyphosate demonstrates low toxicity to fish and oyster species, and therefore is waiving the marine fish and oyster acute toxicity studies on the formulated product.

Acute Toxicity to Estuarine and Marine Organisms Findings

Species	% AI	Results	Conclusions
Grass shrimp	96.7% tech	LC_{50} 281 ppm (207-381)	ranges in toxicity from slightly to practically non-toxic to marine organisms
Fiddler crab	96.7% tech	LC_{50} 934 ppm (555-1570)	
Atlantic oyster	96.7% tech	TL_{50} > 10 mg/L for 48 hours	

These data on marine/estuarine species are acceptable for use in a risk assessment. These data indicate that technical glyphosate is practically non-toxic to grass shrimp, fiddler crab, and

slightly toxic to the Atlantic oyster. Acute toxicity testing on an estuarine fish species is normally required. However, since there is such an extensive data set for this chemical, the Agency can determine that glyphosate demonstrates low toxicity to fish species, and therefore is waiving the marine fish acute toxicity study. (Study ID 00108110, and 00108111)

(b) Summary of Findings

A series of studies were performed on marine/ estuarine species. A 96-hour LC_{50} of 281 ppm was determined for grass shrimp (*Palaemonetas vulgaris*). In a study on fiddler crabs (*Uca pugilator*), it was determined that the 96-hour LC_{50} is 934 ppm glyphosate. Both of these studies indicate technical glyphosate is practically non-toxic to grass shrimp and fiddler crabs. An embryo-larvae 48-hour TL_{50} for Atlantic oyster greater than 10 ppm indicating glyphosate is slightly toxic.

(5) Effects on Non-Target Insects

(a) Acute Toxicity Testing

Acute Toxicity to Honeybees Data

Species	AI %	Results	Conclusions
Honeybee acute oral	tech*CP67573	oral LD_{50} > 100μg/bee	practically non-toxic to honeybees on an acute oral and acute contact basis
Honeybee acute oral	36 % MON2139	oral LD_{50} > 100μg/bee	
Honeybee acute contact	tech*CP67573	contact LD_{50} > 100μg/bee	
Honeybee acute contact	36 % MON2139	contact LD_{50} > 100μg/bee	

* - The percentage of active ingredient used was not reported.

The guidelines require acute toxicity testing to honeybees on the technical when a herbicide is registered as a general use herbicide. Given the multitude of use patterns for which this chemical is registered, acute honeybee toxicity studies are required. Based on these data, glyphosate (CP67573) is considered practically nontoxic on the basis of acute contact toxicity, as well as on

acute oral toxicity. These data satisfy guideline requirements for nontarget insect studies when glyphosate is used as a general use herbicide. (Fiche No. 00026489)

(b) ~~Summary of Findings~~

Four studies were conducted, two on technical glyphosate and two on the formulation MON2139, consisting of 36 % active ingredient. Results from the honeybee acute oral toxicity study indicates both technical and formulated glyphosate are practically nontoxic to the honey bee with LD_{50} values greater than 100 μg/bee. Results from the honeybee acute contact toxicity study indicates both technical and formulated glyphosate are practically nontoxic to the honey bee with LD_{50} values greater than 100 μg/bee.

(6) Effects to Non-Target Plants

When a herbicide is applied as a terrestrial nonfood use, aquatic nonfood use, or as a forestry use, Tier I nontarget phytotoxicity studies are required in order to evaluate the effects of the herbicide on nontarget plants.

(a) Phytotoxicity Testing

Effects on Non-Target Plant Findings

Species	%AI	Results
Selenastrum capricornutum	96.6	4 day EC_{50} = 12.5 mg/l
Navicula pelliculosa	96.6	4 Day EC_{50} = 39.9 mg/l
Skeletonema costatum	96.6	4 day EC_{50} = 0.85 mg/l
Anabaena flos-aquae	96.6	4 day EC_{50} = 11.7 mg/l

Effects on Non-Target Plant Findings		
Lemna gibba	96.6	7 day EC_{50} = 21.5 mg/l

Based on the results of the preceding studies, the data indicates that the 4 day EC_{50} ranged from 0.85 mg/l to 39.9 mg/l for four aquatic plant species, and a 7 day EC_{50} of 21.5 mg/l for one aquatic species. Based on the data submitted, the requirements for Tier I and Tier II Aquatic Plant Growth Studies (122-2 and 123-2) have been fulfilled.

A seed germination/seedling emergence study was conducted (MRID 40159301) on isopropylamine salt of glyphosate CP-70139 (Tech) 50% acid basis. The results indicate that CP-70139 applied at a rate up to 10.0 lb ai/A resulted in <25 % effect on the spectrum of monocots and dicots tested. Based on the results of this study, Tier I data requirements for seed germination/seedling emergence guideline reference 122-1 have been satisfied. (MRIDs 40236901, 40236902, 40236903, 40236934, and 40236905)

(b) Summary of Findings

Based on the results of the aquatic plant growth studies which were conducted on 5 species, the data indicates that the 4 day EC_{50} ranged from 0.85 mg/l to 39.9 mg/l for four aquatic plant species, and a 7 day EC_{50} of 21.5 mg/l for one aquatic species.

A seed germination/seedling emergence study was conducted on isopropylamine salt of glyphosate CP-70139 (Tech) 50% acid basis. The results indicate that CP-70139 applied at a rate up to 10.0 lb ai/A resulted in <25 % effect on the spectrum of monocots and dicots tested.

Based on the use patterns, the method of application, and the chemical properties of glyphosate, additional studies are required to evaluate the effects on nontarget plants. The recommended labels do not preclude off-target movement of glyphosate by drift. Nor do they address the potential off-target movement via terrestrial plants as well as aquatic plants. Therefore, the Agency is requiring terrestrial plant test data to assess potential risk to nontarget plants. The data required are the Tier II

Vegetative Vigor Guideline Reference No. 123-1. In addition, droplet size spectrum (201-1) and drift field evaluation (202-1) data are required.

These three guideline studies, Vegetative Vigor, Droplet Size Spectrum, and Drift Field Evaluation are not considered part of the target data base for reregistration. These data do not affect the reregistration eligibility of glyphosate. If, upon review of the data from these studies, modification in use practices and/or precautionary measures are necessary, the Agency will require all registrants to make label changes as appropriate.

b. Ecological Effects Risk Assessment

Based on the current data, it has been determined that effects to birds, mammals, fish and invertebrates are minimal. Under certain use conditions, glyphosate is expected to cause adverse effects to nontarget aquatic plants. Additional data are needed in order to fully evaluate the effects of glyphosate on nontarget terrestrial plants. This includes results from vegetative vigor testing (123-1), droplet size spectrum (201-1). In addition, the drift field evaluation (202-1) study must be submitted and reviewed. Risk reduction measures cannot be recommended until data are submitted and evaluated.

(1) Non-Endangered Species

(a) Terrestrial Species

The acute oral LD_{50} found for bobwhite quail dosed with technical glyphosate is greater than 3851 mg/kg. This indicates that the chemical is practically non-toxic to an upland game species. On a dietary basis, the available data indicate that, at most, technical glyphosate is slightly toxic to both mallards and bobwhite (LC_{50} > 4640). The articles of Hoerger and Kenaga (1972) and Kenaga (1973) were consulted in order to estimate the maximum

concentration of glyphosate which may occur at the highest application rate for such sites as, cotton and corn. The following chart addresses the major vegetation categories upon which fauna are expected to feed.

Feed Category Concentrations (ppm) @ 5.0625 lbs ai/A	
Short grass	1215
Long grass	557
Leafy crops	632
Forage; small insects	294
Pods; large insects	61
Fruit	35

Comparing these residues to the dietary data for both bobwhite and mallards (LC_{50} > 4640; 1/5th the LC_{50} > 928), higher use rates may produce potentially toxic residues on short grass only (assuming the LC_{50} is just over > 4640). Wildlife ingesting significant amounts of insects, pods and/or fruits should not be affected by single applications.

Directions for some of the use patterns do indicate that applications can be repeated. Multiple treatments could potentially increase residues on dietary items within an extended time period. Also, the available information suggest that glyphosate is relatively persistent. The half-life in soil is as high as 90.2 days. However, avian reproduction studies demonstrated no adverse effects at the highest level tested, 1000 parts per million. Similarly, 90-day dietary studies with dogs and rats indicate no significant abnormalities when the maximum level tested is 2000 parts per million. Based on this, minimal risk is expected.

(b) Aquatic Species

Aquatic organisms do not appear to be sensitive to technical glyphosate. The most sensitive aquatic invertebrate tested is *Chironomus plumosus* with a 48-hr LC_{50} of 55 ppm which is very near to the lower limit of the *Daphnia* chronic MATC of 50 mg/l. The most sensitive fish species are fathead minnow and rainbow trout which have 96-hour LC_{50}s of 84.9 and 86 mg/l. Chronic testing for the technical with fathead minnow provided an MATC of > 25.7 mg/l. Based on the toxicity and the various EEC's the Agency has determined technical glyphosate should not cause acute or chronic adverse effects to aquatic environments. Therefore, minimal risk is expected to aquatic organisms from the technical glyphosate.

(c) Terrestrial Plants and Aquatic Macrophytes

A seed germination/seedling emergence study was conducted on isopropylamine salt of glyphosate CP-70139 (Tech) 50% acid basis. The results indicate that CP-70139 applied at a rate up to 10.0 lb ai/A resulted in <25 % effect on the spectrum of monocots and dicots tested. Considering the use patterns that are terrestrial food crop and non-food crop the above EEC's were considered for evaluating the effects to nontarget plants. The highest exposure of 0.404 lb a.i. (from aerial application, mist blower and sprinkler irrigation) is well below the 10.0 lb a.i./A rate which resulted in < 25 % effect on the monocots and dicots tested. Therefore, it has been determined that the use of glyphosate is not expected to cause adverse effects on seed germination/seedling emergence with the various registered use patterns. (MRID 40159301)

No vegetative vigor (123-1) plant studies have been conducted. Based on the use patterns, the method of application and the chemical properties of glyphosate, additional studies are required to evaluate these effects on nontarget terrestrial plants. The recommended labeling precautions do not preclude off-target movement of glyphosate by drift. To assess potential risk to terrestrial plants the Agency is requiring additional terrestrial plant test data, including results from vegetative vigor testing, droplet size spectrum testing and drift field evaluation. These data are not part of the target data base for reregistration. Risk reduction measures cannot be recommended until data are submitted and evaluated. If, upon review of the data from these studies, modification in use practices and/or precautionary measures are necessary, the Agency will require all registrants to make label changes as appropriate.

The aquatic EEC from direct application of 3.72 ppm was used to estimate exposure. Based on the results of the aquatic macrophyte toxicity data, the 4 day EC_{50} was reported to be as low as 0.85 ppm indicating that there may be adverse effects to nontarget aquatic plant species.

(2) Endangered Species

Based on the toxicity data and the estimated exposure, it is not expected that endangered terrestrial or aquatic organisms will be affected from the use of glyphosate on the registered uses since the EEC's are well below the endangered species criteria (birds = 1/10 LC_{50}, aquatic organisms = 1/20 LC_{50}). However, many endangered plants may be at risk from the use of glyphosate on the registered use patterns. In addition, as discussed in the 1986 Glyphosate Registration Standard, it was determined that based on habitat, the Houston Toad may be at risk from the use of glyphosate on alfalfa.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing glyphosate active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing the isopropylamine and sodium salts of glyphosate. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of glyphosate, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of glyphosate and to determine that glyphosate can be used without resulting in unreasonable adverse effects to man and the environment. The Agency therefore finds that all products containing glyphosate as the active ingredients are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data and the data identified in Appendix B. Although the Agency has found that all uses of glyphosate (isopropylamine and sodium salt formulations) are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing glyphosate, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient glyphosate, the Agency has sufficient information on the health effects of glyphosate and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency

concludes that products containing glyphosate for all uses are eligible for reregistration.

The Agency has determined that glyphosate products, labeled and used as specified in this Reregistration Eligibility Document, will not pose unreasonable risks or adverse effects to humans or the environment.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of glyphosate are eligible for reregistration.

B. Regulatory Position

The following is a summary of the regulatory positions and rationales for glyphosate. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Tolerance Re-assessment

The Agency has determined that aminomethyl phosphonic acid (AMPA), the metabolite of glyphosate, no longer needs to be regulated and therefore this compound will be dropped from the tolerance expression. Also, although the monoammonium salt of glyphosate is not subject to reregistration, the available data are to allow re-assessment of existing tolerances for residues resulting from the application of the monoammonium salt of glyphosate.

Tolerances Listed Under 40 CFR §180.364(a):

The tolerances listed in 40 CFR §180.364(a) are for the combined residues of glyphosate and its metabolite AMPA resulting from application of the isopropylamine salt of glyphosate and/or the monoammonium salt of glyphosate.

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.364(a) for: acerola; alfalfa, forage, seed, and hay; almonds, hulls; artichokes, Jerusalem; asparagus; atemoya; avocados; Bahiagrass; bananas; beets, garden, roots; Bermudagrass; bluegrass; Brassica leafy vegetables group; bromegrass; bulb vegetables group; carambola; carrots; cereal grains

group; citrus fruits group; coffee beans, green; clover; cotton forage; cotton hay; cottonseed; cranberries; cucurbit vegetables group; fescue; figs; foliage of legume vegetables group; fruiting vegetables group; grapes; grass forage, fodder, and hay group; guavas; horseradish; kiwifruit; leafy vegetables group; leaves of the root and tuber vegetables group; legume vegetables group; longan fruit; lychee; mangoes; non-grass animal feeds group, forage and hay; orchardgrass; papayas; parsnips; passion fruit; peanuts; peanuts, vines; pineapple; pistachio; pome fruits group; radishes; rutabagas; ryegrass; sapodilla; sapote; small fruits and berries group; soybeans; soybean, forage; stone fruits group; sugar apple; sugar beets; sweet potatoes; timothy; tree nuts group; turnip roots; wheatgrass; and yams. Certain commodity definitions of the above tolerances are not in accordance with the definitions listed in Table II of Subdivision O; see the tolerance re-assessment table on page 63 for modifications in commodity definitions.

The established crop group tolerances for the now-obsolete "seed and pod vegetables" (0.2 ppm) and "seed and pod vegetables, forage and hay" (0.2 ppm) are inappropriate and are to be replaced with "legume vegetables group (except soybeans)" and "legume vegetables group, foliage of (except soybean forage and hay)," respectively. Soybeans must be excluded from the crop group tolerances because the use pattern for soybeans is different from other legume vegetables, and the established tolerance for soybeans and soybean forage and hay differ by a factor >5x from other legume vegetables. To achieve compatibility with Codex MRLs for selected commodities, the following actions must be taken (see the table on page 68): (i) increase U.S. tolerance for legume vegetables group (except soybeans) from 0.2 ppm to 5 ppm; and (ii) increase U.S. tolerance for soybean hay from 15 ppm to 20 ppm.

The individual tolerances for cranberries (0.2 ppm) and grapes (0.2 ppm) should be revoked since these fruits are covered by the crop group tolerance (0.2 ppm) for small fruits and berries. The tolerance for cotton hay is to be revoked since this is not a raw agricultural commodity of cotton.

Tolerances for wheat, grain and wheat, straw at 4 and 85 ppm, respectively, have been proposed (PP0F3865/FAP2H5635). When these tolerances have been established, the tolerances for the cereal grains group and the cereal grains group, forage, fodder, and straw should be modified to "cereal grains group (except wheat)" and "cereal grains group, forage, fodder, and straw (except wheat straw)", respectively. To achieve compatibility with the Codex MRL for wheat grain, the U.S. tolerance should be established at 5 ppm (see the table on page 68).

