

**Summary of EPA Final Rule on Reporting
Requirements for Adverse Effects Information
Pursuant to Section 6(a)(2) of FIFRA**

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August 6, 1998

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TABLE OF CONTENTS

<u>TOPIC</u>	<u>PAGE</u>
I. Introduction	1
II. Scope of Coverage	2
III. Type of Information That Must Be Reported	5
Toxic or Adverse Effects Incident	5
Failure or Performance Information	12
Toxicological and Ecological	14
Human Epidemiological and Exposure Studies	16
Information on Pesticides in or on Food, Feed or Water	17
Metabolites, Degradates, Contaminants, and Impurities	18
Reporting of Other Information	19
IV. When Information Must Be Submitted to EPA	20
V. How Information Must Be Submitted to EPA	21
VI. What Information Must Be Submitted to EPA	23
VII. Information Obtained Before Effective Date of 6 (a)(2) Rule	25
VIII. Obligations of Former Registrants	26
IX. Penalties	27
X. Suggestions for Implementation	27
Appendix A	32
Appendix B	34

**Summary of EPA Final Rule on
Reporting Requirements for
Adverse Effects Information Pursuant
to Section 6(a)(2) of FIFRA**

I. INTRODUCTION

A. Background

EPA has issued a final rule on the obligation of pesticide registrants to submit to EPA information about possible adverse effects of their pesticide products. This new rule clarifies reporting requirements mandated by Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which requires registrants to report any studies, incidents, or other information indicating adverse effects of EPA registered pesticides.

EPA will use this information as a means of checking its original decision to register a pesticide and to decide what action, if any, is necessary to reduce the risks posed by a particular pesticide. EPA will use the adverse effects information to make regulatory decisions, develop programs, improve label directions and precautions, and identify trends.

The final rule applies to ALL pesticide registrants including manufacturers of active ingredients, formulators of pesticide products, and private label distributors of EPA registered products. Furthermore, the 6(a)(2) rule applies to all pesticides including disinfectants, germicides, fungicides, herbicides, insecticides and all other EPA registered products.

B. Effective Date

This rule was set to become effective June 16, 1998, however, EPA has extended the effective date to August 17, 1998. The extension was granted in response to a letter issued to EPA from several trade associations including ISSA.

C. Summary

The 6(a)(2) final rule establishes specific requirements on what triggers the obligation to report, what information must be reported, when and how the information must be submitted to EPA, and who has the obligation to report. In general, registrants of pesticide products must submit information related to reports of adverse effects incidents (i.e., skin or eye irritation, etc.) concerning their products, scientific studies, failure of product performance, presence of the pesticide in food, feed or in water and other information related to potential risks associated with a product.

The final rule makes clear that registrants are not obligated under 6(a)(2) to investigate, analyze, or verify

incidents or other information that gives rise to reporting before submitting a report to EPA. Furthermore, the Agency recognizes that registrants may disagree with the information it receives concerning adverse effects. Registrants are always free to submit information challenging the validity of 6(a)(2) information either at the time of, or after submission of the information to the Agency. In order to comply with the final rule, however, registrants must submit the required information within the time frame set forth in the rule or risk being subject to enforcement.

Failure to comply with the requirements of the 6(a)(2) final rule will be considered a violation of FIFRA and could result in actions for civil and/or criminal penalties under FIFRA Section 14. (Please see discussion in section IX of this document below.) Failure to comply with these requirements may also constitute grounds for cancellation under FIFRA Section 6 of a pesticide registration.

This summary provides a general overview of the major obligations established in the 6(a)(2) final rule. It should not be considered a substitute for the actual regulation, and members are encouraged to review the text of the 6(a)(2) final rule.

II. SCOPE OF COVERAGE

The final rule requires all pesticide registrants to report information concerning unreasonable adverse effects of their pesticide products to EPA. The scope of the final rule's coverage is defined by the key terms set forth below. For definitions of other key terms used in the 6(a)(2) final rule, please see the Glossary of Terms set forth in Appendix A.

A. Pesticide

As defined by the rule a pesticide is a pesticide product which is or was registered by EPA, and each active ingredient, inert ingredient, impurity, metabolite, contaminant or degradate contained in, or derived from such pesticide product. More importantly for ISSA members, the term pesticide includes antimicrobial disinfectants, germicides and sanitizers, as well as insecticides, rodenticides and fungicides and other EPA registered products.

B. Registrant

The term registrant refers to any person/entity who holds, or ever held a registration for a pesticide product including basic manufacturers of active ingredients, formulators of pesticide products and private label distributors of such products.

Supplemental distributors (i.e., distributors of private label pesticide products) are considered to be registrants and are therefore subject to the Section 6(a)(2) reporting requirements. Failure of a supplemental distributor to report adverse effects information covered by the final rule in a timely manner can result in enforcement action against both the supplemental distributor and the underlying registrant (i.e., formulator, manufacturer, etc.).

Nevertheless, EPA would like to minimize duplicative reporting and would prefer that all reportable information be submitted by the underlying registrant (e.g., formulator of the product) rather than by numerous private label distributors acting for the registrant. Therefore, EPA has requested that

supplemental distributors (i.e., private label distributors) deliver reportable information to the underlying registrant (in sufficient time for the registrant to report) and not to EPA.

Please note, however, that where private label or supplemental distributors choose to submit information to their supplier (i.e., the underlying registrant) rather than directly to EPA, the time for reporting will be calculated from the time that the information is first received by the private label distributor.

Furthermore, where private label distributors have arranged to submit reportable information through their suppliers, certain legal implications arise. For example, assume a private label distributor submits reportable information to their manufacturer/supplier but their supplier fails to report the information to EPA in a timely fashion. EPA may enforce this failure to comply with the adverse effects rule against the distributor and/or the underlying registrant (i.e., the manufacturer/supplier). Alternatively, assume a private label distributor simply fails to submit reportable information to their supplier causing the supplier to fail to comply. Once again, EPA may enforce the violation against the distributor and/or the supplier.

Therefore, where private label distributors arrange to report adverse effects information through their manufacturer/supplier, ISSA recommends that they enter into a contract specifying each other's obligations such as when and how the distributor must report the information to the supplier, and the supplier acknowledging responsibility to submit such information to EPA in a timely fashion. Furthermore, both parties would be wise to incorporate indemnity and hold harmless clauses addressing their respective failure to submit reportable information in a timely manner. (For a more detailed discussion, see section X of this document titled Suggestions For Implementation.)

Even where private label distributors choose to report directly to EPA, legal implications arise. Specifically, failure of a private label distributor to timely report adverse effects information may result in an enforcement action against both the distributor and the underlying registrant (i.e., manufacturer/supplier). Consequently, even in this situation, it is advisable both parties recognize their respective obligations in a contract and agree to indemnify and hold harmless the other party for their failure to report in a timely manner.

C. Agents

Reportable information that comes into the possession of an Agent@ of a registrant while the agent is acting for or on behalf of a registrant will be presumed to be possessed by the registrant for purposes of adverse effects reporting. (See the discussion set forth in section IV(D) of this document for a detailed discussion on this topic.) Whether a person will be considered an agent of a registrant in a given set of circumstances will depend heavily upon the specific facts of that set of circumstances. For purposes of adverse effects reporting, EPA will generally look to the nature of the relationship between the Agent@ and the registrant. The following factors will be significant in the determination of whether someone is considered an agent:

- X Whether the activity conducted by the Agent@ is being conducted for the benefit of the registrant;
- X Whether the registrant is paying (directly or indirectly) for the activity;
- X Whether the registrant has requested that the activity be conducted;
- X The nature of the contractual or financial relationship between the registrant and the Agent@;
- X Whether the agent is expected to perform duties related to the development, testing, sale, or

- registration of a pesticide;
- X Whether the agent reasonably could be expected to come into possession of otherwise reportable information; etc.

Because the registrant is deemed to possess information when certain of its agents possess the information, the registrant may be held liable for failure to submit reportable information in the possession of the agent, whether or not the information is reported to the registrant by the agent.

The sections below address particular circumstances which may create an agency relationship for purposes of adverse effects reporting.

1. *Distributors Other Than Distributors of Private Label Products.* The question of whether a distributor of branded pesticide products (i.e., a non-private label distributor) is an agent in any particular situation will depend upon all the specific facts of the situation.

A distributor that sells a wide variety of brand label pesticide products produced by many different registrants generally would not be considered an agent of a registrant. On the other hand, a distributor that exclusively (or nearly exclusively) distributes or sells a particular registrant's products generally would be considered an agent of a registrant. EPA may consider, however, additional factors including whether the distributor has done anything (i.e., made statements, published advertisements, etc.) that would lead customers of the product to believe the distributor is acting for the registrant or would be an appropriate place for customers to report incidents regarding particular products, as well as the exact nature of the relationship between the registrant and the distributor.

2. *Independent Contractors.* EPA has made it quite clear that if an independent contractor is conducting a pesticide-related work for, and at the behest of a pesticide registrant, the Agency considers the independent contractor an agent for purposes of adverse effects reporting provided the agent reasonably could be expected to come into possession of reportable information.

Examples of independent contractors that reasonably could be expected to come into possession of reportable information include, but are not limited to: poison control centers under contract with a registrant; regulatory consultants; attorneys involved in product liability litigation on behalf of a registrant; investigative personnel such as claims adjustors, field investigators, or laboratories acting directly on behalf of a registrant; sales representatives; etc.

