April 3, 1998

PESTICIDE REGISTRATION NOTICE 98-3

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

ATTENTION: Persons Responsible for Federal Registration of Pesticides

SUBJECT: Guidance on Final FIFRA Section 6(a)(2) Regulations for Pesticide Product Registrants

I. BACKGROUND

On September 19, 1997, EPA published in the Federal Register the final rule codifying EPA's interpretation and enforcement policy regarding section 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), which requires pesticide registrants to report information concerning unreasonable adverse effects of their products to EPA (62 FR 49370). The purpose of the rule is to clarify what information to submit, how and when to submit it, as well as which failures to report information, or delays in reporting, will be regarded by EPA as violations of FIFRA section 6(a)(2), actionable under FIFRA sections 12(a)(2)(B)(ii) and 12(a)(2)(N). In comparison to previous EPA policy statements, some reporting requirements have been expanded, and others reflect increased flexibility or exemptions for reporting specific types of information. This rule will become effective June 16, 1998, and will supersede all previous policy statements pertaining to section 6(a)(2). EPA is working with registrants in anticipation of the rule's effective date to prepare them for implementing the new FIFRA 6(a)(2) regulations smoothly and effectively.

II. PURPOSE

The purpose of this PR notice is to announce the availability of the attached document which will provide registrants comprehensive guidance on implementating the new regulations. The Agency has addressed in depth questions and issues raised by registrants and other parties subsequent to the publication of the final rule. The guidance in this document has been organized alphabetically by subject area, and a table of contents has been provided for ease of reference.

III. FOR FURTHER INFORMATION

Registrants may contact Kathryn Bouvé for information or questions concerning this PR notice and attached guidance document at: Office of Pesticide Programs (7502C), U.S. Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location, telephone number and e-mail address: Crystal Mall #2, Rm. 224, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305-5032, e-mail: Bouve.Kate@epamail.epa.gov.

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Environmental Protection Agency

Attachment to PR Notice 98-3

Guidance on Final FIFRA 6(a)(2) Regulations for Pesticide Product Registrants

April 3, 1998

Environmental Protection Agency
Office of Pesticide Programs

Guidance on Final FIFRA 6(a)(2) Regulations

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(alphabetical by topic)

I. INTRODUCTION

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EPA is working with registrants in anticipation of the rule's effective date to prepare them for implementing the new FIFRA 6(a)(2) regulations smoothly and effectively. The purpose of this document is to provide registrants comprehensive guidance on implementing the new regulations. The Agency has addressed in depth questions and issues raised by registrants and other parties subsequent to the publication of the final rule. The guidance in this document has been organized alphabetically by subject area, and a table of contents has been provided for ease of reference.

For further information, contact Kate Bouvé, Office of Pesticide Programs (7502C), U.S. Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location, telephone number and e-mail address: Crystal Mall #2, Rm. 224, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305-5032, e-mail: Bouve.Kate@epamail.epa.gov.

II. AGENTS: DEFINITION AND REPORTING RESPONSIBILITIES

Many registrants have raised questions about the role of registrant agents in the regulatory program. Whether a person can 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 the purposes of section 6(a)(2), EPA will generally look to the nature of the relationship between the "agent" and the registrant. Facts that will weigh in the determination of whether someone is acting as an agent will include whether the activity conducted is being conducted for the benefit of the registrant; whether the registrant is paying (directly or indirectly) for the activity; whether the registrant has requested that the activity be conducted; the nature of the contractual or financial relationship between the registrant and the person; etc. While the Agency will be guided to some extent by common law principles of agency in determining whether a person is acting as an agent for a registrant, EPA wants to make quite clear that if an "independent contractor" is doing pesticide-related work for, and at the behest of, a pesticide registrant, the

Agency considers the independent contractor an "agent" for purposes of section 6(a)(2) reporting.

The question of whether a retailer or wholesaler is an agent in any particular situation will also depend upon all the specific facts of the situation. As noted in the Preamble to the Final Rule (62 Federal Register at 49374), a distributor (retailer or wholesaler) that sells a wide variety of pesticide products produced by many different registrants would generally 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 would generally be considered an agent of a registrant. The Agency may, however, consider additional factors, including whether the distributor has done anything (made statements, published advertisements, etc.) to lead users to believe that the distributor is acting for the registrant or would be an appropriate place for users to report incidents regarding particular chemicals, as well as the exact nature of the relationship between the registrant and the distributor. In any particular case, all the facts of the particular situation will be used to determine whether a distributor is acting as an agent of a registrant.

Information that comes into the possession of an agent while the agent is acting for or on behalf of a registrant will be presumed to be possessed by the registrant for purposes of section 6(a)(2) if either the agent is expected to perform duties related to the development, testing, sale, or registration of a pesticide, or the agent could be reasonably expected to come into possession of otherwise reportable information. Examples of agents that could be reasonably expected to come into possession of otherwise 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 either directly on behalf of a registrant or on behalf of a company or law firm acting for the registrant; 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.

