

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.

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§ 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: