

Environmental Protection Agency

§ 159.158

§ 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, 1200 Pennsylvania Ave., NW., 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 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,

Environmental Protection Agency

§ 159.160

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.

(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.

(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