Supplemental distributors as defined in 40 CFR section 152.132 will be subject to enforcement action if reportable information in their possession is not submitted to the Agency in a timely manner. Section 152.132 makes clear that both supplemental distributors and registrants are liable for violations pertaining to the distributor product. The supplemental distributor accepts this responsibility when agreeing to become a supplemental distributor under that regulation. If a supplemental distributor has reportable information concerning the distributor product and that information is not provided to the Agency in a timely manner (as specified for the particular type of information in the rule) the Agency believes it has the authority to proceed with enforcement action against both the underlying registrant and the supplemental distributor.

Nevertheless, the Agency would like to minimize duplicative reporting and would prefer

that all reportable information be submitted by the underlying registrant rather than by numerous supplemental distributors acting for that registrant. Therefore, EPA requests that supplemental distributors deliver reportable information to the underlying registrants (in sufficient time for registrants to report) and not to EPA; the Agency strongly prefers receiving reportable information from registrants themselves rather than from their supplemental distributors. This also makes sense from the perspective of good product stewardship, since registrants would presumably want to be aware of adverse effects associated with products distributed by others. Note that where supplemental distributors choose to submit information to registrants rather than directly to EPA, the time for reporting will continue to be calculated from the time that the information is first received by the supplemental distributor.

III. AGGREGATE REPORTING

The regulations establish different requirements for reporting timeframes and for content of incident reports depending on the defined severity categories (see Section VIII. Exposure Types and Severity Categories). The chart that follows summarized the requirements.

ASAP - NLT 15 Days Provide detailed information for each incident	Accum. 1 Month Submit 1 Month Later Provide detailed information for each incident	Accum. 3 Months Submit 2 Months Later Aggregate and submit count of incidents and effects for each product or AI
Human Deaths	Human -Major Moderate Major - Wildlife Plant Water Property Damage	Human - Minor Unknown, etc. All Domestic Animals All other categories for - Wildlife Plant Water Property Damage

The regulations require registrants to report minor or common incidents as defined in the regulations as an aggregate count of incidents and effects for each product. The Agency will reject submissions of minor/common incidents if the summaries are not provided. This is necessary because the Agency expects the volume of incident reporting to increase after the final regulations become effective. To cope with this increase and maintain focus on the most

significant incidents, the Agency developed the aggregate summary format. It speeds the incident screening process and facilitates loading the basic information into the Agency's Incident Data System. Summarizing the information and taking a broad view of the data helps EPA identify patterns of concern regarding products or active ingredients. It is assumed that this approach benefits the registrant, as well.

Some registrants have expressed concern regarding the reliability of incident reports and the degree to which the Agency would be influenced by aggregate summaries. It should be noted that staff members in EPA's Office of Pesticide Programs (OPP) have many years of experience processing and analyzing incident data, and are well aware of the vagaries of incident reports, such as the frequent lack of specific details, uncertainties of causality, the sometimes erroneous assumptions of reporters, etc. The Agency is also aware that large numbers of incident reports may simply reflect a large product sales volume or the existence of toll-free 800 numbers on product labels, making incident reporting easier. OPP staff members are also aware that the Agency may receive multiple reports of the same incident from various sources, which may inflate the number of incident reports for a particular product or chemical. While these can usually be sorted out for individually reported incidents, they cannot be detected in the aggregate reports. EPA takes these factors into account when reviewing aggregate data to determine if the incident reports present patterns of concern. Furthermore, EPA makes this clear in its responses to people who request incident data in order that they not draw inappropriate conclusions from the data.

An overview of the incident data simply identifies where there might be problems and serves as the first step in a process of gathering more information about the products or chemicals. If the aggregate report appears to indicate a problem, the product managers - current or former - are consulted on their knowledge of the product, such as its use, sales volume, risk issues considered during the application process, etc. The product manager will then contact the registrant to request additional information or further analysis of the incidents. As a consequence, the registrant may need to develop additional data on the issue or negotiate risk reduction measures, if appropriate.

Registrants are free to submit supplemental information about incident reports, explaining circumstances such as mis-use, unusual use conditions, or interpreting the data's significance. When OPP receives incident submissions, the entire submission -- the aggregate summary and any explanatory information -- is filmed for archival purposes and future reference. The entire package is forwarded to the Incident Data Officers in the OPP science divisions, who then screen the incidents for significance.

Registrants have requested additional guidance on how to aggregate minor and common incident reports. Generally, two facts are reported: the number of incidents and the number of

adverse effects that occurred as the result of the incidents. What follows is guidance on how to count incidents and effects, and present them to the Agency. The examples are hypothetical.

