ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 159

[OPP–60010H; FRL–5739–1

RIN 2070–AB50

Reporting Requirements For Risk/ Benefit Information

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final Rule.

SUMMARY: This final rule codifies 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. The purpose of the rule is to clarify what 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 are expanded, and others reflect increased flexibility or exemptions for reporting specific types of information. When effective, this rule will supersede all previous policy statements pertaining to section 6(a)(2).
EFFECTIVE DATE: This rule will become effective June 16, 1998.
FOR FURTHER INFORMATION CONTACT: By mail: James V. Roelofs, Office of Pesticide Programs (7506C), U.S. Environmental Protection Agency, 401 M St., SW.,, Washington, DC 20460. Office location, telephone number and e-mail address: Crystal Mall #2, Rm. 1113, 1921 Jefferson Davis Highway, Arlington, VA, (703) 308–2964, e-mail: roelofs.jim@epamail.epa.gov.
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This **Federal Register** document discusses the background of this final rule concerning the reporting of adverse effects information by pesticide registrants. It also addresses, in general terms, the main public comments on the provisions of the proposed rule published in the **Federal Register** of September 24, 1992 (57 FR 44290). In addition, on August 12, 1996, the Agency opened a comment period to receive comments on the burdens that would be imposed by the provisions of a draft final version of the rule (61 FR 41764)(FRL–5388–1). A draft version of the rule dated June 14, 1996 was made available to the public on request at that time. The comment period was subsequently extended twice, on September 20, 1996 (61 FR 49427)(FRL–5396–1) and October 25, 1996 (61 FR 55259)(FRL–5640–7). This preamble provides EPA's final determination with respect to the provisions of the final rule, and provides information on the applicable statutory and regulatory review requirements. A more detailed section-by-section discussion of the public comments on the proposed rule, the related Information Collection Request (ICR), and the Agency's response thereto can be found in the public docket.

This document is organized into 3 units. Unit I provides background on the relevant statutory provisions and the regulatory history of adverse effects reporting. Unit II contains a discussion of the final rule and EPA's response to the major comments submitted on the proposed rule. Unit III discusses compliance with the rulemaking requirements contained in FIFRA and other statutes and executive orders, followed by the regulatory text.

I. Background

A. The Statute

Section 6(a)(2) of FIFRA requires that, ''[i]f at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator.'' Section 6(a)(2) provides an important function by assuring that a previous Agency decision to register a pesticide remains a correct one, and that a registered pesticide can in fact be used without posing unreasonable adverse effects to human health and the environment. Other provisions of FIFRA allow the Agency to require pesticide registrants to develop and submit information the Agency believes it needs in order to evaluate the risks and benefits of pesticide products. Section 6(a)(2), however, provides that registrants must also inform the Agency of certain relevant information relating to their products, even though it was not specifically requested by EPA. It recognizes that registrants may come into the possession of important information that was not anticipated by the Agency, and that without the submission of such information by registrants, EPA would remain without it. Information reportable under this provision includes not only new information derived from scientific studies, but also reports of incidents of adverse effects resulting from the use of pesticide products. Thus, section 6(a)(2) serves to provide an important ongoing check on the correctness of the original decision to register a pesticide.

As a general matter, pesticides may not be sold or distributed in the United States unless they are registered with the EPA (FIFRA section 3(a)). In order to obtain a pesticide registration, an applicant must provide EPA with data (or cite existing data) demonstrating that the proposed registration complies with the requirements for registration (FIFRA section 3(c)(1)(F)). The standard for determining whether an application should be granted is found in FIFRA section 3(c)(5), which provides that in order to grant a registration, EPA must find that a product's composition warrants the proposed claims for it; that the product's labeling and other material required to be submitted comply with FIFRA; that the product will perform its intended function without causing unreasonable adverse effects on the environment; and that, when used in accordance with widespread and commonly recognized practice, the product will not cause unreasonable adverse effects on the environment. FIFRA defines unreasonable adverse effects on the environment as ''any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.'' Thus, a critical aspect of determining whether or not a pesticide should be granted a registration is an evaluation of whether the benefits associated with the use of a pesticide exceed the risks associated with such use.

The burden of demonstrating that a product meets the standards for registration rests at all times on the registrant or applicant for registration. See, e.g., *Industrial Union Dept.* v. *American Petroleum Institute*, 448 U.S. 607, 653 n. 61 (1980); *Environmental Defense Fund* v. *EPA*, 510 F.2d 1292, 1297, 1302 (D.C. Cir. 1975). Section 6(a)(2) only imposes a reporting burden on persons who have registered

pesticides, and only requires reporting of information if that information is: (1) Additional; (2) factual; and (3) regards unreasonable adverse effects on the environment of the pesticide. These three factors were discussed extensively in the comments submitted on the proposed rule.

B. Previous Regulatory Interpretations of Section 6(a)(2)

1. *1978 interpretive statement.* On August 23, 1978, EPA published in the **Federal Register** (43 FR 37611) its interpretation of the requirements imposed by section 6(a)(2). In that interpretive statement, EPA focused on the meaning of two of the three factors pertaining to whether information is reportable: what information is ''regarding'' unreasonable adverse effects on the environment, and what information can be said to be ''factual.'' EPA went on to make clear that it believed information must be submitted under section 6(a)(2) if a registrant possesses the information, the information pertains to a pesticide for which the registrant holds a registration, and ''the information, if true, would be relevant to an Agency decision regarding the risks and benefits of the pesticide, i.e., an Agency decision regarding the registrability of the pesticide or regarding the proper terms and conditions of the registration of the pesticide.'' The statement went on to say that reportable information need only ''pertain or relate to unreasonable adverse effects on the environment; it does not have to indicate, establish, or prove the existence of such effects.'' EPA made clear in the statement that a registrant need not determine that the information would result in a change in the terms and conditions of registration in order for information to be reportable, because the ultimate determination on such registration issues rests with EPA. If the information would be relevant to the Agency's decision-making on whether a pesticide should remain registered and, if so, under what terms and conditions, the information ''regarded'' unreasonable adverse effects on the environment.

In terms of the definition of ''factual,'' the Agency explained that there was no clear demonstration of congressional intent concerning the scope of the information, and that the Agency would therefore interpret the term based upon the function of section 6(a)(2) in the context of FIFRA's regulatory scheme. Since EPA routinely relies on expert opinion in order to make regulatory decisions, and since ''Congress recognized that protection of the health of the public and the environment cannot wait until evidence of unreasonable adverse effects becomes conclusive or universally accepted,'' EPA determined that ''factual'' information should be interpreted broadly to include opinions if the opinions were not ''the unsolicited opinions of persons who are not employed or retained by the registrant to express the opinion and whose opinions would not be admissible under the Federal Rules of Evidence as 'expert' opinion'' (*Id*. at 37613).

2. *1979 policy statement.* On July 12, 1979, EPA published in the **Federal Register** (44 FR 40716) a Statement of Enforcement Policy regarding registrants' obligations under section 6(a)(2). That statement did not curb the scope of section 6(a)(2) as enunciated in the 1978 interpretive statement, but instead indicated that certain information arguably pertinent to the evaluation of the risks and benefits of a pesticide ''are not currently needed by EPA in order to properly discharge its statutory responsibilities under FIFRA and thus need not be submitted by registrants.'' The Policy statement notified registrants of the types of information for which a registrant's failure to report might precipitate enforcement action by EPA. In other words, the policy statement announced as a matter of enforcement discretion that certain types of information need not be submitted by registrants notwithstanding the fact that the information fell within the scope of section 6(a)(2). EPA indicated that it would honor the exemptions from reporting contained in the policy statement until at least 30 days after a modification or revocation of the policy statement was published in the **Federal Register**. This final rule constitutes a revocation of that policy statement; the 1979 Policy Statement will cease to be Agency policy on June 16, 1998.

3. *1985 interpretive rule.* On September 20, 1985, EPA published in the **Federal Register** (50 FR 38115) a Final Interpretive Rule and Statement of Policy concerning reporting obligations under section 6(a)(2). The rule identified those types of information covered by section 6(a)(2) for which enforcement action would be brought if material were not submitted to the Agency, and exempted the reporting of other information covered by the statutory provision. It is not clear whether the Interpretive Rule ever became effective. The **Federal Register** Notice provided that EPA would publish in the **Federal Register** a notice announcing the effective date of the rule, but no subsequent notice was ever published. In light of the issuance of this new Final Rule, the issue of whether the 1985 Rule ever became effective need not be resolved.

4. *The 1992 proposed rule.* On September 24, 1992, the Agency published in the **Federal Register** (57 FR 44290) a proposed rule relating to the submission of information pursuant to section 6(a)(2). The preamble to that rule discussed in detail the Agency's interpretation of section 6(a)(2) and the rationale for the provisions of the proposed rule. Many of those provisions have not changed significantly in this final rule. The Agency continues to endorse the substance of the preamble to the proposed rule. EPA has not always repeated in this preamble material addressed in the proposed rule; the discussion in that preamble should be consulted by anyone seeking additional background on the decisions reflected in this final rule. Throughout this preamble the term ''proposed rule'' refers to the 1992 document.

5. *The 1996 draft final rule.* On August 12, 1996 the Agency opened a comment period to allow interested parties to comment on the Information Collection Request (ICR) and the potential burden that the provisions of the Agency's draft final rule would impose on registrants. The Agency made available a draft final version of the rule which reflected changes the Agency had made from the proposed rule on the basis of comments received and its own experience with section 6(a)(2) information during the years since the proposed rule was published. The Agency received numerous written comments on the provisions of the ICR and the draft final rule, and also received oral comments from interested parties at two meetings held during the comment period. All comments received, as well as memoranda describing the meetings, and memoranda describing the Agency's response to comments are included in the public docket for this rule. The main issues which were raised and addressed by the Agency as a result of comments on the 1996 draft final rule are described in this preamble. Throughout this preamble, the term ''1996 draft'' refers to the draft version of the rule dated June 14, 1996, which was made available to the public on request through the **Federal Register** announcement of August 12, 1996.

C. Current Interpretation of Section 6(a)(2)

In assessing the proper scope of section 6(a)(2), it is necessary to focus on the potential regulatory actions that the Agency can take under FIFRA in its continuing evaluation of whether a

pesticide poses unreasonable adverse effects on the environment. The potential cancellation or suspension of a registration pursuant to section 6 is the most restrictive action EPA can take against a pesticide registration, and these were the regulatory activities most discussed by commenters on the proposed rule. While reportable information under section 6(a)(2) could conceivably result in cancellation or suspension action, this information could also be used by the Agency in other ways. The information could suggest the need for modifications to the terms and conditions of registration which could be necessitated by the balancing of the risks and benefits associated with a particular pesticide. It could also identify information gaps that could result in the request for additional information from registrants pursuant to section 3(c)(2)(B). Finally, it could identify to the Agency pesticides and issues that require closer examination by the Agency.

The Agency thus takes a very broad view of the statutory scope of section 6(a)(2). Although EPA interprets the section as requiring the submission of potentially large amounts of information, the Agency is also sensitive to the burden this could put on both registrants and Agency reviewers. Accordingly, this final rule identifies the material that the Agency considers relevant to determining whether a registered pesticide continues to meet the standards of registration and wants to be submitted under section 6(a)(2), and essentially exempts from the reporting requirements information not covered by the Rule.

This final rule establishes requirements on what information must be reported, when and how the information must be submitted to the Agency, and who has reporting obligations. The nature of the information that must be reported was the principal focus of most of the comments and takes up the bulk of the final rule. Most of this portion of the rule is considered by the Agency to be interpretive in nature and similar to the policy statements issued on section 6(a)(2) in the past. The primary sources of information covered by the rule are scientific studies, reports of incidents involving pesticides, and certain opinions, but other information could also be included if relevant to the risk/benefit balancing involved in the determination of whether a pesticide causes unreasonable adverse effects on the environment.

A number of general comments argued the need for registrants to investigate and verify the validity of information before reporting. The Agency manifestly did not design this final rule to cover only information certified to be valid. Especially in the area of incident reporting, the Agency recognizes and accepts that many reports may prove not to be valid. Registrants are not obligated to investigate, analyze, or verify incidents before reporting to the Agency, and EPA accepts that a reporting registrant may well disagree with either the significance or validity of incident reports. Registrants are free to submit information challenging the validity of section 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 promptly. Failure to submit information because of the incompleteness of ongoing investigations will be considered a violation of both this final rule and of FIFRA.

Finally, EPA wants to serve notice that failure to comply with the requirements of section 6(a)(2), as reflected in this final rule, will be considered a violation of FIFRA sections 12(a)(2)(B)(ii) and 12(a)(2)(N), and could result in actions for civil and/or criminal penalties under FIFRA section 14. Failure to comply with these requirements may also constitute grounds for cancellation under FIFRA section 6 of some or all of a registrant's pesticide registrations, both because such failure means that ''material required to be submitted does not comply with the provisions of [FIFRA]'' and because the Agency may conclude that the registrant has failed to carry its burden of demonstrating that the use of its pesticides do not pose unreasonable adverse effects on the environment. EPA does not intend to pursue cancellation every time section 6(a)(2) may have been violated, but egregious or repeated violations may warrant cancellation rather than, or in addition to, monetary fines.

II. Section-By-Section Discussion

Comments were received on virtually every provision of the 1992 proposed rule, and on the 1996 draft version. As noted earlier, the Agency's detailed response to the comments are contained in documents available in the public docket for this rule. The discussion in this unit is limited to pointing out significant changes to the provisions of the 1992 proposed and 1996 draft rules, or to responding to comments that are, in the Agency's judgment, particularly important to clarify.

A. Section 159.153— Definitions

This section provides a number of definitions applicable to the final rule. Three definitions in particular were subject to a number of comments. Each is addressed in turn.

Pesticide. The definition of pesticide in the proposed rule included ''each active ingredient, inert ingredient, impurity, metabolite, or degradate contained in, or derived from, a pesticide product which is or was registered.'' The 1996 draft added the word ''contaminant'' to this definition. A number of commenters argued that this definition is excessively broad, impractical, and in violation of FIFRA (which defines the term pesticide more narrowly). The Agency has considered the comments, and determined to retain the definition of ''pesticide'' contained in the 1996 draft.

The focus of the statutory definition of ''pesticide'' is to define what products must be registered. The definition is one of intent— essentially any product must be registered if it claims to control pests. This is distinctly different from the question of what information about those products has to be submitted to EPA in order to make the risk and benefit determinations required to establish or maintain registrations. So long as the use of the pesticide results in an adverse effect, it is irrelevant for purposes of whether the information must be submitted whether the effect isactually caused by an active ingredient, an inert ingredient, or a metabolite, degradate, impurity, or contaminant. In short, neither the statutory definition of ''pesticide,'' nor the statutory definition of ''unreasonable adverse effects'' makes any reference to the constituent parts of a pesticide product. It is clearly the intent of the statute that the Agency judge whether the use of the product as a whole poses unreasonable adverse effects, regardless of what constituent part of the product may cause such effects. In practice, a number of pesticide risk assessments have been based in whole or in part on the risks posed by contaminants and impurities, such as dioxins in certain herbicides, or metabolites such as ethylene thiourea (ETU) in the EBDC fungicides. Moreover, a significant number of tolerances (maximum legal residue levels for pesticides on food or feed commodities) include metabolites as part of the tolerance expression established by regulation.