3. *Employees.* EPA considers certain employees of a registrant to be an agent of the registrant if they are employees who are likely to receive information about the effects of pesticides. Examples of employees who are likely to be considered agents include sales personnel, individuals who are responsible for customer complaints, etc.

However, EPA does not consider every employee of a registrant as likely to receive such information. For example, financial and personnel workers, or employees at a manufacturing operation normally would not

be dealing with pesticide effects information nor would they normally be in contact with users of the products or other persons who are likely to report pesticide effects information. Therefore, as a general rule, such employees would not be considered as agents of a registrant.

III. TYPE OF INFORMATION THAT MUST BE REPORTED

The type of information that must be reported under the 6(a)(2) final rule includes: toxic or adverse effects; failure of performance information; certain scientific studies; information on pesticides in or on food, feed or water; and information related to metabolites, degradates, contaminants and impurities. This section describes each of these reporting requirements.

Please review the relevant sections below for an understanding of what situations give rise to reporting under Section 6(a)(2) as well as what information must be submitted. ISSA believes that in the cleaning products industry the greatest source of reportable events will be related to adverse effects experienced by individuals using the product given the nature of the products and how they are applied. In addition, please review the general sections on How Information Must Be Submitted (section V below) and What Information Must Be Submitted (section VI below) for a complete understanding of what must be reported and in what fashion it must be submitted.

A. Toxic or Adverse Effect Incident Reports

1. *Threshold for Reporting.* Information about incidents affecting humans or other Anon-target organisms@ (i.e., domestic animals, wildlife, plants, etc.) must be submitted if each of the following three conditions are met:

- a) The registrant is aware, or has been informed, that a person or non-target organism may have been exposed to a pesticide; and
- b) The registrant is aware, or has been informed, that the person or non-target organism suffered a toxic or adverse effect; and
- c) The registrant has or could obtain information concerning when the incident occurred, the pesticide product involved, and the name of a person to contact regarding the incident.

(Note, if one of these elements is missing, the registrant need not report on the incident.)

2. *Exceptions.* Registrants are not required to submit adverse effects reports to EPA regarding incidents (otherwise meeting the three conditions above) if they meet any of the following six exemptions:

- a) The incident concerns minor skin or eye irritation effects warned of on the label of the product **which is registered for use in residential use sites, AND the effects occurred as a result of use in a residential site.**

(Please note that this exemption does NOT extend to institutional, industrial or other non-residential use sites. Registrants must report information related to incidents involving minor skin or eye irritation or other adverse effects warned of on the label as a result of a pesticide product used in an institutional, industrial or other non-residential site.)

b) The registrant is aware of facts which clearly establish that the reported toxic effect, or reported exposure, did not or will not occur.

c) The registrant has been notified by EPA that the reporting requirement has been waived for this incident or category of incidents.

d) The incident concerns a toxic effect to non-target plants, which were at the use site at the time the pesticide was applied, if the label provides adequate notice of such a risk.

e) It concerns non-lethal phototoxicity to the treated crop if the label provides an adequate notice of such a risk.

f) It concerns a toxic effect to pests not specified on the label, provided that such pests are similar to pests specified on the label.

3. Contents of Individual Incident Reports. For relatively minor incidents (i.e., those including skin or eye irritation, harm to domestic animals, etc.), registrants must provide EPA with an aggregate report (see paragraph 4 below). However, for all other incidents, registrants must submit individual incident reports to the Agency.

Specifically, individual incident reports must be submitted to EPA for adverse effects characterized by the following exposure types and severity category designations: H-A, H-B, H-C, W-A, P-A, G-A, and PD-A. Aggregate reports must be submitted to EPA for adverse effects incidents that meet the criteria of the following exposure types and severity category designations: H-D, H-E, D-A, D-B, D-C, D-D, D-E, W-B, ONT, G-B, G-C, PD-B, and PD-C. (These coded references to exposure types and severity category designations are explained in detail in Appendix B.)

Please note, non-mandatory forms for individual incident and aggregate reports have been developed by a coalition of which ISSA was an active participant. These forms, while not required by EPA, will help facilitate compliance with reporting related to toxic or adverse incidents. Contact ISSA for a complimentary copy of the voluntary forms and instructions.

In regard to individual incident reports, registrants must supply the information outlined in the sections below to the extent the registrant has any of the information. Registrants are not required to conduct an investigation beyond the initial report to collect such information.

When a single incident involves multiple pesticides, the registrant need only report on their specific product.

If a registrant acquires additional information concerning an incident previously reported to EPA, the registrant must submit a follow up report if it meets the criteria set forth in paragraph 6 below.

The following information must be included in individual incident reports and has been grouped into the following major categories by EPA:

a) Administrative.

- i. Name of reporter (i.e., person who reports information to a registrant), address and telephone number.
- ii. Name, address, and telephone number of contact person if different than reporter (i.e., physician, attorney, parent, etc.)
- iii. Incident report status (e.g., new or update); if an update, include the date of original submission.
- iv. Date registrant became aware of the incident.
- v. Date of incident (list Astart@ and Aend@ dates if appropriate).
- vi. Location of incident (city, county, and state).
- vii. Whether incident is part of a larger study.
- viii. Source of the report if different from the reporting registrant.

b) Pesticide Related Information.

- i. Product name.
- ii. Identity of active ingredient(s).
- iii. EPA registration number.
- iv. Whether the product is a concentrate and whether it was diluted for use or used in concentrated form.
- v. Formulation, if known (i.e., granular, liquid, etc.).
- vi. List the above information for other pesticides of the registrant that may have contributed to the incident.

c) Circumstance.

- i. Evidence the label directions were not followed (e.g., yes, no, unknown).
- ii. How exposed (e.g., spill, container failure, mislabeling, equipment failure, etc.).
- iii. Situation (e.g., disposal, diluting, application, transportation, reentry, etc.).
- iv. Site of use (e.g., institutional, industrial, office building, school, hospital, yard, agricultural, commercial turf, greenhouse, etc.).
- v. Whether the applicator of the pesticide product was certified (yes, no, unknown).
- vi. A brief description of the circumstances of the incident.

d) Human Incident. If the incident involved human(s), the following information must be reported:

- i. Route of exposure (i.e., skin, eye, respiratory, oral).
- ii. List of signs, symptoms, adverse effects, etc.
- iii. If laboratory tests were performed, list name of tests and results.
- iv. Submit laboratory reports if available.
- v. Time between exposure and onset of symptoms.
- vi. Whether adverse effect was the result of suicide, homicide or attempted suicide, homicide.
- vii. Type of medical care sought (e.g., poison control center, hospital emergency department, hospital inpatient, private physician, clinic, none sought, or other).
- viii. Demographics (e.g., sex, age).
- ix. If female, whether pregnant or not.
- x. Exposure data (i.e., amount of pesticide, duration of exposure, weight of victim).
- xi. Whether exposure was occupational. If so the nature of the occupation, and number of days (if any) lost due to adverse effect.
- xii. Whether protective clothing, equipment was worn or not (specify type).

e) Domestic Animal Incident. If the incident involved an adverse effect to a domestic animal, the following information must be reported:

- i. Type of animal (e.g., household pet, dog, cat, bird, fish, livestock, poultry, etc.).
- ii. List of signs, symptoms, and adverse effects.
- iii. Breed, species (name and number affected, per adverse effect).
- iv. Route of exposure (e.g., skin, eye, respiratory, oral).
- v. Time between exposure and onset of symptoms.
- vi. If laboratory tests were performed, list name of tests and results.
- vii. If available, submit laboratory reports.

f) Fish, Wildlife, Plants or Other Non-Target Organisms. If the incident involved an adverse effect to fish, wildlife, plants, or other non-target organisms, the following information must be reported:

- i. List species affected, and number of individuals per species.
- ii. List symptoms or adverse effects.
- iii. Magnitude of the effect (e.g., miles of streams, square area of terrestrial habitat).
- iv. Pesticide application rate; intended use site, and method of application.
- v. Description of the habitat and the circumstance under which the incident occurred.
- vi. If plant involved, the type of plant life (i.e., crop, forest, orchard, home garden, ornamental, foliage).
- vii. Formulation of pesticide if not indicated by brand name (i.e., whether granular, flowable, etc.).
- viii. Distance from treatment site.
- ix. If laboratory tests performed, list name of tests and results.
- x. If available, submit laboratory reports.

g) Surface Water. If the incident involved surface water, the following information must be reported:

- i. If based on raw water samples, the water bodies sampled and approximate locations in each water body.
- ii. If raw water samples, proximity of sampling locations to drinking water supply intakes and identities

of systems supplied.

iii. If finished water samples, water supply systems sampled.

iv. If finished water samples, percent surface water source by specific surface water sources to water supply systems.

v. Sample type (i.e., grab, composite).

vi. Sampling times, frequency.

vii. Pesticides and degradates analyzed for and their detection limits.

viii. Method of analysis.

h) Groundwater. If the incident involved groundwater, the following information must be reported:

i. Pesticides and degradates analyzed for and the analytical methods and detection limits.

ii. Sample date.

iii. Amount of pesticide applied (i.e., lbs/acre).

iv. Date of last application.

v. Depth to water.

vi. Latitude, longitude.

vii. Soil series and texture (e.g., sand, silt, clay, etc.).

viii. Frequency of applications per year.

ix. Aquifer description (confined/unconfined).

x. Method of application.

xi. Years pesticide used.

xii. Well use and well identifier.

xiii. Screened interval.