Number of Incidents and Adverse Effects Reported by Exposure Type and Severity Category
Reporting Period January - March 1998

Reg No/ Active Ingredient	Total Incidents	H -D Human- Minor Effects	H - E Human- Unknown, Unspecified, or Delayed Effects	D-A Domestic Animal - Death	D - B Domestic Animal- Major Effects	D - C, D, E Domestic Animal- Moderate, Minor,Unknown or Unspecified
112233-1	30	7	4	1	4	17
112233-13	47	4	10	0	9	37
Active Ingred. X	7	1	0	0	2	4

A single incident can result in effects to multiple exposure types and severity categories, so the total number of effects may exceed the total number of incidents. That is demonstrated in the chart above.

If a single incident affects multiple individuals in one exposure type and severity category, it is reported as one effect for that exposure type/severity combination. For example, if one incident results in the death of 5 domestic animals, it counts as 1 in D-A.

A single incident may involve multiple exposure types and severity categories, and it is counted once for each combination of exposure type and severity category. For example, if one incident results in the death of 2 domestic animals, major effects in 10 domestic animals, and minor effects to 2 humans, it counts as 1 in D-A, 1 in D-B, and 1 in H-D.

If one individual experiences multiple effects that would be classified as major, moderate, and minor, the most severe category only (major) is assigned. Again, see Section VIII. Exposure Types and Severity Categories for expanded definitions.

If a single incident results in major effects in one human, the death of one domestic animal, and moderate effects in 3 domestic animals, the human incident is reported individually. The other effects are aggregated and reported in the quarterly summary. They would count as 1 in D-A and 1 in D-C.

The new Rule does not specify reporting time frames for some reportable items. These will be addressed through technical corrections to the regulations. Please see Section XVIII. Technical Corrections to Regulations, on page 18 of this document, for a discussion of proposed technical corrections.

IV. ATTORNEY-CLIENT AND ATTORNEY WORK-PRODUCT PRIVILEGES--WAIVER REQUESTS

Some registrants requested clarification of the Agency's position on exempting from reporting requirements of 6(a)(2) material covered by the attorney-client and attorney work-product privileges. The Preamble to the Final Rule (62 Fed. Reg. at 49377) states that, "The Agency has no intention to broadly exempt information covered by the attorney work-product doctrine." However, the Preamble also states that the Agency will consider granting a waiver request where it can be shown that: 1) the information is entitled to some privilege; 2) that providing the information to the Agency would substantially prejudice a registrant; and 3) that the information would not be particularly helpful to an analysis of a product's registration status. The Agency expects that it will likely be in a better position to amplify these criteria when and if it has considered some actual requests for waivers.

Any request will be considered in the context of the particular facts involved. A registrant requesting a waiver should address all three of the criteria identified in the Preamble. It is likely that the third criterion will be particularly important to the Agency's deliberations. It is unlikely that the Agency will grant a waiver request unless the Agency knows, in some detail, what information is covered by the request and has determined that the information would not be particularly helpful to the Agency in fulfilling its regulatory responsibilities.

Until the Agency has more experience with waiver requests, registrants wishing to submit such requests are encouraged to first discuss the request with relevant Agency officials. In particular circumstances, the Agency may also place appropriate conditions on waivers, including but not limited to, requiring that the information be formally provided to the Agency at some time in the future.

All waiver requests must be addressed to the 6(a)(2) Officer in the Office of Pesticide Programs. Unless the Agency states otherwise in the future, a registrant may rely on any written grant of a waiver request signed by the 6(a)(2) Officer or any attorney in the Office of General Counsel.

V. AUTHORIZATION TO WAIVE OR MODIFY REPORTING REQUIREMENTS

As in the case of waivers concerning attorney-client or attorney work product privilege,

requests for waivers or modifications of reporting requirements must be addressed to the 6(a)(2) Officer. Unless the Agency states otherwise in the future, a registrant may rely on any written grant of a waiver request signed by the 6(a)(2) Officer or any attorney in the Office of General Counsel.

VI. CAUSATION AND DELAYED EFFECTS

One of the key differences between the regulations and earlier guidance (the 1979 Enforcement Policy) concerns the issue of causation. In the past, an incident was reportable if the registrant inferred that a link existed between the effect and exposure or if similar incidents occurred three or more times. Under the new regulations, neither an inference nor a pattern needs to be established before reporting an incident. If basic information is available -- an effect, an exposure, the identity of the pesticide, location where the incident occurred and a person to contact -- the incident is reportable.

In general, under the new regulations, the agency considers incident reports to be simply allegations of adverse effects caused by exposure to a pesticide. Some incidents are well-investigated and reported in such as way as to establish a strong link between the adverse effect and the exposure. On the other hand, many other reports do not include enough facts to clearly demonstrate causation and registrants are not required under FIFRA 6(a)(2) to investigate the incident to gather additional information. Submission of an incident report by a registrant is not considered to be an admission of causation.

Even incidents in which the reported adverse effects are not consistent with animal testing are reportable. For example, if an allegation is made that exposure to a particular chemical resulted in respiratory system effects, and the registrant is aware, based on scientific data, that the chemical does not cause respiratory system effects, the allegation must still be reported. Incident reports serve as a check on animal and other testing done in support of the registration application. Real world use of the product can cause adverse effects for a whole host of reasons such as species differences, product stability changes, or synergistic effects from different inert ingredients. Please note that a registrant may provide information to interpret incident patterns, describe special circumstances such as misuse, or explain why the effect could not have been caused by exposure to the pesticide. This information will be reviewed along with the incident reports.

Exceptions to incident reporting include those situations in which the registrant has facts that clearly establish that the adverse effect did not or will not occur, or that exposure to a pesticide did not occur. Such facts may involve errors by the reporter. For example, a registrant may be told that a container of pesticide was dumped into a pond and all water fowl in and around the pond died. The reporter may later report that the container held gasoline, not a

pesticide. Therefore, there was no exposure to a pesticide, and the incident is not reportable. Factual errors involving toxic effects could be illustrated by the following example: A greenhouse worker claims he was sick and missed a day's work after he was exposed to a pesticide. However, it was learned that the worker went to a baseball game and lied about being sick. This would not be reportable.

The provision in the regulations that requires submission of incident reports in which the person or non-target organism may suffer a delayed or chronic adverse effect in the future is worth special attention. These are cases in which there is no acute adverse effect, but exposure has occurred, and the reporter expresses concern about possible effects in the future. The primary purpose of this provision is to provide the agency with information about exposures to chemicals which were regulated in ways to ensure that exposure would be very low.

It has been suggested that the agency list specific chemicals that may cause delayed or chronic effects and limit 'may suffer' incidents to those associated with the listed chemicals. The agency will not provide such lists. As registrants are aware, these lists are difficult to define, may exclude effects that could be significant, and are likely to change over time. While occurrence of a delayed effect may be extremely unlikely, the registrant cannot absolutely rule out the possibility. It is probably less burdensome for registrants to simply submit the allegation of chronic or delayed effects to the agency. The Agency may reconsider this requirement in the future. It should be noted that these reports apply to humans only, are to be summarized quarterly, and reported in severity category H-E (symptoms unknown, unspecified or are alleged to be of a delayed or chronic nature that may appear in the future).

Finally, while EPA does not require registrants to report evidence that known exposures have not resulted in symptoms, the Agency is interested in receiving this information because of its usefulness in establishing a No Observed Effect Level for the pesticide in humans and different species of animals. Additionally, the reporting of exposures which do not lead to adverse effects provides a measure of a product's safety.

VII. EXPERT OPINION INFORMATION

Conclusions or opinions of experts must be submitted under FIFRA 6(a)(2) if the registrant possesses the information and either 1) the information is otherwise reportable under one of the substantive provisions of the rule; or 2) the registrant knows, or should reasonably know, that the information, alone or in conjunction with other information, might raise concerns about the continued registration of a pesticide or about the appropriate terms and conditions of registration of a pesticide. As a general matter, the Agency frequently relies on the "weight of evidence" in making pesticide regulatory decisions, and it considers expert opinion that tends to

confirm or validate otherwise reportable information. In this context, expert opinions can play an important role in Agency decision-making.

Examples of reportable expert opinions include, but are not limited to: investigator opinions concluding that exposure to a pesticide may have caused a particular adverse effect; scientific opinions that test data demonstrate that a pesticide causes a particular adverse effect; expert conclusions that a pesticide is likely to migrate into groundwater; expert opinions that a pesticide shares a common mechanism of toxicity with another chemical (an issue relevant to food tolerances under section 408 of the FFDCA as amended in 1996 by the Food Quality Protection Act); expert opinions reflecting that the aggregate risks posed by a pesticide may be higher than previously believed (another issue addressed in section 408 of the FFDCA as amended by the Food Quality Protection Act); expert opinions related to increased resistance to a particular pesticide; etc. In any particular case, if a registrant has questions concerning whether the Agency considers an expert opinion reportable under section 6(a)(2), the registrant is encouraged to either submit the opinion or contact the 6(a)(2) Officer in the Office of Pesticide Programs.

VIII. EXPOSURE TYPE AND SEVERITY CATEGORIES

The 6(a)(2) regulations define the severity categories assigned to each incident. In an effort to provide additional guidance on the assignment of severity categories, the Agency has expanded the definitions for humans and domestic animals. The severity category definitions for humans were derived from standard definitions used by the American Association of Poison Control Centers. The examples of severity categories for domestic animals were prepared in consultation with the National Animal Poison Control Center/American Society for Prevention of Cruelty to Animals.

In cases where multiple symptoms occur in an individual that result from an exposure incident, the most severe symptom should determine the severity category. For example, if an animal has repeated grand mal seizures, vomiting, diarrhea and salivation, the “major” category (D-B) should be used, since seizures are the most severe symptom.

The persistance of symptoms or the development of delayed symptoms should be considered when classifying severity. For example, human cases may report developing common symptoms like headaches, general weakness, memory and concentration problems, depression, irritability, muscular aches and pains, or shortness of breath. If these symptoms last for just a few days and are minimally troublesome (do not require treatment) then they would be classified as minor (H-D). However, if symptoms persist for one month or longer they would be classified as moderate (H-C). Symptoms persisting for two or more months that significantly alter daily activities would be classified as major (H-B).