Thus, the Agency does not believe it can be seriously argued that adverse information about the inert ingredients, metabolites or contaminants in a

pesticide product is outside the statutory scope of what must be reported under section 6(a)(2), or that it is inconsistent in any way with the statutory definition of a pesticide. Moreover, this interpretation is consistent with section 10(d) of FIFRA, which clearly contemplates that the Agency may require registrants to submit, for the purpose of registering pesticide products, information on a product's ''separate ingredients, impurities, or degradation products'' as well as information on the product itself.

EPA recognizes that this definition of pesticide may pose a problem for registrants who do not know the identity of inert ingredients in their products, or for large organizations where the applicability of inert ingredients, metabolites, or degradates to particular pesticide products may not be appreciated by those individuals who obtain adverse information concerning an inert, metabolite, or degradate. In any particular enforcement action that might arise under section 6(a)(2), EPA will consider these factors, as well as the steps a registrant has taken to assure that adverse effects information on both pesticide products and particular chemicals or metabolites is referred to the appropriate personnel in the company.

Registrant. The definition of ''registrant'' in the proposed rule included any person who ''holds or ever held'' a pesticide registration. A number of commenters have challenged the authority of the Agency to apply the requirements of section 6(a)(2) to persons that held, but no longer hold, pesticide registrations. Some commenters argued that former registrants should be excused from reporting obligations after a set period of time (e.g., 3 or 5 years). Other commenters suggested that EPA extend the definition to include persons given emergency exemptions pursuant to section 18 of FIFRA.

EPA has changed the definition of ''registrant'' from both the proposed rule and the 1996 draft to clarify that the definition includes agents acting for a registrant, but does not include persons who could not reasonably be expected to receive reportable information. The Agency did not change the definition insofar as it applies to former registrants, although certain exemptions have now been established to limit the time period of reporting requirements on former registrants, along the lines suggested by various commenters (see further discussion of § 150.160 in Unit G of this preamble.). EPA explained in the preamble to the proposed rule its belief that section 6(a)(2) could be interpreted to put a continuing burden on registrants after a product registration is canceled or transferred. In the case of a transferred registration, for example, the pesticide product may continue to be widely used. Even in the case of canceled products, existing stocks may continue to be sold or used for a long period of time. Thus, the Agency's responsibilities with respect to whether sale or use of a pesticide should be permitted and, if so, under what conditions, do not necessarily end when a registration is sold or canceled. A former registrant may continue to receive information about its former products from consumer complaints or information about accidents well after a product is canceled or transferred. Since this information can affect continued Agency decision-making with respect to the once-registered product, EPA believes relevant information in the hands of former registrants must be provided to the Agency for a reasonable period of time. In its 1996 draft, EPA did not include a cutoff for reporting by former registrants, but has now decided to accept a cutoff of reporting responsibilities at 5 years after cancellation or transfer of a registration for most information, and shorter requirements under certain circumstances.

In order to minimize the burden on former registrants somewhat, the Agency added a new § 159.160 to the proposed rule, providing that for registrants who have left the pesticide business, i.e., hold no active pesticide product registrations, adverse information associated with their formerly held registrations need only be reported for 1 year after they cease to hold any active registration. Similarly, for a person who continues to hold active pesticide registrations, and may therefore be likely to continue to receive adverse information even about formerly registered products, this rule provides that information need not be reported if it is associated only with inert ingredients, contaminants, impurities, metabolites, or degradates contained in formerly registered products and is obtained more than 1 year after the registrant first ceases to hold the registration. Former registrants will still be required to report adverse information involving the formerly-registered pesticide product itself, as well as information involving any of the active ingredients contained in the formerly-registered product, for up to 5 years. If all registrations containing the active ingredient have been canceled, no reports need to be made concerning products containing the ingredient 3 years after the last registration containing the ingredient was canceled.

Finally, the Agency has added two new provisions to this section that were not contained in the proposed rule or the 1996 draft. One of these new provisions (§ 159.160(b)(4)) is necessary to accommodate the 1996 amendments to FIFRA under the Food Quality Protection Act (Pub. L. 104–170) which removed liquid chemical sterilants from the FIFRA statutory definition of ''pesticide.'' These products are no longer regulated under FIFRA, and former registrants of these products have no obligations for reporting information about them to EPA under this part. The second new provision is that information arising from litigation is not subject to the other time limitations of this section, except for products and active ingredients which are wholly canceled or no longer defined as pesticides. EPA is excepting information developed or obtained during the course of litigation from the 5–year cut-off for several reasons. Litigation can produce information that can be helpful to the Agency and that is rarely obtained by EPA, such as testimony of expert witnesses, and in-depth examination of the causes of an incident. A time limit is inappropriate, because litigation-related information may take a long time to surface because of the nature of litigation schedules. Finally, it would not appear to be particularly burdensome to track information developed during the course of litigation, since the information would be coming from limited, discrete sources, and companies presumably are aware of the conduct of litigation to which they are a party.

As to expanding the scope of coverage to holders of exemptions issued pursuant to section 18, the Agency does not believe that such holders are ''registrants'' within the meaning of FIFRA, and they are thus outside the statutory scope of section 6(a)(2). The Agency does have the authority to include adverse information reporting requirements as part of a section 18 exemption, and the Agency already considers this issue as part of its review of requests for such exemptions.

The Agency believes that supplemental distributors operating pursuant to 40 CFR 152.132 are agents acting for a registrant, and are already covered by section 6(a)(2). Failure of a supplemental distributor to report adverse effects information otherwise covered by this Final Rule can result in enforcement action against both the supplemental distributor and the parent

registrant. Regarding agents, the Agency has always considered registrants responsible for the actions of their agents. Clarifying language has been added to the regulatory text to emphasize that registrants will be held liable for the actions of their agents. The new language also makes it clear that for the purposes of reporting under this rule, the Agency considers an agent of the registrant to be a person who is likely to receive information about the effects of pesticides, and who is acting for the registrant at the time the information is received. Such agents could include consultants, contract laboratory researchers, attorneys, investigators, and others. However, the Agency does not consider every direct or indirect employee of a registrant as likely to receive such information. Financial and personnel workers, or even workers in a pesticide manufacturing plant, for example, would not be dealing with pesticide effects information nor would they normally be in contact with product users or other persons who are likely to report pesticide effects information. As a general matter, the issue of whether a retailer or distributor of pesticides is an agent of a registrant will depend upon the nature of the relationship between the retailer/distributor and the registrant. A retailer or distributor that sells a wide variety of pesticide products produced by many different registrants would generally not be considered an agent of any of the registrants. On the other hand, a retailer or distributor that exclusively (or nearly exclusively) distributes or sells a particular registrant's products would generally be considered an agent of that particular registrant.

Water reference level. The water reference level is the level at or above which the Agency wants to be informed of a pesticide's presence in surface water or groundwater. The proposed rule defined water reference level as the limit of detection of a pesticide in water; or alternatively, 10 percent of the Maximum Contaminant Level (MCL) if one has been established by EPA, 10 percent of the most recent draft or final long-term Health Advisory Level (HAL) if there is no MCL, or the lowest detectable amount if there is neither an MCL nor an HAL. Commenters that raised objections to the water reference level argued that the level would result in excessive reporting to the Agency. Commenters suggested that the reference level be set at the MCL or HAL itself rather than at a fraction of the level; the same commenters generally observed that since pesticides for which there is neither an MCL nor an HAL pose less of a concern, the reference level for those should not be set at so low a level as the level of detection.

The terms of this final rule are substantially similar to those of the proposed rule and the 1996 draft. Given the persistence of some pesticides and the sketchy nature of the monitoring of pesticides in surface water and groundwater, the Agency does not believe it appropriate to set the reference level at the MCL or HAL. EPA believes an earlier warning of potential problems with pesticides in water is appropriate and has therefore determined to retain the reference level at 10 percent of the HAL or MCL. The Agency has also decided to retain the level of detection as the reference level for pesticides that have not been assigned an MCL or HAL. EPA believes that, until it has sufficient information about the likelihood of a pesticide making its way into water, it should receive information about detections in water at the earliest possible stage. However, the Agency did modify this provision so that the default requirement to report ''the lowest detectable amount'' when there is no MCL or HAL for a compound does not apply to metabolites, degradates, contaminants or impurities. Detections in water of these components of a pesticide need only be reported when the Agency has identified a specific level of concern in water. Furthermore, this final rule provides that detections below the MCL or HAL do not need to be reported as individual incidents, but are to be reported in aggregated form as described below in relation to incident reporting under § 159.184.

EPA did make one other significant change in the final rule's definition of water reference level. The MCL and HAL levels are based on human toxicity triggers; neither level takes into account the toxicity of pesticides to other life forms. In order to be consistent with other Agency policies related to the protection of water quality, the Agency added to the definition of ''water reference level'' the Ambient Water Quality Criteria for the Protection of Aquatic Life, established under the authority of section 304(a) of the Clean Water Act. If EPA has established such criteria for a specific pesticide, and that level is lower than 10 percent of the MCL or HAL, then the water quality criterion is the reportable reference level. For a compound which is detected in water, the Agency believes the reporting level should be whichever threshold is the most protective of the environment, whether that is the MCL-based trigger derived from estimated toxicity to humans, or water quality criteria derived from estimated risk to aquatic life. Water Quality Criteria documents for over 100 individual compounds, including some pesticides, are published by the Agency and are available from the National Technical Information Service (NTIS) in Springfield, Virginia (telephone 703–487–4650).

B. Section 159.155—When Information Must Be Submitted

The proposed rule and the 1996 draft both required that reportable information be submitted to the Agency within 30 calendar days of the registrant's first becoming aware of the information. A registrant would be considered aware of 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.

In this final rule, the Agency is retaining the requirement that information about studies be reported within 30 days. With regard to information concerning incidents, however, the Agency has agreed with many of the commenters that the time frames for reporting should be differentiated based on the relative severity of the incidents being reported. Accordingly, this final rule has adopted a set of reporting schedules (in § 159.184(d)) based on severity ratings which are consistent with those suggested by many commenters. Specifically, incident information involving human fatalities must be reported within 15 days. Information regarding allegations of serious human illness or fatalities to wildlife, serious plant damage, serious property damage, or water contamination above MCLs or HALs, may be accumulated for 30 days, and reported within 30 days after each accumulation period. All other incident information may be accumulated for 90 days and submitted within 60 days after each accumulation period. The Agency believes that this system will alleviate many of the concerns expressed by commenters that incident information could not be properly characterized or efficiently reported if the 30–day time limit were applied to all individual incidents. This system distinguishes between relatively more serious and relatively less serious incidents in a way that will enable EPA to receive and recognize more quickly information about more serious incidents. In addition, the Agency has decided that for the less serious categories of incidents, individual reports do not

need to be submitted. Instead, the Agency will require aggregated statistical reports— counts of the number and type of incidents, listed by product or active ingredient. This will enable EPA to review possible patterns of incidents and require registrants to submit further detailed information on these incidents only if it seems useful to do so.

Section 159.155(a) also provides that the Agency, with written notification to the registrants, can establish a different reporting period for specific types of reportable information or eliminate the reporting requirement altogether. The Agency believes that this provision will allow the Agency to more easily address those situations where the Agency determines that it does not need all the information otherwise required to be submitted by this rule, or that there is a different approach for a particular situation which can help to reduce the reporting burden on registrants while still providing the Agency with the information it needs. The Agency encourages registrants to continue to forward any ideas on ways to reduce the burden of reporting under section 6(a)(2).

A number of commenters objected to the provision that a registrant would be deemed to possess information if any person acting for or employed by the registrant possesses or knows of the information. Instead, these commenters suggested that it would be more appropriate for the Agency to retain the standard contained in the 1985 Interpretive Rule, which provided that a registrant possesses or knows of information only when the information is possessed or known of by a person acting for or employed by the registrant who is ''capable of appreciating the significance of such information.''

The Agency does not agree with these comments and has retained the requirement as proposed, except for adding language to emphasize that an employee or agent must be ''likely to receive'' reportable information, and that they must be acting for the registrant at the time they receive it. The Agency is concerned that the ''capable of appreciating'' standard would lead to disputes over whether a particular individual is or is not capable of appreciating the significance of information in any particular instance. A registrant should take steps to assure that the results of studies performed by the registrant or at the registrant's request are reported promptly to someone responsible for assuring compliance with section 6(a)(2). Similarly, EPA believes that most registrants probably already have particular individuals designated to receive and/or respond to consumer complaints. The Agency does not believe it is unfair to place upon registrants the burden of assuring that such complaints are routed to people who understand the reporting requirements of section 6(a)(2).

The Agency recognizes that even when a registrant has established a reasonable system for tracking reportable information, information may nonetheless be received by individuals working for that registrant who neither appreciate its significance nor pass it on to personnel who would. The Agency anticipates that its enforcement response to such situations will likely depend upon the identity of the person receiving the information and the steps taken to assure compliance with section 6(a)(2). For example, if a person submits reportable information to an employee of a pesticide registrant that could reasonably be expected to receive the information, such as a sales representative who regularly meets pesticide users, dealers and crop consultants, or a person who takes phone calls from the public, the Agency believes that such an employee should be expected to transmit the information to the appropriate personnel working for the registrant, and the Agency 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 relevant information. For example, the Agency would not regard as reportable information received by employees in such activities as food services, maintenance, finances and accounting, or personnel. Similarly most employees involved in manufacturing would not be expected to receive reportable information, with the exception of industrial hygienists 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; he was not their agent at the time the previous work was done; 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).

C. Section 159.156—How Information Must Be Reported

This section establishes guidelines for how reportable information must be submitted to the Agency. A number of minor modifications were made in order to clarify the procedures for identifying and submitting information pursuant to section 6(a)(2). The most significant comments on this section concern summaries and issues involving confidentiality of information.

1. *Paragraph (f).* The requirement in § 159.156(f) to summarize information concerning a study or incident is one that received a great deal of comment, and one that the Agency has modified from the proposed rule. Commenters raised a number of objections to the proposed requirement that registrants summarize ''all known information'' concerning a study or incident on numerous grounds, including that the requirement exceeded the Agency's statutory authority, that it would be unreasonably burdensome, that it would result in the submission of excessive, extraneous, and unreliable information (especially with regard to incidents), that it could be construed as an admission by a registrant that the information contained in a report (particularly an incident report) is correct, and that it could adversely affect the ability of a registrant to obtain information that might be considered proprietary, privileged, or confidential by someone because such information would have to be turned over to EPA.

The Agency has retained a requirement to summarize information, but in the final rule is providing significant additional guidance on what information needs to be included, and what does not need to be included, in such summaries. It will enable the Agency to quickly ascertain the nature of the information being reported and

therefore more quickly and responsibly fulfill its responsibilities under FIFRA.

