

(2) [Reserved]

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

§ 158.490 Wildlife and aquatic organisms data requirements.

(a) *Table.* Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the wildlife and aquatic organisms data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns										Test substance		Guide-lines 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									
Avian and mammalian testing																
Avian oral LD ₅₀ (preferably mallard or bobwhite).	(1)	[R]	[R]	[R]	[R]	CR	CR	CR	[R]	CR	TGAI	TGAI	TGAI	TGAI	71-1	
Avian dietary LC ₅₀ (preferably mallard and bobwhite).	(1)	[R]	[R]	[R]	[R]	CR	CR	CR	[R]	CR	TGAI	TGAI	TGAI	TGAI	71-2	
Wild mammal toxicity	(2)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	TGAI	TGAI	71-3	
Avian reproduction (preferably mallard and bobwhite).	(3)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	TGAI	TGAI	71-4	
Simulated and actual field testing—mammals and birds.	(2)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TEP	TEP	TEP	TEP	71-5	
Aquatic organism testing																
Freshwater fish LC ₅₀ (preferably rainbow and bluegill).	(1), (7)	[R]	[R]	[R]	[R]	CR	CR	CR	[R]	CR	TGAI	TGAI	TGAI	TGAI	72-1	
Acute LC ₅₀ freshwater invertebrates (preferably <i>Daphnia</i>).	(1), (7)	[R]	[R]	[R]	[R]	CR	CR	CR	[R]	CR	TGAI	TGAI	TGAI	TGAI	72-2	
Acute LC ₅₀ estuarine and marine organisms.	(4), (7)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	TGAI	TGAI	72-3	
Fish early life stage and aquatic invertebrate life-cycle.	(5)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	TGAI	TGAI	72-4	
Fish—life-cycle	(6)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	TGAI	TGAI	72-5	

Kind of data required	(b) Notes	General use patterns										Test substance		Guide-lines 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									
Aquatic organism accumulation.	(8)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI, PAI, or degradation product.	TGAI, PAI, or degradation product.	72-6
Simulated or actual field testing—aquatic organisms.	(2)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TEP	TEP	72-7

Key: R=Required; CR=Conditionally required; []=Brackets (ie. [R], [CR]) indicate data requirements that apply when an experimental use permit is being sought; TGAI= Technical grade of the active ingredient; TEP= Typical end-use product; PAI= Pure active ingredient.

(b) NOTES: The following notes are referred to in column two of the table contained in paragraph (a) of this section.

(1) (i) Data are required as follows to support manufacturing use products and those end-use products for indoor use for which there is no registered manufacturing use product:
 (A) Solid formulation indoor use products require avian oral LD₅₀ (bobwhite), avian dietary LC₅₀ (rainbow trout), and acute LC₅₀ freshwater invertebrate (Daphnia).
 (B) Liquid formulation indoor use products require all tests listed under (b)(1)(i) of this section except the avian oral LD₅₀.

(2) 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.

(3) 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:
 (i) Data required if one or more of the following criteria are met:
 (ii) 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.
 (iii) 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.
 (iv) The pesticide or any of its major metabolites 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.
 (v) 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 exist:
 (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 LC₅₀ or EC₅₀ 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 EC₅₀ or LC₅₀ 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 EC₅₀ or LC₅₀ 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) Physicochemical 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 LC₅₀ or EC₅₀ 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, and amended at 58 FR 34203, June 23, 1993]

§ 158.540 Plant protection data requirements.

(a) *Table.* Sections 158.50 and 158.100 through 158.102 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		Guide- lines ref- erence No.	
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to sup- port MP	Data to sup- port EP			
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood								
Target area phytotoxicity ..	(1)	121-1
Non-target area phytotoxicity.															
Tier I:															
Seed germination/ seedling emer- gence.	(2)	R	122-1
Vegetative vigor	(2)	R	122-1
Aquatic plant growth	(2)	R	122-2
Tier II:															
Seed germination/ seedling emer- gence.	(3)	CR	123-1
Vegetative vigor	(3)	CR	123-1
Aquatic plant growth	(4)	CR	123-2
Tier III:															
Terrestrial field	(3)	CR	124-1
Aquatic field	(4)	CR	124-2

Key: CR=Conditionally required; TGA=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 aquatic 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.

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