If exposure to the pesticide is reported to lead to the development of unusual sensitivity to pesticides, other chemicals, or to odors (sometimes alleged as hypersensitivity or multiple chemical sensitivity), efforts should be made to collect information about specific symptoms such as headaches or shortness of breath. If symptoms persist for two or more months, and significantly alter daily activities then such a case would be classified as major. If symptoms persist for less than two months, the incident would be classified according to the appropriate definition.

H-A - Human Death

§159.814 (5)(i)(A) : "If the person died."

It is reported that the person died as a result of exposure or as a direct complication of exposure to the pesticide.

H-B - Human - Major

§159.184 (5)(i)(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 reproductive 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 or 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.

H-C - Human Moderate

159.184 (5)(i)(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 additonal 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.

H-D - Human Minor

159.184 (5)(i)(D): "If the person alleged or exhibited some symptoms, but they were minimally traumatic. The symptoms resolved rapidly and usually involved 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.

H-E - Symptoms Unknown, Unspecified or May Appear in Future

159.184 (5)(i)(E): "If symptoms are unknown, unspecified or are alleged to be of a delayed or chronic nature that may appear in the future."

A person reporting an incident to a registrant may report exposure and allege an adverse effect. Specific symptoms, however, may be unknown or unspecified. If exposure is reported, no acute adverse effect is alleged, but the reporter informs the registrant they may suffer delayed or chronic effects, the incident is reportable as H-E.

Although not required by the regulation, the agency would be interested in documented cases of measured exposure that do not result in symptoms. If a documented exposure occurred and, based on other available evidence, was likely to lead to an adverse effect, then a report would be filed under this category. This category can be used for reporting evidence that known exposures have not resulted in symptoms. This information is useful in establishing a No Observed Effect Level for the pesticide. Additionally, the reporting of exposures which do not lead to adverse effects provides a measure of a product's safety.

The category could be used when a major contamination has occurred that could foreseeably lead to an adverse effect. An example is the application inside a home of a highly

toxic organophosphate such as methyl parathion. It would be useful to report such incidents to the Agency to ensure that proper enforcement action is taken to prevent mis-use in the future.

D-A - Domestic Animal Death

159.184 (5)(ii)(A): "If the domestic animal died or was euthanized."

It was reported that the animal died or was euthanized as a result of exposure or as a direct complication of exposure to the pesticide.

D-B - Domestic Animal Major

§159.184 (5)(ii)(B): "If the domestic animal exhibited or was alleged to have exhibited symptoms which may have been life-threatening or resulted in residual disability."

Life-threatening effects include, but are not limited to, massive or internal hemorrhage, loss of consciousness, grand mal seizures, paralysis, cardio-respiratory depression and bronchoconstriction requiring immediate treatment. In general, life-threatening effects are any condition which, if untreated, would likely lead to death. Residual disability includes adverse effects which last for an extended period of time after the initial poisoning and may affect the life span for the animal. An example of an adverse effect which may last for an extended period of time is the case of a cat that developed severe weakness lasting for weeks to months after organophosphate exposure. An example of a residual disability that may affect the life span of an animal is the case of a dog which recovered from cholecalciferol rodenticide ingestion but is left with decreased renal function.

D-C - Domestic Animal Moderate

§159.184 (5)(ii)(C): "If the domestic animal exhibited or was alleged to have exhibited symptoms which are more pronounced, more prolonged or 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."

Effects include, but are not limited to, corneal abrasion, difficulty breathing, hyperthermia, isolated focal seizures, gastrointestinal symptoms leading to dehydration, caustic injury to mouth or esophagus, severe muscle weakness, incoordination, tremors and hives. More prolonged effects are those that last one month or longer, such as a persistent skin rash.

D-D - Domestic Animal Minor

§159.184 (5)(ii)(D): "If the domestic animal was alleged to have exhibited symptoms, but they were minimally bothersome. The symptoms resolved rapidly and usually involved skin, eye or respiratory irritation."

Effects include, but are not limited to, excessive salivation, skin rash, itching, conjunctivitis, lethargy, transient cough, mild gastrointestinal symptoms of a short duration and minor behavioral changes such as agitation and hyperactivity.

D-E - Symptoms Unknown, Unspecified or May Appear in Future

§159.184 (5)(ii)(E): "If symptoms are unknown or not specified."

If a documented exposure occurred and, based on other available evidence, was likely to lead to an adverse effect, then a report would be filed under this category. This category can be used for reporting evidence that known exposures have not resulted in symptoms. This information is useful in establishing a No Observed Effect Level for the pesticide in different species of animals. Additionally, the reporting of exposures which do not lead to adverse effects provides a measure of a product's safety.