The Agency does not believe that a summary ought to be construed as an admission by a registrant that the information reported to a registrant and contained in the summary is true and correct. The standard for reportability is not whether the registrant believes a report submitted to it is factual and accurate. The report itself will not automatically be taken by the Agency as an admission by a registrant that it concedes the correctness of information contained in an allegation. Registrants are free to provide with their submissions any information they deem appropriate which may qualify or contest a reported allegation of adverse effects.

As to the suggestion that the proposed rule might hamper registrants' ability to obtain information from individuals, the Agency has little way of knowing whether individuals might not cooperate with registrants or provide them with much information they currently provide if those individuals know that the information might be passed on to EPA. EPA's treatment of any information would be governed by FIFRA section 10 (which involves treatment of Confidential Business Information (CBI) under FIFRA) and by the Freedom of Information Act (FOIA). If the information is not protected under section 10, and if it is not protected from release under FOIA, EPA would be obligated to make it available to members of the public upon request. On the other hand, FOIA does allow agencies to withhold from release medical files and similar material the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, and EPA fully intends to protect such information from release. Section 159.156(i) of the regulatory text refers submitters to the already existing procedures for segregating material deemed confidential under FIFRA section 10.

The Agency does not believe it would be appropriate, as some commenters suggested, to delegate to registrants the determination of whether the information in any particular case is so significant that it should be provided to the Agency. As the United States District Court for the District of Columbia found in the case of *CSMA* v. *EPA*, 484 F.Supp. 513 (1980), this determination belongs to EPA rather than to the regulated community. Under the circumstances, EPA cannot allow registrants to withhold otherwise reportable information on the grounds that persons who submitted it to the registrant might prefer that it not be transmitted to EPA.

In regard to summaries themselves, EPA agrees that the proposed rule was too vague and could have lead to reporting of excessive or extraneous information. The Agency also is sensitive to the need to provide registrants with more guidance on what and how to summarize.

The new § 159.156(f) makes the following changes. First, it refers only to incident reporting, and not laboratory studies. Studies are already subject to requirements that they be identified as section 6(a)(2) information, both by the terms of this rule at § 159.156, and by the existing ''flagging'' criteria for certain toxicity studies at 40 CFR 158.34. This will generally be sufficient for an initial determination of whether the study warrants an expedited scientific review. Thus, a further requirement for summarization is unnecessary. This is clearly not the case for incident information.

Incident information may come to a registrant in many different forms, ranging from consumer complaints by telephone, to detailed investigative reports developed in connection with a lawsuit. After considering all comments on this issue, the Agency has decided to identify the specific items of factual information that would best enable EPA to evaluate quickly and accurately the nature and seriousness of the incident being reported. These data elements vary by type of incident, and are listed in the revised § 159.184, which deals with incident reporting. The revised § 159.156(f) simply refers the registrant to § 159.184.

It must be stressed that the information identified in § 159.184 constitutes the optimal set of information the Agency would like to have regarding different types of incidents. If a registrant does not possess certain information, there is no obligation to commence an investigation or to otherwise generate or obtain information. Registrants need only include in summaries those pieces of information which are both requested in this final rule and which they possess. The 1996 draft provided that if a registrant came into possession of an additional piece of information that would have been included in the original summary, the registrant would have to submit the additional information in a second summary within 30 days of receipt, and reference the earlier submission. In response to comments, the Agency now believes that this provision was unnecessarily burdensome. Accordingly, this final rule (in § 159.184(f)) provides that the obligation to submit follow-up information depends in part on the severity of the incident. Thus, any additional information concerning a human fatality needs to be submitted. Follow-up information also needs to be submitted in cases where the information expands on previously reported circumstantial information about a serious human illness or injury (exposure-severity category H-B) or the most serious level of incidents (''A'' level) for any of the non-human exposure categories. Finally, information needs to be submitted if it alters a previously reported moderate or minor severity rating to the H-A or H-B level for humans or the A level for any other exposure type, as defined by the criteria of § 159.184 (c)(5). The Agency retains the authority under § 159.195(b) to require more detailed information about any incident or group of incidents if it seems useful to do so.

2. *Paragraph (i).* In the proposed rule, confidentiality was dealt with in paragraph (g). As a general matter, the confidentiality of information submitted pursuant to the final rule is governed by section 10 of FIFRA. Any claim that material submitted pursuant to FIFRA section 6(a)(2) is entitled to confidentiality for reasons related to trade secrets or CBI must be viewed in light of FIFRA section 10. Section 10(d) provides that certain information, including ''any information concerning the effects of [a] pesticide on any organism or the behavior of such pesticide in the environment, including but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil'' shall be available for disclosure to the public. Section 10 thus makes clear that information concerning the effects of a pesticide on humans or the environment cannot be withheld from the public on grounds of trade secrecy or business confidentiality.

The Agency expects that most material submitted under section 6(a)(2) will continue to be of the type that is not entitled to confidentiality and must be made available to the public pursuant to section 10(d). Accordingly, the final rule includes a provision requiring that, if registrants consider any portion of a section 6(a)(2) submittal to be confidential, they specify the portion for which confidentiality is desired; they explain why such portion is entitled to confidentiality under the applicable provisions of FIFRA section 10; and they provide a ''sanitized'' version of the submittal that can be publicly released with the confidential information omitted. The sanitization process is identical to that codified in

40 CFR 158.33, and which has applied for years to data submitted to the Agency by pesticide registrants. The new paragraph (i) refers registrants to § 158.33 for the appropriate procedures to handle confidentiality claims.

To clarify this issue, the Agency is preparing a notice in the form of a class determination to registrants. The notice will inform registrants that the Agency will not honor routine business confidentiality claims for material submitted pursuant to section 6(a)(2) and covered by the disclosure provision of section 10(d).

Some commenters suggested that the Agency exempt from the reporting requirements of section 6(a)(2) material covered by the attorney-client or attorney work-product privileges. The Agency has no intention to broadly exempt information covered by the attorney work-product doctrine. Exempting attorney work-product from section 6(a)(2) reporting would make the reportability of investigative work hinge on whether the work was generated at the suggestion of an attorney or of a non-attorney associated with a registrant. The Agency does not believe there is any valid policy reason to exempt from section 6(a)(2) reporting valuable information merely because it was developed at the suggestion of an attorney.

Although the Agency does not know what useful information, if any, might be covered by the attorney-client privilege, the same logic applies as to the work-product doctrine. EPA does not believe it should make registration decisions based upon incomplete information in order to avoid the possibility of affecting registrants' positions in litigation.

The commenters raising this issue did not argue that information covered by the attorney work-product doctrine or the attorney-client privilege is outside the statutory scope of section 6(a)(2). Instead, these commenters suggested that the Agency as a matter of policy craft an exemption for such material from the statutory reporting requirements. This the Agency declines to do. However, a registrant is always free to notify the Agency of its possession of potentially privileged information which falls under the scope of section 6(a)(2) and request that the Agency not require the submission of certain specified information in a particular case. EPA does not commit to granting such requests, but neither does it rule out the possibility of exempting otherwise submittable information in particular circumstances where it can be shown that the information is entitled to some privilege, that providing it to the Agency would substantially prejudice a registrant, and that the information would not be helpful to an analysis of a product's registration status. No such request will be honored unless it is made in writing and sent or delivered to one of the addresses listed in § 159.156, and has been granted in writing by a responsible Agency official.

Although it was not raised by any of the commenters, the Agency considered amending this section (§ 159.156), to allow registrants to submit information to the Agency through the use of regular first class mail and electronic transmission. It is important to point out that the regulation already allows the Agency to easily and quickly specify alternate methods for submissions at anytime in the future through the issuance of a Pesticide Registration Notice (PR-Notice).

The Agency did not specify the use of regular first class mail as an acceptable method for section 6(a)(2) submissions, because providing verification of the mailing by the registrant and receipt by the Agency provides important protections to both the registrant and the Agency. It eliminates the possibility of debate over whether an item was actually submitted, and by informing registrants whether an item actually was received, it enables registrants to resubmit materials in a timely manner if a document is not in fact received by the Agency. In addition, the Agency believes that the additional cost is insignificant for sending it return receipt, certified or registered mail, which is only likely to add between $1.10 and $4.85 to the cost of that mailing, with other options, i.e., priority mail or express mail, only costing between $2.25 and $10.00.

As for including electronic transmission as an acceptable method for section 6(a)(2) submissions, the Agency is working hard to establish the necessary framework and policies that will enable EPA to accept electronic submissions of information collections, including those under FIFRA. However, the Agency is still in the process of addressing the major issues associated with allowing electronic submissions in general (including the establishment of a system that also ensures the protection of any CBI, provides a reasonable degree of data integrity to ensure that information contents are not scrambled or misread by the system, and ensures that registrants receive their desired proof of delivery and receipt, etc. Needless to say, the Agency is very committed to the use of electronic transmission as an acceptable mechanism for submitting information to the Agency, and as soon as the issues are resolved, electronic submission will be an option for submissions under section 6(a)(2).

D. Section 159.157—Recordkeeping Requirements

The proposed rule provided for 5 years of record retention for most types of information submitted to comply with the rule, but 10 years retention for certain information, such as information alleging adverse effects to one or two human beings. These retention periods were intended, in part, to enable registrants to determine whether information on certain incidents, which would not have been reportable by itself, would turn out in time to be part of a series of three similar incidents, and would thus have become reportable under the provisions of the proposed rule. Since the ''series of three'' concept has been dropped from this rule, the different record keeping requirements no longer have any purpose, and are deleted from all sections of this rule where they were previously mentioned. The question remains whether any record keeping should be required. The proposed rule provided that a copy of any submission to the Agency, and proof of delivery to the Agency, be retained for 5 years. The Agency considers all information derived from a reportable incident to fall within the scope of section 6(a)(2), but believes that if summaries are provided, additional information will rarely be needed. The Agency also believes that most registrants will retain records of adverse information reported to them for their own needs, and the Agency recommends that they do so. The Agency has concluded, however, that there is little value to EPA in having registrants retain copies of their submissions, and therefore has eliminated this requirement entirely.

E. Section 159.158—What Information Must be Submitted

This section provides guidance on what particular types of information must be submitted. The proposed rule contained four paragraphs. For clarity, the Agency has restructured § 159.158 into only two paragraphs; paragraph (a) identifies the general requirements formerly contained in paragraphs (a) and (b) in the proposed rule, and the new paragraph (b) describes the exceptions to reporting requirements formerly contained in paragraphs (c) and (d) in the proposed rule. The most significant issue for the general reporting requirements of paragraph (a) concerns opinion information.

A number of commenters objected that opinion information is not factual

information, and thus is not subject to the reporting requirements of section 6(a)(2). As support for this objection, they cite the case of *CSMA* v. *EPA*, supra, in which the court opined that opinion information was not subject to reporting under section 6(a)(2).

EPA has determined to retain the proposed provision without change in the final rule. As stated in the preamble to the proposed rule, the Agency does not believe that the issue of opinion information was properly before the District Court in the CSMA case or was any part of the holding or basis for the decision in the case. The Agency also believes that, if the issue were presented to a court today, certain types of opinion information would be found within the scope of section 6(a)(2).

As noted in the preamble to the proposed rule, the Agency is frequently obliged to make decisions in at least partial reliance on expert opinion. Indeed, often the Agency must resolve scientific issues under a ''weight of evidence'' approach, because the state of science makes a more definitive resolution impossible. For example, a conclusion as to whether a particular growth seen in a sacrificed test animal is a benign or malignant growth is not a matter of uncontestable fact, but rather, is the expression of an informed judgment by a trained professional (i.e., an expert opinion). Such expert opinions often serve as the basis for subsequent decisions about whether a chemical might pose a cancer risk to humans. These conclusions are based on a combination of observations and expert opinions; experts can and do disagree, and no conclusion can be considered indisputable fact. Yet such opinions play an important role in whether a pesticide should be registered and under what conditions. Indeed, studies submitted by registrants or applicants for registration frequently contain the conclusions and opinions of experts concerning the results and import of those studies. Where those conclusions and opinions suggest that a pesticide may pose a significant risk or a risk greater than previously presumed, the Agency believes those conclusions and opinions must be reported to the Agency pursuant to section 6(a)(2).

In order to be reportable, an opinion must meet two criteria. First, the opinion must relate to information that is relevant to the risk/benefit balance applicable to a particular registered pesticide. Second, the opinion must be from either an employee or agent of the registrant; a person from whom the registrant requested the opinion; or a person who could be considered an expert with regard to the matter on which the opinion was uttered. The Agency believes opinions from these categories of people are more likely to have credibility and/or warrant further investigation than are opinions from people not falling into these categories.

In terms of whether a conclusion or opinion can be said to have been rendered by an expert, previous publications of the Agency have suggested that registrants should be guided by whether the individual rendering the conclusion or opinion would, by virtue of his or her knowledge, skill, experience, training, or education, be qualified as an expert under Rule 702 of the Federal Rules of Evidence to testify to the opinions or conclusions on the subject at issue.

The Agency considers trained professionals to be experts in their trained field for purposes of section 6(a)(2) reporting. If a medical doctor expresses a conclusion or opinion on a person's medical condition and the causes of that condition, the conclusion or opinion must be reported, regardless of whether the registrant believes the information to be valid or correct, or whether the registrant believes the expert performed an appropriate investigation upon which to base the conclusion or opinion. It must be left to the Agency to evaluate the validity of the conclusion or opinion and determine the appropriate response to the information.

Finally, this discussion of expert opinion does not mean that the Agency intends to exclude reports of adverse effects in cases where an average person would reasonably suspect that pesticide exposure was a likely cause. For example, where someone develops tremors shortly after using a pesticide, 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.

The Agency believes that information that does not directly involve the registered pesticide may nonetheless be reportable under section 6(a)(2). For example, if a registrant of a chemical in a particular class receives a study using two other chemicals in the same class (for which the registrant does not hold any registrations), and the study shows that the other two have a similar, reportable feature, if the registrant concludes that the registered pesticide might have the same reportable feature, this information must be submitted under section 6(a)(2), even though the study did not directly involve the registered pesticide itself. The appropriate test is whether the information is relevant to a registered pesticide rather than whether the information is derived from a study or use of the registered pesticide.

In addition, the Agency believes that the registrant is responsible for submitting any reportable information in his possession or control, including any reportable information that the registrant may receive. In other words, registrants are obligated to submit otherwise reportable information which they receive electronically or orally; information need not be submitted to a registrant in writing in order for the information to be reportable.

Section 159.158(b) establishes categories of information that the Agency will exempt from reporting under section 6(a)(2): Information that is clearly erroneous; information that has previously been submitted to the Agency; and published books or articles. The provisions covering clearly erroneous information are unchanged from the proposed rule and the 1996 draft. With regard to previously submitted information, the Agency has added a new paragraph (b)(2)(iv) to § 159.158, which expands the criteria for what constitutes ''previously submitted information'' to include information submitted to EPA's Office of Pollution Prevention and Toxics under the provisions of section 8(e) of the Toxic Substances Control Act (TSCA). Without this change, information on chemicals already submitted under TSCA section 8(e) would also have to be submitted under section 6(a)(2) if the chemical was any constituent part of a pesticide product. As many commenters noted, the manufacturers of chemicals that have a variety of uses, including, but not limited to inert ingredients of pesticide products, are likely to have submitted adverse effects information under TSCA section 8(e), and may not be pesticide registrants, while pesticide registrants may be unaware of such submissions. The Agency agrees with commenters that the Office of Pesticide Programs can identify and obtain TSCA section 8(e) submissions concerning pesticide inert ingredients. In the event, however, that a chemical becomes the subject of an application to be registered as a new active ingredient, this new provision does reference the existing requirement of 40 CFR 152.50(f)(3) that an applicant for registration must submit the same information that would be required under section 6(a)(2) for a registered product.