The existing and conflicting tolerances for alfalfa (200 ppm), alfalfa fresh and hay (0.2 ppm), clover (200 ppm), and forage legumes (except soybeans and peanuts; 0.4 ppm) should be deleted. Concomitant with the deletion of these tolerances, a tolerance of 100 ppm for residues in or on the non-grass animal feeds group, forage and hay, is to be established. The available data from alfalfa, lespedeza, and trefoil will support this crop group tolerance.

The established tolerances for "forage grasses" (0.2 ppm), "grasses, forage" (0.2 ppm), Bahiagrass (200 ppm), Bermudagrass (200 ppm), bluegrass (200 ppm), bromegrass (200 ppm), fescue (200 ppm), orchardgrass (200 ppm), ryegrass (200 ppm), timothy (200 ppm), and wheatgrass (200 ppm) is to be deleted. Concomitant with the deletion of these tolerances, a tolerance for residues in on or on the grass forage, fodder, and hay group is to be established at 100 ppm. The available data indicate that following registered use, residues in or on the grass forage, fodder, and hay group will not exceed 100 ppm.

Individual tolerances exist for residues in or on salsify and the following tropical/subtropical crops: breadfruit; canistel; cherimoya; cocoa beans; coconut; dates; genip; jaboticaba; jackfruit; persimmons; sapote (black and white); soursop; and tamarind. There are currently no registered uses of glyphosate on these crop sites. These tolerances will be revoked.

A tolerance of 200 ppm has recently been established for residues in or on soybean straw (FR 42701, 9/16/92). However, this tolerance is to be revoked since this is not a raw agricultural commodity of soybeans. The tolerance for soybeans, hay should be raised to cover this desiccant use.

The expression negligible residues (N) should be deleted. For a complete listing of appropriate commodity definition changes and recommendations, see the table on page 63.

Tolerances Listed Under 40 CFR §180.364(b):

The tolerances listed in 40 CFR §180.364(b) are for the combined residues of glyphosate and its metabolite AMPA resulting from application of the glyphosate isopropylamine salt and/or glyphosate monoammonium salt for herbicidal and plant growth regulator purposes and/or the sodium sesqui salt for plant regulator purposes.

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.364(b) for: liver and kidney of cattle, goats, hogs, horses, poultry, and sheep; peanuts; peanuts, hay; peanuts, hulls; sugarcane; fish; and shellfish. See the table on page 63 for modifications in commodity definitions.

Tolerances Listed Under 40 CFR §180.364(c):

The tolerances listed in 40 CFR §180.364(c) are for the combined residues of glyphosate and its metabolite AMPA resulting from the use of irrigation water containing residues of 0.5 ppm following applications on or around aquatic sites, and are established at 0.1 ppm. The Agency's Office of Water has established a maximum contaminant level (MCL) of 0.7 ppm for glyphosate *per se* in drinking water (FR Notice: Vol. 57, No. 138, page 31776, dated July 17, 1992).

Sufficient data are available to ascertain the established tolerances listed in 40 CFR §180.364(c) for the crop groupings Brassica leafy vegetables group; bulb vegetables group; cereal grains group; citrus fruits group; cucurbit vegetables group; foliage of legume vegetables group; forage, fodder, and straw of the cereal grains group; fruiting vegetables group; grass forage, fodder and hay group; leafy vegetables group; leaves of the root and tuber vegetables group; legume vegetables group; non-grass animal feeds group, forage and hay; pome fruits group; root and tuber vegetables group; stone fruits group; tree nuts group; and the individual commodities avocados, cottonseed, and hops. See the table on page 63 for modifications in commodity definitions.

Tolerances Listed Under 40 CFR §185.3500:

The tolerances listed in 40 CFR §185.3500(1) are for the combined residues of glyphosate and its metabolite AMPA resulting from the application of the glyphosate for herbicidal purposes and/or the sodium sesqui salt for plant regulator purposes.

Sufficient data are available to ascertain the adequacy of the established food additive tolerances listed in 40 CFR §185.3500(1) for sugarcane, molasses. See the table on page 63 for modifications in commodity definitions.

The tolerances listed in 40 CFR §185.3500(2) are for the combined residues of glyphosate and its metabolite AMPA resulting from the application of the isopropylamine salt of glyphosate for herbicidal purposes.

Sufficient data are available to ascertain the adequacy of the established food additive tolerances listed in 40 CFR §185.3500(2) for olives (imported), palm oil, dried tea and instant tea. See the table on page 63 for modifications in commodity definitions.

A 12-ppm food additive tolerance for wheat milling fractions (except flour) has been proposed (FAP2H5635). To achieve compatibility with the Codex MRL for wheat bran, unprocessed, the U.S. tolerance should be established at 40 ppm (see the table on page 68).

Tolerances Listed Under 40 CFR §186.3500:

The tolerances listed in 40 CFR §186.3500(a) are for the combined residues of glyphosate and its metabolite AMPA.

Sufficient data are available to ascertain the adequacy of the established feed additive tolerances listed in 40 CFR §186.3500(a) for dried citrus pulp and soybean hulls. See the table on page 63 for modifications in commodity definitions.

A tolerance has recently been established at 1.0 ppm for the combined residues of glyphosate and AMPA in citrus, molasses (FR 42701, 9/16/92).

Existing tolerances of glyphosate are currently established in the Title 40 of the Code of Federal Regulations, §180.364. The reassessment of the established tolerances is set forth in the Tolerance Reassessment Table as follows.

Commodity	Current Tolerance [1] (ppm)	Tolerance [2] Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 180.364(a):			
Acerola	0.2		
Alfalfa Alfalfa, fresh and hay Clover Forage legumes (except soybeans and peanuts)	200.0 0.2 200.0 0.4	Revoke and establish at 100	*Non-grass animal feeds group, forage and hay*
Almond hulls	1		*Almonds, hulls*
Artichokes, Jerusalem	0.2		
Asparagus	0.5		
Atemoya	0.2		
Avocados	0.2		
Bahiagrass Bermudagrass Bluegrass Bromegrass Fescue Forage grasses Grasses, forage Orchardgrass Ryegrass Timothy Wheatgrass	200.0 200.0 200.0 200.0 200.0 0.2 0.2 200.0 200.0 200.0 200.0	Revoke and establish at 100	*Grass forage, fodder, and hay group*
Bananas	0.2		
Beets	0.2		*Beets, garden, roots*
Beets, sugar	0.2		*Sugar beets*
Breadfruit	0.2	Revoke	No registered uses
Canistel	0.2	Revoke	No registered uses
Carambola	0.2		
Carrots	0.2		
Cherimoya	0.2	Revoke	No registered uses
Chicory	0.2		*Chicory, roots*
Citrus fruits	0.2		*Citrus fruits group*
Cocoa beans	0.2	Revoke	No registered uses
Coconut	0.1	Revoke	No registered uses

Commodity	Current Tolerance [1] (ppm)	Tolerance [2] Reassessment (ppm)	Comment/*Correct Commodity Definition*
Coffee beans	1		*Coffee beans, green*
Cotton, forage	15		
Cotton, hay	15	Revoke	Not in Table II, Subdivision O, PAG
Cottonseed	15		
Cranberries	0.2	Revoke	Covered under small fruits and berries group
Dates	0.2	Revoke	No registered uses
Figs	0.2		
Forage grasses Grasses, forage	0.2 0.2	0.2	*Forage, fodder, and straw of cereal grains group (except wheat straw)*
Fruits, small and berries	0.2		*Small fruits and berries group*
Genip	0.2	Revoke	No registered uses
Grain crops	0.1		*Cereal grains group (except wheat)*
Grapes	0.2	Revoke	Covered under small fruits and berries group
Guavas	0.2		
Horseradish	0.2		
Jaboticaba	0.2	Revoke	No registered uses
Jackfruit	0.2	Revoke	No registered uses
Kiwifruit	0.2	0.1	see Codex Harmonization Table
Leafy vegetables	0.2		*Leafy vegetables (except Brassica) group* and *Leaves of root and tuber vegetables group*
Longan	0.2		*Longan fruit*
Lychee	0.2		
Mamy sapote	0.2		*Sapote*
Mangoes	0.2		
Nuts	0.2		*Tree nuts group*
Olives	0.2		
Papayas	0.2		
Parsnips	0.2		*Parsnips, roots*
Passion fruit	0.2		

Commodity	Current Tolerance [1] (ppm)	Tolerance [2] Reassessment (ppm)	Comment/*Correct Commodity Definition*
Peanut, forage	0.5		*Peanuts, vines*
Persimmons	0.2	Revoke	No registered uses
Pineapple	0.1		*Pineapples*
Pistachio nuts	0.2		*Pistachios*
Pome fruits	0.2		*Pome fruits group*
Potatoes	0.2		
Radishes	0.2		*Radishes, root*
Rutabagas	0.2		*Rutabagas, root*
Salsify	0.2	Revoke	No registered uses
Sapodilla	0.2		
Sapote, black	0.2	Revoke	No registered uses
Sapote, white	0.2	Revoke	No registered uses
Seed and pod vegetables	0.2	5	see Codex harmonization Table; *Legume vegetables group (except soybeans)*
Seed and pod vegetables, forage Seed and pod vegetables, hay	0.2 0.2	0.2	*Foliage of legume vegetables group (except soybean forage and hay)*
Soursop	0.2	Revoke	No registered uses
Soybeans	20		
Soybeans, forage	15		
Soybeans, hay	15	200	Raised to cover desiccant use.
Soybeans, straw	200	Revoke	Not in Table II, Subdivision O, PAG
Stone fruit	0.2		*Stone fruits group*
Sugar apple	0.2		
Sweet potatoes	0.2		
Tamarind	0.2	Revoke	No registered uses
Turnips	0.2		*Turnips, roots*
Vegetables, bulb	0.2		*Bulb vegetables group*
Vegetables, cucurbit	0.5		*Cucurbit vegetables group*
Vegetables, fruiting (except cucurbits) group	0.1		*Fruiting vegetables group*
Vegetables, leafy, Brassica (cole)	0.2		*Brassica leafy vegetables group*
Yams	0.2		

Commodity	Current Tolerance [1] (ppm)	Tolerance [2] Reassessment (ppm)	Comment/*Correct Commodity Definition*
Wheat, grain	N/A	5.0	see Codex harmonization Table
Wheat, straw	N/A	85 (proposed)	
Tolerances listed under 40 CFR §180.364(b):			
Cattle, kidney	0.5	2.0	see Codex harmonization Table
Cattle, liver	0.5	2.0	see Codex harmonization Table
Fish	0.25		
Goats, kidney	0.5		
Goats, liver	0.5		
Hogs, kidney	0.5	1.0	see Codex harmonization Table
Hogs, liver	0.5	1.0	see Codex harmonization Table
Horses, kidney	0.5		
Horses, liver	0.5		
Peanuts	0.1		
Peanut, hay	0.5		*Peanuts, hay*
Peanut, hulls	0.5		*Peanuts, hulls*
Poultry, kidney	0.5		
Poultry, liver	0.5		
Sheep, kidney	0.5		
Sheep, liver	0.5		
Shellfish	3.0		
Sugarcane	2.0		
Tolerances listed under 40 CFR 180.364(c):			
Avocados	0.1		
Citrus	0.1		*Citrus fruits group*
Cottonseed	0.1		
Cucurbits	0.1		*Cucurbit vegetables group*
Forage grasses	0.1		*Grass forage, fodder, and hay group*
Forage legumes	0.1		*Non-grass animal feeds group, forage and hay*
Fruiting vegetables	0.1		*Fruiting vegetables group*

Commodity	Current Tolerance [1] (ppm)	Tolerance [2] Reassessment (ppm)	Comment/*Correct Commodity Definition*
Grain crops	0.1		*Cereal grains group* and *Forage, fodder, and straw of cereal grains group*
Hops	0.1		
Leafy vegetables	0.1		*Leafy vegetables (except Brassica) group* and *Brassica (cole) leafy vegetables group*
Nuts	0.1		*Tree nuts group*
Pome fruits	0.1		*Pome fruits group*
Root crop vegetables	0.1		*Root and tuber vegetables group* and *Leaves of root and tuber vegetables group* and *Bulb vegetables group*
Seed and pod vegetables	0.1		*Legume vegetables group* and *Foliage of legume vegetables group*
Stone fruit	0.1		*Stone fruits group*
Tolerances listed under 40 CFR §185.3500(a)(1):			
Molasses, sugarcane	30.0		*Sugarcane, molasses*
Tolerances listed under 40 CFR §185.3500(a)(2):			
Oil, palm	0.1		*Palm oil, refined*
Olives, imported	0.1		
Tea, dried	1.0		
Tea, instant	7.0	Revoke	Not in Table II, Subdivision O, PAG
Wheat milling fractions (except flour)	N/A	40	see Codex harmonization Table
Tolerances listed under 40 CFR §186.3500(a):			
Citrus, pulp, dried	1.0		
Citrus molasses	1.0		*Citrus, molasses*
Soybean hulls	100		*Soybeans, hulls*

1 Tolerances are for the combined residues of glyphosate and its metabolite AMPA.
2 Tolerances are now for glyphosate *per se*.

CODEX HARMONIZATION TABLE

Several maximum residue limits (MRLs) for glyphosate have been established by Codex in various commodities. The Codex MRLs (currently expressed in terms of glyphosate *per se*) and applicable U.S. tolerances (expressed in terms of the combined residues of glyphosate and its metabolite AMPA) are listed in the table below. The Agency has determined that AMPA no longer needs to be regulated and therefore will be deleted from the tolerance expression. Based on this determination, the expression of the U.S. tolerances and the Codex MRLs will be harmonized, and both will now be expressed in terms of glyphosate *per se*.

Codex MRLs and applicable U.S. tolerances. Recommendations for compatibility are based on conclusions following reassessments of U.S. tolerances (see Tolerance Reassessment Table, above).

Commodity	MRL (Step) (mg/kg)	U.S. Tolerance (ppm)	Recommendation
Barley	20 (CXL)	0.1 (Cereal grains group, except wheat)	
Beans (dry)	2 (CXL)	0.2 (Legume vegetables group, except soybeans)	
Cattle meat	0.1(CXL)		
Cattle milk	0.1(CXL)		
Cattle, edible offal	2 (CXL)	0.5 (Cattle, liver & kidney)	increase U.S. tolerances
Cottonseed	0.5(CXL)	15	
Eggs	0.1(CXL)		
Hay or fodder (dry) of grasses	50 (CXL)	100 (Grass forage, fodder, and hay group)	
Kiwifruit	0.1(CXL)	0.2	decrease U.S. tolerance
Maize	0.1(CXL)	0.1	
Oats	20 (CXL)	0.1 (Cereal grains group, except wheat)	
Peas (dry)	5 (CXL)	0.2 (Legume vegetables group, except soybeans)	increase U.S. tolerance
Pig meat	0.1(CXL)		
Pig, edible offal	1 (CXL)	0.5 (Hogs, liver & kidney)	increase U.S. tolerances
Poultry meat	0.1(CXL)		
Rape seed	10 (CXL)		
Rice	0.1(CXL)	0.1 (Cereal grains group, except wheat)	
Sorghum	0.1(CXL)	0.1 (Cereal grains group, except wheat)	
Soya bean fodder	20 (Step 8)	15 (Soybeans, hay)	
Soya bean forage (green)	5 (Step 8)	15 (Soybeans, forage)	
Soya bean (dry)	5 (Step 8)	20 (Soybeans)	
Soya bean (immature seeds)	0.2(CXL)		

Commodity	MRL (Step) (mg/kg)	U.S. Tolerance (ppm)	Recommendation
Straw and fodder (dry) of cereal grains	100 (CXL)	0.2 (Forage, fodder, and straw of cereal grains group, except wheat straw)	
Sweet corn (corn-on-the-cob)	0.1(CXL)	0.1 (Cereal grains group, except wheat)	
Wheat	5 (CXL)	4 (proposed)	increase U.S. tolerance proposal
Wheat bran, unprocessed	40 (Step 6)	12 (proposed)	increase U.S. tolerance proposal
Wheat flour	0.5(Step 8)		
Wheat whole meal	5 (Step 8)	12 (proposed)	

The following conclusions can be made regarding efforts to harmonize the U.S. tolerances with the Codex MRLs:

- Compatibility between the U.S. tolerances and permanent Codex MRLs exists in or on: corn (field and sweet); rice; and sorghum.