IX. EXTRATERRITORIAL ADVERSE EFFECT INFORMATION

Information derived from studies or incidents occurring outside the United States is reportable if the information is relevant to a pesticide registration held by the registrant possessing the information and if the information is otherwise reportable under section 6(a)(2). In any particular case, the reportability of a study or incident may be affected by the differences, if any, between the formulation of product involved in the foreign information and the formulation of products registered in the United States, as well as other study or incident conditions which may or may not be relevant to conditions in the United States (soil type, crop sites, directions and conditions of use). All submissions to EPA must be in English; untranslated foreign language documents will not be accepted.

Until the Agency gains greater experience in determining what otherwise reportable information associated with studies or incidents occurring outside the United States is not helpful in making regulatory decisions concerning pesticides registered in this country, the Agency will consider all such information to be reportable unless an expert concludes that differences between the formulation of product involved in the foreign information and product registered in the United States make the information irrelevant to the product registered in the United States. In any particular case, a registrant can inquire from the 6(a)(2) Officer whether particular information should be reported. After the Agency has gained more experience evaluating information associated with foreign studies or incidents, the Agency may revise this guidance.

X. INFORMATION INVOLVING CHEMICALS SIMILAR TO REGISTERED CHEMICALS

Information involving a chemical different from any contained in a registrant's registered pesticides is nonetheless reportable by that registrant if the registrant knows or should know that the information is relevant to the registered pesticide and is otherwise reportable under section 6(a)(2). Examples of types of information that a registrant should know are relevant to its registered product include, but are not limited to, a study of a chemical in the same class as the registered pesticide where the study suggests (or the registrant knows that an expert concludes) that it applies to all chemicals in the class; certain toxicity information relating to a chemical which the Agency or an expert has concluded shares a common mechanism of toxicity with the registrant's registered pesticide; etc. In any particular case, the determining factor is likely to be the nature of the information available to the registrant suggesting that the otherwise reportable information is relevant to the registrant's registered product.

XI. IMPLEMENTING RULE BEFORE THE EFFECTIVE DATE

Although the regulations were published in the Federal Register on September 19, 1997, they do not become effective until June 16, 1998. Some registrants may wish to implement some or all of the rule before its effective date. Registrants should contact the Agency in writing and specify the portions of the rule they would like to implement before the effective date. Such a request should not be considered granted unless and until granted in writing by a responsible Agency official. As a general matter, the Agency expects to be in a position to grant such requests expeditiously and certainly does not want to discourage any registrant from implementing the new rule before its effective date.

XII. MINIMUM INFORMATION REPORTABLE

The regulations specify minimum information that must be available in order to make the incident reportable. Those information elements are: an exposure may have occurred; an adverse effect has occurred or a delayed or chronic adverse effect may occur in the future; the pesticide can be identified (product name, product registration number, or active ingredient); the location where the incident occurred; and a person to contact for more information about the incident. It should be noted that reportable information may arise from newspaper articles.

Identification of the pesticide is critical to the Agency’s ability to take regulatory action to address risk. If the person reporting an incident does not provide sufficient information for the registrant to be able either to identify the product involved by name and/or registration number, or to identify the active ingredient used in the product, the incident is not reportable.

It should be noted that an active ingredient can be identified even though a specific product can not be identified. The active ingredient can be identified through analyzing water or an animal carcass, or through the general knowledge of the user. For example, someone may report that he knows he put diazinon on the lawn, but threw away the packaging so he cannot report the name of the product.

In other cases, the person reporting the incident to the registrant reports the name of a product, but does not know the product registration number. Often, the registrant can determine the product in question because the registrant sells only one product by that name. Alternatively, the registrant can at least identify the active ingredient because all products using that name contain the same active ingredient. In other cases, however, the reported product 'name' is so general that a specific product or active ingredient cannot be identified. For example, the reporter says he used an Ortho product in the garden and experienced nausea and dizziness. The Ortho product line includes many different products containing many different active ingredients. In this example, the incident would not be reportable.

XIII. PLANT DAMAGE INCIDENT EXEMPTIONS

The regulations exempt registrants from reporting certain incidents of plant damage and registrants have asked EPA to clarify those exemptions. These exemptions are related to pesticide product labels, which can include warnings of possible damage to plants related to use. The warning may apply to the treated crop as well as non-target plants.

The label may warn that the treated crop could be damaged if the product is not used according to the label instructions. The misdirected application of a broad-spectrum herbicide such as glyphosate or paraquat can result in damage to the treated crop. For example, an apple orchard may be sprayed to control weeds beneath the trees. If the spray is misdirected and is taken up by the apple trees, the pesticide can cause damage, such as reduced yield. Since the label warns of that risk, however, that incident would not be reportable. The regulations exempt reporting of non-lethal damage to the treated crop if the label warns of that effect. However, if non-lethal damage to the treated crop occurs and there is no label warning, that incident would be reportable. It may indicate the need to require an additional label warning. If there is <u>lethal</u> damage to the treated crop -- with or without a label warning-- the incident is reportable.