Many commenters noted that the proposed rule would have required the submission of published information, while the 1985 Interpretive Rule exempted from the reporting

requirements any information contained completely in ''any scientific article or publication which has been abstracted in Biological Abstracts, Chemical Abstracts, Index Medicus, or Pesticides Abstracts'' if the abstract clearly identified the active ingredient or registered pesticide to which the information pertains. The 1996 draft would have required submission of scientific articles or published literature (including those abstracted in the identified abstracts) only if that information pertained to epidemiological studies and incident reports. In response to comments, the Agency has decided to exempt all published articles abstracted in recognized data bases of scientific and medical literature, including articles concerning epidemiological studies and incidents. The Agency believes that conducting its own literature searches will generally be sufficient to identify useful published information. However, in the event that a registrant does become aware of published information concerning one of their pesticide products that would be otherwise reportable under this part, and the material does not appear to be abstracted in any recognized and generally available data base, the information would be reportable.

F. Section 159.159—Information Obtained Before Promulgation of the Rule

The Agency added this new section to the 1996 draft in order to address the issue of reporting previously-obtained information raised by a number of commenters. The proposed rule did not address this issue. If the final rule were silent on the issue, then under the terms of the rule as originally proposed, any previously unsubmitted information which became reportable under the final rule would have to be submitted within 30 days. Such a requirement would probably not be feasible for registrants or EPA. The Agency has decided to limit the scope of reporting previously-obtained information in a number of ways.

The 1996 draft would have required that studies reportable under §§ 159.165, 159.170, 159.179, or 159.188, would be limited to reporting of studies completed within 5 years of the effective date of this rule. It should be understood that registrants are already required to comply with the obligation to report toxicology studies, failure of performance for health-related products, and other information required by previous Agency policy statements and guidance concerning section 6(a)(2) information. The Agency now believes that other data call-in activities are likely to have brought in previously unreported studies likely to be of use to the Agency, and is therefore eliminating this requirement to submit previously obtained studies.

It is important to note that nothing in this final rule relieves any registrant of liability for failure to report information that should have been submitted under previous statements of the section 6(a)(2) policy. However, any registrant who submits previously reportable information pursuant to § 159.159 should note that the Agency's Enforcement Response Policy for FIFRA addresses the Agency's policy for responding to registrants who self-confess violations. Substantial penalty reductions may also be available to registrants who submit previously reportable information under the Agency's Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations Final Policy Statement, 60 FR 66708 (December 22, 1995) (''Self-Disclosure Policy'')(FRL–5400–1). The Self-Disclosure Policy has several important goals, including encouraging greater compliance with the laws and regulations which protect human health and the environment through self-policing, discovery, disclosure, correction and prevention of violations. If specific criteria are met, reductions in gravity-based penalties up to 100% are available under the Self-Disclosure Policy. Registrants are advised that the criteria in the Self-Disclosure Policy are strictly applied. In particular, registrants should note that the Self-Disclosure Policy requires notification to EPA of the possible violation within 10 days of discovery.

In addition, the Agency's Final Policy on Compliance Incentives for Small Businesses, which became effective June 10, 1996, provides small businesses with incentives to participate in on-site compliance assistance programs and to conduct environmental audits. Under this policy, EPA will eliminate civil penalties provided that the small business satisfies all of the following four criteria:

(1) The small business has made a good faith effort to comply with applicable environmental requirements (through on-site assistance programs or voluntary audits and disclosures).

(2) The small business was not subject to any enforcement actions for the current violation and has not been subject to two or more enforcement actions for environmental violations in the past 5 years.

(3) The small business corrects the violation and remedies any associated harm within 6 months of discovery (an additional 6 months may be granted if pollution prevention technologies are being used).

(4) The violation has not caused and does not have the potential to cause serious harm to public health, safety or the environment, it does not have the potential to present imminent and substantial endangerment to public health or the environment, and it does not involve criminal conduct.

To further limit the burden of reporting previously obtained information, the final § 159.159(a)(1) provides only for reporting of incident information obtained since January 1, 1994, and that such required incident reporting be limited to human hospitalizations or fatalities, and domestic animal or non-target wildlife fatalities only, since these categories of incident information are more likely to warrant regulatory action by EPA.

Section 159.159 further eases the burden of reporting previously held information by providing a full year for registrants to respond, and by also providing that registrants shall submit an inventory of reportable material, rather than submitting individual incident reports. This will enable the Agency to selectively decide when to ask for more detailed submissions if it seems likely that information valuable for regulatory decision-making can be retrieved. As described in § 159.159(b)(2), an inventory is a listing of the number and kind of incidents associated with a particular ingredient or product, using the exposure type and severity categories set forth in the rule in § 159.184(c)(5).

G. Section 159.160—Exceptions Relating to Former Registrants

This new section was added to the 1996 draft to clarify that former registrants are not obligated to report adverse information on their formerly-registered products more than 1 year after they cease to hold the registration, provided that they hold no active pesticide registrations. A former registrant who has entirely left the pesticide business is considered less likely to receive reportable information than an active registrant, and it would be a greater burden on such companies to keep a reporting system in place. In this final rule the obligations of former registrants have been further limited in several ways. For a person who continues to hold one or more active pesticide registrations, information need not be reported if it is associated with inert ingredients, contaminants, impurities, metabolites, or degradates contained in formerly-registered products more than 1 year after the

registrant first ceases to hold the registration. Former registrants who still hold one or more active registrations will still be required to report adverse information involving the formerly-registered pesticide product itself, as well as information involving any of the active ingredients contained in the formerly-registered product, for a period of 5 years after they cease to hold the registration, but not indefinitely, as the 1996 draft would have required. Finally, a provision has been added to require that information arising from litigation is reportable regardless of the time elapsed after the registrant ceases to hold the registration (except in the case of wholly canceled active ingredients). The Agency believes this would not be unduly burdensome, since the former-registrant would clearly be aware of receiving the information through the litigation process, and it pertains only to pesticide chemicals that have recently been or are still being actively marketed, for which EPA has an on-going interest in receiving reportable information.

H. Section 159.165—Toxicological and Ecological Studies

This section identifies the parameters for reporting information from toxicological and ecological studies. The proposed rule dealt with toxicological and ecological studies together, and provided that the results of an incomplete or complete study of the toxicity of a pesticide to any human or non-target organism be reported if it showed a toxic effect, when compared to a previously submitted, valid study:

(1) In a different organ or tissue of the test organism.

(2) At a lower dosage, or after a shorter exposure period, or after a shorter latency period.

(3) At a higher incidence or frequency.

(4) In a different species, strain, sex, or generation of test organism.

(5) By a different route or medium of exposure.

(6) Through a different pharmacokinetic, metabolic, or biological mechanism.

Many commenters argued that EPA should only require the submission of studies that show significantly greater or different toxic effects than previously submitted studies. In particular, they suggested that the Agency not require studies showing a similar toxic effect in the same species of test organism. Commenters also suggested that the Agency not require the submission of acute toxicity studies unless the information would result in a change in toxicity category of the chemical. Some commenters alleged that the registrants of generic products—those no longer protected by patents and manufactured by more than one company—would not necessarily know whether a particular test result was new or more serious than previously reported information, thus making compliance difficult.

In response to some of these comments, the Agency has made a number of changes in the final rule. The most significant revision is that EPA has established separate standards for studies designed to determine the toxicity of pesticides to humans (revised § 159.165(a)), and for studies designed to determine the toxicity of pesticides to non-target plants and wildlife (new § 159.165(b)). The requirements for submission of toxicological studies are not substantially changed. However, as suggested by some commenters, this 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).

The Agency has made greater changes in the requirements for submission of ecological studies. The proposed rule simply referred to ''non-target organisms'' and applied the same standards as for studies relating to potential human toxicity. The new § 159.165(b) specifies what the Agency wants in the areas of acute toxicity, chronic toxicity, and phytotoxicity. The Agency believes these revisions will give much clearer guidance to registrants, and result in submissions most likely to be of value to Agency decision-making. The Agency has also provided some flexibility in relation to acute toxicity studies using the same or similar species.

In relation to incomplete studies, a number of commenters noted that the 1996 draft did not provide any guidance concerning reporting information from incomplete studies. In this final rule, the Agency has expanded § 159.165(d) to clarify the situations in which results of an incomplete study need to be reported. The language of this paragraph is essentially the same as the Agency used in its 1985 interpretive rule. These provisions are designed to ensure that severe adverse effects appearing in test organisms before the completion of a study are reportable, and also that results must be reported before the final analysis of a study is completed, if enough time has elapsed since the end of actual testing that a final analysis could have been completed.

The Agency does not agree that manufacturers of generic chemicals are at any unreasonable disadvantage in complying with the rule. The requirement to report new or more serious effects has been in place since 1979, and is not changed by this rule. If a registrant is in any doubt about the significance of a study result, they can ask EPA to provide the Data Evaluation Reviews (DERs) for their chemical. DERs are summaries of reviews of studies submitted to EPA in support of pesticide chemical registrations. These documents are available on request to the public, and provide EPA's conclusions about study results, including such numerical parameters as No Observed Effect Levels (NOELs) which can be used to determine whether a new study is showing a more serious effect than previously reported information. There is no significant burden to registrants to obtain these documents.

I. Section 159.170—Human Epidemiological and Exposure Studies

The proposed rule required that registrants submit any information concerning any study upon which a person described in § 159.158(b) has concluded, or an expert would conclude, that a positive correlation or association may exist between exposure to a pesticide and either a toxic effect in humans or residues of the pesticide in human tissue or body fluid, whether or not the registrant considers any observed correlation to be significant. This provision is largely unchanged. The final rule slightly modifies the description of exposure monitoring studies; such studies are reportable if they indicate exposure which is higher than indicated by previously available reports, data, or exposure estimates.

J. Section 159.178—Information about Pesticides on Food or Feed, or in Water

The proposed rule would have required the reporting of information by registrants relating to the presence of pesticides in food or feed if the level of pesticide detected in the food or feed was in excess of an established tolerance, food additive regulation, or action level with the exception of information regarding residues resulting solely from studies conducted under authority of FIFRA section 5 (experimental use permits). In response to comments, the Agency has expanded this exemption to make clear that controlled studies designed to test a pesticide product are generally exempt from this requirement provided that treated crops bearing excess residue levels as a result of experimental applications are not marketed as food or feed.

Information concerning the presence of pesticides in water would have to have been reported if the presence of the

pesticide in most surface waters, groundwater, or drinking water exceeded the water reference level. These provisions are essentially unchanged in the final rule. However, the 1996 draft and this final rule include a provision that detections of metabolites, degradates, contaminants or impurities in water need not be reported unless EPA has identified a specific reference point, such as a draft or final MCL or HAL, or has estimated an HAL based on an established Reference Dose, and notified registrants of that estimated HAL.

A number of commenters thought that the rule as proposed and the 1996 draft version would result in an excessive number of reports of questionable value, particularly of detections in water. The Agency recognizes that there may be a large number of detects of pesticides in water, and that the value of each incremental report may be small. The Agency also recognizes that there may be duplicate reports of the same detect submitted by different registrants. The Agency has established water reference levels that are designed to provide EPA with an early warning that a pesticide may be present in water before that presence has reached impermissible levels. However, in response to comments, and in order to assure that the information received is as useful as possible to the Agency, EPA is requiring in this final rule, that detections below MCLs or HALs be aggregated into quarterly statistical summaries to help reduce the burden of reporting for registrants.

In response to comments received, the Agency would like to clarify its position on reporting residues of inerts, metabolites, degradates, impurities, or contaminants on food or feed commodities. This issue hinges on whether the presence of the residue on food or in feed would require a tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA). Under the FFDCA, food is considered adulterated if chemical residues are detected on the food unless the chemical residues are covered by a tolerance, or the chemical has been specifically exempted from needing a tolerance, or the chemical is generally considered safe. At 40 CFR 180.2, EPA identified a number of chemicals considered ''safe'' under the meaning of section 408 of the FFDCA, and has also exempted (40 CFR 180.1001) a number of substances from the requirements of a tolerance.

K. Section 159.179— Metabolites, Degradates, Contaminants, and Impurities

The purpose of the 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. In response to comments, the provisions of this section in this final rule have been modified to better reflect the Agency's intention that this provision be consistent with the Agency's policy on cross-contamination (PR Notice 96–8, October 31, 1996) and the requirements governing when impurities must be identified in a product's composition (see, e.g., 40 CFR 158.155, 158.167 and 158.175). In PR-Notice 96–8, EPA set out the Agency's interpretation of the term ''toxicologically significant'' as it applies to contaminants in pesticide products that are also pesticide active ingredients (Ais). That PR-Notice provides risk-based concentration levels of such contaminants that will generally be considered toxicologically significant. The concentrations are defined according to the type of the pesticide that is contaminated and the pesticide category of the contaminant. As provided by this regulation, registrants must report to EPA any contaminant exceeding the toxicologically significant levels using the procedures for reporting such contamination that were established in the PR-Notice.

In general, the cited regulations in part 158 and the cross-contamination policy serve to assure that all batches of a given pesticide product meet certain standards of uniformity and that the Agency has information about all the significant components of a product's composition. At the same time, these regulations and policies recognize that it could be either impossible or prohibitively expensive to manufacture a pesticide product without any detectable impurities in it. The Agency therefore allows the presence of certain impurities in pesticide products below various levels without requiring that the registrant include information about the impurities in its formula or elsewhere in its application, and without considering the product containing such impurities to be inconsistent with the composition of the registered product. Section 159.179 provides that registrants do not have to notify EPA pursuant to section 6(a)(2) of the presence of any impurities or contaminants that would not have to be discussed in an application for registration or where the Agency has concluded that the presence of the contaminant does not render a product's composition inconsistent with the composition accepted by the Agency as part of the product's registration. However, where the presence of an impurity or contaminant would have to have been identified in the application materials or if the presence exceeds the levels allowed in the cross-contamination policy (or any similar policy issued by the Agency in writing), registrants are required under § 159.179 to report the presence of the contaminant or impurity to EPA.

The Agency notes that impurities which are not also pesticide active ingredients that occur during manufacture of a pesticide are already subject to certain reporting requirements under the provisions of 40 CFR 158.167 and/or 158.175. For purposes of reporting under the present rule, any detection of a manufacturing impurity at levels greater than the expected level reported to the Agency pursuant to § 158.167 or greater than a certified limit established pursuant to § 158.175 must be reported as section 6(a)(2) information.

