

Environmental Protection Agency

§ 159.165

met. Such information shall be submitted in the same manner and according to the same schedules as it would have to be submitted by a current registrant of a pesticide product to which the information pertained.

[62 FR 49388, Sept. 19, 1997; 63 FR 33582, June 19, 1998]

§ 159.165 Toxicological and ecological studies.

Adverse effects information must be submitted as follows:

(a) *Toxicological studies.* (1) The results of a study of the toxicity of a pesticide to humans or other non-target domestic organisms if, relative to all previously submitted studies, they show an adverse effect under any of the following conditions:

(i) That is in a different organ or tissue of the test organism.

(ii) At a lower dosage, or after a shorter exposure period, or after a shorter latency period.

(iii) At a higher incidence or frequency.

(iv) In a different species, strain, sex, or generation of test organism.

(v) By a different route of exposure.

(2) Acute oral, acute dermal, acute inhalation or skin and eye irritation studies in which the only change in toxicity is a numerical decrease in the median lethal dose (LD₅₀), median lethal concentration (LC₅₀) or irritation indices, are not reportable under this part unless the results indicate a more restrictive toxicity category for labeling under the criteria of 40 CFR 156.10(h).

(b) *Ecological studies.* The results of a study of the toxicity of a pesticide to terrestrial or aquatic wildlife or plants if, relative to all previously submitted studies, they show an adverse effect under any of the following conditions:

(1) At levels 50 percent or more lower than previous acute toxicity studies with similar species, including determinations of the median lethal dose (LD₅₀), median lethal concentration (LC₅₀), or median effective concentration (EC₅₀).

(2) At lower levels in a chronic study than previous studies with similar species.

(3) In a study with a previously untested species the results indicate the

chronic no observed effect level (NOEL) is 10 percent or less of the lowest LC₅₀ or LD₅₀ for a similar species.

(4) For plants when tested at the maximum label application rate or less, if either of the following conditions is met:

(i) More than 25 percent of terrestrial plants show adverse effects on plant life cycle functions and growth such as germination, emergence, plant vigor, reproduction and yields.

(ii) More than 50 percent of aquatic plants show adverse effects on plant life cycle functions and growth such as germination, emergence, plant vigor, reproduction and yields.

(c) Results from a study that demonstrates any toxic effect (even if corroborative of information already known to the Agency), must be submitted if the pesticide is or has been the subject of a Formal Review based on that effect within 5 years of the time the results are received. Within 30 calendar days of the publication of a Notice of Commencement of a Formal Review in the FEDERAL REGISTER, all information which has become reportable due to the commencement of the Formal Review must be submitted.

(d) *Incomplete studies.* Information from an incomplete study of the toxicity to any organism of a registered pesticide product or any of its ingredients, impurities, metabolites, or degradation products which would otherwise be reportable under paragraphs (a), (b) or (c) of this section must be submitted if the information meets any one of the following three sets of criteria:

(1) *Short-term studies.* A study using a test regimen lasting 90 calendar days or less, and all of the following conditions are met:

(i) All testing has been completed.

(ii) A preliminary data analysis or gross pathological analysis has been conducted.

(iii) Final analysis has not been completed.

(iv) A reasonable period for completion of the final analysis not longer than 90 calendar days following completion of testing has elapsed.

(v) Comparable information concerning the results of a completed study would be reportable.

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(2) *Long-term studies.* A study using a test regimen lasting 90 calendar days or less, and all of the following conditions are met:

- (i) All testing has been completed.
- (ii) A preliminary data analysis or gross pathological analysis has been conducted.
- (iii) Final analysis has not been completed.
- (iv) A reasonable period of completion of final analysis (not longer than 1 year following completion of testing) has elapsed.
- (v) Comparable information concerning the results of a completed study would be reportable.

(3) *Serious adverse effects.* Any study in which testing or analysis of results is not yet complete but in which serious adverse effects have already been observed which may reasonably be attributed to exposure to the substances tested, because the effects observed in exposed organisms differ from effects observed in control organisms, are atypical in view of historical experience with the organism tested, or otherwise support a reasonable inference of causation, and 30 days have passed from the date the registrant first has the information.

[62 FR 49388, Sept. 19, 1997; 63 FR 33582, June 19, 1998]

§ 159.167 Discontinued studies.

The fact that a study has been discontinued before the planned termination must be reported to EPA, with the reason for termination, if submission of information concerning the 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

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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 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