Labels may also warn of the possibility of damage to non-target plants at the use site. For example, 2,4-D may be applied to wheat, but in addition to killing the weeds (pests) listed on the label, it kills volunteer corn or sorghum present in the wheat field. Corn and sorghum are neither the listed pests nor the treated crop. But if the label warns of this possibility, the incident is not reportable.

If, however, a pesticide moves by way of primary drift, secondary surface runoff, or secondary aerial movement from the treatment site to untreated areas and plant injury occurs, the

plant injury is reportable to the Agency. Primary spray drift is the off-target movement of pesticide spray from the treatment site to untreated areas at the time of pesticide application. Secondary surface runoff is pesticide movement in surface water or sediment from the treatment site to untreated sites days, weeks, or months after the initial pesticide application. Secondary aerial movement is the off-target movement of a pesticide via volatilization, co-distillation, evapo-transpiration, and/or wind blown soil particles from the treatment site days, week, or months after the initial pesticide application. Some environmental and climatic factors that may affect pesticide movement off-target include wind, temperature and temperature inversions, humidity, and irrigation/rainfall patterns, in addition to soil-related factors such as soil type, soil slope, and soil conservation. These variable conditions cannot be fully anticipated at the time of registration. Examples of reportable incidents may be injury to crops that are irrigated with groundwater that is contaminated with a persistent herbicide or injury to plants following a rainfall. Receiving incident reports of plant damage is essential to refining use directions in order to prevent damage in the future.

XIV. PREVIOUSLY-SUBMITTED INFORMATION

If a registrant knows that adverse effects information concerning their registered product has already been submitted to the Agency by another party in a timely manner, it does not have to report the information. The burden is on the registrant, however, to ensure that the information was, indeed, submitted by another party.

A related issue is the submission of additional information about a specific 6(a)(2) submission provided to the Agency at an earlier time. Registrants are obligated to submit additional information as a follow-up to previously submitted data or incident reports. In the case of incident reports, the following types of information should be submitted:

- any of the required information specified in the regulations about a human death;
- the identification of the pesticide, circumstance information, or a laboratory report for major human incidents (H-B) or fatalities of wildlife (W-A) (*Note*: Since fatalities of domestic animals are aggregated and reported statistically, the registrant may hold the additional information until the Agency requests it be submitted.);
- any information that would result in re-categorizing the incident into any of the following: human death (H-A), human major (H-B), domestic animal death (D-A) or the "A" level (the most serious category) for any other exposure or incident type (fish or wildlife, plants, water contamination, or property damage).

This additional information should be provided by the registrant making the initial report if that registrant obtains the information. If another party made the initial submission, but a

registrant obtains the additional information about their product, the registrant is obligated to submit the information to the agency.

XV. REPORTABLE INJURIES AND PROPERTY DAMAGE

Some incidents appear to be unrelated to the pesticidal characteristics of the product. For example, an incident in which someone's leg is broken as a result of a pesticide container falling off a forklift would not be reportable. On the other hand, if a pesticide container explodes, lacerates someone's face, but no poisoning symptoms occur, the incident would be reportable. The adverse effect was due to factors related to the chemistry or characteristics of the pesticide product. Odor complaints need not be reported if the only complaint is the offensive nature of the odor. On the other hand, if someone reports that a product has a bad odor and that the odor made the person nauseous and gave them a headache, the incident is reportable. The registrant cannot be sure that the nausea and headache are not poisoning effects.

Regarding property damage, §159.184(a) does limit reporting of incidents to situations in which a person or non target organism suffered a toxic or adverse effect or may suffer a delayed or chronic adverse effect in the future. The Agency takes the position, however, that an incident that results in property damage that could have caused direct human injury, such as fire or explosion, or an incident that requires substantial clean-up or renders a structure uninhabitable, would be reportable under §159.195. Under §159.195, information is reportable if it raises concerns about the continued registration of a product or about the appropriate terms and conditions of registration of a product. For example, an acutely toxic pesticide is stored in a house and the product leaks from the container as a result of faulty packaging. The house is so contaminated with the pesticide that the people living in the house are evacuated and the property is condemned. That incident would be reportable under §159.195.

XVI. RESPONSIBILITIES OF NON-PESTICIDE DIVISION EMPLOYEES

The definition of "registrant" provides a two part test for excluding an employee of a registrant from an obligation to report adverse effects information. An employee who is not expected to perform any activities related to the development, testing, sale, or registration of a pesticide (as defined in the rule) and who could not reasonably be expected to come into possession of information that is otherwise reportable is not obligated to report that information. Conversely, persons who could reasonably be expected to come into possession of information on the toxicity of chemicals, even if they work outside the area of pesticides, should be informed of their obligation to report the information under FIFRA 6(a)(2), as well as their obligation to report information under section 8(e) of the Toxic Substances Control Act (TSCA) as described in Part 2 of the March 16, 1978 Policy Statement (43 FR 11111).

XVII. SUBMISSION DUE DATE

§159.156 of the rule specifies the time frames for submitting reportable information. The rule provides that the submission may either be mailed by certified or registered mail, be delivered in person or by courier service, or delivered by such other methods as the Agency deems appropriate. Registrants should note that the EPA Office of Pesticide Programs considers the date a document is pin-punched as the official document receipt date. In the case of a document delivered to OPP by courier, the pin-punch date is the same date the document was received in EPA. However, in the case of a document delivered by the U.S. Postal Service by certified or registered mail, there is usually a time lag of at least two working days between the date the a submission is received in the general EPA mail center and the date it is delivered to OPP and pin-punched. Therefore, registrants should take this time lag into account, in addition to the USPS delivery lag time, when opting to send 6(a)(2) reporting documents via the U.S. Postal Service so that the document can be pin-punched by OPP within specified reporting timeframes. It should be noted that certified mail green cards or registered or certified mail receipt logs indicate only that a package from some party was received -- it is not proof of the contents of the package. The best documentation of receipt of 6(a)(2) submissions is the pin-punched document itself.

XVIII. TECHNICAL CORRECTIONS TO THE REGULATIONS

The Agency plans to publish technical corrections to the regulations in the Federal Register. The corrections will address errors in the regulations published on September 19, 1997. As such they are not subject to notice and comment. The corrections will be of four types:

A) Reporting Time Frame Corrections

Most of the corrections ensure that time frames for submitting all types of adverse effects information are clearly established. In the Proposed Rule the time frame for reporting all information was 30 days. In response to comments the Agency decided to allow for different reporting schedules for different types of information. As a result, however, the final regulations erroneously failed to establish time frames for the submission of certain types of information. The time frame technical corrections will specify that:

- The following types of information must be received by EPA no later than the 30th calendar day after the registrant first possesses or knows of the information: pesticides in food or feed above the tolerance level or if no tolerance has been established; pesticides in water above the MCL or HAL; metabolites, degradates, contaminants, and impurities; efficacy failure studies for public health products; substantiated incidents of pest resistance; and other information described in §159.195.

- 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.

In the discussion of §159.178 - Information about Pesticides in Food, Feed or Water, the preamble to the final regulations states that information about detections of pesticides in water below the MCL or HAL but otherwise reportable must be aggregated into quarterly statistical summaries as described in §159.184(d)(3) and (e). Corrections will be made to the regulations to specify that detections of pesticides in water described in §159.178(b) below the MCL or HAL, but otherwise reportable may be accumulated for 3 months and submitted by the end of the second month following the accumulation period.

B) Required Information about Pesticide Detections in Food, Feed or Water

Other technical corrections ensure that useful information is submitted to the Agency. Although these information items are implied, the technical corrections will specify that:

- Required information about detections of pesticides in food, feed, or water described in §159.178 will be that specified in the list of reportable information required for incidents (§159.184(c)) - administrative, pesticide, circumstance, and appropriate incident specific information. For detections in food or feed, the appropriate incident specific information would be sample type, sampling times/frequency, pesticides analyzed for, amount found, detection limits, and method of analysis. For detections of pesticides in surface water, the required information would be the incident-specific list for surface water (§159.184(c)(4)(iv)). For detections of pesticides in ground water, the required information would be the incident specific list for ground water (§159.184(c)(4)(v)).

- Required information about detections of pesticides in food, feed, or water will include the amount of pesticide detected. This will be added to §159.184(c)(4)(iv) and (v).

C) Corrections of Typographical and Cross Referencing Errors

Other technical corrections to the regulations will include corrections of typographical errors and minor cross referencing errors.

D) Definition of Registrant

The definition of registrant in §159.153 will be changed to comport with the statutory definition of registrant. Other language in the current definition will be moved to 159.155(b).

XIX. VOLUNTARY INCIDENT REPORTING FORMS

As a service to its members, the Chemical Producers and Distributors Association

(CPDA) has formed a work group to design standardized forms for capturing and submitting individual incident reports and aggregate reports. OPP staff are participating in this effort. The individual incident form is designed to capture the basic information about the incident in order to determine if it is reportable (exposure, adverse effect, contact person, pesticide identification, and where it occurred). In addition, it will foster the process by which registrants categorize each incident by exposure type and severity category and determine how much information is to be reported and when to submit the reports. An aggregate report format is also being designed. Detailed instructions accompany both forms. This will support aggregate reporting of appropriate categories of exposure types and severity as specified in the regulations. Use of the form will be voluntary. The form will be distributed to interested parties by CPDA.

The Agency is committed to electronic submission of incident reports but not at the present time. Both the regulated community and the Agency need to gain experience in implementation of the new regulations and meeting the data management challenges they present. For example, the voluntary form may well need fine-tuning over time. In addition, OPP is working on other electronic submission efforts to gain valuable experience that can be applied to electronic reporting of incidents, as well as other types of information. OPP will work closely with registrants before embarking on electronic submission efforts.