L. Section 159.184—Toxic or Adverse Effect Incident Reports

One of the most important routes by which adverse effects information can come to the attention of the Agency is through toxic or adverse effect incident reports. Many of the Agency's registration decisions are predictive in nature. In contrast, incident reports can provide the Agency with information depicting the practical impacts of pesticide use, including real-world effects of pesticide use. The Agency considers incident reporting to be a vital component of section 6(a)(2).

The 1992 proposed rule version of § 159.184 imposed different reporting requirements for single incidents as opposed to a series of incidents involving three or more organisms. Incidents involving a single person or non-target organism were only reportable if the registrant (or other qualified person) had concluded that a causal relationship might exist between exposure to the pesticide and the toxic effect, or if the alleged effect were previously unreported or more severe than previously reported effects. If the ''three or more'' trigger was met, an incident or incidents had to be reported without regard to whether the registrant had concluded that a causal relationship existed between exposure and the effect or whether the toxic effect had previously been reported to the Agency.

The proposed § 159.184 was the subject of a large number of comments challenging the provision alternatively as too broad as well as too narrow. The Agency reconsidered § 159.184 in the light of recent experience, as well as the comments received on both the 1992 and 1996 versions, and has determined that the threshold for reporting incident information needed to be changed in a number of ways and that registrants could benefit from more specific guidance in this preamble.

The provision for reporting incident information in this final rule requires the reporting of any single incident involving humans or nontarget organisms if:

1. The registrant has been informed that a person or non-target organism may have been exposed to a pesticide.

2. The registrant has been informed that the person or nontarget organism has suffered or may suffer (or may have suffered) a toxic effect.

3. The registrant has a certain minimum level of information enabling them to pursue further information on the incident if they wish, such as the identity of the product involved, the location where the incident occurred, and the name of a person to contact concerning the incident.

This third provision was added in response to comments on the 1996 draft, and is designed to eliminate completely anonymous or very incomplete reports that can not be deemed meaningful by either registrants or EPA.

Individual incidents otherwise meeting the general standard need not be reported if they meet any of six criteria for exemption. Most of these exemptions concern effects which are already warned of on the label. The most significant exemption, in EPA's view, is to allow an exemption for reporting of skin or eye irritation effects warned of on the label of a product which is registered for use in residential use sites, and the incident was alleged to occur in a residential use site. Many commenters suggested this exemption. EPA's reason for accepting this suggestion is that the burden of reporting the information and for EPA to process it probably outweighs its value. There may be numerous allegations of such effects because of the high volume of products involved, but such incidents are relatively minor in terms of health effects significance. Moreover, such reports are nearly impossible to verify, and are not likely to lead to regulatory action in the absence of clear and specific evidence that the labeling or packaging of the product in question is inadequate to protect the public.

This rationale, however, does not support including non-residential use sites in this exemption, i.e., uses in institutional, industrial, and agricultural settings. In contrast to homeowners, the customer base for non-residential uses is likely to be familiar with pesticide hazards and the importance of the label directions, and in many cases, the users are actually trained in their use. Thus, if it is determined that a significant number of adverse effects continues to occur in this group regardless of label warnings, the Agency might well require changes to the terms and conditions of registration (such as requiring different warning statements, application methods, or the use of personal protective equipment) to respond to the situation. The Agency will reexamine the application of reporting requirements to non-residential products for minor effects warned about on the label in 3 years. If EPA determines that this information is no longer needed for some or all non-residential situations, the Agency will notify registrants accordingly pursuant to § 159.155(a).

In this final rule, the Agency has eliminated the distinction between single incidents and a series of incidents. The Agency also eliminated the requirement, for single incidents, that the registrant or an employee, consultant, or expert, must have determined that the reported effect may have resulted from the reported exposure. These changes were made partly in response to comments received, and partly because the Agency determined that much valuable information was not submitted to the Agency while the higher threshold embodied in previous policies was in effect.

Under the 1996 draft, incidents would have been reported whenever a registrant was informed that a human or other organism had been exposed to a pesticide and the registrant had been informed either that the human or other organism had thereafter suffered an adverse effect or that the exposure that occurred was unexpected and an adverse effect may have occurred thereafter or may occur in the future.

In this final rule, the term ''unexpected exposure'' has been eliminated. Many commenters felt that it was too ambiguous, and also that it was unfair to require reporting of ''unexpected exposures'' in situations in which no specific symptoms or adverse effects were alleged, since this would not be evidence of an adverse effect. In EPA's view, there are two separate issues here. With regard to ''unexpected exposures'', EPA is willing to eliminate this language as a criterion for routine reporting requirements under this final rule, on the grounds that it is ambiguous, and in most cases would not result in useful information being submitted. However, the Agency wishes to make it very clear that on some occasions it may have an interest in ''unexpected exposure'' information, and may require it to be submitted as section 6(a)(2) information at its discretion. For example, in regulating certain highly toxic pesticides EPA has required such measures as special protective clothing for applicators, restricted reentry intervals for treated fields, the use of closed mixing and loading systems, closed cabs for applicators or flaggers, and related measures, all designed to minimize the likelihood of exposure. Since one of the purposes of section 6(a)(2) is to obtain information that will show whether previous registration decisions are effectively protecting health and the environment, the Agency believes that information about ''unexpected exposures,'' even when these exposures are the subject of label warnings, is within the purview of section 6(a)(2). In those circumstances where the Agency considers it important to receive information concerning unexpected exposures, EPA will notify registrants that such information must be submitted pursuant to § 159.195(b).

The second issue raised by commenters concerns whether specific symptoms have been reported. Some commenters felt that in the absence of concrete evidence of adverse effects to exposed individuals there is no basis for a report under section 6(a)(2). In essence, these commenters are objecting to the reporting criteria of § 159.184(a)(2) that the registrant has been informed that a person ''may have suffered or may suffer'' an adverse effect. The Agency disagrees with these comments. The standard for reporting an incident is that there be both an allegation of exposure and an allegation of possible harm. This does not mean that the exposed person must be visibly ill for an incident to be reportable. Many pesticides are associated with health risks which are not necessarily those of acute toxicity. Exposure to certain pesticides may pose risks of birth defects, reproductive disorders, chronic nerve, liver, thyroid, heart, or other organ damage, or cancer. Any of these effects would be a legitimate cause of concern to exposed individuals, and none of them would necessarily be visible or apparent in the short term. Accordingly, the Agency rejects the

argument that only overt evidence of adverse effects is reportable.

The Agency recognizes that the lower threshold for reporting of incidents contained in this final rule might result in the submission of information which is not sufficiently reliable or detailed to warrant regulatory action. On the other hand, such information might well provide the Agency with advance warning of potential problems and could identify issues that warrant increased review and investigation. The Agency is aware of a number of instances in the past in which information that could well have resulted in regulatory action or investigation was not reported under previous policy determinations on incident reporting under section 6(a)(2). These include instances in which litigation involving allegations of adverse effects caused by pesticide products has not been promptly reported by registrants pursuant to section 6(a)(2).

Registrants should be aware that the Agency considers information related to a lawsuit involving an allegation of adverse effects due to a pesticide to be clearly reportable under the terms of the final rule, unless the registrant is aware of facts which establish that the alleged exposure and effect did not or will not occur. The Agency expects to be informed of incident information in a timely manner, regardless of whether the registrant agrees with the substance of the incident report.

In addition to changing the threshold for reporting incident information, the Agency has identified in this section of the final rule the information elements that must be included in incident reports if the information is available to the registrant. For the convenience of both registrants and Agency reviewers, EPA hopes to develop new and more efficient ways to submit this type of information, such as direct electronic submission of data. The Agency has elected to delay the effective date of this final rule to 9 months after publication primarily in order to work with all interested parties to seek the least burdensome and most efficient ways to implement reporting requirements. Until alternative reporting methods are adopted, the Agency urges registrants to use the simple list format set out in the final rule.

As noted earlier, registrants are not obligated to investigate incidents in order to acquire information to satisfy any particular data element. If a registrant lacks information, it does not need to be provided. In its 1996 draft, the phrasing of the rule text appeared to require that if, after an initial report is made, a registrant acquired information related to any element previously unreported, the information should be reported and reference the earlier submission. Many commenters on the 1996 draft noted that this provision could result in numerous submissions of minor factual information of little use to the Agency. EPA agrees, and has accepted commenters' suggestions to modify this final rule to provide that follow-up information need only be submitted when it pertains to human fatalities, materially alters the circumstance information concerning serious human injuries/illnesses or wildlife fatalities, or alters previously reported low severity levels up to the ''A'' or ''B'' level of severity for human incidents, or the ''A'' level for all other incidents, as defined by the exposure type and severity labeling criteria set out in the rule text at § 159.184(c)(5).

Unless directed otherwise by the Agency, registrants are not obligated to provide the Agency with any additional information on an incident other than what is summarized in providing the relevant data elements. The Agency may ask for additional information in the registrant's possession pursuant to § 159.195, but in the absence of such a request, providing the information called for in the data elements is all that a registrant must do in submitting incident information under section 6(a)(2).

Finally, the rule requires the registrant to assign an ''exposure type and severity label'' to each incident. These labels categorize what was exposed (i.e., humans, domestic animals, fish or wildlife, plants, or involves contamination of water), and the severity of the alleged incident. The assignment of a label will not be interpreted by the Agency as agreement by the registrant with the substance of any incident reported, nor will it be interpreted as registrant agreement with the particular rating assigned. The purposes of the ratings are for registrants to determine reporting requirements and time frames and for the Agency to quickly categorize the nature and scope of the adverse effect being alleged.

The Agency offers the following response to the significant comments received on the issue of incident reporting:

A large number of commenters argued that the proposed rule would result in the submission of much information of dubious value that would overwhelm Agency review resources. The Agency shares the commenters' concern that section 6(a)(2) information be properly managed and that significant submissions not be overwhelmed. The Agency does not believe (as many of the commenters seem to imply) that the appropriate response is to exempt most incident information from reporting requirements. Instead, the Agency has liberalized the time frames for reporting, and instituted aggregated statistical reporting for incidents of a relatively less serious nature, in order to make the incoming information easier to manage for both registrants and the Agency. The Agency also hopes to develop more sophisticated and efficient methods such as electronic submission. EPA also expects to use the authority in § 159.155 to reduce the number of certain types of repetitive reports.

A few commenters argued that a requirement to report unsubstantiated and uninvestigated incidents is unreasonable, excessively burdensome, and excessively expensive. Many registrants, however, routinely receive incident reports or consumer complaints and already have procedures for gathering and evaluating such reports. Keeping the Agency informed of these reports should not impose a significant additional burden, particularly since less severe incidents can be reported as aggregated counts and not as individual reports.

The Agency appreciates that the threshold for reporting incidents is far less than conclusive assurance that a reported toxic effect was caused by reported pesticide exposure, and expects that its regulatory decisions will be based upon an appropriate evaluation of all the relevant information available to the Agency. The Agency understands that with the elimination of the provision that called for registrant judgment as to whether there is a cause and effect relationship between reported exposure and a reported toxic effect, registrants are being directed to report information with which they may disagree. Regulatory decisions will take into account the quality and reliability of any information received. The Agency neither presumes the validity of incident reports nor views such reports as admissions against interest by the submitter.

A number of commenters suggested that the reporting criteria be narrowed so that only additional or new unreasonable adverse effects are reported to the Agency, and that registrants should not be required to report incidents involving effects anticipated or warned about on pesticide labels. To the extent that the commenters are suggesting that additional reports of previously

understood effects ought not to be reported, the Agency strongly disagrees. The frequency of occurrence of an adverse effect is extremely important information to pesticide decision-making. The Agency also generally disagrees that incidents involving effects warned about on labels should not be reported. Such incidents can provide important information about the adequacy of label warnings and whether additional steps need to be taken to provide the desired protection. However, the Agency recognizes that minor skin or eye irritation effects warned of on the label of home-use products are not likely to be the source of reports warranting regulatory action, and will exempt this category of incidents from routine reporting requirements at this time.

Similarly, the Agency has a responsibility to consider misuse of pesticides as a factor in determining whether a product is adequately labeled, or should be registered at all. If misuse incidents involving non-target organisms were exempted, as the proposed rule would have provided, potentially significant information for recognizing problem pesticides could be lost. Therefore the Agency has eliminated that proposed exemption.

One commenter suggested that the rule include a provision exempting from reporting incidents involving non-labeled pests. The Agency agrees, and has added such a provision in the final rule. Incidents involving toxic effects to non-labeled pests that are similar in kind to pests on the label (e.g., insects or weeds) need not be reported. However, if an event involves a toxic effect to an unrelated species (e.g., an insecticide kills birds or mammals, even if regarded as pests) the incident must be reported.

M. Section 159.188—Failure of Performance Information

Section 6(a)(2) requires the submission of information concerning unreasonable adverse effects on the environment. The term ''unreasonable adverse effects'' is statutorily described as a risk/benefit balance. Thus, although section 6(a)(2) reporting has primarily focused upon the risks posed by pesticide use, the statutory language includes within its scope information concerning the benefits of pesticide use.

In its 1979 Policy Statement, the Agency announced that it would consider it an actionable violation of section 6(a)(2) to fail to report information that a pesticide may not have performed efficaciously when used against organisms which pose a potential threat to public health. At that time, the Agency essentially exempted from reporting all failure of efficacy information involving pesticides used against organisms that did not pose a potential threat to human health.

The provision in the 1992 proposed rule involving the reporting of failure of performance information required that such information be reported in three circumstances:

1. Information concerning incidents in which a pesticide allegedly failed to perform as claimed against target organisms which, if not controlled, might pose an immediate risk to human health and the registrant has been provided with sufficient information to investigate the allegation and was unable to establish that the reported failure of performance did not occur.

2. Information concerning a series of three or more incidents occurring within 10 years involving allegations that the pesticide did not perform as claimed against target organisms which, if not controlled, might pose a risk to human health and the registrant has been provided with sufficient information to investigate the allegations and was unable to establish that the reported failures of performance did not occur; or information concerning studies demonstrating that the pesticide may not perform in accordance with any public health claims.

3. Information concerning a series of three or more incidents occurring within 10 years involving allegations that a pesticide that has been the subject of a special review or cancellation or suspension proceeding pursuant to sections 6(b) or 6(c) of FIFRA failed to perform as claimed, or showed a reduction in efficacy, involving a use that was a subject of the special review or suspension or cancellation proceeding.

The Agency received a large number of comments addressing this provision of the proposed rule. Some commenters objected to the scope of the provision because it did not require the submission of all efficacy failure information. Other commenters objected to the requirement to submit any failure of efficacy information. Many commenters objected to any requirement to submit consumer complaints that a product might not have worked as effectively as the consumer would have desired, especially in the context of household use products. A number of commenters asked for clarification of many of the provisions of the proposed rule, including the differentiation between uses that might pose an immediate risk to human health and uses which might only pose a risk to human health.

The Agency has decided to restructure and clarify the provisions of this section in the final rule. The 1996 draft rule would have required the submission of information concerning failure of efficacy in the situations enumerated below. The revisions adopted by EPA in this final rule are noted in each case.