- xiv. Annual cumulative rainfall.
- xv. Maximum rainfall and date.
- xvi. Cumulative irrigation (inches).
- xvii. Hydrologic group.
- xviii. Hydraulic conductivity.
- xix. pH.
- xx. Organic matter or organic carbon (percent).
- xxi. If property damage, provide a description.

i) Exposure Types and Severity. Individual incident reports must include information describing the type of exposure and the severity of the adverse effects using an appropriate 2-letter designation code set forth in Appendix B.

4. Aggregate Reports. Under the 6(a)(2) final rule, certain adverse effects incidents of a minor nature must be submitted in the form of an aggregate report instead of an individual incident report. Specifically, the following type of incidents must be submitted in the form of an aggregate report: H-D, H-E, D-A, D-B, D-C, D-D, D-E, W-B, P-B, ONT, G-B, G-C, PD-B, PD-C. (Please see Appendix B for a full description of these coded references.)

Non-mandatory forms for aggregate and individual incident reports have been developed by a coalition of which ISSA was an active participant. These forms while not required by EPA, will help facilitate compliance with reporting related to toxic or adverse incidents. Contact ISSA for a complimentary copy of the voluntary forms and instructions.

In general, aggregate reports must include the following information:

- a) The time period covered by the report.
- b) For each exposure and severity label category, a count of the number of incidents, listed by product registration number (if known) or active ingredient.
- c) A count of domestic animal incidents in categories (other than D-A or D-B) which can be added together and reported as a single number.

5. Time Requirements for Submitting Incident Information. Information concerning toxic or adverse effects incidents must be submitted within the time frames set forth for the various exposure and severity

categories as described below. According to the final rule, the clock starts running when a registrant first becomes aware of the information. EPA states that a registrant would be considered aware of such information when any officer, employee, agent or other person acting for or employed by the registrant, and considered likely to receive relevant information, first comes into possession of, or knows of, such information. (Please see section IV(D) below for a detailed discussion on this particular issue.)

a) For allegations involving human fatality (H-A), registrants must submit the required information no later than 15 days after learning of such an allegation.

b) For allegations involving H-B, H-C, W-A, P-A, G-A, and PD-A exposure and severity categories, registrants may accumulate information concerning such incidents for a 30 day period and submit the required information within 30 days of each 30 day accumulation period (i.e., if receive information on September 1, must submit information by November 1).

c) For incidents meeting all other exposure and severity categories (i.e., H-D, H-E, D-A, D-B, D-C, D-D, D-E, W-B, P-B, ONT, G-B, G-C, PD-B, and PD-C) registrants may accumulate information concerning such incidents for 90 days and submit the required information within 60 days of the end of each 90-day accumulation period. (In effect, this time requirement applies to aggregate reports only.)

(Note: Please refer to Appendix B for the definition of the exposure and severity categories. Also refer to Appendix C which sets forth a quick reference guide to the reporting timeframes for the various severity categories.)

6. Reporting Additional Information. If, after the submission of an incident report to EPA, a registrant acquires additional information concerning that incident, the information must be submitted within the same time frame as set forth in paragraph 5 above if any of the following conditions apply:

a) The information concerns an alleged human fatality (H-A), AND the information consists of any of the information set forth in this document in section III(A)(3)(a)-(d) above.

b) The information concerns an incident originally reported as a major human illness or injury (H-B), or fatality to a domestic animal (D-A), or wildlife fatality (W-A), AND the additional information consists of Apesticide or Acircumstance information set forth in this document in section III(A)(3)(b) and (c) above, or is a laboratory report concerning persons or animals involved in the incident.

c) The information concerns any incident NOT originally reported under the exposure and severity categories H-A or H-B for human incidents, or at the AA level of severity for any other exposure and severity category, AND the new information would result in labeling the incident H-A or H-B, or at the AA level for any other exposure and severity category described in Appendix B.

B. Failure of Performance Information

The final 6(a)(2) rule requires registrants to report to EPA information related to the pesticide product's failure to perform. Specifically, registrants must report information concerning incidents or studies involving: the failure of a pesticide to perform as claimed against public health microorganisms; failure of a pesticide to

control animals, including insects, that present a threat to public health; and a pest (including microorganisms) having developed resistance to ANY pesticide (both public health and non-public health products under certain circumstances).

The following is a summary of the reporting requirements related to failure of product performance information.

1. *Microorganisms that Pose a Risk to Human Health.* [Note: Certain liquid chemical sterilants are not subject to this reporting requirement because they have been removed from EPA=s jurisdiction and are now regulated by FDA. See PR Notice 98-2]. Registrants must submit information to EPA related to the product=s failure to perform against microorganisms that pose a risk to human health if the information conforms to one of the following two situations:

a) The registrant receives/possesses information which concerns an incident that meets ALL of the following conditions:

i. The registrant has been informed that a pesticide product may not have performed as claimed against target microorganisms.

ii. The possible failure(s) of the pesticide to perform as claimed involved the use against microorganisms which may pose a risk to human health, referred to as public health pests. (Note: EPA is developing a list of public health pests that will include harmful microorganisms.)

iii. The pesticide product=s use site is other than residential. In other words, incidents involving a product=s failure to perform against a public health pest in a house are exempt from 6(a)(2) reporting. However, an incident involving the failure of a product, such as a disinfectant, to perform in an institutional setting is subject to 6(a)(2) reporting if it also meets the other two criteria above.

b) The registrant has information about a study which indicates that the pesticide may not perform in accordance with one or more claims made by the registrant regarding uses intended for the control of microorganisms that may pose a risk to human health (including any of the microorganisms of Apublic health@ concern to be listed by EPA).

2. *Animals/Insects that Pose a Risk to Public Health.* EPA defines animals/insects that pose a risk to human health as those that may Acause disease in humans, either directly or as a disease vector; produce toxins that are harmful to humans; or cause direct physical harm to humans.@ (Note: EPA is developing a list of public health pests that will include such animals and insects.)

Registrants must submit information to EPA related to the product=s failure to perform against animals/insects that pose a risk to human health if the information conforms to one of the following two situations:

a) The registrant receives/possess information that meets ALL of the following conditions:

- i. The registrant has been informed by a municipal, state, or federal public health official that a pesticide product may not have performed as claimed against target animals/insects.
- ii. The possible failure(s) of the pesticide to perform as claimed involved the use against animals/insects that pose a risk to human health.
- iii. The registrant has or could obtain information concerning where the incident occurred, the pesticide product involved, AND the name of a person to contact regarding the incident.

b) The registrant has information about a study which indicates that the pesticide may not perform in accordance with one or more claims by the registrant regarding uses intended for the control of animals/insects that pose a risk to human health (including any of the animals/insects of Apublic health@ concern to be listed by EPA).

3. *Development of Pesticide Resistance.* Registrants must report to EPA information concerning the substantiation of any incident of a pest (including harmful microorganisms) having developed resistance to any pesticide (both public health and non-public health) that occurred under conditions of use, application rates, and methods specified on the label if one or both of the following are met:

a) The survival of the suspected pesticide resistant pest was Asignificantly higher@ than that of a known susceptible pest when both the suspected resistant and susceptible pests were treated with the pesticide under controlled conditions. (EPA is expected to issue guidance defining what is Asignificantly higher@ survival rate for suspected resistant pests.)

b) Biochemical tests or DNA sequencing indicate that the pest is resistant to the pesticide.

4. *When Information Must be Submitted.* Registrants must submit information about a study indicating the pesticide may not perform in accordance with one or more label claims no later than 30 days after the registrant first possesses or knows of such information. All other incidents of efficacy failure of public health products may be accumulated for 1 month and submitted by the end of the month following the accumulation period. Please also review section IV below which covers other key issues related to the timing of the submission to EPA.

C. Toxicological and Ecological Studies

Registrants must submit information to EPA related to adverse effects as demonstrated under certain toxicological and ecological studies. This reporting requirement is triggered under the following circumstances.

1. *Toxicological Studies.* Registrants must report the results of a study related to the toxicity of a pesticide to humans or other non-target domestic organisms (i.e., domestic animals, wildlife, plants, etc.) if, relative to all previously submitted studies, they show an adverse effect under ANY ONE of the following conditions:

- a) The adverse effect is in a different organ or tissue of the test organism.
- b) The adverse effect occurs at a lower dosage, or after a shorter exposure period, or after a shorter latency period.
- c) The adverse effect occurs at a higher incidence or frequency.
- d) The adverse effect is in a different species, strain, sex, or generation of test organism.
- e) The adverse effect occurs by a different route of exposure.

2. Acute Toxicological Studies. Studies related to acute oral, acute dermal, acute inhalation or skin and eye irritation in which the only change in toxicity is a numerical decrease in the LD₅₀, median LC₅₀ or irritation indices, are not reportable UNLESS the results indicate a more restrictive toxicity category for labeling. In effect, the final rule exempts reporting of acute toxicity studies if the results would not lead to a more restrictive toxicity category for labeling as provided in 40 CFR 156.10(h).

3. Ecological Studies. Registrants must report information related to a study of the toxicity of a pesticide to terrestrial or aquatic wildlife or plants if they show an adverse effect (relative to all previously submitted studies) under ANY ONE of the following conditions:

- a) The adverse effect occurs at levels 50% or more lower than previous acute toxicity studies with similar species, including determinations of the LD₅₀, LC₅₀ or EC₅₀.
- b) The adverse effect occurs at lower levels in a chronic study than previous studies with similar species.
- c) In a study with a previously untested species the results indicate the chronic no observed effect level (NOEL) is 10% or less of the lowest LC₅₀ or LD₅₀ for a similar species.
- d) In regard to plants only, when tested at the maximum label applications rate or less, if:
 - i. More than 25% of terrestrial plants show adverse effects on plant life cycle functions and growth such as germination, emergence, plant vigor, reproduction and yields; or
 - ii. More than 50% of aquatic plants show adverse effects on plant life cycle functions and growth such as germination, emergence, plant vigor, reproduction and yields.