- The levels of U.S. tolerances should be increased, toxicological and DRES considerations permitting, to achieve compatibility with the Codex MRLs in or on the following commodities: (i) liver and kidney of cattle (from 0.5 to 2.0 ppm); (ii) liver and kidney of hogs (from 0.5 to 1.0 ppm); and (iii) legume vegetables group (except soybeans) (from 0.2 to 5 ppm);

- The level of the U.S. tolerance should be decreased to achieve compatibility with the Codex MRLs in or on kiwifruit (from 0.2 to 0.1 ppm).

- The U.S. tolerances in or on the following commodities were based on registered use patterns in the U.S. and cannot be lowered to achieve compatibility with the Codex MRLs: (i) grass forage, fodder, and hay group; (ii) soybeans; and (iii) soybeans, forage.

- Wheat grain and wheat bran tolerances of 4 and 12 ppm, respectively, have been proposed. To achieve compatibility with Codex, these tolerance levels should be increased, toxicological and DRES considerations permitting, to 5 and 40 ppm, respectively.

- Wide differences (>5x) exist between the U.S. tolerances and permanent Codex MRLs in or on the following commodities: barley; beans (dry); soybeans, hay; cottonseed; oats; forage, fodder, and straw of cereal grains. The decision to harmonize residue levels in or on these commodities cannot be made at this time.

- No questions of compatibility exist with respect to commodities where: (i) no Codex MRLs have been established, but U.S.

tolerances exist; and (ii) Codex MRLs have been established, but U.S. tolerances do not exist.

2. Labeling Rationale

While studies show that glyphosate is no more than slightly toxic to birds and is practically non-toxic to fish and honeybees, a toxic inert in glyphosate end use products necessitates the labelling of some products "toxic to fish" since some glyphosate products are applied directly to aquatic environments.

3. Endangered Species Statement

The Agency does have concerns regarding exposure of endangered plant species to glyphosate. In the June 1986 Registration Standard, the Agency discussed consultations with the US Fish and Wildlife Service (FWS) on hazards to crops, rangeland, silvicultural sites, and the Houston toad which may result from the use of glyphosate. Because a jeopardy opinion resulted from these consultations, the agency imposed endangered species labeling requirements in the Registration Standard to mitigate the risk to endangered species. Since that time, additional plant species have been added to the list of endangered species. At the present time, EPA is working with the FWS and other federal and state agencies to develop a program to avoid jeopardizing the continued existence of all listed species by the use of pesticides. When the Endangered Species Protection Program is implemented and subsequent guidance is given, endangered species labeling amendments may be required on affected end-use products. Labeling statements for end use products will likely refer users to county specific bulletins specifying detailed limitations on use to protect endangered species.

V. ACTIONS REQUIRED BY REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of glyphosate for the above eligible uses has been reviewed and determined to be substantially complete. The Agency will be calling in data on processed potatoes in a separate DCI. However, the following additional generic data are required at this time. These additional generic data are not part of the target data base for

glyphosate and do not affect the reregistration eligibility of glyphosate. (See Appendices for the Generic Data Call-In Notice.)

Name of Study	Guideline Number
Tier II Vegetative Vigor	123-1
Droplet Size Spectrum	201-1
Drift Field Evaluation	202-1

2. Labeling Requirements for Manufacturing-Use Products

Effluent Discharge Labeling Statement

All manufacturing-use or end-use products that may be contained in an effluent discharged to the waters of the United States or municipal sewer systems must bear the following revised effluent discharge labeling statement.

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

All affected products distributed or sold by registrants and distributors (supplemental registrants) must bear the above labeling by October 1, 1995. All products distributed or sold by persons other than registrants or supplemental registrants after October 1, 1997 must bear the correct labeling. Refer to PR Notice 93-10 or 40 CFR 152.46(a)(1) for additional information.

B. **End-Use Products**

1. Additional Product-Specific Data Requirements

Section 4(g)(2)B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not,

commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10 and other applicable documents. Please follow the instructions in the Pesticide Reregistration Handbook with respect to labels and labeling. Furthermore, the following additional labeling must be present on glyphosate end-use product labels.

a. Nonaquatic

"Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters and rinsate."

b. Aquatic

"Do not contaminate water when disposing of equipment washwaters and rinsate. Treatment of aquatic weeds can result in oxygen loss from decomposition for dead plants. This loss can cause fish kills."

c. Worker Protection Standard

Compliance

Any product whose labeling reasonably permits use in the commercial or research production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS), and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7," which reflect the requirements of EPA's labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR Part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7 and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-

11 are to be on the product labeling exactly as instructed in those notices.

After April 21, 1994, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR-Notice-complying labeling when they are distributed or sold by the primary registrant or any supplementally registered distributor.

After October 23, 1995, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR-Notice-complying labeling when they are distributed or sold by any person.

Personal Protective Equipment

Do not add any additional personal protective equipment requirements to the labels of glyphosate end-use products, however, any existing personal protective equipment on those labels must be retained.

Entry Restrictions

Products not Primarily Intended for Home Use

Uses Within the Scope of the WPS: A 12-hour restricted entry interval (REI) is required for all uses within the scope of the WPS (see PR Notice 93-7) on all end-use products, except those intended primarily for home use (see tests in PR Notice 93-7 and 93-11). This REI should be inserted into the standardized REI statement required by PR Notice 93-7. The personal protective equipment for early entry should be the PPE required for applicators of glyphosate, except any applicator requirement for an apron or respirator is waived. This PPE should be inserted into the standardized early entry PPE statement required by PR Notice 93-7."

Sole-active-ingredient end-use products that contain glyphosate must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on their current labeling must be removed.

Multiple-active-ingredient end-use products that contain glyphosate must compare the entry restrictions set forth in this section to the entry restrictions on their current labeling and retain the more protective. A specific time-period in hours or days is considered more protective than "sprays have dried" or "dusts have settled."

Uses Not Within the Scope of the WPS: Do not add any additional entry restrictions for uses not within the scope of the WPS, however, any entry restrictions on the current product labeling for those uses must be retained.

Products Primarily Intended for Home Use: For products primarily intended for home use (see tests in PR Notice 93-7 and 93-11), do not add any additional entry restrictions for such products, however, any entry restrictions on the current product labeling must be retained.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this RED. Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; State of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell glyphosate products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than registrants may distribute or sell such products for 50 months from the date of issuance of this RED.

VI. APPENDICES

Appendix A

Use Patterns Subject to Reregistration

Appendix A is approximately 200 pages long and is not being included in the mailing of the RED. Instead, a summary of eligible sites and use groups is provided. Interested parties may order a copy of the full Appendix A per the instructions in Appendix D.

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Site and Use Groups

Site	Use Group	Use Group Category Desc.
ACEROLA (WEST INDIES CHERRY)	TERRESTRIAL FOOD CROP	Food/Feed Uses
AGRICULTURAL DRAINAGE SYSTEMS	AQUATIC FOOD CROP	Food/Feed Uses
AGRICULTURAL FALLOW/IDLELAND	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
ALFALFA	TERRESTRIAL FEED CROP	Food/Feed Uses
ALMOND	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
APPLE	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
APRICOT	TERRESTRIAL FOOD CROP	Food/Feed Uses
ARTICHOKE, JERUSALEM	TERRESTRIAL FOOD CROP	Food/Feed Uses
ASPARAGUS	TERRESTRIAL FOOD CROP	Food/Feed Uses
ATEMOYA	TERRESTRIAL FOOD CROP	Food/Feed Uses
AVOCADO	TERRESTRIAL FOOD CROP	Food/Feed Uses
BANANA	TERRESTRIAL FOOD CROP	Food/Feed Uses
BARLEY	TERRESTRIAL FEED CROP	Food/Feed Uses
BARLEY	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
BEANS	TERRESTRIAL FEED CROP	Food/Feed Uses
BEANS	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
BEECH NUT	TERRESTRIAL FOOD CROP	Food/Feed Uses
BEETS	TERRESTRIAL FOOD CROP	Food/Feed Uses
BEETS (UNSPECIFIED)	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses

Site	Use Group	Use Group Category Desc.
BLACKBERRY	TERRESTRIAL FOOD CROP	Food/Feed Uses
BLUEBERRY	TERRESTRIAL FOOD CROP	Food/Feed Uses
BOYSENBERRY	TERRESTRIAL FOOD CROP	Food/Feed Uses
BRAZIL NUT	TERRESTRIAL FOOD CROP	Food/Feed Uses
BREADFRUIT (BREADNUT)	TERRESTRIAL FOOD CROP	Food/Feed Uses
BROCCOLI	TERRESTRIAL FOOD CROP	Food/Feed Uses
BRUSSELS SPROUTS	TERRESTRIAL FOOD CROP	Food/Feed Uses
BUCKWHEAT	TERRESTRIAL FEED CROP	Food/Feed Uses
BUCKWHEAT	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
BUTTERNUT	TERRESTRIAL FOOD CROP	Food/Feed Uses
CABBAGE	TERRESTRIAL FOOD CROP	Food/Feed Uses
CABBAGE, CHINESE	TERRESTRIAL FOOD CROP	Food/Feed Uses
CALAMONDIN	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
CARAMBOLA (JALEA)	TERRESTRIAL FOOD CROP	Food/Feed Uses
CARROT (INCLUDING TOPS)	TERRESTRIAL FOOD CROP	Food/Feed Uses
CASHEW	TERRESTRIAL FOOD CROP	Food/Feed Uses
CAULIFLOWER	TERRESTRIAL FOOD CROP	Food/Feed Uses
CELERY	TERRESTRIAL FOOD CROP	Food/Feed Uses

Site	Use Group	Use Group Category Desc.
CHARD, SWISS	TERRESTRIAL FOOD CROP	Food/Feed Uses
CHERIMOYA	TERRESTRIAL FOOD CROP	Food/Feed Uses
CHERRY	TERRESTRIAL FOOD CROP	Food/Feed Uses
CHESTNUT	TERRESTRIAL FOOD CROP	Food/Feed Uses
CHICORY	TERRESTRIAL FOOD CROP	Food/Feed Uses
CITRON (CITRUS)	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
CITRUS HYBRIDS OTHER THAN TANGELO	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
COCOA	TERRESTRIAL FOOD CROP	Food/Feed Uses
COFFEE	TERRESTRIAL FOOD CROP	Food/Feed Uses
COLLARDS	TERRESTRIAL FOOD CROP	Food/Feed Uses
CORN	TERRESTRIAL FEED CROP	Food/Feed Uses
CORN (UNSPECIFIED)	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
CORN, FIELD	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
COTTON (UNSPECIFIED)	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
CRANBERRY	TERRESTRIAL FOOD CROP	Food/Feed Uses
CRESS, WATER	TERRESTRIAL FOOD CROP	Food/Feed Uses
CUCUMBER	TERRESTRIAL FOOD CROP	Food/Feed Uses
CURRANT	TERRESTRIAL FOOD CROP	Food/Feed Uses
DATE	TERRESTRIAL FOOD CROP	Food/Feed Uses

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Site	Use Group	Use Group Category Desc.
DEWBERRY	TERRESTRIAL FOOD CROP	Food/Feed Uses
EGGFRUIT TREE (CANISTEL)	TERRESTRIAL FOOD CROP	Food/Feed Uses
EGGPLANT	TERRESTRIAL FOOD CROP	Food/Feed Uses
ELDERBERRY	TERRESTRIAL FOOD CROP	Food/Feed Uses
ENDIVE (ESCAROLE)	TERRESTRIAL FOOD CROP	Food/Feed Uses
FIG	TERRESTRIAL FOOD CROP	Food/Feed Uses
FILBERT (HAZELNUT)	TERRESTRIAL FOOD CROP	Food/Feed Uses
GARLIC	TERRESTRIAL FOOD CROP	Food/Feed Uses
GOOSEBERRY	TERRESTRIAL FOOD CROP	Food/Feed Uses
GOURDS	TERRESTRIAL FOOD CROP	Food/Feed Uses
GRAPEFRUIT	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
GRAPES	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
GRASS FORAGE/FODDER/HAY	TERRESTRIAL FEED CROP	Food/Feed Uses
GREENHOUSES-IN USE	GREENHOUSE FOOD CROP	Food/Feed Uses
GROUNDCHERRY (STRAWBERRY TOMATO/TOMATILLO)	TERRESTRIAL FOOD CROP	Food/Feed Uses
GUAVA	TERRESTRIAL FOOD CROP	Food/Feed Uses
HICKORY NUT	TERRESTRIAL FOOD CROP	Food/Feed Uses
HORSERADISH	TERRESTRIAL FOOD CROP	Food/Feed Uses

Site	Use Group	Use Group Category Desc.
HUCKLEBERRY	TERRESTRIAL FOOD CROP	Food/Feed Uses
IRRIGATION SYSTEMS	AQUATIC FOOD CROP	Food/Feed Uses
JABOTICABA	TERRESTRIAL FOOD CROP	Food/Feed Uses
JACKFRUIT	TERRESTRIAL FOOD CROP	Food/Feed Uses
KALE	TERRESTRIAL FOOD CROP	Food/Feed Uses
KITEMBILLA (CEYLON GOOSEBERRY)	TERRESTRIAL FOOD CROP	Food/Feed Uses
KIWI FRUIT	TERRESTRIAL FOOD CROP	Food/Feed Uses
KOHLRABI	TERRESTRIAL FOOD CROP	Food/Feed Uses
KUMQUAT	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
LAKES/PONDS/RESERVOIRS (WITH HUMAN OR WILDLIFE USE)	AQUATIC FOOD CROP	Food/Feed Uses
LEEK	TERRESTRIAL FOOD CROP	Food/Feed Uses
LEMON	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
LENTILS	TERRESTRIAL FEED CROP	Food/Feed Uses
LENTILS	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
LETTUCE	TERRESTRIAL FOOD CROP	Food/Feed Uses
LIME	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
LITCHI NUT	TERRESTRIAL FOOD CROP	Food/Feed Uses
LOGANBERRY	TERRESTRIAL FOOD CROP	Food/Feed Uses
LONGAN	TERRESTRIAL FOOD CROP	Food/Feed Uses

Site	Use Group	Use Group Category Desc.
LOQUAT	TERRESTRIAL FOOD CROP	Food/Feed Uses
MACADAMIA NUT (BUSHNUT)	TERRESTRIAL FOOD CROP	Food/Feed Uses
MAMEY (MAMMEE APPLE)	TERRESTRIAL FOOD CROP	Food/Feed Uses
MANGO	TERRESTRIAL FOOD CROP	Food/Feed Uses
MARMALADEBOX (GENIPAPO)	TERRESTRIAL FOOD CROP	Food/Feed Uses
MAYHAW (HAWTHORN)	TERRESTRIAL FOOD CROP	Food/Feed Uses
MELONS	TERRESTRIAL FOOD CROP	Food/Feed Uses
MELONS, CANTALOUPE	TERRESTRIAL FOOD CROP	Food/Feed Uses
MELONS, HONEYDEW	TERRESTRIAL FOOD CROP	Food/Feed Uses
MELONS, MANGO	TERRESTRIAL FOOD CROP	Food/Feed Uses
MELONS, MUSK	TERRESTRIAL FOOD CROP	Food/Feed Uses
MELONS, WATER	TERRESTRIAL FOOD CROP	Food/Feed Uses
MELONS, WINTER (CASABA/CRENSHAW/HONEYDEW/PERSIAN)	TERRESTRIAL FOOD CROP	Food/Feed Uses
MILLET (PROSO)	TERRESTRIAL FEED CROP	Food/Feed Uses
MILLET, PROSO (BROOMCORN)	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
MUSTARD	TERRESTRIAL FOOD CROP	Food/Feed Uses
MUSTARD	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
NECTARINE	TERRESTRIAL FOOD CROP	Food/Feed Uses

