(B) Liquid formulation indoors use products require all tests listed under (b)(1)(i) of this section except the avian oral $LD_{50}$.
(ii) Data are not required to support:
(A) Indoor end-use products consisting of a gas/highly volatile liquid or a highly reactive solid.
(B) Indoor end-use products for which there is a manufacturing use product registration.
(2) Tests required on a case-by-case basis depending on the results of lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics.
(3) Data required if one or more of the following criteria are met:
(i) Birds may be subjected to repeated or continued exposure to the pesticide or any of its major metabolite degradation products, especially preceding or during the breeding season.
(ii) The pesticide or any of its major metabolites or degradation products are stable in the environment to the extent that potentially toxic amounts may persist in avian feed.
(iii) The pesticide or any of its major metalolites or degradation products is stored or accumulated in plant animal tissues, as indicated by its octanol/water partition coefficient, accumulation studies, metabolic release and retention studies, or as indicated by structural similarity to known bioaccumulative chemicals.
(iv) Any other information, such as that derived from mammalian reproduction studies that indicates the reproduction in terrestrial vertebrates may be adversely affected by the anticipated use of the pesticide product.
NOTE: Prior to conducting this test to support the registration of an avicide, the applicant should consult the Agency.
(4) Data required if the product is intended for direct application to the estuarine or marine environment, or the product is expected to enter this environment in significant concentrations because of its expected use or mobility pattern.
(5) Data from fish early life-stage tests or life-cycle tests with aquatic invertebrates (on whichever species is most sensitive to the pesticide as determined from the results of the acute toxicity tests) are required if the product is applied directly to water or expected to be transported to water from the intended use site, and when any one or more of the following conditions apply:
(i) If the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity.
(ii) If any $LC_{50}$ or $EC_{50}$ value determined in acute toxicity testing is less than 1 mg/l; or
(iii) If the estimated environmental concentration in water is equal to or greater than 0.01 of any $EC_{50}$ or $LC_{50}$ determined in acute toxicity testing.
(iv) If the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any $EC_{50}$ or $LC_{50}$ determined in acute toxicity testing and any of the following conditions exist:
(A) Studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected.
(B) Physiochemical properties indicate cumulative effects.
(C) The pesticide is persistent in water (e.g., half-life in water greater than 4 days).
(6) Data are required if end-use product is intended to be applied directly to water or expected to transport to water from the intended use site, and when any of the following conditions apply:
(i) if the estimated environmental concentration is equal to or greater than one-tenth of the no-effect level in the fish early life-stage or invertebrate life-cycle test.
(ii) If studies of other organisms indicate the reproductive physiology of fish may be affected. NOTE: The applicant should consult the Agency prior to these tests to support the registration of a pesticide.
(7) Data from testing with the applicant's end-use product or a typical end-use product is required to support the registration of each end-use product which meets any one of the following conditions:
(i) The end-use pesticide will be introduced directly not an aquatic environment when used as directed.
(ii) The $LC_{50}$ or $EC_{50}$ of the technical grade of active ingredient is equal to or less than the maximum expected environmental concentration (MEEC) or the estimated environmental concentration (EEC) in the aquatic environment when the end-use pesticide is used as directed.
(iii) An ingredient in the end-use formulation other than the active ingredient is expected to enhance the toxicity of the active ingredient or to cause toxicity to aquatic organisms.
(8) Required if significant concentrations of the active ingredient and/or its principal degradation products are likely to occur in aquatic environments and may accumulate in aquatic organisms.

[49 FR 42881, Oct. 24, 1984. Redesignated at 53 FR 15993, May 4, 1988, as amended at 58 FR 34203, June 23, 1993]

## § 161.540 Plant protection data requirements.

(a) *Table*. Sections 161.100 through 161.102 describe how to use this table to determine the plant protection data requirements and the substance to be tested.

| Kind of data required | (b) Notes | General use patterns | | | | | | | | | Test substance | | Guidelines reference No. |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Terrestrial | | Aquatic | | Greenhouse | | Forestry | Domestic outdoor | Indoor | Data to support MP | Data to support EP | |
| | | Food crop | Nonfood | Food crop | Nonfood | Food crop | Nonfood | | | | | | |
| Target area phytotoxicity .. | (1) | ..... | ..... | ..... | ..... | ..... | ..... | ..... | ..... | ..... | EP ..... | EP ..... | 121–1 |