4. Pesticide Subject to Formal Review. Registrants must report information related to results from a study that demonstrate ANY toxic effect (even if corroborative of information already known to EPA) if the pesticide is or has been the subject of a Formal Review by EPA based on that effect within 5 years of the time the results are received. Such information must be submitted within 30 calendar days of Commencement of a Formal Review in the *Federal Register*.

5. Incomplete Studies. Registrants must submit information from an incomplete study of the toxicity to

any organism of a registered pesticide or any of its ingredients, impurities, metabolites or degradation products which would otherwise be reportable under paragraphs 1, 2, or 3 of this section if the information meets any one of the following three sets of criteria:

a) Short-Term Studies. In regard to a study using a test regimen lasting 90 calendar days or less and:

- i. All testing has been completed.
- ii. A preliminary data analysis or gross pathological analysis has been conducted.
- iii. Final analysis has not been completed.
- iv. A reasonable period for completion of the final analysis not longer than 90 calendar days following completion of testing has elapsed.
- v. Comparable information concerning the results of a completed study would be reportable.

b) Long-Term Studies. A study using a test regimen lasting more than 90 calendar days and:

- i. All testing has been completed.
- ii. A preliminary data analysis or gross pathological analysis has been conducted.
- iii. Final analysis has not been completed.
- iv. A reasonable period of completion of final analysis (not longer than 1 year following completion of testing) has elapsed.
- v. Comparable information concerning the results of a completed study would be reportable.

c) Serious Adverse Effects. Registrants must submit information related to any study in which testing or analysis of results is not yet complete but in which serious adverse effects have already been observed and which may reasonably be attributed to exposure to the substances tested because the effects observed in exposed organisms, are atypical in view of historical experience with the organism tested, or otherwise support a reasonable inference of causation.

d) Discontinued Studies. Registrants must report to EPA information about the fact that a study has been discontinued before the planned termination if submission of the information concerning the study, is or would have been, required under this part.

6. When Information Must Be Submitted. In general, unless otherwise noted, information on the aforementioned studies must be submitted to EPA no later than 30 calendar days after the registrant first possesses or knows of the reportable information. Please review section IV below for a general discussion

of other key issues related to the timing of such submissions to EPA.

D. Human Epidemiological and Exposure Studies

Registrants must submit information concerning any study that a person meeting the criteria in section VI(A)(2) below has concluded, or might reasonably conclude, shows that a correlation may exist between exposure to a pesticide and observed adverse effects in humans.

Registrants must also submit information concerning exposure monitoring studies that indicate higher levels of risk or exposure than would be expected based on previously available reports, data, or exposure estimates.

In either case, such information must be submitted regardless of whether the registrant considers any observed correlation or association to be significant.

The registrant must submit such information to EPA no later than 30 calendar days after the registrant first possesses or knows of the aforementioned studies. Please review section IV below for a general discussion of other key issues related to the timing of such submissions to EPA.

E. Information on Pesticides in or on Food, Feed or Water

1. Food and Feed. Registrants must submit to EPA information that shows that the pesticide is present on food or feed at a level in excess of established levels.

Registrants, however, are not required to submit to EPA information on excess residues resulting solely from studies conducted under the authority of FIFRA Section 5 or under other Acontrolled research studies conducted to test a pesticide product,@ provided that the treated crop is not marketed as a food or feed commodity.

2. Water.

a) Information must be submitted if it shows that a pesticide is present above the water reference level in:

- i. Waters of the United States (as defined in to 40 CFR 122.2 except paragraph (d) of 40 CFR 122.2).
- ii. Ground water.
- iii. Finished drinking water.

b) If the lowest detectable amount of the pesticide is reported the detection limit must also be reported.

c) Information need not be submitted regarding the detection of a pesticide in waters of the United States or finished drinking water if the following two conditions are met:

- i. The pesticide is registered for use in finished drinking water or surface water; and
- ii. The amount detected does not exceed the amounts reported by a registrant in its application for registration as resulting in these waters from legal applications of the pesticide.

d) Information need not be submitted concerning detections of pesticides in waters of the United States, ground water, or finished drinking water if the substance detected is an inert ingredient, or a metabolite, degradate, contaminant or impurity of a pesticide product, unless at least one of the following conditions are met:

- i. EPA has established or proposed a maximum contaminant level (MCL) or health advisory level (HAL) for that substance; or
- ii. EPA has estimated a health advisory level based on an established reference dose (RFD) for that substance, and notified registrants of that level.

3. *When Information Must Be Submitted.* Registrants must submit information related to the above reportable events no later than 30 days after the registrant first knows or possesses such information. Please review section IV below for a general discussion of key issues related to the timing of such submissions to EPA.

F. Metabolites, Degradates, Contaminants, and Impurities

The purpose of this section is to ensure that the Agency is informed when registrants learn of toxicologically significant new breakdown products or when they learn of higher levels of contamination than were previously known to be associated with their pesticide products.

1. *Metabolites and Degradates.* Registrants must submit to EPA information which shows the existence of any metabolite or degradate of a pesticide product if:

- a) The metabolite or degradate may occur or be present under conditions of use of the pesticide product, and the existence of the metabolite or degradate or the association of the metabolite or degradate with the pesticide product has not been previously reported to EPA; or
- b) The metabolite or degradate has been previously reported, but it is detected at levels higher than any previously reported; and one of the conditions in paragraphs (I) or (ii) below is met:
 - i. Any person, as defined in section VI(A)(2) below, has concluded that the metabolite or degradate may pose a toxicological or ecological risk based on any one or more of the following:

- ! The physical or chemical properties of the metabolite or degradate.

! Data regarding structurally analogous chemicals.

! Data regarding chemical reactivity of the metabolite or degradate and structurally analogous substances.

! Data on the metabolite or degradate.

ii. The registrant has concluded, or has been advised by any person, as defined in section VI(A)(2) below, that the metabolite or degradate, or analogous chemical:

! May have any experimentally determined half-life greater than 3 weeks as shown from laboratory aerobic soil metabolism studies or field dissipation studies.

! May have any experimentally determined resistance to hydrolytic degradation, or photolytic degradation on soil or in water, under any conditions resulting in degradation of less than 10% in a 30-day period.

2. Contaminants and Impurities. Registrants must report to EPA information related to the presence in any pesticide product of a contaminant or impurity not previously identified by the registrant as part of the pesticide product's approval composition if the contaminant or impurity is present in the product in any of the following quantities:

a) Quantities greater than 0.1% by weight.

b) Quantities that EPA considers, and so informs registrants, to be of toxicological significance.

c) Quantities that the registrant considers to be of toxicological significance.

d) Quantities above a level for which the registrant has information indicating that the presence of the contaminant or impurity may pose a risk to human health or the environment.

e) Quantities that a person (as defined in the section below titled What Information Must Be Submitted) has informed the registrants are likely to be of toxicological significance.

3. When Information Must Be Submitted. Registrants must submit information related to the above reportable events no later than 30 days after the registrant first knows or possesses such information. Please also review section IV below for a general discussion of other key issues related to the timing of such submissions to EPA.

G. Reporting of Other Information

Under the Section 6(a)(2) final rule, EPA requires registrants to submit to the Agency certain information not covered in any of the paragraphs above as follows:

1. Information Known by, or Which Reasonably Should be Known by Registrant. The registrant

must submit information (other than that described in paragraphs A thru F above) if the registrant knows, or reasonably should know, that if the information should prove to be correct, EPA might regard the information, alone or in conjunction with other information about the pesticide as raising concerns about the continued registration of a product or about the appropriate terms and conditions of registration of a product.

The Agency intends to take enforcement action pursuant to this provision only when it believes a registrant clearly should have known that information would have been considered important by EPA in its evaluation of a pesticide product registration. For example, if a registrant is aware that the registration decision for one of its products was based upon an assumption by EPA that is called into question by some new piece of information, that information must be provided under this provision of the final rule. In situations where a registrant is unsure how this provision applies to specific information, registrants are encouraged to seek advice from EPA.

Examples of the types of information which must be provided under this section (if not already reportable under some other provision of the final rule) include but are not limited to information showing:

- a) Previously unknown or unexpected bioaccumulation of a pesticide by various life forms.
- b) Greater than anticipated drift of pesticides to non-target areas.
- c) Use of a pesticide may pose any greater risk than previously believed or reported to the Agency.
- d) Use of pesticide provides or creates secondary pest infestations.
- e) Any information which might tend to invalidate a study submitted to the Agency to support a pesticide registration.

2. *Exception.* A registrant is not obligated under paragraph (1) above to provide information to EPA if the registrant is aware of facts which establish that otherwise reportable information is not correct.

3. *Additional Information Designated by EPA.* Registrants must submit to EPA information (other than that described in paragraphs A thru F above) if the registrant has been informed by EPA that each additional information has the potential to raise questions about the continued registration of a product or about the appropriate terms and conditions of registration of product. This information must be submitted within the time frame specified in EPA's notice to registrants.

4. *When Must Information Be Submitted.* A registrant must submit information related to the above reportable events no later than 30 days after the registrant first knows or possesses such information. Also, please review section IV below for a general discussion of other key issues related to the timing of such submissions to EPA.