Site	Use Group	Use Group Category Desc.
NONGRASS FORAGE/FODDER/STRAW/HAY	TERRESTRIAL FEED CROP	Food/Feed Uses
OATS	TERRESTRIAL FEED CROP	Food/Feed Uses
OATS	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
OKRA	TERRESTRIAL FOOD CROP	Food/Feed Uses
OLIVE	TERRESTRIAL FOOD CROP	Food/Feed Uses
ONION	TERRESTRIAL FOOD CROP	Food/Feed Uses
ORANGE	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
PAPAYA	TERRESTRIAL FOOD CROP	Food/Feed Uses
PARSLEY	TERRESTRIAL FOOD CROP	Food/Feed Uses
PARSNIP	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
PASSION FRUIT	TERRESTRIAL FOOD CROP	Food/Feed Uses
PASTURES	TERRESTRIAL FEED CROP	Food/Feed Uses
PEACH	TERRESTRIAL FOOD CROP	Food/Feed Uses
PEANUTS (UNSPECIFIED)	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
PEAR	TERRESTRIAL FOOD CROP	Food/Feed Uses
PEAS (UNSPECIFIED)	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
PECAN	TERRESTRIAL FOOD CROP	Food/Feed Uses
PEPPER	TERRESTRIAL FOOD CROP	Food/Feed Uses
PERSIMMON	TERRESTRIAL FOOD CROP	Food/Feed Uses

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Site	Use Group	Use Group Category Desc.
PINEAPPLE	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
PISTACHIO	TERRESTRIAL FOOD CROP	Food/Feed Uses
PLANTAIN	TERRESTRIAL FOOD CROP	Food/Feed Uses
PLUM	TERRESTRIAL FOOD CROP	Food/Feed Uses
POMEGRANATE	TERRESTRIAL FOOD CROP	Food/Feed Uses
POTATO, WHITE/IRISH	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
PRUNE	TERRESTRIAL FOOD CROP	Food/Feed Uses
PUMMELO (SHADDOCK)	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
PUMPKIN	TERRESTRIAL FOOD CROP	Food/Feed Uses
QUINCE	TERRESTRIAL FOOD CROP	Food/Feed Uses
RADISH	TERRESTRIAL FOOD CROP	Food/Feed Uses
RAPE	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
RASPBERRY (BLACK, RED)	TERRESTRIAL FOOD CROP	Food/Feed Uses
RHUBARB	TERRESTRIAL FOOD CROP	Food/Feed Uses
RICE	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
RICE, WILD	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
RUTABAGA	TERRESTRIAL FOOD CROP	Food/Feed Uses
RYE	TERRESTRIAL FEED CROP	Food/Feed Uses

Site	Use Group	Use Group Category Desc.
RYE	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
SAPODILLA	TERRESTRIAL FOOD CROP	Food/Feed Uses
SAPOTA, WHITE	TERRESTRIAL FOOD CROP	Food/Feed Uses
SITE NOT SPECIFIED	USE GROUP FOR SITE 00000	Food/Feed Uses
SORGHUM	TERRESTRIAL FEED CROP	Food/Feed Uses
SORGHUM	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
SOURSOP	TERRESTRIAL FOOD CROP	Food/Feed Uses
SOYBEANS (UNSPECIFIED)	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
SPINACH	TERRESTRIAL FOOD CROP	Food/Feed Uses
SQUASH (SUMMER)	TERRESTRIAL FOOD CROP	Food/Feed Uses
SQUASH (WINTER)	TERRESTRIAL FOOD CROP	Food/Feed Uses
STREAMS/RIVERS/CHANNELED WATER	AQUATIC FOOD CROP	Food/Feed Uses
SUGAR APPLE (CUSTARD APPLE)	TERRESTRIAL FOOD CROP	Food/Feed Uses
SUGAR BEET	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
SUGARCANE	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
SWEET POTATO	TERRESTRIAL FOOD CROP	Food/Feed Uses
TAMARIND	TERRESTRIAL FOOD CROP	Food/Feed Uses
TANGELO	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
TANGERINES	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses

Site	Use Group	Use Group Category Desc.
TARO	TERRESTRIAL FOOD CROP	Food/Feed Uses
TEA	TERRESTRIAL FOOD CROP	Food/Feed Uses
TOMATO	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
TRITICALE	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
TURNIP	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
WALNUT (ENGLISH/BLACK)	TERRESTRIAL FOOD CROP	Food/Feed Uses
WHEAT	TERRESTRIAL FEED CROP	Food/Feed Uses
WHEAT	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
YAM	TERRESTRIAL FOOD CROP	Food/Feed Uses
AGRICULTURAL FALLOW/IDLELAND	TERRESTRIAL NON-FOOD CROP	Non-Food/Non-Feed Uses
AGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS	TERRESTRIAL NON-FOOD CROP	Non-Food/Non-Feed Uses
AGRICULTURAL UNCULTIVATED AREAS	TERRESTRIAL NON-FOOD CROP	Non-Food/Non-Feed Uses
AIRPORTS/LANDING FIELDS	TERRESTRIAL NON-FOOD CROP	Non-Food/Non-Feed Uses
AQUATIC AREAS/WATER	AQUATIC NON-FOOD INDUSTRIAL	Non-Food/Non-Feed Uses
AQUATIC AREAS/WATER	AQUATIC NON-FOOD OUTDOOR	Non-Food/Non-Feed Uses
CHRISTMAS TREE PLANTATIONS	TERRESTRIAL NON-FOOD CROP	Non-Food/Non-Feed Uses
CONIFER RELEASE	FORESTRY	Non-Food/Non-Feed Uses
DRAINAGE SYSTEMS	AQUATIC NON-FOOD INDUSTRIAL	Non-Food/Non-Feed Uses

Site	Use Group	Use Group Category Desc.
FOREST PLANTINGS (REFORESTATION PROGRAMS)	FORESTRY	Non-Food/Non-Feed Uses
FOREST TREES (ALL OR UNSPECIFIED)	FORESTRY	Non-Food/Non-Feed Uses
GOLF COURSE TURF	TERRESTRIAL NON-FOOD CROP	Non-Food/Non-Feed Uses
GREENHOUSE-EMPTY	INDOOR NON-FOOD	Non-Food/Non-Feed Uses
HOUSEHOLD/DOMESTIC DWELLINGS OUTDOOR PREMISES	OUTDOOR RESIDENTIAL	Non-Food/Non-Feed Uses
INDUSTRIAL AREAS (OUTDOOR)	TERRESTRIAL NON-FOOD CROP	Non-Food/Non-Feed Uses
NONAGRICULTURAL OUTDOOR BUILDINGS/STRUCTURES	TERRESTRIAL NON-FOOD CROP	Non-Food/Non-Feed Uses
NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS	TERRESTRIAL NON-FOOD CROP	Non-Food/Non-Feed Uses
NONAGRICULTURAL UNCULTIVATED AREAS/SOILS	TERRESTRIAL NON-FOOD CROP	Non-Food/Non-Feed Uses
ORNAMENTAL AND/OR SHADE TREES	TERRESTRIAL NON-FOOD CROP	Non-Food/Non-Feed Uses
ORNAMENTAL AND/OR SHADE TREES	TERRESTRIAL NON-FOOD+OUTDOOR RESIDE	Non-Food/Non-Feed Uses
ORNAMENTAL AND/OR SHADE TREES	TERRESTRIAL+GREENHOUSE NON-FOOD CRO	Non-Food/Non-Feed Uses
ORNAMENTAL HERBACEOUS PLANTS	TERRESTRIAL NON-FOOD+OUTDOOR RESIDE	Non-Food/Non-Feed Uses
ORNAMENTAL LAWNS AND TURF	TERRESTRIAL NON-FOOD CROP	Non-Food/Non-Feed Uses
ORNAMENTAL LAWNS AND TURF	TERRESTRIAL NON-FOOD+OUTDOOR RESIDE	Non-Food/Non-Feed Uses
ORNAMENTAL WOODY SHRUBS AND VINES	TERRESTRIAL NON-FOOD CROP	Non-Food/Non-Feed Uses
ORNAMENTAL WOODY SHRUBS AND VINES	TERRESTRIAL NON-FOOD+OUTDOOR RESIDE	Non-Food/Non-Feed Uses
ORNAMENTAL WOODY SHRUBS AND VINES	TERRESTRIAL+GREENHOUSE NON-FOOD CRO	Non-Food/Non-Feed Uses
PATHS/PATIOS	TERRESTRIAL NON-FOOD CROP	Non-Food/Non-Feed Uses

Site	Use Group	Use Group Category Desc.
PAVED AREAS (PRIVATE ROADS/SIDEWALKS)	TERRESTRIAL NON-FOOD CROP	Non-Food/Non-Feed Uses
RECREATIONAL AREAS	TERRESTRIAL NON-FOOD CROP	Non-Food/Non-Feed Uses
SEWAGE SYSTEMS	AQUATIC NON-FOOD INDUSTRIAL	Non-Food/Non-Feed Uses
SITE NOT SPECIFIED	USE GROUP FOR SITE 00000	Non-Food/Non-Feed Uses
URBAN AREAS	TERRESTRIAL NON-FOOD CROP	Non-Food/Non-Feed Uses

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Site	Use Group	Use Group Category Desc.
PEANUTS (UNSPECIFIED)	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses
SUGARCANE	TERRESTRIAL FOOD+FEED CROP	Food/Feed Uses

Appendix B

Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for the pesticide glyphosate covered by this Reregistration Eligibility Document. It contains generic data requirements that apply to glyphosate in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR, Part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487 - 4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

Data Supporting Guideline Requirements for the Reregistration of Glyphosate

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-2A	Start. Mat. & Mnfg. Process	all	00161333
61-2B	Formation of Impurities	all	00161333
62-1	Preliminary Analysis	all	40405401, 00161333
63-2	Color	all	00161333
63-3	Physical State	all	00161333
63-4	Odor	all	00161333
63-5	Melting Point	all	00161333
63-6	Boiling Point	all	00161333
63-7	Density	all	00161333
63-8	Solubility	all	00161333
63-9	Vapor Pressure	all	41096101, 00161333
63-10	Dissociation Constant	all	00161333
63-11	Octanol/Water Partition	all	00161333
63-12	pH	all	00161333
63-13	Stability	all	00161333, 40559301
63-17	Storage stability	A C	41573601, 00039142, 00061553, 00040083, 00061555, 00051980, 00108129, 00053002, 00108102

Data Supporting Guideline Requirements for the Reregistration of Glyphosate

REQUIREMENT		USE PATTERN	CITATION(S)
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral - Quail/Duck	A B C D F G H	00108204
71-2A	Avian Dietary - Quail	A B C D F G H	00108107
71-2B	Avian Dietary - Duck	A B C D F G H	00076492
71-3	Wild Mammal Toxicity	A B C D F G H	00076492
71-4A	Avian Reproduction - Quail	A B C D G	00108207
71-4B	Avian Reproduction - Duck	A B C D G	00036328, 00111953
72-1A	Fish Toxicity Bluegill	A B C D F G H	00136339, GS-0178025
72-1B	Fish Toxicity Bluegill - TEP	A B C D G	15296, 152599, 152601, 152767
72-1C	Fish Toxicity Rainbow Trout	A B C D F G H	00108112, 00108205
72-1D	Fish Toxicity Rainbow Trout - TEP	A B C D G	00070895, 00078661, 00070897, 00078662, 00078655, 00078664, 00078656, 00078665, 00078658, 00108205, 00078659, 00124760, GS0178025, 5298, 152766, 152903, 155477
72-2A	Invertebrate Toxicity	A B C D F G H	00108172
72-2B	Invertebrate Toxicity - TEP	A B C D G	00070893, 00078666, 00078657, 00124762, 00078660, GS0178025, 0078663, 152597, 152600, 152602, 152768

Data Supporting Guideline Requirements for the Reregistration of Glyphosate

REQUIREMENT		USE PATTERN	CITATION(S)
72-3B	Estuarine/Marine Toxicity - Mollusk	A B C D	00108110
72-3C	Estuarine/Marine Toxicity - Shrimp	A B C D	00108111
72-4B	Life Cycle Invertebrate	A B C D G H	00124763
72-5	Life Cycle Fish	A B C D G H	00108171
122-1A	Seed Germination/Seedling Emergence	B D G	40159301
122-2	Aquatic Plant Growth	B D G	40236901, 40236902, 40236903, 40236904, 40236905
123-2	Aquatic Plant Growth	B D G	40236901, 40236902, 40236903, 40236904, 40236905
141-1	Honey Bee Acute Contact	A B G H	00026489
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	A B C D F G H	00067039, 41400601
81-2	Acute Dermal Toxicity - Rabbit/Rat	A B C D F G H	00067039, 41400602
81-4	Primary Eye Irritation - Rabbit		41400603, 41400604
81-6	Dermal Sensitization - Guinea Pig		00137137, 00137138, 00137139, 00137140
82-1A	90-Day Feeding - Rodent		00036803, 40559401

Data Supporting Guideline Requirements for the Reregistration of Glyphosate

REQUIREMENT		USE PATTERN	CITATION(S)
82-2	21-Day Dermal - Rabbit/Rat	A B C D F G H	00098460
83-1A	Chronic Feeding Toxicity - Rodent	A C D F H	00098460, 00093879
83-1B	Chronic Feeding Toxicity - Non-Rodent	A C D F H	00162912, 41728701, 00153374
83-2A	Oncogenicity - Rat	A C D F H	41728701, 41643801, 00093879
83-2B	Oncogenicity - Mouse	A C D F H	00130406, 00150564
83-3A	Developmental Toxicity - Rat	A B C D F G H	00046362
83-3B	Developmental Toxicity - Rabbit	A B C D F G H	00046363
83-4	2-Generation Reproduction - Rat	A C D H	00081674, 00105995, 41621501
84-2A	Gene Mutation (Ames Test)	A B C D F G H	00078620, 00132683
84-2B	Structural Chromosomal Aberration	A B C D F G H	00046364, 00132681, 00132685
84-4	Other Genotoxic Effects	A B C D F G H	00078619, 00132686, 00132685
85-1	General Metabolism	A C D F G H	40767101, 40767102
ENVIRONMENTAL FATE			
161-1	Hydrolysis	A B C D F G H	00108192
161-2	Photodegradation - Water	A B C D G	41689101
161-3	Photodegradation - Soil	A G	41335101
162-1	Aerobic Soil Metabolism	A B F G H	42372501

Data Supporting Guideline Requirements for the Reregistration of Glyphosate

REQUIREMENT		USE PATTERN	CITATION(S)
162-3	Anaerobic Aquatic Metabolism	C D	42372502
162-4	Aerobic Aquatic Metabolism	C D	42372503
163-1	Leaching/Adsorption/ Desorption	A B C D	00108192
164-1	Terrestrial Field Dissipation	A B H	42765001
164-2	Aquatic Field Dissipation	C D	42383201
164-3	Forest Field Dissipation	G	41552801
165-1	Confined Rotational Crop	A C	42372504, 41543201, 41543202
165-3	Accumulation - Irrigated Crops	C D	42372505, 40541305
165-4	Bioaccumulation in Fish	A B C D G	41228301

RESIDUE CHEMISTRY REFERENCES ARE CONTAINED IN THE BODY OF THE RED UNDER SECTION III, B

Appendix C

Citations Considered to be Part of the Data Base Supporting the Reregistration of Glyphosate

GUIDE TO APPENDIX C

1. **CONTENTS OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including published literature, in those instances where they have been considered, are included.

