
40 C.F.R. § 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 156.62.

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