IV. WHEN INFORMATION MUST BE SUBMITTED TO EPA

Unless otherwise stated in section III above, the time table for submitting the type of information described

in section III is as follows:

A. Scientific Studies

Reportable information concerning scientific studies must be received by EPA no later than the 30th calendar day after the registrant first possesses or knows of the reportable information.

B. Toxic or Adverse Effect Incidents

Reportable information concerning toxic or adverse effects incidents must be reported according to the schedule set forth in section III(A)(5) above, which differentiates reporting times depending on the severity of the incident.

C. EPA Discretion

At its discretion, EPA may notify a registrant in writing of a different reporting period that will apply to specific types of reportable information or eliminate reporting requirements entirely. Such notification supersedes otherwise applicable reporting requirements set forth in the Section 6 (a)(2) final rule.

D. When Does Registrant First Possess or Know of Reportable Information

The calculation of the appropriate reporting time frame begins at the time the registrant first possesses or knows of reportable information. For purposes of this final rule, a registrant possesses or knows of information at the time any officer, employee, agent, or other person acting for the registrant first comes into possession of, or knows of, such information. Furthermore, an employee, agent, etc. of the registrant must be Alikely to receive@ reportable information, AND they must be acting for the registrant at the time they receive it in order for the reportable information to be considered in the possession of the registrant.

The issue is clear in those situations where a registrant has designated particular individuals to receive and/or respond to complaints from customers. When these individuals receive a telephone call or other communication about reportable information, the registrant is deemed to be in possession of the information at that point.

EPA recognizes however that, even when a registrant has established a reasonable system for tracking information deemed reportable under Section 6(a)(2), information may nonetheless be received by individuals working for that registrant who neither appreciate its significance nor pass it on to personnel who would. In regard to such situations, EPA anticipates that its enforcement response will most likely depend upon the identity of the person receiving the information and the steps taken to assure compliance with the Section 6(a)(2) final rule.

For example, if a customer submits reportable information to an employee of a pesticide registrant that could Areasonably be expected to receive the information@ (such as a sales person, or person who takes calls from customers) EPA believes that such an employee should be expected to transmit the information to the appropriate personnel working for the registrant. In such a situation, EPA would likely take enforcement action for failure to report such information within the appropriate time period.

On the other hand, EPA recognizes that many employees of a company would not be expected to receive such relevant information. For example, EPA would not regard as reportable information received by employees in such activities as human resources, finances, accounting, and maintenance. Similarly, most

employees in manufacturing would not be expected to receive reportable information with the exception of industrial hygiene or safety officers specifically employed to monitor worker health effects.

An example of information that is not reportable is when a registrant hires a scientist to conduct toxicity studies on a particular pesticide, and that scientist has previously worked at a university where he performed research on the toxic properties of the pesticide in question. The scientist's previous work was not performed for the registrant, and he was not their agent at the time the previous work was done. Therefore, the previous work does not become reportable under Section 6(a)(2) (assuming that the work would otherwise be reportable) just because the scientist is hired by the registrant to perform a new study.

As another example, a consultant is hired by Registrant B to help with the registration of a pesticide (to give general advice, and to review and conduct studies). The consultant previously worked for Registrant A to help with a special review. During the course of the earlier work the consultant reviewed comparative toxicity studies involving a number of pesticides, including Registrant B's. The consultant was not an agent of Registrant B when this study was performed, and Registrant B has no Section 6(a)(2) reporting obligations with respect to that study (unless the consultant provides it to Registrant B at any time, in which case it is reportable because the registrant (rather than the agent) possesses the information).

V. HOW INFORMATION MUST BE SUBMITTED

A submission to EPA under the Section 6(a)(2) final rule must be tendered to the Agency in the form and fashion specified in this section as well as meet the other requirements specified in section III, IV and VI of this document. The only acceptable methods of delivery to EPA are by mail or delivered in person including the use of a courier service.

A. Mail

The report may be mailed by certified or registered mail to the following address:

Document Processing Desk - 6(a)(2)
Office of Pesticide Programs - (7504C)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

B. Delivery

The report may be delivered in person or by courier service or by such other methods as EPA deems appropriate to the following address:

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

C. Cover Letter

The reportable information submitted under 6(a)(2) must be accompanied by a cover letter which includes the following information.

1. A prominent statement that the information is being submitted in accordance with FIFRA Section 6(a)(2).
2. Contain the name of the submitter, registrant name, EPA registration number, date of transmittal to EPA, the type of study or incident being reported (as described in section III of this document), and a statement of why the information is considered reportable under Section 6(a)(2).
3. Identify the substance tested or otherwise covered by the information (including, if known, the EPA registration number to which the information pertains, and if known, the CAS registry number).

D. Incident Reporting

In reporting toxic or adverse effect incidents, registrants must provide the information set forth in section III(A)(3) or (4) of this document, to the extent such information is available.

E. Scientific Studies

In submitting scientific studies, registrants must follow the procedures set forth in 40 CFR 158.32.

If the information being submitted is part of a larger package being submitted in order to comply with another provision of FIFRA, registrants must identify in the transmittal the individual studies being submitted under the Section 6(a)(2) final rule.

If a submission includes a study subject to the Aflagging@ requirements of 40 CFR 158.34, registrants must comply with the requirements of that section, and, if the flagging statement is positive, registrants must also identify it as 6(a)(2) information in the transmittal.

F. Confidentiality

If a claim of confidentiality is made under FIFRA Section 10 for information relating to any part of a study or incident report contained in the submission, registrants must follow the procedures set forth in 40 CFR 158.33 regarding the identification and segregation of information claimed to be confidential.

G. Follow-Up Reports

If a submission is a follow-up to an earlier study or incident report submitted to EPA, the transmittal must state that fact, and must cite the earlier submission as follows:

1. The registrant must cite the Master Record Identifier (MRID) number if the earlier submission was a study to which EPA assigned an MRID.
2. If the previous submission was an incident report to which no MRID number was assigned, cite the date of the initial submission of the incident information or report.

VI. WHAT INFORMATION MUST BE SUBMITTED

This section provides guidance on what particular types of information must be submitted under the various

reporting events detailed in section III of this document. Paragraph A of this section identifies general requirements, while paragraph B sets forth types of information that are exempt from the Section 6(a)(2) reporting requirements.

A. General Requirements

1. General Information. Information which is reportable under this final rule (as detailed in section III of this document) must be submitted if:

- a) The registrant possesses or receives the information; and
- b) The information is relevant to the assessment of the risks or benefits of one or more specific pesticide registrations currently or formerly held by the registrant.

2. Opinion Information. In order to be reportable, an opinion must meet two criteria:

- a) The opinion must relate to information that is relevant to the assessment of risks and/or benefits applicable to a particular registered pesticide product; and
- b) The opinion or conclusion must be rendered by either:
 - i. An employee or agent of the registrant; or
 - ii. A person from whom the registrant requested the opinion; or
 - iii. A Qualified expert² with regard to the matter on which the opinion was uttered. (Please see Appendix A, Glossary of Key Terms for a definition of qualified expert.)

Please note that EPA's reference here to a qualified expert does not mean that the Agency intends to exclude reports of adverse effects in cases where an average person would reasonably suspect that a pesticide exposure was a likely cause. For example, where someone develops a skin rash shortly after splashing an EPA registered disinfectant on their skin, common sense would suggest a link between pesticide exposure and the effect. Such an event would be reportable even if it were not brought to the attention of a trained professional.

B. Exceptions

The following categories of information generally are exempt from reporting under Section 6(a)(2).

1. Clearly Erroneous Information. Information need not be submitted if before the date on which the registrant must submit such information ALL of the following conditions must be met:

- a) The registrant discovers that any analysis, conclusion, or opinion was predicated on data that were erroneously generated, recorded or transmitted, or computational.
- b) Every author of such analysis, conclusion, or opinion (or as many authors as can be contacted) has acknowledged in writing that the analysis, conclusion, or opinion was improper and has either corrected

the original analysis, conclusion, or opinion accordingly, or provided an explanation as to why it can not be corrected.

c) As a result of the correction, the information is no longer required to be reported under the 6(a)(2) final rule, or if no correction was possible, the authors agree that the original analysis, conclusion, or opinion has no scientific validity.

2. *Previously Submitted Information.* Information regarding an incident, study, or other occurrence need not be submitted if before the date on which the registrant must submit such information, the registrant is aware that the reportable information concerning the incident, study, or other occurrence is contained completely in one of the following:

a) Documents officially logged in by the EPA Office of Pesticide Programs (OPP).

b) EPA publications, EPA hearing records, or publications cited by EPA in *Federal Register* notices.

c) Any other documents which are contained in the official file and records of the EPA OPP.

d) Any documents officially logged in by EPA Office of Pesticide Pollution Prevention and Toxics under Section 8(e) of the Toxic Substance Control Act.

3. *Publications.* A published article or report containing information otherwise reportable under 6(a)(2) need not be submitted if it meets one of the following criteria.

a) Any scientific article or publication which has been abstracted in a recognized database of scientific literature if the abstract in question clearly identified the active ingredient or the registered pesticide to which the information pertains.

b) Reports on publications which have been made available to the public by any of the following federal agencies: Center for Disease Control and Prevention, Consumer Products Safety Commission, Department of Agriculture, Department of the Interior, Food and Drug Administration or any other agency or institute affiliated with the Department of Health and Human Services.