2 **UNITS OF ENTRY.** The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. **IDENTIFICATION OF ENTRIES.** The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID Number". This number is unique to the citation, and should be uses whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifying number is also to be used whenever specific reference is needed.

4. **FORM OF ENTRY.** In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. **Author.** Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown a identifiable laboratory or testing facility

as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

b. **Document Date.** The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. **Title.** In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. **Trailing Parentheses.** For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received".

(2) Administrative Number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is de-faulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL", which stands for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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00015760 Kincaid, L. (1979) Metolachlor + Glyphosate + Linuron; Dual 8E + Roundup 4E + Lorox 50W: AG-A No. 4763 I,II. (Unpublished study including letter dated May 23, 1978 from J.D. Riggleman to Robert A. Kahrs, received Mar 16, 1979 under 100-583; prepared in cooperation with E.I. du Pont de Nemours & Co., Inc. and ADC Laboratories, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237821-B)

00015761 Schnappinger, M.G. (1979) Metolachlor + Glyphosate + Linuron; Dual 8E + Roundup 4E + Lorox 50W: AG-A No. 4886 I,II. (Unpublished study including letter dated May 23, 1978 from J.D. Riggleman to Robert A. Kahrs, received Mar 16, 1979 under 100-583; prepared in cooperation with E.I. du Pont de Nemours & Co., Inc. and ADC Laboratories, submitted by Ciba-Geigy Corp., Greensboro, N.C.: CDL:237821-C)

00015762 Searcy, V.; Herman, D. (1979) Metolachlor + Glyphosate + Linuron; Dual 8E + Roundup 4E + Lorox 50W: AG-A No. 4893 I,II. (Unpublished study including letter dated May 23, 1978 from J.D. Riggleman to Robert A. Kahrs, received Mar 16, 1979 under 100-583; prepared in cooperation with E.I. du Pont de Nemours & Co., Inc. and ADC Laboratories, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237821-D)

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Appendix D

List of Available Related Documents

The following is a list of available documents related to glyphosate. Its purpose is to provide a path to more detailed information if it is required. These accompanying documents are part of the Administrative Record for glyphosate and are included in the EPA's Office of Pesticide Programs Public Docket.

1. Health and Environmental Effects Science Chapters

2. Detailed Label Usage Information System (LUIS) Report

3. Glyphosate RED Fact Sheet (included in this RED)

4. PR Notice 91-2 (Included in this RED) Pertains to the Label Ingredient Statement

5. Complete Appendix A which details the use patterns subject to reregistration

Federal publications on glyphosate are available and may be purchased from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

1. Pesticide Fact Sheet (No. EPA-738-F-93-011) for Glyphosate

2. Registration Standard for Pesticide Products Containing Glyphosate as the Active Ingredient (The 1986 Registration Standard): NTIS Stock No. PB87-103214

Appendix E

Pesticide Reregistration Handbook

PESTICIDE REREGISTRATION HANDBOOK

HOW TO RESPOND TO THE
REREGISTRATION ELIGIBILITY DOCUMENT (RED)

OFFICE OF PESTICIDE PROGRAMS

ENVIRONMENTAL PROTECTION AGENCY

OCTOBER 1991

PRODUCT REREGISTRATION HANDBOOK

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PESTICIDE REREGISTRATION HANDBOOK

I. INTRODUCTION

A. Purpose and Content of this Handbook

This Handbook provides instructions to registrants on how to respond to the Reregistration Eligibility Document (hereafter referred to as the "RED") and how to reregister products.

Section I is this introduction.

Section II contains step-by-step instructions which must be followed by registrants responding to the RED.

Section III provides additional instructions on the format, content and other aspects of generic data, product specific data and labels/labeling which may be required to be submitted.

Detailed instructions are in the Appendix.

B. The Reregistration Eligibility Document (RED)

Under Section 4 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended in 1988, EPA is required to reregister pesticides that were first registered before November 1, 1984. The RED describes in detail the subject chemical, its uses and its regulatory history; describes EPA's decision concerning the eligibility of the uses of the chemical for reregistration; and explains the scientific and regulatory bases for this decision. EPA's reviews of the data by scientific discipline are available upon request.[1] Appendices to the RED contain: (1) a Data Dall-In Notice which requires submission of generic and product specific data and which gives directions for responding, (2) a listing of existing studies that satisfy generic data requirements and (3) a bibliography of the generic studies EPA has reviewed.

C. The Reregistration Process

Reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of EPA's review is to reassess the potential hazards arising from the currently registered uses of the pesticide, to determine whether the data base is substantially complete or there is need for additional generic data, and to determine whether the pesticide is eligible for reregistration. This decision is issued as the RED.

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[1] EPA's science reviews and information on the registered uses considered for EPA's analyses may be obtained from: EPA, Freedom of Information, 401 M St., S.W., Washington, D.C. 20460.

If the RED declares that some or all uses of the chemical are eligible for reregistration, affected registrants must first respond within 90 days of receipt to the data call-in portion of the RED. Within 8 months of receiving the RED, registrants must submit or cite any data and labels/labeling required for each product. EPA has until 14 months after the RED is issued (i.e., 6 months after the registrants' 8 month deadline) to review the submission for each product and decide whether to reregister it based on the following criteria:

--whether all of the product specific data and labels/labeling are acceptable,

--whether all of the uses on the label/labeling are eligible,

--whether all of the active ingredients in the product are eligible, and

--if no List 1 toxic inert ingredient is contained in the product (a List 1 inert is permitted only if all data for it have been submitted and EPA determines that the inert does not pose any unreasonable adverse effects in that product).

Products which meet all of these criteria will be reregistered. Products which do not meet all of these criteria, but which have acceptable product specific data and labeling, will be processed as amendments in order to implement label changes required by the RED.

II. INSTRUCTIONS FOR RESPONDING

A. How and When to Respond

This section provides directions for submitting timely and adequate responses necessary to reregister products containing the active ingredient covered by the RED. Registrants must follow these steps exactly to avoid suspension of their products. All products containing the active ingredient in the RED [i.e., manufacturing use products, end use products and special local need (SLN or Section 24c) registrations] are subject to the requirements of the RED. Figure 1 summarizes how and when to respond to the RED. A step-by-step explanation follows.

Step 1. Are Expedited Label Changes Required? In some instances, EPA may conclude that certain changes to product labels/labeling must be implemented rapidly. If the RED requires expedited label/labeling changes, registrants must submit the items below by the deadline specified in the RED. If expedited label changes are not required, go to Step 2.

a. Application for Registration (EPA Form 8570-1). Complete

and sign the form. In Section II, insert the phrase "Expedited Amendment in Response to the Reregistration Eligibility Document for (insert case name for chemical)." Applications for expedited label changes will be processed as applications for amended registration. Use only an original application form with a red identifier number in the upper right-hand corner.

b. Five (5) copies of revised draft label and labeling. Refer to the RED for label/labeling changes and follow the instructions in Section III.C. and the Appendix of this Handbook for revising the label and labeling for each product.

Step 2. Are data required? If the RED requires generic or product specific data, you must follow the directions in the data call-in notice in the RED. All registrants must respond for all products within 90 days of receipt; products for which an adequate response is not received on time will be subject to suspension. No time extensions will be given for responding within 90 days.

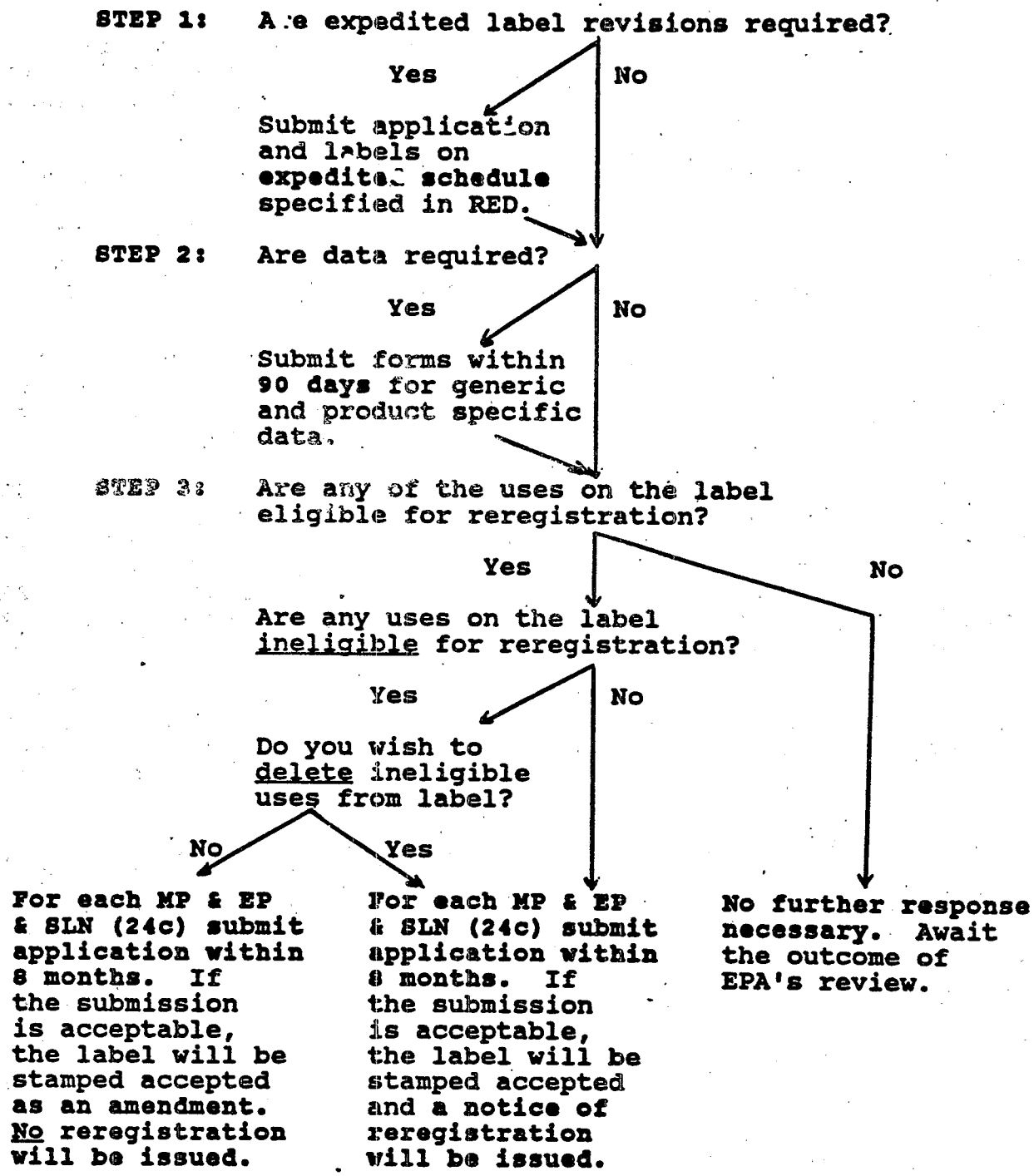
Step 3. Are Uses of a Pesticide Eligible for Reregistration? If any uses of the active ingredient(s) covered by the RED are eligible for reregistration, follow these instructions. If no uses are eligible, no further response may be needed (see page 5).

EPA's decision on the eligibility of each of the uses of the active ingredient(s) is presented in the RED. If any uses of a chemical are eligible for reregistration, registrants for manufacturing-use products (MPs), end-use products (EPs) and special local needs registrations (SLNs), must submit the items below for each product within 8 months of the date of issuance of the RED:

a. Application for Reregistration (use EPA Form 8570-1). Complete and sign the form. In Section II of that form, check the box "Other" and insert the phrase "Application for Reregistration." Use only an original application form with a red identifier number in the upper right-hand corner.

b. Five (5) copies of revised draft label and labeling. Refer to the RED for labeling changes specific to the active ingredient, follow the instructions in Section III.C. of this Handbook and refer to the Appendix of this Handbook for guidance on current requirements for labels and labeling. If there are ineligible uses on the label or labeling, you may delete such uses and avoid all requirements and consequences which may be associated with ineligible uses (e.g, generic data requirements, cancellation, suspension, etc.). If you delete certain uses now and those uses become eligible for reregistration later, you must submit an amendment application to add those uses back to the label.

FIGURE 1. HOW AND WHEN TO RESPOND TO THE REREGISTRATION ELIGIBILITY DOCUMENT (RED) FOR MANUFACTURING USE PRODUCTS (MPs), END-USE PRODUCTS (EPs) and SPECIAL LOCAL NEEDS REGISTRATIONS (SLNs).



c. **Product Specific Data. You must follow the instructions in the Data Call-In Notice in the RED and in Section III of this Handbook. Responses to the data call in are due within 90 days of receipt of the RED and submission or citation of data is due within 8 months of the issuance of the RED.**

d. **Two (2) copies of the current Confidential Statement of Formula (EPA Form 8570-4, revised February 85).** Two completed and signed CSF forms must be submitted for the basic formulation and for each alternate formulation. If CSFs are not provided for the alternate formulas, they will not be reregistered and will no longer be acceptable. The Appendix of this Handbook has specific instructions for completing the CSF form.

e. **Certification With Respect to Citation of Data (EPA Form 8570-31).** This form must be completed, signed and submitted for each product to assure that the data compensation provisions of FIFRA are met.

B. When No Response is Needed

If no uses of a pesticide are eligible for reregistration, it is unlikely that you will be required to submit product specific data or labeling. Uses of an active ingredient may be declared ineligible for reregistration for two possible reasons:

--Available data indicate that one or more of the criteria for an in-depth special review have been met;

--Additional generic data are required.

In the first instance, if the active ingredient is placed into special review, reregistration activities associated with those uses of the chemical are stopped until EPA makes a final determination. At that time, EPA will indicate which uses may be eligible for reregistration and which uses are to be cancelled. If some or all of the previously ineligible uses become eligible for reregistration, EPA will start the reregistration process for products containing only eligible uses.

In the second instance, based upon the review of studies for an active ingredient during reregistration, additional generic data (e.g., second- or third-tier studies) may be needed (see the RED). In such cases, the chemical's uses will not be eligible for reregistration until the additional generic data have been submitted to and reviewed and found acceptable by EPA. If the data are reviewed and found to be acceptable, EPA will indicate which uses will be eligible for reregistration and will initiate reregistration of products containing previously ineligible uses. If the data are not submitted, products containing the active ingredient may be suspended.

C. Where to Respond

By U.S. Mail:

Document Processing Desk (insert distribution code)
Office of Pesticide Programs (H7504C)
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

By express mail or by hand delivery:

Document Processing Desk (insert distribution code)
Office of Pesticide Programs (H7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

These mailing addresses and the following distribution codes must be used to assure the timely receipt and processing of your submissions. Not using them may significantly delay the handling of your submissions:

RED-SRRD-xxx (where xxx is the case code given on the front of the RED)--use this distribution code for all responses pertaining to or containing generic data. Such responses include the 90-day response forms for generic data or hard copies of generic data.

RED-RD-PMxx (where xx is the Product Manager team number)--use this distribution code for all responses pertaining to or containing product specific data or labeling. Such responses would include expedited labeling amendments, 90-day responses to product specific data requirements, hard copies of product specific data and applications for reregistration.

III. SUBMISSION OF DATA AND LABELS/LABELING

This section provides additional instructions concerning responses required for generic data, product specific data and labels/labeling.

A. Generic Data

During EPA's evaluation of an active ingredient for reregistration, additional generic data requirements may be identified that registrants must fulfill. In some instances these data requirements would have to be satisfied before an active ingredient or some of its uses could be declared eligible for reregistration. In other cases, these new data requirements would not affect the eligibility of the active ingredient, but would be necessary to confirm EPA's assessment of that chemical.

Any new data requirements and how they affect reregistration eligibility of a chemical are discussed in the RED. If new generic data requirements are imposed in a Data Dall-In Notice in the RED, registrants must respond as described in that Notice. The RED also contains instructions for completing these forms, a citation of EPA's legal authority for requiring the new data, a listing of options available to registrants for satisfying the data requirements and the name of the contact person for inquiries.

B. Product Specific Data

Product specific data may be required for the reregistration of each pesticide product in three areas--product chemistry, acute toxicity and efficacy.

1. Product Chemistry

Following are instructions for submitting product-specific data and a discussion of EPA's policy on inert ingredients.

a. Data

All data requirements for MPs, EPs and SLNs (24c's) are specified in the Data Call-In Notice in the RED. In addition:

--If you cite data from another identical, registered product, you must identify the EPA registration number of that product.

--If the product-specific data submitted or cited do not pertain to an identical formulation to the product submitted for reregistration, then new product-specific data are required to be submitted by the deadline specified in the Data Call-In Notice. The only exception is for products which EPA "groups" together a being similar enough to depend on the same data. Such groupings are discussed in the appendix to the RED (for acute toxicity purposes, for example), if it was feasible to do so.

b. Inert Ingredients

EPA has implemented a strategy for regulating inert ingredients which affects the reregistration of pesticide products. This strategy, issued on April 22, 1987 (52 FR 13305-13309) and updated on November 22, 1989 (54 FR 48314-48316), adopted certain policies designed to reduce the potential for adverse effects from pesticide products containing intentionally added inert ingredients. EPA divided the known inert ingredients into four categories:

--Inerts of toxicological concern (List 1) for which available data demonstrate toxic effects of concern (includes about 50 chemicals).

--Potentially toxic inerts (List 2) for which only limited data are available, but such data or the chemical structure suggest the potential for toxicity (includes about 60 chemicals).

--Inerts of unknown toxicity (List 3) for which no data or bases for suspecting toxic effects are available (includes up to 2,000 chemicals).

--Inerts of minimal concern (List 4) which are generally regarded as innocuous (includes about 290 chemicals).

When a RED is issued and any uses of an active ingredient are declared eligible for reregistration, all products containing that active ingredient will be subject to reregistration. EPA will, as part of the reregistration review, examine the inert ingredients of each product prior to reregistration to ensure that they do not present unreasonable risks. In reviewing the product chemistry data, EPA will identify List 1 inerts. EPA will continue to encourage registrants to eliminate any List 1 inerts present. Reregistration of products containing only List 2, 3 or 4 inerts will be unaffected by the inerts strategy.

Consistent with the strategy on inerts, **a product containing a List 1 inert ingredient will <u>not</u> be reregistered until a full risk assessment of the product has been conducted, based on the data called in for that inert ingredient.** However, the existing registration of a product containing a List 1 inert will remain valid as long as the product bears the required label warning and is in compliance with any outstanding DCI, or other activity under the inerts strategy.

Any product containing a List 2, 3 or 4 inert <u>may</u> be reregistered <u>if</u> it meets all other requirements for reregistration. As the inerts strategy is implemented and data for the List 2 and 3 inerts are reviewed, EPA may move these inerts to the other Lists. If an inert were moved to List 1, products containing that inert would become ineligible for reregistration. Inert ingredients must also meet normal registration and tolerance requirements, as applicable.

2. <u>Acute Toxicity</u>

The data call-in notice in the RED specifies the acute toxicity data required for reregistration of each MP or EP. It indicates whether any of the standard tests have been waived and, if so, why.

If feasible, EPA will "batch" products that are similar with respect to their acute toxicity so that one set of tests can support reregistration of each baatch of products. This approach will impose the least amount of testing necessary to adequately support the registration and labeling for pesticide products. The

main benefits of this approach are to minimize the need for animal testing, reduce the expense to registrants to generate the tests and decrease the resources EPA must spend on reviewing data. Registrants may contact other registrants with products in the same "batch" to decide whether to provide or depend on one set of data; alternatively, registrants may choose to conduct their own studies.

3. Product Performance

Consult the Data Call-In section of the RED to determine whether Product Performance data are required for your product.

Product performance (efficacy) data are generated in studies designed to document how candidate pesticide formulations perform as pest control agents. These data include tests run to determine whether a formulation is lethal to certain pest species, to document the effectiveness of the formulation in controlling pest species in actual use situations, and to determine whether certain claims beyond mere control of a pest (e.g., "six-month residual effect," "kills Warfarin resistant house mice," etc.) are justified.

EPA has standard protocols for certain efficacy tests. In general, standard methods have been developed for tests needed to substantiate claims that have been made frequently for pesticide products. As the scope of potential pesticidal claims is extremely broad, the Agency does not have standard methods for tests needed to substantiate many pesticide claims, especially those that are uncommon. The Product Performance Guidelines, Subdivision G, offer general guidance for developing protocols for efficacy testing. Proposed protocols should be submitted to EPA for review before tests are initiated.

a. Efficacy Data Submission Waiver Policy

FIFRA gives the Administrator of EPA authority "to waive data requirements pertaining to efficacy" but does not require that efficacy data requirements be waived for any class of pesticide product registered under Section 3 of the Act. As a matter of policy, EPA does not require submission of efficacy data to support many types of pesticidal claims but does require submission of such data for certain types of claims. As noted in 40 CFR 158.640, this waiver applies to the submission of efficacy data rather than to the generation of efficacy data. EPA expects each registrant to "ensure through testing that his products are efficacious when used in accordance with commonly accepted pest control practices."

This general policy notwithstanding, EPA may, at any time, require a registrant to submit efficacy data to support any claim made for a product. EPA also may require that certain claims of effectiveness be established before a Section 3 registration is granted.

b. Claims and Products for Which Efficacy Data Generally Are Required

Submission of efficacy data at reregistration typically is required for the following types of products:

1. products claimed to control microorganisms that pose potential threats to public health;

2. products claimed to control vertebrate pests that may directly or indirectly transmit diseases to humans;

3. potentially very hazardous products for which EPA determines that it is necessary to conduct a "risk-benefits" analysis;

4. products of types for which EPA has reasons (e.g., consumer complaints, unlikely claims, unusual use patterns, etc.) to question claims; and

C. Labels and Labeling

To remain in compliance with FIFRA, the label and labeling of each product must be revised to meet the requirements for reregistration as described below. "Labeling" includes the container label and any written, printed or graphic matter that accompanies the pesticide in U.S. commerce at any time (such as technical bulletins, collateral labeling, etc.). **Applications for new uses or labeling changes that do not pertain to reregistration must be filed separately from the application for reregistration described in Step 3 earlier.** Changes to labeling which must be made for reregistration include, but are not limited to:

1. Labeling changes specified in the RED. Such changes may include statements on RESTRICTED USE, groundwater hazards, protective clothing/equipment, endangered species, environmental hazards, etc.

2. The format and content of labeling as described in 40 CFR 156.10. When further acute testing is needed, the currently accepted precautionary statements will usually be retained until testing is completed and the data are reviewed.

3. Labeling changes required by Pesticide Regulatory (PR) Notices, regulations, regulatory decisions and policies issued by EPA which are relevant to the pesticide. Your product's labeling must reflect any applicable requirements which are in effect at the time the RED is issued. Some existing notices are referred to in Section B. of the Appendix.

APPENDIX

A. Confidential Statement of Formula and Instructions

B. Instructions for Label Contents

C. Sample Label Formats--General Use & Restricted Use

D. Label Regulations (40 CFR 156.10)

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065)

Form Approved. OMB No. 2070-0060. Approval expires 9-30-90

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	b. Lower Limit	15. Purpose in Formulation

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

20. Phone No. *(Include Area Code)*

21. Date

EPA Form 8570-4 (Rev. 2-85) Previous editions are obsolete.

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product-specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

l. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for all active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

B. INSTRUCTIONS FOR LABEL CONTENTS

40 CFR 156.10 and Pesticide Regulatory (P.R.) Notices require that specific labeling statements appear at certain locations on the label. The sample label formats in Appendix C show where these statements are to be placed.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. [40 CFR 156.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the producer, registrant or person for whom the product is produced are required on the label and should be located at the bottom of the front panel or at the end of the label text. [40 CFR 156.10(c)]

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is normally required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural

formulations, the pounds per gallon of active ingredient must be indicated on the label. [40 CFR 156.10(h)(iv)]

Item 6C. NAMES TO BE USED IN INGREDIENT STATEMENT - The acceptable common name, if there is one, shall be used, followed by the chemical name. If no common name has been established, the chemical name alone shall be used. Chemicals related to the active ingredient are allowed to be listed only if efficacy data supporting such claims are submitted or referenced. If such data are provided, the related chemicals must be listed separately and not as a portion of the active ingredient.

Item 6D. INERT INGREDIENTS RECLASSIFIED AS ACTIVE INGREDIENTS - If EPA has reclassified chemicals from inert ingredient status to active ingredient status, registrants of affected products must change the ingredient statement accordingly (See 52 FR 13307-8, April 22, 1987). If such pesticides have food uses, tolerances must either be established for such uses, or an exemption from the requirement for tolerances must be obtained.

Item 6E. NOMINAL CONCENTRATION - The amount of active ingredient declared in the ingredient statement must be the nominal concentration of the product as defined in 40 CFR 158.153(i) and described in P.R. Notice 91-2.

Item 7. WARNINGS AND PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 156.10(h)(1)(i)].

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 156.10(h)(1)(i)].

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "see Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 156.10(h)(1)(iii)].

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation). If your product has been classified for restricted use, then these requirements apply:

1. **All uses restricted.** The following statements must be placed in a black box at the top of the front panel of the label and labeling:

   a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word [see table in 40 CFR 156.10(h)(1)(iv)]. No statements of any kind may appear above this RUP statement.

   b. The reason for the the restricted use classification must appear below the RUP statement. The RED will prescribe this statement.

   c. A summary statement of the terms of restriction must appear directly below this reason statement on the front panel. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification." The RED will specify what statement must be used.

2. **Some but not all uses restricted.** If the RED states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

   a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

   b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

   c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a restricted entry interval (REI) has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in

accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to P.R. Notices 83-3 and 84-1 to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10(i)(2)]

COLLATERAL LABELING .

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. Collateral labeling must be made part of the response to the RED and submitted for review.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
& DOMESTIC ANIMALS
CAUTION

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL
HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

CROP:

CROP:

CROP:

PRODUCT NAME

ACTIVE INGREDIENT: _____ %
INERT INGREDIENTS: _____ %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.

NET CONTENTS

CROP:

CROP:

CROP:

CROP:

STORAGE AND DISPOSAL

STORAGE

DISPOSAL

WARRANTY STATEMENT

LABEL FORMAT FOR UNCLASSIFIED PRODUCTS

LABEL FORMAT FOR PRODUCTS CLASSIFIED FOR RESTRICTED USE

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

DANGER

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

STORAGE AND DISPOSAL

STORAGE

DISPOSAL

CROP:

RESTRICTED USE PESTICIDE

Due to (insert reason*)

FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION

(*for example, "Due to high acute toxicity.")

PRODUCT NAME

ACTIVE INGREDIENT: _____ %

INERT INGREDIENTS: _____ %

TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

DANGER—POISON

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED

IF INHALED

IF ON SKIN

IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY

TOWN, STATE

ESTABLISHMENT NO.

EPA REGISTRATION NO.

NET CONTENTS

CROP:

CROP:

CROP:

CROP:

CROP:

WARRANTY STATEMENT

submitter has asserted a confidential business information claim concerning the material).

(5) A copy of each document, proposal, or other item of written material concerning the Registration Standard provided by the Agency to any person or party outside of government (within 15 working days after the item is made available to such person or party).

(6) A copy of the Registration Standard;

(7) With respect to a Registration Standard for which the Agency has determined that a substantially complete chronic health and teratology data base exists, a copy of the FEDERAL REGISTER notice concerning availability of a proposed Registration Standard, and a copy of each comment received in response to that notice (within 10 working days after receipt by the Agency, or 15 working days if the submitter has asserted a confidential business information claim concerning the material).

(8) A copy of the FEDERAL REGISTER notice announcing the issuance of the Registration Standard (within 10 working days after the publication of the notice).

(c) *Index of the docket.* The Agency will establish and keep current an index to the docket for each Registration Standard. The index will include, but is not limited to:

(1) A list of each meeting between the Agency and any person or party outside of government, containing the date and subject of the meeting, the names of participants and the name of the person requesting the meeting.

(2) A list of each document in the docket by title, source or recipient(s), and the date the document was received or provided by the Agency.

(d) *Availability of docket and indices.* (1) The Agency will make available to the public for inspection and copying the docket and index for any Registration Standard.

(2) The Agency will establish and maintain a mailing list of persons who have specifically requested that they receive indices for Registration Standard dockets. On a quarterly basis, EPA will distribute the indices of new materials placed in the public docket to these persons. Annually, EPA will require that persons on the list renew their requests for inclusion on the list.

(3) The Agency will issue annually in the FEDERAL REGISTER (in conjunction with the annual schedule notice specified in § 155.25) a notice announcing the availability of docket indices.

(4) Each FEDERAL REGISTER notice of availability of a Registration Standard will announce the availability of the docket index for that Standard.

§ 155.34 Notice of availability.

(a) The Agency will issue in the FEDERAL REGISTER a notice announcing the issuance and availability of Registration Standard which:

(1) Concerns a previously unregistered active ingredient; or

(2) Concerns a previously registered active ingredient, and the Registration Standard states that registrants will be required (under FIFRA section 3(c)(2)(B)) to submit chronic health (including, but not limited to, chronic feeding, oncogenicity and reproduction) or teratology studies.

(b) Interested persons may submit comments concerning any Registration Standard described by paragraph (a) of this section at any time.

(c) The Agency will issue in the FEDERAL REGISTER a notice announcing the availability of, and providing opportunity for comment on, each proposed Registration Standard which concerns a previously registered active ingredient for which the Agency has determined that a substantially complete chronic health and teratology data base exists. Following the comment period and issuance of the Registration Standard, the Agency will issue in the FEDERAL REGISTER a notice of availability of the Registration Standard.

PART 156—LABELING REQUIREMENTS FOR PESTICIDES AND DEVICES

AUTHORITY: 7 U.S.C. 136-136y.

§ 156.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regu-

lations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 153.240, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 152.132.

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semi-solid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average con-

tent of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC_{50}	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter	From 2. thru 20 mg/liter	Greater than 20 mg/liter.
Dermal LD_{50}	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such

that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	16	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in paragraph (j) of this section immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See Table in § 162.10(h)(1)(iv))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of paragraph (j)(2) of this section.

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in paragraph (h)(1)(iv) of this section), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978. Redesignated and amended at 53 FR 15991, 15999, May 4, 1988]

Appendix F

Generic and Product-Specific Data Call-In

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC AND PRODUCT SPECIFIC
DATA CALL-IN NOTICE

FEB 16 1994

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment A of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 7; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3 (for both generic and product specific data), the Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this

information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-96).

This Notice is divided into six sections and seven Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I	-	Why You are Receiving this Notice
Section II	-	Data Required by this Notice
Section III	-	Compliance with Requirements of this Notice
Section IV	-	Consequences of Failure to Comply with this Notice
Section V	-	Registrants' Obligation to Report Possible Unreasonable Adverse Effects
Section VI	-	Inquiries and Responses to this Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
4 - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Cost Share and Data Compensation Forms

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredients.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Forms: Attachment 3

(for both generic and product specific data requirements). Depending on the results of the studies required in this Notice, additional studies/testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in the Requirements Status and Registrant's Response Forms (Attachment 3) within the timeframes provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (Telephone number: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

You must use the correct forms and instructions when completing your response to this Notice. The type of Data Call-In you must comply with (Generic or Product Specific) is specified in item number 3 on the four Data Call-In forms (Attachments 2 and 3).

