Attachment B

Final Regulation for FIFRA Section 6(a)(2) Reports
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Title 40: Protection of Environment

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PART 159—STATEMENTS OF POLICIES AND INTERPRETATIONS

Section Contents

Authority: 7 U.S.C. 136–136y.

Source: 63 FR 49388, Sept. 19, 1997, unless otherwise noted.

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§ 159.152 What the law requires of registrants.

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(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.

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FIFRA section 6(a)(2), the definitions set forth in FIFRA section 2 and in 40 CFR part 152 apply to this part unless superseded by a definition in paragraph (b) of this section.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

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.

[62 FR 49388, Sept. 19, 1997, as amended at 63 FR 33582, June 19, 1998]

§ 159.155 When information must be submitted.

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(a) The following reportable information must be received by EPA not later than the 30th calendar day after the registrant first possesses or knows of the information:

(1) Scientific studies described in §159.165.

(2) Information about discontinued studies described in §159.167.

(3) Human epidemiological and exposure studies described in §159.170.

(4) Detection of a pesticide in or on food or feed described in §159.178(a).

(5) Detection of metabolites, degradates, contaminates, impurities described in §159.179.

(6) Failure of performance studies described in §159.188(a)(2), (b)(2), and (c).

(7) Other information described in §159.195.

(b) Reportable information concerning detections of pesticides in water described in §159.178(b), adverse effects incidents described in §159.184(a), and efficacy failure incidents described in §159.188 (a)(1) and (b)(1) must be reported according to the time frames set forth in §159.184(d).

(c) 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.

(d) 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; provided that, such person performs any activities for the registrant related to the development, testing, sale or registration of a pesticide or the person could be reasonably expected to come into possession of information otherwise reportable under this part. In the case of information known to or possessed by an agent or other person acting for the registrant, a registrant is responsible for such information only if the agent or other person acquired such information while acting for the registrant.

[63 FR 33582, June 19, 1998]

§ 159.156 How information must be submitted.

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A submission under FIFRA section 6(a)(2) must be delivered to the Office of Pesticide Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b).

(a) 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).

(b) 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.

(c) 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).

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

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

(f) 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.

(g) 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.

(h) 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.

(i) 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.

[63 FR 49388, Sept. 19, 1997, as amended at 69 FR 39864, July 1, 2004; 71 FR 35545, June 21, 2006]

§ 159.158 What information must be submitted.

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(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 who meets any of the following:

(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 that date on which the registrant must submit such information if 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 following categories:

(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 both of the following conditions are met:

(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.

[62 FR 49388, Sept. 19, 1997; 63 FR 33582, June 19, 1998]

§ 159.159 Information obtained before promulgation of the rule.

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(a) Notwithstanding any other provision of this part, information held by registrants on August 17, 1998 which has not been previously submitted to the Agency, but which is reportable under the terms of this part, must 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 any of the following:

(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(c).

(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.

[62 FR 49388, Sept. 19, 1997; 63 FR 33582, June 19, 1998, as amended at 63 FR 41193, Aug. 3, 1998]

§ 159.160 Obligations of former registrants.

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(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.

[62 FR 49388, Sept. 19, 1997; 63 FR 33582, June 19, 1998]

§ 159.165 Toxicological and ecological studies.

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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 either of the following conditions is met:

(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 regimine lasting 90 calendar days or less, and all of the following conditions are met:

(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 regimine lasting 90 calendar days or less, and all of the following conditions are met:

(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.

[62 FR 49388, Sept. 19, 1997; 63 FR 33582, June 19, 1998]

§ 159.167 Discontinued studies.

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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.

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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.

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(a) *Food and feed.* Information must be submitted if it shows that the pesticide is present in or 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. The information to be submitted is the same as that required in §159.184(c)(1), (2), (3), and (4)(iv)(E), (F), (G), and (H).

(b) *Water.* (1) Information must be submitted if it shows that a pesticide is present above the water reference level in any of the following instances:

(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.

(5) Information to be submitted is the same as that required in §159.184(c)(1), (2), (3), (4)(iv) and (v), and (5)(vi).

[62 FR 49388, Sept. 19, 1997; 63 FR 33582, June 19, 1998]

§ 159.179 Metabolites, degradates, contaminants, and impurities.

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

(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 either of the following conditions 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.

[62 FR 49388, Sept. 19, 1997; 63 FR 33582, June 19, 1998]

§ 159.184 Toxic or adverse effect incident reports.

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(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 for each pesticide that may have contributed to the incident, 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.

(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 degredates analyzed for, the detection limits, and the amount detected.

(H) Method of analysis.

(v) If ground water:

(A) Pesticides and degredates analyzed for, the analytical method used, the detection limits, and the amount detected.

(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 following criteria 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 more individuals 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 relatively common or herding species or 5 or more individuals of a rare or solitary species.

(E) Involves effects to, or illegal pesticide treatment (misuse) of a substantial tract of habitat (greater than or equal to 10 acres, terrestrial or aquatic).

(F) Involves a major spill or discharge (greater than or equal to 5,000 gallons) of a pesticide.

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

(iv) *Plants.* If an alleged effect involves damage to plants, label the incident P-A if the following criterion 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, reports of detections of pesticides in water, and efficacy failure incidents may be described in §159.188(a)(1) and (b)(1), 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; Wildlife, W-A; Plants, P-A; Water, G-A; Property Damage, PD-A.

(3) Incidents or reports of detections of pesticides in water meeting all other exposure and severity label categories, information may be accumulated by registrants for 90 days and submitted within 60 days after 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.

[62 FR 49388, Sept. 19, 1997; 63 FR 33583, June 19, 1998]

§ 159.188 Failure of performance information.

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(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.

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(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 section 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.

[62 FR 49388, Sept. 19, 1997; 63 FR 33583, June 19, 1998]

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