

**§ 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.