4. *Information Concerning Former Inerts, Contaminants or Impurities.* A registrant need not submit information otherwise reportable under 6(a)(2) concerning a chemical compound that was at one time an inert ingredient or a contaminant or impurity of a pesticide product if:

a) The compound has been eliminated from the registered product due to changes in manufacturing processes, product formulation or by other means.

b) The registrant has informed the appropriate product manager in the Office of Pesticide Programs in writing of the previous presence of the inert, contaminant, or impurity in the product and its subsequent elimination from the product.

VII. INFORMATION OBTAINED BEFORE EFFECTIVE DATE OF 6(a)(2) RULE.

The Section 6(a)(2) final rule also requires registrants to report to EPA information otherwise subject to reporting that it received or possessed prior to the effective date of the final rule. This section sets forth the type of information that must be reported, as well as when it must be reported.

A. Type of Information That Must be Reported

Registrants must report to the Agency about any information it possesses or receives on or before August 17, 1998 (the new effective date of the 6(a)(2) rule) which has not been previously submitted to EPA but which is otherwise reportable under the 6(a)(2) rule IF the information meets ANY of the following criteria.

1. Toxic or Adverse Effect Incidents. The information is reportable as a toxic or adverse effect incident (as described in section III(A) of this document), AND pertains to an incident that is alleged to have occurred on or after January 1, 1994, AND involves one of the following:

- a) A fatality or hospitalization of the human being (H-A, H-B).

- b) A fatality of a domestic animal (D-A).

- c) A fatality or fatalities to fish or wildlife if the incident meets the criteria for the exposure type and severity category designation W-A set forth in Appendix A.

2. Information Requested by EPA. Registrants must submit information obtained previously to the effective date if EPA requests such information as described in section III(G) of this document.

B. Schedule for Reporting Previously Obtained Information

If a registrant possesses information required to be submitted as described above in section VII(A)(1), the registrant must submit that information on or before June 16, 1999. However, if the information subject to reporting is of the type requested by EPA (described above in VII(A)(2)), then the information must be submitted in accordance with any schedule contained in EPA's request for information.

C. Content and Format of Information to be Submitted

In regard to information requested to be submitted as described in section VII(A)(1), the information must be submitted in accordance with section V(2) above. In addition, registrants shall submit an inventory of reportable material instead of individual incident reports. An inventory must include the number and type of incidents (as set forth in VII(A)(1)) associated with a particular product or active ingredient, and for each type of incident the numbers of fatalities or hospitalizations involved.

VIII. OBLIGATIONS OF FORMER REGISTRANTS

This section defines the circumstances under which former registrants of pesticide products are obligated to report to EPA under the 6(a)(2) rule. This section also addresses the various exceptions EPA has set forth to limit the responsibilities of those who previously were the registrant of a pesticide product.

A. General Requirement

In general, a former registrant of a pesticide is obligated under the 6(a)(2) final rule to submit information concerning the registration of a pesticide product previously held by the registrant (and otherwise reportable under 6(a)(2)) for a period of 5 years after the registration of the pesticide product has been canceled or

transferred to another registrant. The reporting requirements for former registrants are limited by the exceptions set forth in VIII(B) below.

B. Exceptions

Former registrants are exempt from the general reporting requirements described above in VIII(A) if any one of the following conditions are applicable:

1. Former registrants are not obligated to report adverse information on their formerly registered products more than one year after they cease to hold the registration, provided that they hold no active pesticide registrations.
2. Former registrants need not report information if it is solely associated with inert ingredients, contaminants, impurities, metabolites, or degradates contained in formerly registered products more than one year after the registrant first ceases to hold the registration.
3. Former registrants are not required to report adverse information associated with an active ingredient or a formerly registered product, and the active ingredient or every active ingredient contained in the formerly registered product has not been contained in any pesticide product registered in the United States for any part of the three year period preceding the date on which the registrant first obtained the information.
4. Former registrants are not required to submit adverse information that pertains solely to a formerly registered product that no longer meets the definition of Apesticide@ as set forth in section 2(u) of FIFRA.

C. Information Arising From Litigation

A former registrant is obligated to submit information otherwise reportable under Section 6(a)(2) concerning formerly registered pesticide products which arises in the course of litigation concerning the adverse effects of such products, regardless of when the information is first acquired. However information arising from litigation need not be reported if the criteria in section VIII(B)(3) or (B)(4) are met.

D. When Information Must Be Submitted.

Former registrants must submit information related to reportable studies no later than 30 days after the registrant knows or possesses such information. All other reportable incident information must be submitted within the time frame set forth in section III(A)(5) above. Also, please review section IV above for a general discussion of other key issues related to the timing of such submissions to EPA.

IX. PENALTIES

Registrants that fail to comply with the Section 6(a)(2) final rule could be subject to enforcement actions for civil and/or criminal penalties under FIFRA Section 14. This section provides for a maximum civil penalty of \$5,000 for each offense. In more serious cases, registrants may be subject to a maximum criminal penalty of \$50,000, or imprisonment for no more than one year. Failure to comply with Section 6(a)(2) may also result in the cancellation of the pesticide registration.

X. SUGGESTIONS FOR IMPLEMENTATION

A. General

1. Review the Regulation. Companies subject to the Section 6(a)(2) reporting requirements should review the regulation to identify those aspects of the rule that will have an impact on their businesses. ISSA expects that the distributors and manufacturers of institutional-use pesticide products (i.e., disinfectants, sanitizers, germicides, fungicides, insecticides, and other EPA registered products) will be most affected by the following types of reporting requirements: toxic or adverse effect incidents experienced by individuals (especially in regard to minor effects such as skin or eye irritation); and reportable studies.

It is important that key personnel be trained in regard to the relevant areas of the 6(a)(2) rule and understand their corresponding responsibilities.

2. Establish a Point Person or Team. Companies should establish a point person or team to whom all 6(a)(2) information will be channeled. These individuals should be knowledgeable and responsible for the following: determining whether information channeled to them is reportable; compiling reports to EPA; submission of reports within the time frames set forth in the final rule; and follow-up reporting as may be required.

3. Identify Agents and Employees Who Are Likely to Receive Reportable Information. Companies should identify employees and agents who are likely to receive information reportable under the 6(a)(2) final rule. Such individuals are likely to include sales personnel, individuals who are designated to receive customer complaints, consultants, lawyers, etc. At the very least, these individuals should be instructed so as to recognize the significance of information they may receive, and whom to report it to within the company.

4. Establish Information Flows Within and Outside Company. Companies must establish information flows so that affected employees and agents know to whom 6(a)(2) information must be transmitted within the company for ultimate submission to EPA.

Manufacturers should consult with their private label distributors to determine how reportable information received by distributors will be reported by EPA. It should be clearly established whether private label distributors will report directly to EPA or to their manufacturer/supplier as the Agency prefers.

In the event private label distributors choose to report to their suppliers rather than EPA, then it is important that the responsibilities of each party be clearly spelled out such as: when distributors must report; the preferred format for reporting; to whom the information should be transmitted; and the obligation of the manufacturer/supplier to transmit the information to EPA in a timely manner. Potential liability issues should also be addressed (see below).

Where private label distributors prefer to report directly to EPA, it is recommended that distributors be put on notice of their responsibilities, and that potential liability be addressed (see below).

5. Train Employees/Agents and Point Person/Team. Companies will need to instruct employees and agents who are likely to receive 6(a)(2) information so that they recognize significant information.

Furthermore, these individuals must know who, within the company, to transfer this information. The point person or team also needs to be trained to recognize information that is reportable under 6(a)(2), the format in which the company will submit the information, the time frame for submission, and any potential for follow-up reporting.

B. Distributors

1. Establish Process to Collect Information. Covered distributors (i.e., distributors of private label pesticide products, exclusive brand distributors, etc.) need to establish a process by which to collect 6(a)(2) information including: the identification of a point person or team who will be responsible for submitting 6(a)(2) information to EPA or their manufacturer/supplier; identification of employees/agents who are likely to receive such information; establishment of information flows internally and externally; and training of affected employees/agents.

2. External Communications. Covered distributors need to work with the primary registrant of the product (i.e., their manufacturer supplier) and establish a flow of 6(a)(2) information between the two companies.

C. Liability

Because reporting adverse effects information may involve the cooperation of manufacturers/suppliers and distributors, liability may arise in situations where either party fails to fulfill their respective responsibilities. For example, where private label distributors choose to report to their suppliers, the failure of the distributor to submit reportable information may result in enforcement against the distributor and the supplier.

Therefore, in situations where distributors may choose or be expected to submit reportable information through their suppliers (i.e., in the case of private label distributors, or exclusive distributors), it is advisable that both parties express their respective responsibilities in the form of a contractual agreement. Furthermore, each party should acknowledge their responsibilities and indemnify and hold harmless the other party for their failure to perform which may result in an EPA enforcement action or other liability. An indemnity and hold harmless provision should also be used in those situations where private label distributors choose to report directly to EPA. In this instance, manufacturers should be sure that such distributors acknowledge their reporting responsibilities and agree to indemnify and hold harmless the manufacturer from any liability that may arise from the distributor=s failure to report.

ISSA has included sample 6(a)(2) agreements addressing these issues in Appendix D. Please be aware, however, that contract law varies state by state. Also you may wish to modify these sample agreements to better address your particular circumstances and policies. Therefore, before using the sample 6(a)(2) agreements attached in Appendix D, you would be wise to consult with a local attorney.

Glossary of Key Terms

For purposes of the Section 6(a)(2) final rule, the following definitions of key terms are applicable.