1. Information concerning incidents involving the failure of a pesticide to perform as claimed against target microorganisms which, if uncontrolled, might pose a threat to human health if the pesticide's function is not a residential use and the registrant has or could obtain information concerning where the incident occurred, the pesticide or product involved, and the name of a person to contact regarding the incident; and information concerning any study indicating that a pesticide might not perform as claimed when used to control microorganisms that might pose a risk to human health, including any of the public health antimicrobials identified in 40 CFR part 158. This provision is retained in the final rule, except to note that certain liquid chemical sterilants that would have been covered by this provision have been removed from FIFRA jurisdiction by the Food Quality Protection Act of 1996 (Pub. L. 104–170).

2. For pesticides used for the purpose of controlling animals (including insects) that might cause disease in humans (either directly or as disease vectors), produce toxins that are harmful to humans, or cause direct physical harm to humans, information must be submitted concerning incidents in which the registrant has been informed by a municipal, State, or Federal public health official that the product may not have performed as claimed and the registrant has or could obtain sufficient information concerning where the incident occurred, the pesticide or product involved, and the name of a person to contact regarding the incident; and information must be submitted concerning studies that indicate that the pesticide may not perform as claimed when used to control animals or insects that might pose a risk to human health. This provision has been retained without change from the 1996 draft version of the rule.

3. Under the 1996 draft, information would have to have been submitted concerning studies involving the failure of a pesticide to perform against a pest as claimed if the performance of the pesticide in the study was less than the

performance standard specified in the Pesticide Assessment Guidelines for Product Performance (Subdivision G) or, if no performance standard is specified or suggested in the Guidelines, if the performance of the pesticide was less than or equal to that of an untreated control, and the pesticide label does not warn the user that the pest control failure might occur when the pesticide is used under the conditions in which the failure occurred. In this final rule, this provision has been eliminated. Many commenters noted that ''failure of performance'' information would often arise from deliberate product testing studies, which would be irrelevant for regulatory purposes, since they do not reflect actual use conditions, or from consumer allegations, which would be very difficult to evaluate. The Agency agrees, and has eliminated this provision.

4. The 1996 draft would have required submission of information concerning substantiation of any incident of pest resistance to any pesticide which occurs in actual use according to the label, whether or not the pesticide has any health-related uses. Under the 1996 draft, an incident of pest resistance would be considered substantiated if the survival of the suspected pesticide-resistant pest was significantly higher than that of a known susceptible pest when both the suspected resistant and susceptible pests were treated with the pesticide under the same conditions, or biochemical tests or DNA sequencing indicate that a pest has developed resistance to a pesticide. Under the 1996 draft, incidents involving suspected pest resistance to a pesticide would have been reported if the incident occurred in the same state or in a state adjacent to a state where a substantiated incident or study has taken place and the incident involved the same pest as the substantiated incident.

In this final rule, the Agency is retaining the requirement for information concerning substantiated incidents of pest resistance. It is clear to EPA that pest resistance is a very significant factor in determining the benefits of specific pesticides, and that such information may be critical to specific regulatory decisions that weigh the risks and benefits of pesticide products. However, the Agency does recognize that unsubstantiated allegations of resistance would be of questionable value and is willing to dispense with routine reporting of such allegations, since they would be difficult to use in decision making.

Several commenters on the 1996 draft were concerned that there is no generally agreed upon standard for identifying a ''significantly higher'' survival rate for an allegedly resistant pest species, and that this may make it difficult for registrants to comply with the requirement to report ''substantiated incidents.'' The Agency believes that the concept of a ''significantly higher'' survival rate for suspected resistant pests is the correct place to begin to define a standard for substantiated incidents. The Agency acknowledges that this is an area of science where there is at present no clear cut standard. Accordingly, the Agency will work to develop guidance on this issue with input from all interested parties.

The provision for submitting failure of performance of public health antimicrobial pesticides requires registrants to submit information concerning all incidents and all studies involving the possible failure of efficacy of any public health use of an antimicrobial pesticide unless the registrant cannot obtain minimal specified information regarding an incident or if the use involved in the efficacy failure is a residential use. EPA does not believe that residential uses are likely to be important public health uses, and it believes that the people most likely to be reporting such incidents (ordinary consumers instead of trained health professionals) have less expertise than those that are likely to be involved in reporting incidents involving non-residential uses.

The Agency has eliminated the distinction between uses that might pose an immediate risk to human health and uses that might pose a risk to human health, and is requiring the submission of all reportable incidents rather than a series of three. In reviewing the Proposed Rule, the Agency discovered that it was ambiguous on the subject of whether studies involving efficacy failures of public health pesticides were reportable under section 6(a)(2). The final rule makes clear that any study indicating a lack of efficacy of a public health antimicrobial pesticide must be reported to the Agency, except for those chemicals which are liquid chemical sterilants no longer regulated as pesticides pursuant to the FIFRA amendments of 1996.

The Agency established a separate provision for the reporting of incidents and studies involving non-antimicrobial public health pesticides. These pesticides include many insecticides, rodenticides, and other pesticides that control living organisms (other than microbial organisms) that pose a potential health risk to humans. Again, the Agency has eliminated the distinction between an immediate risk to public health and a risk to public health. All incidents meeting the provisions of this final rule must be reported. In order to avoid the submission of potentially less reliable reports, however, the Agency has decided to require the submission of incident allegations only if the allegation has been made by a government employee (at the Federal, State, or local level) involved in the public health field. For example, an incident involving efficacy failure of a mosquitocide reported by an employee of a mosquito control district would be reportable under this provision; a similar incident reported to a registrant by a private citizen would not be reportable. As with antimicrobial pesticides, any study indicating a lack of efficacy of a public health non-antimicrobial pesticide must be reported to the Agency.

For uses of pesticides other than public health uses, the Agency is not requiring the reporting of information concerning incidents where a product is asserted not to have performed in accordance with label claims. In its 1996 draft, the Agency considered requiring the submission of studies that indicate that a pesticide's performance failed to meet the guidelines established by the Agency for product performance or, in the absence of a performance guideline, failed to achieve greater pest control than occurred without any pesticide use. However, in response to comments, the Agency now believes that most failure of performance information would be difficult to evaluate, and this type of information is not being required except in the case of substantiated incidents of pest resistance.

The Agency has decided not to differentiate in this provision between pesticide uses that were once the subject of a special review or cancellation or suspension hearing and all other pesticide uses. If the Agency determines that it needs additional information concerning possible failure of performance of any pesticide, including one that was the subject of a special review or cancellation or suspension hearing, the Agency can request that information pursuant to § 159.195 of this final rule. In addition, if the conclusion of a special review or cancellation or suspension hearing clearly provides (or provided) that the pesticide product was being allowed to remain on the market only because the product was significantly more effective than alternative products, registrants would be obligated to provide information calling into question the

continuing efficacy of the product under § 159.195.

Finally, the Agency has determined that substantiated information about pest resistance is another area where failure of performance information may assist the Agency in the performance of its regulatory role. The Agency is therefore requiring the submission of information concerning the occurrence of pest resistance under actual conditions of use, where such information meets a defined standard of reliability. The 1996 draft would also have required reporting of unsubstantiated allegations of pest resistance if they involved the same pest/crop combinations as substantiated incidents, and occurred in the same or adjacent states as substantiated incidents. However, the Agency now believes that this requirement would result in submissions that would be difficult to evaluate and of dubious value, and prefers to rely on controlled studies of pest resistance that are more likely to produce useful information. As noted above, EPA will work to develop guidance for the regulated community to define the level of results in a study that can be considered substantiation of resistance.

Several commenters, noting that efficacy against pests is the primary benefit offered by pesticide products, argued that EPA has no authority to require information on efficacy failure (or any other lack of benefits information) under section 6(a)(2). To support this position, one commenter cited the District Court decision in the CSMA case. The Agency appreciates that the court in that case opined that benefits information was outside the scope of section 6(a)(2). However, the Agency believes that the court was clearly incorrect on this point. Section 2(bb) of FIFRA defines unreasonable adverse effects on the environment as including the consideration of information on benefits as well as risks. It is clear under FIFRA that a failure of efficacy of a product could tip the risk/benefit balance in favor of cancellation of a product or specific uses of a product. Under such circumstances, the Agency believes there is no question that failure of efficacy information falls within the statutory scope of material covered by section 6(a)(2).

N. Section 159.195—Reporting of Other Information

The 1992 proposed rule required the submission of information not included within any of the other provisions of the rule if the registrant is not aware of facts which establish that the information is incorrect and the registrant knows, or should know, that if the information should prove to be correct, EPA would regard the information either alone or in conjunction with other information as having the potential to raise questions about the continued registration of a product or about the appropriate terms and conditions of registration of a product. Similar general provisions have been included in all previous Agency policy statements and interpretations of section 6(a)(2).

In response to a comment, the Agency added one example to the types of information that must be reported under § 159.195(a) of this final rule. Specifically, the Agency is making it clear that it considers any information which might tend to invalidate in any way a study submitted to the Agency to support a pesticide registration, to be reportable under section 6(a)(2).

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 the Agency in its evaluation of a pesticide product registration. If a registrant is aware that the registration decision for one of its products was based upon an assumption by the Agency that is called into question by some new piece of information, that information must be provided under this provision if it is not already reportable under some other provision of this final rule. In situations where a registrant is unsure how this provision applies to specific information, the Agency encourages the registrant to seek advice from EPA.

The Agency on occasion may notify a registrant that it considers a particular type of information to be reportable pursuant to section 6(a)(2). Such a notification to the registrant removes any question concerning whether the registrant should know that the Agency considers the information important. In order to eliminate any possible confusion on this point, EPA has added a specific provision spelling out a registrant's obligation when it is informed that the Agency desires the submission of specific information pursuant to section 6(a)(2).

III. Statutory Review Requirements

In accordance with section 25 of FIFRA, a copy of the final rule was provided to the Secretary of the Department of Agriculture (USDA), the FIFRA Scientific Advisory Panel (SAP), the Committee on Agriculture, Nutrition and Forestry of the U.S. Senate, and the Committee on Agriculture of the U.S. House of Representatives. EPA did not receive any comments.

IV. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) determined that this rule was a ''significant regulatory action'' because there was a potential for it to raise novel legal or policy issues related to the implementation of a statutory mandate. The Agency determined that this final rule is unlikely to have a major economic impact on pesticide registrants, and no impact on any other sector of the economy, or on any other government entities, programs or policies. The aggregate annual impact on the private sector is estimated to be about $15.7 million in the first year, and about $8 million annually thereafter. The basis for EPA's determination is contained in the Information Collection Request prepared for this rule (see Unit IV.D. below).

In addition, the rule is consistent with the purposes of FIFRA, and does not conflict with any other statutory mandate or with the principles of the Executive Order. This action was submitted to OMB for review pursuant to this Executive Order, and any comments or changes made during that review have been documented in the public record.

B. Unfunded Mandates Reform Act and Executive Order 12875

This final rule does not contain any ''Federal mandate'' that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or for the private sector in any 1 year. Therefore, this action is not subject to the requirements of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104-4, or Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993).

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this action will not have a significant economic impact on a substantial number of small entities. This determination is based on the burden analysis included in the Information Collection Request discussed in Unit IV. D. below. In summary, EPA estimates that in the first year of implementation this regulation will impose a total cost of about $15.7 million and a total burden of 195,942 hours, which would decrease in year two to about $8 million

and 83,172 burden hours annually for subsequent years. Since the estimated cost and burden is distributed among approximately 2,100 pesticide registrants, the average per registrant cost and burden in the first year of implementation is estimated to be $7,461 and 93.31 burden hours, decreasing in subsequent years to an annual cost of $3,870 and 39.61 burden hours. Naturally, this average estimate may not be reflective of an individual registrants costs and burdens, since the individual costs and burdens are directly related to such things as the number of products, the number of employees, and the number of incident reports or studies the individual registrant receives and therefore must provide to EPA. In addition, the basis for estimating the anticipated increase in cost and burden includes several assumptions that may have artificially inflated the estimates. The Agency will reevaulate these estimates in 3 years, when the Agency seeks an extension of the Information Collection Request.

Our expectation, based on actual reporting under the existing requirements, is that the registrants with significant market share will most likely experience most of the burden. We therefore expect only a fraction of the registrants that are impacted to be small businesses, particularly with regard to the retroactive report provision, which requires registrants to provide information that is in their possession and not previously submitted to EPA with regard to a complaint involving fatalities or hospitalizations related to their pesticide which occurred during the last 3½ years. Registrants are only required to submit summaries and have up to an entire year to submit the information to EPA. The Agency does not believe that this requirement will have any significant adverse impacts on either small or large registrants, since allegations involving such serious adverse effects like fatalities or hospitalizations are relatively rare and are most likely to be easily recognizable by the registrants, given their own need to know this information.

The Agency discussed this determination with the Chief Counsel for Advocacy of the Small Business Administration (SBA), during the OMB review under Executive Order 12866. A copy of the SBA comments, and EPA's response, has been placed in the docket for this rulemaking.

D. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, the current information collection activities relating to section 6(a)(2) are conducted under an Information Collection Request (EPA ICR No. 1204) approved by the Office of Management and Budget (OMB) under OMB Control No. 2070–0039. An amendment to this ICR to cover the information collection requirements contained in this final rule was submitted to OMB under the provisions of 5 CFR 1320.11. Comments addressing the Agency's costs and burden estimates in the proposed rule and in response to the Agency's request for additional comments last summer, were taken into consideration and are reflected in the final ICR, which was submitted and subsequently approved by OMB.

The reporting burden for the first year of this collection of information includes an estimated 5.9 hours per submission of scientific studies, 2.3 hours per submission of incident reports, 9.3 hours per registrant for reviewing their records for, and submitting to the Agency, any fatality and hospitalizations not previously submitted to the Agency, 0.3 hours per registrant for the potential need to track a submission in order to provide subsequent follow-up, and 4.8 hours per registrant for rule familiarization and training. The annual reporting burden for this collection of information in subsequent years is estimated to be 5.9 hours per submission of scientific studies, 2.3 hours per submission of incident reports, 0.3 hours per registrant for the potential need to track a submission in order to provide subsequent follow-up, and 2.6 hours per registrant for continued training. These estimates include the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to respond to a collection of information; search existing data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

No person is required to respond to a collection of information unless it displays a currently valid OMB control number. OMB control numbers for EPA regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

A copy of the final ICR has been placed in the docket for this final rule and may also be obtained from Sandy Farmer, Regulatory Information Division, OPPE, U.S. Environmental Protection Agency (2137), 401 M St., SW., Washington, DC 20460, by calling (202) 260–2740, or by e-mail to farmer.sandy@epamail.epa.gov. If you should have any additional comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, increasing electronic submissions, etc.., please address them to the Director of the Regulatory Information Division at the address listed above for Sandy Farmer. Please be sure to include the EPA and OMB ICR number in any correspondence.

E. Executive Order 12898

Pursuant to Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), the Agency has considered environmental justice related issues with regard to the potential impacts of this action on the environmental and health conditions in low-income and minority communities and has determined that this final rule will not adversely affect environmental justice.

