

**§ 159.152**

- 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.

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

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FIFRA section 6(a)(2), the definitions set forth in FIFRA section 2 and in 40 CFR part 152 apply to this part unless superseded by a definition in paragraph (b) of this section.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

*Established level* means a tolerance, temporary tolerance, food additive regulation, action level, or other limita-

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tion 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,

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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; 73 FR 75596, Dec. 12, 2008]

### § 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 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 or § 161.32 of this chapter, as applicable.