

§ 159.170

study is, or would have been, required under this part.

§ 159.170 Human epidemiological and exposure studies.

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.

(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

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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.

(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.

(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.