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nontarget area phytotoxicity. | | | | | | | | | | | | | |
| Tier I: | | | | | | | | | | | | | |
| Seed germination/seedling emergence. | (2) | ..... | R | ..... | R | ..... | ..... | R | ..... | ..... | TGAI ..... | TGAI ..... | 122–1 |
| Vegetative vigor ..... | (2) | ..... | R | ..... | R | ..... | ..... | R | ..... | ..... | TGAI ..... | TGAI ..... | 122–1 |
| Aquatic plant growth | (2) | ..... | R | ..... | R | ..... | ..... | R | ..... | ..... | TGAI ..... | TGAI ..... | 122–2 |
| Tier II: | | | | | | | | | | | | | |
| Seed germination/seedling emergence. | (3) | ..... | CR | ..... | CR | ..... | ..... | CR | ..... | ..... | TGAI ..... | TGAI ..... | 123–1 |
| Vegetative vigor ..... | (3) | ..... | CR | ..... | CR | ..... | ..... | CR | ..... | ..... | TGAI ..... | TGAI ..... | 123–1 |
| Aquatic plant growth | (4) | ..... | CR | ..... | CR | ..... | ..... | CR | ..... | ..... | TGAI ..... | TGAI ..... | 123–2 |
| Tier III: | | | | | | | | | | | | | |
| Terrestrial field ..... | (3) | ..... | CR | ..... | CR | ..... | ..... | CR | ..... | ..... | TEP ..... | TEP ..... | 124–1 |
| Aquatic field ..... | (4) | ..... | CR | ..... | CR | ..... | ..... | CR | ..... | ..... | TEP ..... | TEP ..... | 124–2 |

Key: CR=Conditionally required; TGAI=Technical grade of the active ingredient; EP=End-use product; TEP=Typical end-use product.
(b) NOTES. The following notes are referenced in column two of the table contained in paragraph (a) of this section.
(1) Data are required for Special Review and certain public health situations.
(2) Data are required for pesticides to be used in forests and natural grasslands. For herbicide used in forest site preparation; the acquatic plant growth tests will be required. Data are required to support products to be used in other locations when any of the following conditions are met:
(i) Phytotoxicity problems concerning the product arise and open literature data are not available to address the problems.
(ii) The product may pose hazards to endangered or threatened species.
(iii) Special Review has been initiated on the product.
(3) Required if a 25 percent or greater detrimental effect was found in 1 or more plant species in the corresponding test of the previous tier.
(4) Required if a 50 percent or greater detrimental effect was found on any plant species in the corresponding test of the previous tier.

[49 FR 42881, Oct. 24, 1984. Redesignated at 53 FR 15993, May 4, 1988, as amended at 58 FR 34203, June 23, 1993]

## § 161.590 Nontarget insect data requirements.

(a) *Table*. Sections 161.100 through 161.102 describe how to use this table to determine the nontarget insect data requirements and the substance to be tested.

| Kind of data required | (b) Notes | General use pattern | | | | | | | | | Test substance | | Guidelines reference No. |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Terrestrial | | Aquatic | | Greenhouse | | Forestry | Domestic outdoor | Indoor use | Data to support MP | Data to support EP | |
| | | Food crop | Nonfood | Food crop | Nonfood | Food crop | Nonfood | | | | | | |
| Nontarget insect testing—pollinators | | | | | | | | | | | | | |
| Honey bee acute contact $LD_{50}$. | (1) | [CR] | [CR] | [CR] | [CR] | ..... | ..... | [CR] | [CR] | ..... | TGAI ..... | TGAI ..... | 141–1 |
| Honey bee—toxicity of residues on foliage. | (1), (2) | CR | CR | CR | CR | ..... | ..... | CR | CR | ..... | TEP ..... | TEP ..... | 141–2 |
| Honey bee subacute feeding study. | (3) | ..... | ..... | ..... | ..... | ..... | ..... | ..... | ..... | ..... | ..... | ..... | 141–4 |