

## Environmental Protection Agency

## § 159.155

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 level* 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.

(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, contaminants, 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

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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.

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.

(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