

§ 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