F. Executive Order 13045

This final rule will not have an economic impact of $100 million or more and, therefore, does not require special considerations or OMB review under Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

V. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 159

Environmental protection, Pesticides and pests, Policy statements, Reporting and recordkeeping requirements.

Dated: September 11, 1997.

Carol M. Browner,

Administrator.

Therefore, 40 CFR chapter I is amended as follows:

1. By adding a new part 159 consisting of subparts A, B, and C, which are reserved, and subpart D to read as follows:

PART 159—STATEMENTS OF POLICIES AND INTERPRETATIONS

Subparts A—C [Reserved]

Subpart D—Reporting Requirements for Risk/Benefit Information

Sec.
159.152 What the law requires of registrants.
159.153 Definitions.
159.155 When information must be submitted.
159.156 How information must be submitted.
159.158 What information must be submitted.
159.159 Information obtained before promulgation of the rule.
159.160 Exception relating to former registrants.
159.165 Toxicological and ecological studies.
159.167 Discontinued studies.
159.170 Human epidemiological and exposure studies.
159.178 Information on pesticides in or on food, feed, or water.
159.179 Metabolites, degradates, contaminants, and impurities.
159.184 Toxic or adverse effect incident reports.
159.188 Failure of performance information.
159.195 Reporting of other information.

Authority: 7 U.S.C. 136–136y.

Subparts A—C [Reserved]

Subpart D—Reporting Requirements for Risk/Benefit Information

§ 159.152 What the law requires of registrants.

(a) Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) states: ''If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator.''

(b) Section 152.50(f)(3) of this chapter requires applicants to submit, as part of an application for registration, any factual information of which he is aware regarding unreasonable adverse effects of the pesticide on humans or the environment, which would be required to be reported under section 6(a)(2) if the product were registered.

(c) Compliance with this part will satisfy a registrant's obligations to submit additional information pursuant to section 6(a)(2) and will satisfy an applicant's obligation to submit additional information pursuant to § 152.50(f)(3) of this chapter.

§ 159.153 Definitions.

(a) For the purposes of reporting information pursuant to FIFRA section 6(a)(2), the definitions set forth in FIFRA section 2 and in 40 CFR part 152 apply to this part unless superseded by a definition in paragraph (b) of this section.

(b) For purposes of reporting information pursuant to FIFRA section 6(a)(2), the following definitions apply only to this part:

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(c) 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 out-patient 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 invertebrates, insects, arachnids, aquatic plants (including macrophyte, floating, and submerged plants), and terrestrial (all non-aquatic) plants.

Water reference leve 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, or if 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.

§ 159.155 When information must be submitted.

(a) Reportable information concerning scientific studies must be received by EPA not later than the 30th calendar day after the registrant first possesses or knows of the reportable information. Reportable information concerning adverse effects incidents must be reported according to the schedules set forth in § 159.184(d), which differentiates reporting times depending on the severity of the incident. EPA may, in its discretion, 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 this part.

(b) For purposes of this part 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.

§ 159.156 How information must be submitted.

A submission under FIFRA section 6(a)(2) must be delivered as specified in either paragraph (a) or (b) of this section, and must meet the other requirements of this section:

(a) Be mailed by certified or registered mail to the following address, or such other address as the Agency may subsequently specify in writing:

Document Processing Desk—6(a)(2), Office of Pesticide Programs—7504C, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

(b) Be delivered in person or by courier service or by such other methods as the Agency deems appropriate to the following address, or to such other address as the Agency may subsequently specify in writing: Document Processing Desk—6(a)(2), Office of Pesticide Programs, Room 266A, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, Virginia 22202.

(c) Include a cover letter which contains the information requested in paragraphs (d) and (e) of this section, and a prominent statement that the information is being submitted in accordance with FIFRA section 6(a)(2).

(d) Contain the name of the submitter, registrant name and registration number, date of transmittal to EPA, the type of study or incident being reported under §§ 159.165 through 159.195, and a statement of why the information is considered reportable under this part.

(e) Identify the substance tested or otherwise covered by the information (including, if known, the EPA registration number(s) to which the information pertains, and if known, the CAS Registry Number).

(f) In reporting incidents, provide the data listed in § 159.184, to the extent such information is available.

(g) In submitting scientific studies, follow the procedures set forth in § 158.32 of this chapter.

(h) If the information is part of a larger package being submitted in order to comply with another provision of FIFRA (e.g., sections 3(c)(2)(B), 4(e)(1)(E)), identify in the transmittal the individual studies being submitted under this part.

(i) 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, follow the procedures set forth in § 158.33 of this chapter regarding the identification and segregation of information claimed to be confidential.

(j) If a submission includes a study subject to the flagging requirements of § 158.34 of this chapter, comply with the requirements of that section, and, if the flagging statement is positive, identify it as 6(a)(2) information in the transmittal.

(k) 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) If the earlier submission was a study to which EPA assigned a Master Record Identifier number (MRID), cite the 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.

§ 159.158 What information must be submitted.

(a) *General.* Information which is reportable under this part must be submitted if the registrant possesses or receives the information, and 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. Information relevant to the assessment of the risks or benefits also includes conclusion(s) or opinion(s) rendered by a person:

(1) Who was employed or retained (directly or indirectly) by the registrant, and was likely to receive such information.

(2) From whom the registrant requested the opinion(s) or conclusion(s) in question.

(3) Who is a qualified expert as described in § 159.153(b).

(b) *Exceptions*—(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 are met:

(i) The registrant discovers that any analysis, conclusion, or opinion was predicated on data that were erroneously generated, recorded, or transmitted, or on computational errors.

(ii) Every author of each such analysis, conclusion, or opinion, or as many authors as can be contacted through the use of reasonable diligence, 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 cannot be corrected.

(iii) As a result of the correction, the information is no longer required to be reported under FIFRA section 6(a)(2), 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 that incident, study, or other occurrence is contained completely in one of the following:

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

(ii) EPA publications, EPA hearing records, or publications cited in EPA **Federal Register** notices.

(iii) Any other documents which are contained in the official files and records of the EPA Office of Pesticide Programs.

(iv) Any documents officially logged in by the EPA Office of Pollution Prevention and Toxics under the provisions of section 8(e) of the Toxic Substances Control Act, provided that if the information pertains to a chemical compound which, subsequent to the submission of data under section 8(e), becomes the subject of an application for registration as a pesticide active ingredient, information is submitted to the Office of Pesticide Programs as required by 40 CFR 152.50(f)(3).

(3) *Publications.* A published article or report containing information otherwise reportable under this part need not be submitted if it fits into either of the categories described in paragraphs (b)(3)(i) or (b)(3)(ii) of this section.

(i) Any scientific article or publication which has been abstracted in a recognized database of scientific and medical literature, such as Medline, ENBASE, Toxline or Index Medicus, if the abstract in question clearly identified the active ingredient or the registered pesticide(s) to which the information pertains. Otherwise reportable information received by or known to the registrant prior to publication of an abstract concerning the information must be reported and may not be withheld pending such publication.

(ii) Reports or publications which have been made available to the public by any of the following Federal agencies: Centers 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. Otherwise reportable

information concerning research which was performed, sponsored, or funded by the registrant which may also appear in forthcoming Government reports or publications must be reported and may not be withheld pending publication.

(4) *Information concerning former inerts, contaminants or impurities.* Notwithstanding any other provisions of this part, a registrant need not report information concerning a chemical compound that was at one time an inert ingredient or a contaminant or impurity of a pesticide product, and would otherwise be reportable under this part, if:

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

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

§ 159.159 Information obtained before promulgation of the rule.

(a) Notwithstanding any other provision of this part, information held by registrants on June 16, 1998 which has not been previously submitted to the Agency, but which is reportable under the terms of this part, must to be submitted to the Agency if it meets any of the following criteria.

(1) Information is otherwise reportable under § 159.184, and pertains to an incident that is alleged to have occurred on or after January 1, 1994, and to have involved:

(i) A fatality or hospitalization of a human being.

(ii) A fatality of a domestic animal.

(iii) 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 § 159.184(c)(5)(iii).

(2) Submission of the information is requested by the Agency pursuant to § 159.195(b).

(b) If a registrant possesses information required to be submitted by paragraph (a)(1) of this section, the registrant must submit on or before June 16, 1999 in accordance with § 159.156(c), (d), and (e) an inventory of the incidents that meet the requirements of paragraphs (a)(1) of this section. Such an inventory must include the separate number of incidents that meet the requirements of paragraphs (a)(1)(i), (a)(1)(ii), and (a)(1)(iii) of this section, and for each type of incident, the total numbers of fatalities or hospitalizations involved.

(c) If a registrant possesses information required to be submitted by paragraph (a)(2) of this section, the information must be submitted in accordance with any schedule contained in the Agency's request for the information.

§ 159.160 Obligations of former registrants.

(a) *General.* A former registrant is obliged to continue to submit information concerning the registration of a pesticide product previously held by the registrant and otherwise reportable under the provisions of this part for a period of 5 years after the registration of the pesticide product has been canceled or transferred to another registrant, with the exceptions provided by paragraph (b) of this section.

(b) *Exceptions.* Notwithstanding the provisions of paragraph (a) of this section, a former registrant is not obligated to report information pursuant to this part if any of the following conditions are applicable:

(1) The information is first obtained by the person more than 1 year after the date on which the person ceased to hold the registration of the product to which the information pertains, and the person holds no active pesticide registrations, or for some other reason cannot reasonably be expected to receive information concerning the formerly-registered product.

(2) The information is associated solely with an inert ingredient, contaminant, impurity, metabolite, or degradate contained in a product, and the information is first obtained by the person more than 1 year after the date upon which the person ceased to hold the registration of the product.

(3) The information is 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 3–year period preceding the date on which the person first obtained the information.

(4) The information pertains solely to a formerly-registered product that no longer meets the definition of ''pesticide'' in section 2(u) of FIFRA (7 U.S.C. section 136(u)).

(c) *Information arising from litigation.* Notwithstanding any other provisions of this section, a former registrant is obliged to submit information otherwise reportable under this part concerning formerly-registered pesticide products which arises in the course of litigation concerning the effects of such products, regardless of when the information is first acquired, provided that neither of the provisions of paragraphs (b)(3) or (b)(4) of this section are met. Such information shall be submitted in the same manner and according to the same schedules as it would have to be submitted by a current registrant of a pesticide product to which the information pertained.

§ 159.165 Toxicological and ecological studies.

Adverse effects information must be submitted as follows:

(a) *Toxicological studies.* (1) The results of a study of the toxicity of a pesticide to humans or other non-target domestic organisms if, relative to all previously submitted studies, they show an adverse effect under any of the following conditions:

(i) That is in a different organ or tissue of the test organism.

(ii) At a lower dosage, or after a shorter exposure period, or after a shorter latency period.

(iii) At a higher incidence or frequency.

(iv) In a different species, strain, sex, or generation of test organism.

(v) By a different route of exposure.

(2) Acute oral, acute dermal, acute inhalation or skin and eye irritation studies in which the only change in toxicity is a numerical decrease in the median lethal dose (LD_{50}), median lethal concentration (LC_{50}) or irritation indices, are not reportable under this part unless the results indicate a more restrictive toxicity category for labeling under the criteria of 40 CFR 156.10(h).

(b) *Ecological studies.* The results of a study of the toxicity of a pesticide to terrestrial or aquatic wildlife or plants if, relative to all previously submitted studies, they show an adverse effect under any of the following conditions:

(1) At levels 50 percent or more lower than previous acute toxicity studies with similar species, including determinations of the median lethal dose (LD_{50}), median lethal concentration (LC_{50}), or median effective concentration (EC_{50}).

(2) At lower levels in a chronic study than previous studies with similar species.

(3) In a study with a previously untested species the results indicate the chronic no observed effect level (NOEL) is 10 percent or less of the lowest LC_{50} or LD_{50} for a similar species.

(4) For plants when tested at the maximum label application rate or less, if:

(i) More than 25 percent of terrestrial plants show adverse effects on plant life

cycle functions and growth such as germination, emergence, plant vigor, reproduction and yields.

(ii) More than 50 percent of aquatic plants show adverse effects on plant life cycle functions and growth such as germination, emergence, plant vigor, reproduction and yields.

(c) Results from a study that demonstrates any toxic effect (even if corroborative of information already known to the Agency), must be submitted if the pesticide is or has been the subject of a Formal Review based on that effect within 5 years of the time the results are received. Within 30 calendar days of the publication of a Notice of Commencement of a Formal Review in the **Federal Register**, all information which has become reportable due to the commencement of the Formal Review must be submitted.

(d) *Incomplete studies.* Information from an incomplete study of the toxicity to any organism of a registered pesticide product or any of its ingredients, impurities, metabolites, or degradation products which would otherwise be reportable under paragraphs (a), (b) or (c) of this section must be submitted if the information meets any one of the folowing three sets of criteria:

(1) *Short-term studies.* 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.

(2) *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 that 1 year following completion of testing) has elapsed.

(v) Comparable information concerning the results of a completed study would be reportable.

(3) *Serious adverse effects.* Any study in which testing or analysis of results is not yet complete but in which serious adverse effects have already been observed which may reasonably be attributed to exposure to the substances tested, because the effects observed in exposed organisms differ from effects observed in control organisms, are atypical in view of historical experience with the organism tested, or otherwise support a reasonable inference of causation, and 30 days have passed from the date the registrant first has the information.

§ 159.167 Discontinued studies.

The fact that a study has been discontinued before the planned termination must be reported to EPA, with the reason for termination, if submission of information concerning the study is, or would have been, required under this part.

§ 159.170 Human epidemiological and exposure studies.

Information must be submitted which concerns any study that a person described in § 159.158(a) has concluded, or might reasonably conclude, shows that a correlation may exist between exposure to a pesticide and observed adverse effects in humans. Information must also be submitted which concerns exposure monitoring studies that indicate higher levels of risk or exposure than would be expected based on previously available reports, data, or exposure estimates. Such information must be submitted regardless of whether the registrant considers any observed correlation or association to be significant.

§ 159.178 Information on pesticides in or on food, feed or water.

(a) *Food and feed.* Information must be submitted if it shows that the pesticide is present on food or feed at a level in excess of established levels, except that information on excess residues resulting solely from studies conducted under authority of FIFRA section 5 or under other controlled research studies conducted to test a pesticide product need not be submitted, provided that the treated crop is not marketed as a food or feed commodity.

(b) *Water.* (1) 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 § 122.2 of this chapter, except paragraph (d) of § 122.2.

(ii) Ground water.

(iii) Finished drinking water.

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

(3) Information need not be submitted regarding the detection of a pesticide in waters of the United States or finished drinking water if the pesticide is registered for use in finished drinking water or surface water and the amount detected does not exceed the amounts reported by a registrant in its application for registration, as resulting in those waters from legal applications of the pesticide.

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

§ 159.179 Metabolites, degradates, contaminants, and impurities.

(a) *Metabolites and degradates.* Information which shows the existence of any metabolite or degradate of a pesticide product must be submitted if:

(1) 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.