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for generic and product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

1. Generic Data Requirements

The options for responding to this Notice for generic data requirements are: (a) voluntary cancellation, (b) delete use(s), (c) claim generic data exemption, (d) agree to satisfy the generic data requirements imposed by this Notice or (e) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the generic data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

Two forms apply to generic data requirements, one or both of which must be used in responding to the Agency, depending upon your response. These two forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, (contained in Attachments 2 and 3, respectively).

The Data Call-In Response Forms must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms also must be submitted if you do not qualify for a Generic Data Exemption or are not requesting voluntary cancellation of your registration(s). Please note that the company's authorized representative is required to sign the first page of both Data Call-In Response Forms and the Requirements Status and Registrant's Response Forms (if this form

is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation -

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit completed Generic and Product Specific Data Call-In Response Forms (Attachment 2), indicating your election of this option. Voluntary cancellation is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice, which are contained in Section IV-C.

b. Use Deletion -

You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form (Attachment 3), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 under item 9 in the instructions for the Requirements Status and Registrant's Response Forms. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, is allowed only if the product bears an amended label.

c. Generic Data Exemption -

Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient if the active ingredient in the product is derived exclusively from

purchased, registered pesticide products containing the active ingredient. EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

(i). The active ingredient in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient and is purchased from a source not connected with you;

(ii). Every registrant who is the ultimate source of the active ingredient in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

(iii). You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

d. Satisfying the Generic Data Requirements of this Notice

There are various options available to satisfy the generic data requirements of this Notice. These options are discussed in Section III-C.1. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the Requirements Status and Registrant's Response Form and item 6b on the Data Call-In Response Form. If you choose item 6b (agree to satisfy the

generic data requirements), you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "GENERIC" in item number 3.

e. Request for Generic Data Waivers.

Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

2. Product Specific Data Requirements

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this Notice or (c) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, for product specific data (contained in Attachments 2 and 3, respectively). The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form also must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on both the Generic and Product Specific Data Call-In Response Forms. If you choose this option, you must complete both Data Call-In response forms. These are the only forms that you are required to complete.

If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

b. Satisfying the Product Specific Data Requirements of this Notice.

There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C.2. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the product specific Requirements Status and Registrant's Response Form and item numbers 7a and 7b (agree to satisfy the product specific data requirements for an MUP or EUP as applicable) on the product specific Data Call-In Response Form. Note that the options available for addressing product specific data requirements differ slightly from those options for fulfilling generic data requirements. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements. It is important to ensure that you are using the correct forms and instructions when completing your response to the Reregistration Eligibility Decision document.

c. Request for Product Specific Data Waivers.

Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose this option, you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "PRODUCT SPECIFIC" in item number 3.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

If you acknowledge on the Generic Data Call-In Response Form that you agree to satisfy the generic data requirements (i.e. you select item number 6b), then you must select one of the six options on the Generic Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide you to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified timeframe (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)

(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data

If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG) and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware

that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost share or agreeing to share in the cost of developing that study. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports or protocols. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2. Agreement to Share in Cost to Develop Data

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3. Offer to Share in the Cost of Data Development

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept the offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost-sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed to or, failing agreement, to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its

commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant normally will be subject to initiation of suspension proceedings, unless you commit to submit, and do submit, the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4. Submitting an Existing Study

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly Met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3 "'[r]aw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR

160.3, means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 also must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants also must certify at the time of submitting the existing study that such GLP information is available for post May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data usually are not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5. Upgrading a Study

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option also should be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally, your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria, as well as a certification regarding protocol compliance with Agency requirements.

Option 6. Citing Existing Studies

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable, or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core-minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option, you must

provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

2. Product Specific Data

If you acknowledge on the product specific Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select option 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time-frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)

(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)

(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2. Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, registrants may only choose this option for

acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option.

Option 3. Offer to Share in the Cost of Data Development --The same requirements for generic data (Section III.C.I., Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

Option 4. Submitting an Existing Study -- The same requirements described for generic data (see Section III.C.1., Option 4) apply to this option for product specific data.

Option 5. Upgrading a Study -- The same requirements described for generic data (see Section III.C.1., Option 5) apply to this option for product specific data.

Option 6. Citing Existing Studies -- The same requirements described for generic data (see Section III.C.1., Option 6) apply to this option for product specific data.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, and in the generic data requirements section (III.C.1.), as appropriate.

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are not appropriate for your product.

a. Low Volume/Minor Use Waiver

Option 8 under item 9 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing

this provision, EPA considers low volume pesticides to be only those active ingredients whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver, the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

(i). Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient. If applicable to the active ingredient, include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

(ii) Provide an estimate of the sales (pounds and dollars) of the active ingredient for each major use site. Present the above information by year for each of the past five years.

(iii) Total direct production cost of product(s) containing the active ingredient by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

(iv) Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient, such as costs of initial registration and any data development.

(v) A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vi) A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vii) For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient, direct production costs of product(s) containing the active ingredient (following the parameters in item 2 above), indirect production costs of product(s) containing the active ingredient (following the parameters in item 3 above), and costs of data development pertaining to the active ingredient.

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume/minor use waiver will result in denial of the request for a waiver.

b. Request for Waiver of Data

Option 9, under Item 9, on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the requirement is inappropriate. You must submit a

rationale explaining why you believe the data requirements should not apply. You also must submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice are not appropriate to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

2. Product Specific Data

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the product specific Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to

FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

   i. Inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a <u>Requirements Status and Registrant's Response Form.</u>

   ii. Fulfill the commitment to develop and submit the data as required by this Notice; or

   iii. Otherwise take appropriate steps to meet the requirements stated in this Notice,

unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1) EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2) EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3) EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when

a section 3(c)(2)(B) data request is outstanding generally would not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You also must explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden, the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on a case-by-case basis.

Requests for voluntary cancellation received <u>after</u> the 90 day response period required by this Notice will not result in the agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due, <u>unless</u> you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3-year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. <u>REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS</u>

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the

Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice must include completed Data Call-In Response Forms (Attachment 2)and completed Requirements Status and Registrant's Response Forms (Attachment 3), for both (generic and product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Generic and Product Specific Data Call-In Response Forms need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Prevention, Pesticides and Toxic Substances (OPPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Daniel M. Barolo, Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
4 - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Cost Share and Data Compensation Forms

Attachment 1

Chemical Status Sheet

GLYPHOSATE: DATA CALL-IN CHEMICAL STATUS SHEET

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the data base for glyphosate are contained in Generic DCI and Product Specific DCI Requirements Status and Registrant's Response forms (Attachment 3).

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data base for glyphosate, please contact Eric Feris, the Review Manager for this chemical through the Virginia Relay (1-800-828-1140) at (703) 308-8048.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Frank Rubis at (703) 308-8184.

All responses to this Notice should be submitted to:

Eric Feris
Special Review and Reregistration Division (7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: Glyphosate

Attachment 2

Generic DCI and Product Specific DCI Response Forms with Instructions

Instructions For Completing
The
"Data Call-In Response Forms"
For The Generic And Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide Fungicide and Rodenticide Act. **The type of data call-in (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.** BOTH "Data Call-In Response" forms must be completed.

Although the form is the same for both generic and product specific data, instructions for completing these forms are different. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 4 have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.

Item 2. **ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. **ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

Item 4. **ON BOTH FORMS:** This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this Data Call-In but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. **ON BOTH FORMS:** Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms.

Item 6a. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and

incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data Call-In. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

NOTE: **Item 6a and 6b are not applicable for Product Specific Data.**

Item 7a. **ON THE PRODUCT SPECIFIC DATA FORM:** For each manufacturing use product (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

Item 7b. For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do not complete the Requirements Status and Registrant's Response form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

If you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver.

NOTE: **Item 7a and 7b are not applicable for Generic Data.**

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 8. **ON BOTH FORMS:** This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialled and dated in the space provided for the certification.

Item 9. **ON BOTH FORMS:** Enter the date of signature.

Item 10. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 11. **ON BOTH FORMS:** Enter the phone number of your company contact.

Note: You may provide additional information that does not fit on this form in a signed letter that accompanies your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

United States Environmental Protection Agency
Washington, D. C. 20460

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY 1234 MAIN STREET ANYWHERE, USA 54321	0178 Glyphosate	GENERIC FEB 16 1994

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
		N.A.	N.A.		

8. Certification
I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative _____

9. Date

10. Name of Company Contact

11. Phone Number

United States Environmental Protection Agency
Washington, D. C. 20460

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY 1234 MAIN STREET ANYWHERE, USA 54321	0178 Glyphosate	PRODUCT SPECIFIC FEB 16 1994

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
		N.A.	N.A.		

8. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

Attachment 3

Generic DCI and Product Specific DCI Requirements Status and Registrants' Response Forms with Instructions

Instructions For Completing
The
"Requirements Status and Registrant's Response Forms"
For The Generic and Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide Fungicide and Rodenticide Act. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.** Both "Requirements Status and Registrant's Response" forms must be completed.

Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 8 have been preprinted on the form. Item 9 must be completed by the registrant as appropriate. Items 10 through 13 must be completed by the registrant before submitting a response to the Agency.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"
Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.

Item 2. **ON THE GENERIC DATA FORM:** This item identifies the case number, case name, EPA chemical number and chemical name.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the case number, case name, and the EPA Registration Number of the product for which the Agency is requesting product specific data.

Item 3. **ON THE GENERIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the type of Data Call-In. The date of issuance is also date stamped. Note the unique identifier number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.

Item 5. **ON BOTH FORMS:** This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"
Generic and Product Specific Data Call-In

Item 6. **ON BOTH FORMS:** This item identifies the code associated with the use pattern of the pesticide. In the case of efficacy data (product specific requirement), the required study only pertains to products which have the use sites and/or pests indicated. A brief description of each code follows:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food crop
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

Item 7. **ON BOTH FORMS:** This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

EUP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Indredient or Pute Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP ___%	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"
Generic and Product Specific Data Call-In

TGAI	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates
*	See: guideline comment

Item 8. This item completed by the Agency identifies the time frame allowed for submission of the study or protocol identified in item 5.

ON THE GENERIC DATA FORM: The time frame runs from the date of your receipt of the Data Call-In notice.

ON THE PRODUCT SPECIFIC DATA FORM: The due date for submission of product specific studies begins from the date stamped on the letter transmitting the Reregistration Eligibility Decision document, and not from the date of receipt. However, your response to the Data Call-In itself is due 90 days from the date of receipt.

Item 9. **ON BOTH FORMS:** Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

Option 1. **ON BOTH FORMS:** (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocols and progress reports required in item 5 above.

Option 2. **ON BOTH FORMS:** (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating

that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.

However, for Product Specific Data, I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if the Agency indicates in an attachment to this notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

Option 3. **ON BOTH FORMS:** (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice apply as well.

However, for Product Specific Data, I understand that this option is available only for acute toxicity or certain efficacy data and only if the Agency indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option.

Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of

existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

Option 5. **ON BOTH FORMS:** (Upgrading a Study) I will submit by the specified due date, or will cite data to

upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

Option 6. **ON BOTH FORMS:** (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.

However, for Product Specific Data, I am citing another registrant's study. I understand that this option is available **ONLY** for acute toxicity or certain efficacy data and **ONLY** if the cited study was conducted on my product, an identical product or a product which the Agency has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s). If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

FOR THE GENERIC DATA FORM ONLY: The following three options (Numbers 7, 8, and 9) are responses that apply only to the "Requirements Status and Registrant's Response Form" for generic data.

Option 7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"
Generic and Product Specific Data Call-In

Option 8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Option 9. (Request for Waiver of Data) I have read the statements concerning data waivers other than low-volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

FOR PRODUCT SPECIFIC DATA: The following option (number 7) is a response that applies to the "Requirements Status and Registrant's Response Form" for product specific data.

Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meetingthe data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days-of my receipt of the Agency's written decision, submit a revised "Requirements Status" form specifying the option chosen. I also

understand that the deadline for submission of data as specified by the original Data Call-In notice will not change.

Item 10. **ON BOTH FORMS:** This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. **ON BOTH FORMS:** Enter the date of signature.

Item 12. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 13. **ON BOTH FORMS:** Enter the phone number of your company contact.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that the Agency can ensure that its records are correct.

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary

1. Company name and Address

2. Case # and Name
0178 Glyphosate
Chemical # and Name 103601
Isopropylamine glyphosate

3. Date and Type of DCI
GENERIC
FEB 16 1994

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
123-1(b)	Vegetative vigor					ABCDEFJK	TGAI	12 mos.	
201-1	Droplet size spectrum					ABCDEJ	TEP	12 mos.	
202-1	Drift field evaluation		Y			ABCDEJ	TEP	24 mos.	

10. Certification
I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
SAMPLE COMPANY
1234 MAIN STREET
ANYWHERE, USA 54321

2. Case # and Name
0178 Glyphosate

EPA Reg. No. 70-269

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 70-RD-3263
FEB 16 1994

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
61-1	Product identity & composition (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(a)	Descriptn starting materials, (1,2) productn & formulatn process					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
61-2(b)	Discussion of formation of (1,3) impurities					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
62-1	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-3	Physical state					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
63-5	Melting point (6)					ABCDEFGHIJKLMNO	TGAI	8 mos.	
63-6	Boiling point (7)					ABCDEFGHIJKLMNO	TGAI	8 mos.	
63-7	Density					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
63-8	Solubility					ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-9	Vapor pressure					ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	

10. Certification
I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D. C. 20460

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OMB No. 2070-0107
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1. Company name and Address
SAMPLE COMPANY
1234 MAIN STREET
ANYWHERE, USA 54321

2. Case # and Name
0178 Glyphosate

EPA Reg. No. 70-269

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 70-RD-3263
FEB 16 1994

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-10	Dissociation constant					ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-11	Octanol/water partition coefficient (8)					ABCDEFGHIJKLMNO	PAI	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
63-13	Stability					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-15	Flammability (11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-16	Explodability (12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-17	Storage stability					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-18	Viscosity (13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility (14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-20	Corrosion characteristics					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage (15)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
	Acute Toxic - Regular Chemical								
81-1	Acute oral toxicity-rat (1,36,37)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
81-2	Acute dermal toxicity-rabbit/rat (1,2,37)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
81-3	Acute inhalation toxicity-rat (3)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
81-4	Primary eye irritation-rabbit (2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-5	Primary dermal irritation (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
SAMPLE COMPANY
1234 MAIN STREET
ANYWHERE, USA 54321

2. Case # and Name
0178 Glyphosate

EPA Reg. No. 70-269

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 70-RD-3263
FEB 16 1994

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
81-6	Dermal sensitization (4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0178 Glyphosate

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or cite data pertaining to the purchased product. [NOTE: If a product is a 100 percent repackage of another registered product that is purchased, and any use for the product does not differ from those of the purchased and registered source, users are not subject to any data requirements identified in the tables.]; TEP = typical end-use product; TGAI = technical grade of the active ingredient; PAI = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

Use Categories Key:

A - Terrestrial food crop	B - Terrestrial food feed crop	C - Terrestrial nonfood crop	D - Aquatic food crop	E - Aquatic nonfood outdoor
F - Aquatic nonfood Industrial	G - Aquatic nonfood residential.	H - Greenhouse food crop	I - Greenhouse nonfood crop	J - Forestry
K - Residential outdoor	L - Indoor food	M - Indoor nonfood	N - Indoor Medical	O - Indoor residential

Footnotes: [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

Prod Chem - Regular Chemical

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).
2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.
3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.
4 To support registration of an MP or EP, whether produced by an integrated system or not, the technical grade of Active Ingredient must be analyzed. If the technical grade of Active Ingredient cannot be isolated, a statement of composition of the practical equivalent of the technical grade of Active Ingredient must be submitted. Data on EPs or MPs will be required on a case-by-case basis.
5 Certified limits are not required for inert ingredients in products proposed for experimental use.
6 Required if technical chemical is solid at room temperature.
7 Required if technical chemical is liquid at room temperature.
8 Required if technical chemical is organic and non-polar.
9 Required if test substances are dispersible with water.
10 Required if product contains an oxidizing or reducing agent.
11 Required if product contains combustible liquids.
12 Required if product is potentially explosive.
13 Required if product is a liquid.
14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.
15 Required if end-use product is liquid and is to be used around electrical equipment.