Established level means a tolerance, temporary tolerance, food additive regulation, action level, or other limitation on pesticide residues imposed by law, regulation, or other authority.

Formal Review means Special Review Rebuttable Presumption Against Registration (RPAR), FIFRA Section 6(2) suspension proceeding, or FIFRA Section 6(b) cancellation proceeding, whether completed or not.

Hospitalization means admission for treatment to a hospital, clinic or other health care facility. Treatment as an outpatient is not considered to be hospitalization.

Maximum contaminant level (MCL) means the maximum permissible level, established by EPA, for a contaminant in water which is delivered to any user of a public water system.

Non-target organism means any organism for which pesticidal control was either not intended or not legally permitted by application of a pesticide.

Pesticide means a pesticide product which is or was registered by EPA, and each active ingredient, inert ingredient, impurity, metabolite, contaminant or degradate contained in, or derived from, such pesticide product.

Qualified expert means one who, by virtue of his or her knowledge, skill, experience, training, or education, could be qualified by a court as an expert to testify on issues related to the subject matter on which he or she renders a conclusion or opinion. Under Rule 702 of the Federal Rules of Evidence, a person may be qualified as an expert on a particular matter by virtue of knowledge, skill, experience, training, or education. In general, EPA wants registrants to report information when a person has relevant expert credentials, e.g., a medical doctor giving a medical opinion, a plant pathologist giving an opinion on plant pathology, etc.

Registrant includes any person who holds, or ever held, a registration for a pesticide product issued under FIFRA section 3 or 24(c), including any employee or agent of such a person; provided that any employee or agent who is not expected to perform any activities related to the development, testing, sale or registration of a pesticide, and who could not reasonably be expected to come into possession of information that is otherwise reportable under this part, shall not be considered a registrant for purposes of this part; and provided further that information possessed by an agent shall only be considered to be

possessed by a registrant if the agent acquired such information while acting for the registrant.

Similar species means two or more species belonging to the same general taxonomic groups: The general taxonomic groups for purposes of this requirement are: mammals, birds, reptiles, amphibians, fish, aquatic plants (including macrophyte, floating, and submerged plants), and terrestrial (all non-aquatic) plants.

Water reference level means the level specified in paragraph (1) or (2) of this definition, whichever is lower.

1. Ten percent of the maximum contaminant level (MCL) established by EPA, or if no MCL has been established by EPA, 10 percent of the most recent draft or final long-term health advisory level (HAL) established by EPA has not published or proposed an MCL or HAL, the lowest detectable amount of the pesticide.

2. The ambient water quality criteria for the protection of aquatic life, established by EPA pursuant to section 304(a) of the Clean Water act.

Exposure Types and Severity Category Designations

I. Humans

If an effect involves a human, the appropriate 2-letter exposure types and severity categories and their designations are as follows:

A. H-A: If the person died.

H-A shall be indicated if it is reported that the person died as a result of exposure or as a direct complication of exposure to the pesticide.

B. H-B: If the person alleged or exhibited symptoms which may have been life-threatening, or resulted in adverse reproductive effects or in residual disability.

Life-threatening effects include, but are not limited to, intracranial hemorrhage, repeated seizures, grand mal seizures, coma, clinical evidence of renal failure, respiratory depression or bronchoconstriction requiring immediate treatment, cardiovascular instability, cardiac arrest, respiratory arrest, or patients who require mechanical ventilation. In general, life-threatening effects are any condition which if untreated would likely lead to death.

Adverse reproduction effects include, but are not limited to: premature or low weight birth, spontaneous abortion, miscarriage, or stillbirth; birth defects, including mental retardation; and infertility in men and women.

Residual disability is any adverse effect which lasts for months or years after the initial poisoning and limits a major activity, e.g., require continuous health care, time off work, or modification of daily activities. Examples include delayed neuropathy, renal damage requiring dialysis, permanent change in vision, development of chronic respiratory disease such as asthma.

C. H-C: If the person alleged or exhibited symptoms more pronounced, more prolonged or of a more systemic nature than minor symptoms. Usually some form of treatment of the person would have been indicated. Symptoms were not life-threatening and the person has returned to his/her pre-exposure state of health with no additional residual disability.

Effects include, but are not limited to, a corneal abrasion, blurred vision with pinpoint pupils, high fever, disorientation (confusion, hallucinations), isolated brief seizures, profuse sweating, drooling, gastro-intestinal symptoms leading to dehydration, caustic injury to mouth or esophagus, severe muscle weakness, incoordination, tremor, or hives. More prolonged effects are those that last one month or longer, such as a persistent skin rash.

D. H-D: If the person alleged or exhibited some symptoms, but they were minimally traumatic. The symptoms resolved rapidly and usually involve skin, eye or respiratory irritation.

Effects include, but are not limited to, skin rash, itching, conjunctivitis (red, tearing eyes), drowsiness, transient cough, headache, joint pain, agitation, restlessness, or mild gastro-intestinal symptoms such as self-limited diarrhea, stomach cramps, or nausea. These effects are reported to have lasted less than one month.

E. H-E: If symptoms are unknown or not satisfied.

II. Domestic Animals

If an effect involves a domestic animal, the appropriate 2-letter notation is as follows:

A. D-A: If the domestic animal died or was euthanized.

B. D-B: If the domestic animal exhibited or was alleged to have exhibited symptoms which may have been life-threatening or resulted in residual disability.

C. D-C: If the domestic animal exhibited or was alleged to have exhibited symptoms which are more pronounced, more prolonged or of a more systemic nature than minor symptoms. Usually some form of treatment would have been indicated to treat the animal. Symptoms were not life-threatening and the animal has returned to its pre-exposure state of health with no additional residual disability.

D. D-D: If the domestic animal was alleged to have exhibited symptoms, but they were minimally bothersome. The symptoms resolved rapidly and usually involve skin, eye or respiratory irritation.

E. D-E: If symptoms are unknown or not specified.

III. Fish or Wildlife

If an alleged effect involves fish or wildlife, the incident shall be categorized as W-A if any of the criteria listed in paragraphs (A) through (G) of this section are met, or W-B if none of the criteria are met:

A. Involves any incident caused by a pesticide currently in Formal Review for ecological concerns.

- B. Fish: Affected 1,000 or more individuals of a schooling species, or 50 or more individuals of a non-schooling species.
- C. Birds: Affected 200 or more individuals of a flocking species, or 50 or more individuals of a songbird species, or 5 or more individuals of a predatory species.
- D. Mammals, reptiles, amphibians: Affected 50 or more individuals of a relatively common or herding species or 5 or more individuals of a rare or solitary species.
- E. Involves effects to, or illegal pesticide treatment (misuse) of a substantial tract of habitat (greater than or equal to 10 acres, terrestrial or aquatic).
- F. Involves a major spill or discharge (greater than or equal to 5,000 gallons) of a pesticide.
- G. Involves adverse effects caused by a pesticide, to federally listed endangered or threatened species .

IV. Plants

If an alleged effect involves damage to plants, label the incident P-A if the single criterion listed in paragraph (A) of this section is met, or P-B if the criterion is not met:

- A. The effect is alleged to have occurred on more than 45 percent of the acreage exposed to the pesticide.
- B. (Reserved)

V. Other Non-Target Organisms

If an alleged effect involves damage to non-target organisms other than fish, wildlife or plants (for example, beneficial insects), the incident shall be categorized as ONT.

VI. Water Contamination

If a pesticide is alleged in groundwater, surface water or finished drinking water, the incident shall be categorized as follows:

- A. G-A: If the pesticide was detected at levels greater than the maximum contaminant level (MCL) or health advisory (HAL) or an applicable criterion for ambient water quality.
- B. G-B: If the pesticide was detected at levels greater than 10 percent of the MCL, HAL, or criterion for ambient water quality but does not exceed the MCL or other applicable level.

C. G-C: If the pesticide was detected at levels less than 10 percent of the MCL, HAL, or other applicable level, or there is no established level of concern.

VII. Property Damage

If an incident involves alleged property damage the applicable term(s) shall be included along with any other applicable effect category label; for example, AH.B: property damage. In addition, the incident shall be categorized as follows:

A. PD-A: The product is alleged to have caused damage in a manner that could have caused direct human injury, such as fire or explosion.

B. PD-B: The product is alleged to have caused damage in excess of \$5,000.

C. PD-C: Any allegation of property damage that does not meet the criteria of paragraphs (A) or (B) of this section, including cases in which the level of damages is not specified.

VIII. Individual Incident Report

Individual incident reports must be submitted to EPA for adverse effects incidents that are characterized by the following Aexposure types and severity category designations: H-A, H-B, H-C, W-A, P-A, G-A, and PD-A.

IX. Aggregate Reports

Aggregate reports must be submitted to EPA for adverse effects incidents that are characterized by the following Aexposure types and severity category designations: H-D, H-E, D-A, D-B, D-C, D-D, D-E, W-B, P-B, ONT, G-B, G-C, PD-B, and PD-C.