(2) 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 paragraph (a)(3)(i) or (ii) of this section is met:

(i) Any person described in § 159.158(a) has concluded that the metabolite or degradate may pose a toxicological or ecological risk based on any one or more of the following:

(A) The physical or chemical properties of the metabolite or degradate.

(B) Data regarding structurally analogous chemicals.

(C) Data regarding chemical reactivity of the metabolite or degradate and structurally analogous substances.

(D) Data on the metabolite or degradate.

(ii) The registrant has concluded, or has been advised by any person described in § 159.158(a) that the metabolite or degradate, or analogous chemicals, may have any experimentally determined half-life greater than 3 weeks as shown from laboratory aerobic soil metabolism studies or field dissipation studies, or 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 percent in a 30-day period.

(b) *Contaminants and impurities.* The presence in any pesticide product of a contaminant or impurity not previously identified by the registrant as part of the pesticide product's approved composition must be reported pursuant to this part if the contaminant or impurity is present in the product in any of the following quantities:

(1) Quantities greater than 0.1 percent by weight (1,000 parts per million).

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

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

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

(5) Quantities that a person described in § 159.158(a) has informed the registrant is likely to be of toxicological significance.

§ 159.184 Toxic or adverse effect incident reports.

(a) *General.* Information about incidents affecting humans or other non-target organisms must be submitted if the following three conditions are met:

(1) The registrant is aware, or has been informed that a person or non-target organism may have been exposed to a pesticide.

(2) The registrant is aware, or has been informed that the person or non-target organism suffered a toxic or adverse effect, or may suffer a delayed or chronic adverse effect in the future.

(3) The registrant has or could obtain information concerning where the incident occurred, the pesticide or product involved, and the name of a person to contact regarding the incident.

(b) *Exceptions.* Information regarding an incident need not be submitted if any of the following conditions are met:

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

(2) The registrant has been notified in writing by the Agency that the reporting requirement has been waived for this incident or category of incidents, and the registrant has not been notified in writing by the Agency that the waiver is rescinded.

(3) It 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.

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

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

(6) It concerns minor skin or eye irritation effects warned of on the label of a product which is registered for use in residential use sites, and the effects occurred as a result of use in a residential site.

(c) *Required information on individual incidents.* To the extent that the registrant has any of the information listed in paragraphs (c)(1) through (c)(4) of this section, the registrant must supply the information on each pesticide incident that meets the requirements outlined in paragraph (a) of this section. If the registrant acquires additional information concerning an incident previously reported to the Agency under this part, such information shall be reported if it meets the criteria set forth in paragraph (f) of this section. In the future, the Agency may by notice specify a format for such submissions. The Administrative, Pesticide, Circumstance and Exposure Type(s) of information must be reported for individual incidents, except where the provisions of paragraph (e) of this section allow for aggregated summary forms of reporting, or if EPA in the future grants permission in writing for alternative reporting formats. The registrant must also provide one or more Exposure Type and Severity categories and their designations for each incident as set forth in paragraph (c)(5) of this section, depending on the applicability of the criteria listed below. The criteria listed should be used in assigning a category. For example, an incident which allegedly caused serious but non-fatal effects to human beings and domestic animals might be designated ''H-B: D-B.'' When a single incident involves multiple pesticides, the registrant need only report on their specific product. However, if a single incident involves more than one type of non-target organism -- for example, both humans and domestic animals are involved -- all appropriate available information dealing with each of the victims must also be reported. The informational items below are grouped by sections for ease in reporting pesticide incidents.

(1) *Administrative.* Pesticide incident reports must be submitted if the registrant possesses or receives any of the following information, and the incident meets the minimum requirements set forth in paragraph (a) of this section:

(i) Name of reporter, address, and telephone number.

(ii) Name, address, and telephone number of contact person (if different than reporter).

(iii) Incident report status (e.g., new or update); if update, include the date of original submission.

(iv) Date registrant became aware of the incident.

(v) Date of incident (if appropriate, list start and end dates).

(vi) Location of incident (city, county and state).

(vii) Is incident part of a larger study.

(viii) Source if different from reporting registrant.

(2) *Pesticide.* Pesticide incident reports must be submitted if the registrant possesses or receives any of the following information, and the incident meets the minimum requirements set forth in paragraph (a) of this section:

(i) Product name.

(ii) Active ingredient(s).

(iii) EPA Registration Number.

(iv) Diluted for use, or concentrate.

(v) Formulation, if known.

(vi) List the same information under paragraphs (c)(2)(i) through (c)(2)(v) for other pesticides that may have contributed to this incident.

(3) *Circumstance.* Pesticide incident reports must be submitted if the registrant possesses or receives any of the following information, and the incident meets the minimum requirements set forth in paragraph (a) of this section:

(i) Evidence the label directions were not followed (e.g., yes, no, unknown).

(ii) How exposed (e.g., spill, drift, equipment failure, container failure, mislabeling, runoff, etc.).

(iii) Situation (e.g., household use, mixing/loading, application, reentry, disposal, transportation, other (describe)).

(iv) Use site (e.g., home, yard, commercial turf, agricultural (specify crop), industrial, building/office, school, nursery, greenhouse, pond/lake/stream, well, forest/woods, other.

(v) Applicator certified (yes, no, unknown).

(vi) A brief description of the circumstances of the incident.

(4) *Other incident specific information.* Pesticide incident reports must be submitted if the registrant possesses or receives any of the following information, and the incident meets the minimum requirements set forth in paragraph (a) of this section:

(i) If the incident involves humans:

(A) Route of exposure (skin, eye, respiratory, oral).

(B) List signs/symptoms/adverse effects.

(C) If laboratory tests were performed, list name of test(s) and results.

(D) If available, submit laboratory report(s).

(E) Time between exposure and onset of symptoms.

(F) Was adverse effect the result of suicide/homicide or attempted suicide/homicide.

(G) Type of medical care sought, (e.g., none, Poison Control Center, hospital emergency department, hospital inpatient, private physician, clinic, other).

(H) Demographics (sex, age, occupation).

(I) If female, pregnant?

(J) Exposure data: amount of pesticide; duration of exposure; weight of victim.

(K) Was exposure occupational; days lost due to illness.

(L) Was protective clothing worn (specify).

(ii) If domestic animal:

(A) Type of animal (e.g., livestock, poultry, bird, fish, household pet e.g., dog/cat etc.).

(B) List signs/symptoms/adverse effects.

(C) Breed/species (name and number affected, per adverse effect).

(D) Route of exposure (e.g., skin, eye, respiratory, oral).

(E) Time between exposure and onset of symptoms.

(F) If laboratory test(s) performed, list name of tests and results.

(G) If available, submit laboratory report(s).

(iii) If fish, wildlife, plants or other non-target organisms:

(A) List species affected, and number of individuals per species.

(B) List symptoms or adverse effects.

(C) Magnitude of the effect (e.g., miles of streams, square area of terrestrial habitat).

(D) Pesticide application rate, intended use site (e.g., corn, turf), and method of application.

(E) Description of the habitat and the circumstances under which the incident occurred.

(F) If plant, type of plant life (i.e., crop, forest, orchard, home garden, ornamental, forage).

(G) Formulation of pesticide if not indicated by brand name (granular, flowable).

(H) Distance from treatment site.

(I) If laboratory test(s) performed, list name of test(s) and results.

(J) If available, submit laboratory report(s).

(iv) If surface water:

(A) If raw water samples, water bodies sampled and approximate locations in each water body.

(B) If raw water samples, proximity of sampling locations to drinking water supply intakes and identities of systems supplied.

(C) If finished water samples, water supply systems sampled.

(D) If finished water samples, percent surface water source by specific surface water sources to water supply system(s).

(E) Sample type (grab, composite).

(F) Sampling times/frequency.

(G) Pesticides and degradates analyzed for and their detection limits.

(H) Method of analysis.

(v) If ground water:

(A) Pesticide and degradates analyzed for and the analytical methods and detection limits.

(B) Sample date.

(C) Amount pesticide applied (lbs-ai/acre).

(D) Date of last application.

(E) Depth to water.

(F) Latitude/longitude.

(G) Soil series and texture (sand/silt/clay).

(H) Frequency of applications per year.

(I) Aquifer description (confined/unconfined).

(J) Method of application.

(K) Years pesticide used.

(L) Well use and well identifier.

(M) Screened interval.

(N) Annual cumulative rainfall (inches).

(O) Maximum rainfall and date.

(P) Cumulative irrigation (inches).

(Q) Hydrologic group.

(R) Hydraulic conductivity.

(S) pH.

(T) Organic matter or organic carbon (percent).

(vi) If property damage.

(A) Provide description.

(B) [Reserved]

(5) *Exposure types and severity category designations*—(i) *Humans.* If an effect involves a human, provide the appropriate 2-letter exposure types and severity categories and their designations, based upon the following categories:

(A) H-A: If the person died.

(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.

(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.

(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.

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

(ii) *Domestic animals.* If an effect involves a domestic animal, provide the appropriate 2-letter notation based upon the following categories:

(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 respirator irritation.

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

(iii) *Fish or wildlife.* If an alleged effect involves fish or wildlife, label the incident W-A if any of the criteria listed in paragraphs (c)(5)(iii)(A) through (c)(5)(iii)(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 forecological concerns.

(B) Fish: Affected 1,000 or more individuals of a schooling species or 50 or moreindividuals of a non-schooling species.

(C) Birds: Affected 200 or more individuals of a flocking species, or 50 or moreindividuals of a songbird species, or 5 or more individuals of a predatory species.

(D) Mammals, reptiles, amphibians: Affected 50 or more individuals of a relativelycommon 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 apesticide.

(G) Involves adverse effects caused by a pesticide, to federally listed endangered orthreatened species.

(iv) *Plants.* If an alleged effect involves damage to plants, label the incident P-A if the single criterion listed in paragraph (c)(5)(iv)(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), label the incident ONT.

(vi) *Water contamination.* If a pesticide is alleged to have been detected in groundwater, surface water or finished drinking water, label the incident in accordance with the following criteria:

(A) G-A: If the pesticide was detected at levels greater than the maximum contaminant level (MCL) or health advisory level (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 a 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, ''H-B: property damage.'' Label the incident in accordance with the following criteria:

(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 (c)(5)(vii)(A) or (B) of this section, including cases in which the level of damages is not specified.

(d) *Time requirements for submitting incident information.* Information concerning incidents reportable under this section must be submitted within the time frames listed for different exposure and severity categories, as follows:

(1) For allegations involving human fatality (H-A), registrants must submit the required information, to the extent it is available, no later than 15 days after learning of an allegation.

(2) Information concerning incidents which meet the criteria for the following exposure and severity category labels described in paragraph (c)(5) of this section may be accumulated for a 30-day period, and submitted to the Agency within 30 days after the end of each 30-day accumulation period: for Humans, H-B, and H-C; for Wildlife, W-A; for Plants, P-A; for Water, G-A; for Property Damage, PD-A.

(3) For incidents meeting all other exposure and severity label categories, information may be accumulated by registrants for 90 days and submitted within 60 days of the end of each 90-day accumulation period.

(e) *Aggregated reports.* For incidents that are reportable under the schedule requirements of paragraph (d)(3) of this section, in lieu of individual reports containing the information listed in paragraphs (c)(1) through (c)(4) of this section, registrants must provide an aggregated report listing:

(1) The time period covered by the report.

(2) For each exposure and severity label category, a count of the number of incidents, listed by product registration number (if known) or active ingredient.

(3) 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.

(f) *Reporting additional information.* If, after the submission of an incident report to the Agency, a registrant acquires additional information concerning that incident, the information should be submitted within the same time frame as applied to the original incident report, if any of the following conditions apply:

(1) The information concerns an alleged human fatality (H-A), and the information consists of any of the elements listed in paragraphs (c)(1) through (c)(4) of this section.

(2) The information concerns an incident originally reported as alleging a major human illness or injury (H-B), or fatality to a domestic animal (D-A), or wildlife (W-A), and the additional information consists of pesticide or circumstance information listed in paragraphs (c)(2) or (c)(3) of this section, or is a laboratory report concerning persons or animals involved in the incident.

(3) The information concerns any incident not originally reported with one of the exposure and severity labels H-A, or H-B for human incidents, or at the ''A'' level of severity for any other exposure or incident type, and the new information would result in labeling the incident H-A or H-B for a human incident, or at the ''A'' level of severity for any other exposure or incident type listed in paragraph (c)(5) of this section.

§ 159.188 Failure of performance information.

(a) *Microorganisms that pose a risk to human health.* Information must be submitted which concerns either incidents described in paragraph (a)(1) of this section or a study described in paragraph (a)(2) of this section:

(1) Information which concerns an incident which 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 failures of the pesticide to perform as claimed involved the use against microorganisms which may pose a risk to human health.

(iii) The pesticide product's use site is other than residential.

(iv) The registrant has or could obtain information concerning where the incident occurred, the pesticide or product involved, and the name of a person to contact regarding the incident.

(2) 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 control of microorganisms that may pose a risk to human health, including any of the public health antimicrobials identified in part 158 of this chapter.

(b) *Animals that pose a risk to human health.* For the purposes of this section, any animal (including insects) poses a risk to human health if it may cause disease in humans, either directly or as a disease vector; produce toxins that are harmful to humans; or cause direct physical harm to humans. Information must be submitted which concerns either incidents described in paragraph (b)(1) of this section or a study described in paragraph (b)(2) of this section.

(1) Information which concerns an incident which meets all of the following conditions:

(i) The registrant has been informed by municipal, State, or Federal public health officials that a pesticide product may not have performed as claimed against target animals.

(ii) The possible failures of the pesticide to perform as claimed involved the use against animals that pose a risk to human health.

(iii) The registrant has or could obtain information concerning where the

incident occurred, the pesticide or product involved, and the name of a person to contact regarding the incident.

(2) A study which indicates that the pesticide may not perform in accordance with one or more claims by the registrant regarding uses intended for control of animals that pose a risk to human health, including any of the public health pesticides identified in part 158 of this chapter.

(c) *Development of pesticide resistance.* Information must be submitted concerning substantiation of any incident of a pest 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 either of the following conditions is met:

(1) The survival of the suspected pesticide-resistant pest was significantly higher than that of a known susceptible pest when both the suspected resistant and susceptible pests were treated with the pesticide under controlled conditions.

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

§ 159.195 Reporting of other information.

(a) The registrant shall submit to the Administrator information other than that described in §§ 159.165 through 159.188 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. Examples of the types of information which must be provided if not already reportable under some other provision of this Part include but are not limited to information showing:

(1) Previously unknown or unexpected bioaccumulation of a pesticide by various life forms.

(2) Greater than anticipated drift of pesticides to non-target areas.

(3) Use of a pesticide may pose any greater risk than previously believed or reported to the Agency.

(4) Use of a pesticide promotes or creates secondary pest infestations.

(5) Any information which might tend to invalidate a study submitted to the Agency to support a pesticide registration.

(b) A registrant is not obligated under paragraph (a) of this sectioin to provide information to the Administrator if the registrant is aware of facts which establish that otherwise-reportable information is not correct.

(c) The registrant shall submit to the Administrator information other than that described in §§ 159.165 through 159.188 if the registrant has been informed by EPA that such 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 a product.

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