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0178 Glyphosate

Footnotes (cont.):

3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.
36 Special testing (acute, subchronic, and/or chronic) is required for organophospates, and may be required for other cholinesterase inhibitors and other pesticides which have demonstrated a potential to adversely affect the visual system. Registrants should consult with the agency for development of protocols and methodology prior to initiation of studies.
37 Testing of the EP dilution is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

Attachment 4

EPA Grouping of End Use Products for meeting Acute Toxicology Data Requirements

EPA'S BATCHING OF GLYPHOSATE PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient glyphosate, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Batching has been accomplished using the readily available information described above, and frequently acute toxicity data on individual products has been found to be incomplete. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the

product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Fifty-six products were found which contain glyphosate as the active ingredient. The products have been placed into five batches and a "no batch" category in accordance with the active and inert ingredients, type of formulation and current labeling. Table 1 identifies the products in each batch. Table 2 lists the twenty-seven products which have been placed in the "no batch" category.

The Agency requires that products in batch four include separate primary eye irritation studies for each product within these batches. The remaining acute toxicity requirements for the products in batch four may be satisfied by one of the procedures described above.

Table 1

Batch	EPA Reg. No.	% Glyphosate	Formulation Type
1	70-269	0.96	Liq
	239-2467	0.5	Liq
	524-330	0.96	Liq
	7401-304	0.5	Liq
	7401-307	0.5	Liq
	7401-357	1.0	Liq
	7401-400	1.0	Liq
	7401-401	0.5	Liq
	7401-402	0.5	Liq
	7401-403	0.5	Liq
	10370-282	0.96	Liq
	10583-14	0.96	Liq
	46515-5	0.96	Liq
	56644-64	0.96	Liq
2	19713-320	0.96	Aerosol
	46515-7	0.96	Aerosol
3	70-284	5.0	Liq
	7401-306	5.0	Liq
	7401-404	5.0	Liq
	34911-25	5.0	Liq
	46515-3	5.0	Liq
	56644-48	5.0	Liq
4	524-339	41.0	Liq
	524-454	41.0	Liq
5	524-318	53.5	Liq
	524-343	53.8	Liq
	524-350	53.8	Liq
	19713-364	53.8	Liq

Table II lists products that were either considered not to be similar or the Agency lacked sufficient information for decision making and were not placed in any batch. Registrants of these products are responsible for meeting the acute toxicity data requirements separately for each product.

Table 2 (No batch)

EPA Reg. No.	% Glyphosate and other actives	Formulation Type
239-2469	Glyphosate 5.0	Liq
239-2509	Glyphosate 0.5, Acifluorfen 0.12	Liq
239-2516	Glyphosate 0.25, Oxyfluorfen 0.25	Liq
239-2596	Glyphosate 0.75	Aerosol
524-308	Glyphosate 41.0	Liq
524-326	Glyphosate 41.5	Liq
524-332	Glyphosate 75.0	Solid
524-333	Glyphosate 62.0	Liq
524-341	Glyphosate 14.8, Alachlor 27.6	Liq
524-370	Glyphosate 18.0	Liq
524-376	Glyphosate 13.3, 2,4-D 11.1	Liq
524-382	Glyphosate 28.6	Liq
524-390	Glyphosate 16.5, Dicamba 7.0	Liq
524-420	Glyphosate 96.3	Solid
524-421	Glyphosate 76.0	Solid
524-435	Glyphosate 83.5	Capsular
524-439	Glyphosate 7.7, Oxadiazon 14.9	Liq
524-440	Glyphosate 25.1	Liq
524-445	Glyphosate 41.0	Liq
524-449	Glyphosate 12.4, Oryzalin 11.8	Liq
524-450	Glyphosate 15.8	Liq
524-451	Glyphosate 0.96	Liq
524-452	Glyphosate 60.0	Solid
524-432	Glyphosate 18.3	Liq
7401-405	Glyphosate 10.0	Liq
935-48	Glyphosate 12.9, 2,4-D 20.6	Liq
10370-283	Glyphosate 10.0	Liq
10583-15	Glyphosate 8.2	Liq

Attachment 5

EPA Acceptance Criteria

SUBDIVISION D

Guideline	Study Title
Series 61	Product Identity and Composition
Series 62	Analysis and Certification of Product Ingredients
Series 63	Physical and Chemical Characteristics

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Name of technical material tested (include product name and trade name, if appropriate).

2.____ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient.

3.____ Name and upper certified limit for each impurity or each group of impurities present at $\geq$ 0.1% by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at <0.1%.

4.____ Purpose of each active ingredient and each intentionally-added inert.

5.____ Chemical name from Chemical Abstracts index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert.

6.____ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient.

7.____ Description of each beginning material in the manufacturing process.

____ EPA Registration Number if registered; for other beginning materials, the following:

____ Name and address of manufacturer or supplier.
____ Brand name, trade name or commercial designation.
____ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity.

8.____ Description of manufacturing process.

____ Statement of whether batch or continuous process.
____ Relative amounts of beginning materials and order in which they are added.
____ Description of equipment.
____ Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained.
____ Statement of whether process involves intended chemical reactions.
____ Flow chart with chemical equations for each intended chemical reaction.
____ Duration of each step of process.
____ Description of purification procedures.
____ Description of measures taken to assure quality of final product.

9.____ Discussion of formation of impurities based on established chemical theory addressing (1) each impurity which may be present at $\geq$ 0.1% or was found at $\geq$ 0.1% by product analyses and (2) certain toxicologically significant impurities (see #3).

62 Analysis and Certification of Product Ingredients

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered. Use a table to present the information in items 6, 7, and 8.

Does your study meet the following acceptance criteria?

1.____ Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at $\geq$ 0.1%.
2.____ Degree of accountability or closure $\geq$ ca 98%.
3.____ Analyses conducted for certain trace toxic impurities at lower than 0.1% (examples, nitrosamines in the case of products containing dinitroanilines or containing secondary or tertiary amines/alkanolamines plus nitrites; polyhalogenated dibenzodioxins and dibenzofurans). [Note that in the case of nitrosamines both fresh and stored samples must be analyzed.].
4.____ Complete and detailed description of each step in analytical method used to analyze above samples.
5.____ Statement of precision and accuracy of analytical method used to analyze above samples.
6.____ Identities and quantities (including mean and standard deviation) provided for each analyzed ingredient.
7.____ Upper and lower certified limits proposed for each active ingredient and intentionally added inert along with explanation of how the limits were determined.
8.____ Upper certified limit proposed for each impurity present at $\geq$ 0.1% and for certain toxicologically significant impurities at <0.1% along with explanation of how limit determined.
9.____ Analytical methods to verify certified limits of each active ingredient and impurities (latter not required if exempt from requirement of tolerance or if generally recognized as safe by FDA) are fully described.
10.____ Analytical methods (as discussed in #9) to verify certified limits validated as to their precision and accuracy.

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered.

Does your study meet the following acceptance criteria?

63-2 Color

____ Verbal description of coloration (or lack of it)
____ Any intentional coloration also reported in terms of Munsell color system

63-3 Physical State

____ Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"
____ Based on visual inspection at about 20-25° C

63-4 Odor

____ Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds"
____ Observed at room temperature

63-5 Melting Point

____ Reported in °C
____ Any observed decomposition reported

63-6 Boiling Point

____ Reported in °C
____ Pressure under which B.P. measured reported
____ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity

____ Measured at about 20-25° C
____ Density of technical grade active ingredient reported in g/ml <u>or</u> the specific gravity of liquids reported with reference to water at 20° C. [Note: <u>Bulk</u> density of registered products may be reported in lbs/ft^3 or lbs/gallon.]

63-8 Solubility

____ Determined in distilled water and representative polar and non-polar solvents, including those used in formulations and analytical methods for the pesticide
____ Measured at about 20-25° C
____ Reported in g/100 ml (other units like ppm acceptable if sparingly soluble)

63-9 Vapor Pressure

____ Measured at 25° C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25° C)
____ Experimental procedure described
____ Reported in mm Hg (torr) or other conventional units

63-10 Dissociation Constant

____ Experimental method described
____ Temperature of measurement specified (preferably about 20-25°C)

63-11 Octanol/water Partition Coefficient

____ Measured at about 20-25° C

____ Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350)

____ Data supporting reported value provided

63-12 pH

____ Measured at about 20-25° C

____ Measured following dilution or dispersion in distilled water

63-13 Stability

____ Sensitivity to metal ions and metal determined

____ Stability at normal and elevated temperatures

____ Sensitivity to sunlight determined

SUBDIVISION F

Guideline	Study Title
81-1	Acute Oral Toxicity in the Rat
81-2	Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig
81-3	Acute Inhalation Toxicity in the Rat
81-4	Primary Eye Irritation in the Rabbit
81-5	Primary Dermal Irritation Study
81-6	Dermal Sensitization in the Guinea Pig

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ At least 5 young adult rats/sex/group.
3.____ Dosing, single oral may be administered over 24 hrs.
4.____ Vehicle control if other than water.
5.____ Doses tested, sufficient to determine a toxicity category or a limit dose (5000 mg/kg).
6.____ Individual observations at least once a day.
7.____ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
8.____ Individual daily observations.
9.____ Individual body weights.
10.____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-2 Acute Dermal toxicity in the Rat, Rabbit or Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1._____ Identify material tested (technical, end-use product, etc).
2._____ At least 5 animals/sex/group.
3.*_____ Rats 200-300 gm, rabbits 2.0-3.0 kg or guinea pigs 350-450 gm.
4._____ Dosing, single dermal.
5._____ Dosing duration at least 24 hours.
6.*_____ Vehicle control, only if toxicity of vehicle is unknown.
7._____ Doses tested, sufficient to determine a toxicity category or a limit dose (2000 mg/kg).
8._____ Application site clipped or shaved at least 24 hours before dosing.
9._____ Application site at least 10% of body surface area.
10._____ Application site covered with a porous nonirritating cover to retain test material and to prevent ingestion.
11._____ Individual observations at least once a day.
12._____ Observation period to last at least 14 days.
13._____ Individual body weights.
14._____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Product is a gas, a solid which may produce a significant vapor hazard based on toxicity and expected use or contains particles of inhalable size for man (aerodynamic diameter 15 μm or less).
3.____ At least 5 young adult rats/sex/group.
4.____ Dosing, at least 4 hours by inhalation.
5.____ Chamber air flow dynamic, at least 10 air changes/hour, at least 19% oxygen content.
6.____ Chamber temperature, 22° C ($\pm$2°), relative humidity 40-60%.
7.____ Monitor rate of air flow.
8.____ Monitor actual concentrations of test material in breathing zone.
9.____ Monitor aerodynamic particle size for aerosols.
10.____ Doses tested, sufficient to determine a toxicity category or a limit dose (5 mg/L actual concentration of respirable substance).
11.____ Individual observations at least once a day.
12.____ Observation period to last at least 14 days.
13.____ Individual body weights.
14.____ Gross necropsy on all animals.

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive, causes severe dermal irritation or has a pH of ≤ 2 or ≥ 11.5.
3.____ 6 adult rabbits.
4.____ Dosing, instillation into the conjunctival sac of one eye per animal.
5.____ Dose, 0.1 ml if a liquid; 0.1 ml or not more than 100 mg if a solid, paste or particulate substance.
6.____ Solid or granular test material ground to a fine dust.
7.____ Eyes not washed for at least 24 hours.
8.____ Eyes examined and graded for irritation before dosing and at 1, 24, 48 and 72 hr, then daily until eyes are normal or 21 days (whichever is shorter).
9.*___ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3.____ 6 adult animals.
4.____ Dosing, single dermal.
5.____ Dosing duration 4 hours.
6.____ Application site shaved or clipped at least 24 hours prior to dosing.
7.____ Application site approximately 6 cm^2.
8.____ Application site covered with a gauze patch held in place with nonirritating tape.
9.____ Material removed, washed with water, without trauma to application site.
10.____ Application site examined and graded for irritation at 1, 24, 48 and 72 hr, then daily until normal or 14 days (whichever is shorter).
11.*____ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.___ Identify material tested (technical, end-use product, etc).
2.___ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3.___ One of the following methods is utilized:
   _____ Freund's complete adjuvant test
   _____ Guinea pig maximization test
   _____ Split adjuvant technique
   _____ Buehler test
   _____ Open epicutaneous test
   _____ Mauer optimization test
   _____ Footpad technique in guinea pig.
4.___ Complete description of test.
5.*___ Reference for test.
6.___ Test followed essentially as described in reference document.
7.___ Positive control included (may provide historical data conducted within the last 6 months).

Criteria marked with an * are supplemental and may not be required for every study.

Attachment 6

List of all Registrants sent this DCI

List of All Registrants Sent This Data Call-In Notice

Case # and Name
0178 Glyphosate
Chemical # and Name
103601 Isopropylamine glyphosate (N-(phosphonomethyl)gly

Company Number	Company Name	Additional Name	Address	City & State	Zip
000070	WILBUR-ELLIS COMPANY		BOX 16458	FRESNO CA	93755
000239	CHEVRON CHEMICAL CO	ORTHO CONSUMER PRODUCTS DIVISION	940 HENSLEY ST	RICHMOND CA	94804
000524	MONSANTO CO	AGENT FOR: MONSANTO AGRICULTURAL C	700 14TH ST, N.W. SUITE 1100	WASHINGTON DC	20005
000935	OCCIDENTAL CHEMICAL CORPORATION		DEVELOPMENT CENTER, V-81 BOX 344	NIAGARA FALLS NY	14302
007401	VOLUNTARY PURCHASING GROUP, INC.		P. O. BOX 460	BONHAM TX	75418
010370	ROUSSEL UCLAF CORP		95 CHESTNUT RIDGE RD	MONTVALE NJ	07645
010583	LUNDAL ASSOCIATES INC		7493 E TIMBERLANE COURT.	SCOTTSDALE AZ	85258
019713	DREXEL CHEMICAL CO		BOX 9306	MEMPHIS TN	38109
034911	HI-YIELD CHEMICAL COMPANY		BOX 460	BONHAM TX	75418
046515	CELEX CORPORATION		377 AMELIA ST.	PLYMOUTH MI	48170
056644	SECURITY PRODUCTS COMPANY OF DELAW		BOX 59084	MINNEAPOLIS MN	55459
066459	KAUAI TARO GROWERS ASSOCIATION		BOX 427	HANALEI HI	96714

Attachment 7

Cost Share/Data Compensation Forms

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 3-3

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Chemical Name	EPA Chemical Number

I Certify that:

1. For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(D) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are: (check one)

   [ ] All companies on the data submitters' list for the active ingredient listed on this form (Cite-All Method or Cite-All Option under the Selective Method). (Also sign the General Offer to Pay below.)

   [ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form."

3. That I have previously complied with section 3(c)(1)(D) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date
Name and Title (Please Type or Print)	

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D).

Signature	Date
Name and Title (Please Type or Print)	

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 3-31

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Chemical Name	EPA Chemical Number

I Certify that:

My company is willing to develp and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included a offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on al terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company name above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	