Quick Reference Guide to Reporting Timeframes

SEVERITY CATEGORIES and/or Other Reporting Categories	REPORTING TIMEFRAMES
Human Deaths (H-A)	<p>ASAP - No later than 15 days</p> <p>Submission Format: Individual Report</p> <p>Provide detailed information for each incident</p>
<p>Scientific Studies described in (159.165)</p> <p>Information about discontinued studies (159.167)</p> <p>Human epidemiology and exposure studies (159.167)</p> <p>Detection of an unauthorized pesticide in or on food or feed (159.178)</p> <p>Detection of metabolites, degradates, contaminants, impurities (159.179)</p> <p>Failure of performance studies related to public health products (159.188 (a)(2), (b)(2))</p> <p>Substantiated incidents of pest resistance (159.188 (c))</p> <p>Other information described in (159.195)</p> <p>Property Damage with risk to human health (PD-A) and other information (159.195)</p>	<p>Submit within 30 calendar days</p> <p>Submission Format:</p> <ul style="list-style-type: none"> - Individual Report (Food/Feed, Property Damage with risk of injury to humans) - For all other submissions refer to 159.156
<p>Human B Major (H-B)</p> <p>Human B Moderate (H-C)</p> <p>Major B Wildlife (W-A)</p> <p style="padding-left: 40px;">Plant (P-A)</p> <p>Detection of pesticide in water at levels greater than MCL/HAL (G-A) (159.178 (b) & 159.184 (c)(5))</p> <p>Efficacy failure incidents regarding public health products (159.188 (a)(1) & (b)(1))</p>	<p>Accumulate 1 Month</p> <p>Submit by the end of the month following the accumulation period</p> <p>Submission Format: Individual Report</p> <p>Provide detailed information for each incident as required in section 159.184(c)</p>
<p>Human B Minor (H-D)</p> <p style="padding-left: 40px;">Unspecified or Unknown effects (H-E)</p> <p>All Domestic Animal (D-A, B, C, D, E)</p> <p>All Other Categories for Wildlife (W-B)</p>	<p>Accumulate 3 Months</p> <p>Submit by the end of the 2nd month following the accumulation period</p> <p>Submission Format: Aggregate</p>

Plant (P-B) Detection of pesticide in water below MCL/HAL but otherwise reportable (G-B, C) (159.178 (b) & 159.184 (c)(5))	Aggregate and submit count of incidents and effects for each product or AI as required in section 159.184(e)
Incomplete toxicological and ecological studies (159.165(d))	Consult section 159.165(d) when testing is completed but study not finalized

APPENDIX D

SAMPLE 6(a)(2) AGREEMENTS

Attached are two sample 6(a)(2) agreements for formulators and distributors. The first sample contemplates an arrangement by which private label distributors will report adverse effects information to their formulator/supplier for ultimate submission to EPA. The other sample addresses the situation where a private label distributor chooses to report directly to EPA.

Please be aware that contract law varies state to state. In addition, you may wish to modify the sample agreement to meet your particular needs and circumstances. Therefore, before using the sample agreements, you would be wise to consult with a local attorney to ensure the document is legally binding.

**SAMPLE 6(a)(2) AGREEMENT WHEREBY
PRIVATE LABEL DISTRIBUTORS AGREE TO SUBMIT REPORTABLE
INFORMATION TO FORMULATORS FOR ULTIMATE SUBMISSION TO EPA**

This agreement made this ___ day of _____, 1998, is entered into by and between the ABC Formulator Company, [STREET ADDRESS], [CITY, STATE], hereinafter referred to as AABC,@ and XYZ Distributor Company, [STREET ADDRESS], [CITY, STATE], hereinafter referred to as AXYZ.@

WHEREAS, the U.S. Environmental Protection Agency (EPA) issued a final regulation which codifies EPA=s interpretation and enforcement policy regarding section 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (hereinafter referred to as the A6(a)(2) rule@), which requires all registrants of pesticide products to report information concerning adverse effects of their pesticide products to EPA. (See 40 CFR Part 159, Subpart D.)

WHEREAS, XYZ is a supplemental registrant of pesticide products supplied by ABC under XYZ=s private label, and therefore, has duties and obligations under the 6(a)(2) rule to report to EPA information concerning adverse effects of these pesticide products.

WHEREAS, ABC is a registrant of pesticide products, and therefore, has duties and obligations under the 6(a)(2) rule to report to EPA information concerning adverse effects of ABC=s pesticide products including those sold under XYZ=s private label.

WHEREAS, EPA has requested that supplemental registrants, such as XYZ, deliver information reportable under the 6(a)(2) rule to the underlying registrant, such as ABC, for ultimate submission to EPA.

Now, therefore, it is agreed as follows:

1. XYZ agrees to submit to ABC on a timely basis information it knows of or possesses or which is known or possessed by its agents or employees and which is reportable under the 6(a)(2) rule and which relates to pesticide products supplied by ABC to XYZ under XYZ=s private label. For purposes of this paragraph only, a Atimely basis@ shall be defined as follows: for incidents involving human fatalities, XYZ shall submit appropriate information immediately; and for all other reportable information, XYZ shall submit appropriate information within 10 business days of receiving or knowing of such information, or within 10 business days of its agents or employees knowing or possessing of such information.

2. ABC agrees to submit to EPA on a timely basis information it receives from XYZ which relates to pesticide products supplied by ABC to XYZ under XYZ=s private label and which is reportable under the 6(a)(2) rule. For purposes of this paragraph, a Atimely basis@ shall mean submission within the time lines set forth in the 6(a)(2) rule as codified at 40 CFR Part 159, Subpart D.

3. XYZ shall indemnify and hold ABC harmless from any and all enforcement actions brought by EPA against ABC for ABC=s failure to timely report to EPA under the 6(a)(2) rule as a result of negligent, intentional or other acts of XYZ, its employees or agents which result in a failure by XYZ to submit to ABC on a timely basis (as defined in Paragraph 1) information reportable under the 6(a)(2) rule related to the pesticide products supplied to XYZ by ABC under XYZ=s private label.

4. ABC shall indemnify and hold XYZ harmless from any and all enforcement actions brought by EPA against XYZ for failure to timely report to EPA under the 6(a)(2) rule as a result of negligent, intentional or other acts of ABC, its employees or agents which result in a failure by ABC to submit to EPA on a timely basis (as described in Paragraph 2) information reportable under the 6(a)(2) rule which was submitted to ABC by XYZ and which relates to pesticide products supplied by ABC to XYZ under XYZ=s private label.

5. This Agreement may be modified or terminated by written consent of both parties.

6. This Agreement shall be governed by, construed and enforced in accordance with the laws of the State of [FILL IN PREFERRED STATE].

IN WITNESS THEREOF, the parties have hereunto executed this Agreement this ___ day of ___, 1998.

Signature/Title/Date
ABC Formulator Co.

Signature/Title/Date
XYZ Distributor Co.

SAMPLE 6(a)(2) AGREEMENT WHERE PRIVATE LABEL DISTRIBUTOR CHOOSES TO SUBMIT REPORTABLE INFORMATION DIRECTLY TO EPA

This agreement made this ___ day of _____, 1998, is entered into by and between the ABC Formulator Company, [STREET ADDRESS], [CITY, STATE], hereinafter referred to as AABC,@ and XYZ Distributor Company, [STREET ADDRESS], [CITY, STATE], hereinafter referred to as AXYZ.@

WHEREAS, the U.S. Environmental Protection Agency (EPA) issued a final regulation which codifies EPA =s interpretation and enforcement policy regarding section 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (hereinafter referred to as the A6(a)(2) rule@), which requires all registrants of pesticide products to report information concerning adverse effects of their pesticide products to EPA. (See 40 CFR Part 159, Subpart D.)

WHEREAS, XYZ is a supplemental registrant of pesticide products supplied by ABC under XYZ =s private label, and therefore, has duties and obligations under the 6(a)(2) rule to report to EPA information concerning adverse effects of these pesticide products.

WHEREAS, ABC is a registrant of pesticide products, and therefore, has duties and obligations under the 6(a)(2) rule to report to EPA information concerning adverse effects of ABC =s pesticide products including those sold under XYZ =s private label.

WHEREAS, XYZ has chosen to report adverse effects information under the 6(a)(2) rule related to pesticide products supplied by ABC to XYZ under XYZ =s private label directly to EPA rather than deliver such information to ABC for submission to EPA.

WHEREAS, ABC may be subject to an enforcement action by EPA if XYZ fails to report to EPA adverse effects information related to pesticide products supplied by ABC to XYZ under XYZ =s private label and which are subject to the 6(a)(2) rule.

Now, therefore, in consideration for ABC agreeing to continue to supply XYZ with pesticide products under XYZ =s private label, XYZ agrees to:

1. Submit to EPA on a timely basis information it knows of or possesses or which is known or possessed by its agents and employees and which is reportable under the 6(a)(2) rule and which relates to pesticide products supplied by ABC to XYZ under XYZ =s private label. For purposes of this paragraph only, a Atimely basis @ shall mean submission within the time lines set forth in the 6(a)(2) rule as codified at 40 CFR Part 159, Subpart D.
2. Indemnify and hold ABC harmless from any and all enforcement actions brought by EPA against ABC for ABC =s failure to timely report to EPA under the 6(a)(2) rule as a result of negligent, intentional or other acts of XYZ, its employees or agents which result in a failure by XYZ to submit to EPA on a timely basis (as defined in Paragraph 1)

information reportable under the 6(a)(2) rule related to the pesticide products supplied to XYZ by ABC under XYZ=s private label.

3. This Agreement may be modified or terminated by written consent of both parties.

4. This Agreement shall be governed by, construed and enforced in accordance with the laws of the State of FILL IN PREFERRED STATE.

IN WITNESS THEREOF, the parties have hereunto executed this Agreement this ___ day of _____, 1998.

Signature/Title/Date
ABC Formulator Co.

Signature/Title/Date
XYZ Distributor Co.

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