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						
Mammalian predacides	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	.....	.....	EP*	96–17

Key: R=Required; CR=Conditionally required; [ ]=Brackets (*i.e.*, [R], [CR]) indicate data requirements that apply to products for which an experimental use permit is being sought; EP=End-use product* (asterisk identifies those data requirements that end-use applicants (*i.e.*, "formulators") must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source); MP=Manufacturing 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) The Agency has waived all requirements to submit efficacy data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.

(2) [Reserved]

[49 FR 42881, Oct. 24, 1984, as amended at 50 FR 46766, Nov. 13, 1985. Redesignated at 53 FR 15993, May 4, 1988, and amended at 58 FR 34203, June 23, 1993]

§ 158.690 Biochemical pesticides data requirements.

(a) *Biochemical pesticide product analysis data requirements*—(1) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the biochemical pesticides—product analysis data requirements and the substance to be tested.

Kind of data required	(2) 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						
Product identity	.....	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	151–10
Manufacturing process	(i)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* and TGAI.	151–11
Discussion of formation of unintentional ingredients.	(ii)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* and TGAI.	151–12
Analysis of samples	(iii)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	MP and TGAI.	EP* and TGAI.	151–13
Certification of limits	.....	[R]	R	[R]	R	[R]	R	R	R	R	MP	EP*	151–15
Analytical methods	.....	R	R	R	R	R	R	R	R	R	MP	EP*	151–16
Physical and chemical properties.	.....	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* and TGAI.	151–17

Submittal of samples	(iv)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	MP and TGAI, PAI.	EP*, TGAI and PAI.	151–18

Key: R=Required CR=Conditionally required; MP=Manufacturing-use product; EP*=End-use product (asterisk identifies those data requirements that end-use applicants (*i.e.*, "formulators") must satisfy, provided that their active ingredient(s) (are) purchased from a registered source); TGAI=Technical grade of the active ingredient; [ ]=Brackets (*i.e.*, [R], [CR]) indicate data requirements that apply when an experimental use permit is being sought.

(2) NOTES.The following notes are referenced in column two of the table contained in paragraph (a)(1) of this section.

(i) If an experimental use permit is being sought, a schematic diagram and/or description of the manufacturing process will suffice if the pesticide is not already under full scale production.

(ii) If the product is not already under full scale production and an experimental use permit is being sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.

(iii) Required to support registration of each manufacturing-use product and end use products produced by an integrated formulation system. Data on other end use products will be required on a case-by-case basis. For pesticides in the production stage, a rudimentary product analytical method and data will suffice to support an experimental use permit.

(iv) Routinely required for products produced by an integrated formulation system. Required on a case-by-case basis for other products or materials.

(b) *Biochemical pesticides residue data requirements.* (1) Table. Sections 158.50 and 158.100 though 158.102 describe how to use this table to determine the biochemical pesticides—residue data requirements and the substance to be tested.

Kind of data required	(2) 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						
Chemical identity	(i), (ii), (xiv)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	TGAI	TGAI	153–3
Directions for use	(i), (iii), (xiv)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	.....	.....	153–3
Nature of the residue:													
Plants	(i), (xiv)	[CR]	.....	[CR]	.....	[CR]	.....	.....	[CR]	.....	PAIRA	PAIRA	153–3
Livestock	(i), (iv), (xiv)	[CR]	.....	[CR]	.....	[CR]	.....	.....	[CR]	.....	PAIRA and plant metabolites.	PAIRA and plant metabolites.	153–3
Residue analytical method	(i), (v), (xiv)	[CR]	.....	[CR]	.....	[CR]	.....	.....	[CR]	.....	TGAI and metabolites.	TGAI and metabolites.	153–3
Magnitude of the residue:													
Crop field trials	(i), (xiv)	[CR]	.....	[CR]	.....	[CR]	.....	.....	[CR]	.....	TEP	TEP	153–3
Processed food/feed	(i), (vi)	[CR]	.....	[CR]	.....	[CR]	.....	.....	.....	.....	EP	EP	153–3
Meat/mild/poultry/ eggs.	(i), (vii)	[CR]	.....	[CR]	.....	[CR]	.....	.....	.....	[CR]	TGAI or plant metabolites.	TGAI or plant metabolites.	153–3
Potable water	(i), (viii)	.....	.....	[CR]	[CR]	.....	.....	.....	.....	.....	EP	EP	153–3
Fish	(i), (ix)	.....	.....	[CR]	[CR]	.....	.....	.....	.....	.....	EP	EP	153–3
Irrigated crops	(i), (x)	.....	.....	[CR]	[CR]	.....	.....	.....	.....	.....	EP	EP	153–3
Food handling	(i), (xi)	.....	.....	.....	.....	.....	.....	.....	.....	[CR]	EP	EP	153–3
Reduction of residue	(i), (xii)	[CR]	.....	[CR]	.....	[CR]	.....	.....	.....	.....	Residue of concern.	Residue of concern.	153–3
Proposed tolerance	(i), (xiii)	[CR]	.....	[CR]	.....	[CR]	.....	.....	.....	.....	Residue of concern.	Residue of concern.	153–3

Kind of data required	(2) Notes	General use patterns									Test substance		Guideline 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						
Reasonable grounds in support of the petition.	.....	[CR]	.....	[CR]	.....	[CR]	.....	.....	.....	.....	.....	.....	153–3

Key: CR=Conditionally required data; TGAI=Technical grade of the active ingredient; PAIRA=Pure active ingredient, radio labeled; TEP=typical end-use product, MP=Manufacturing-use product; [ ]=Brackets (*i.e.*, [CR]) indicate data requirements that apply when an experimental use permit is being sought.

(2) NOTES. The following notes are referenced in column two of the table contained in paragraph (b)(1) of this section.

(i) Residue chemistry data requirements shall apply to biochemical pesticide products when any one or more of the following conditions apply:

(A) Tier II or III toxicology data are required, as specified for biochemical agents in (c)(1) of this section.

(B) The application rate of the product exceeds 0.7 ounces (20 grams) active ingredient per acre per application.

(C) The application rate of the product exceeds a level determined to be comparable to 0.7 ounces active ingredient per application but the application rate is not expressable in terms of ounces per acre per application.

(ii) The same chemical identity data as required in (a)(1) of this section are required, with emphasis on impurities that could constitute a residue problem.

(iii) Required information includes crops to be treated, rate of application, number and timing of applications, preharvest intervals, and relevant restrictions.

(iv) Data on metabolism in livestock are required when residues occur on a livestock feed, or the pesticide is to be applied directly to livestock.

(v) A residue method suitable for enforcement of tolerances is needed whenever a numeric tolerance is proposed Exemptions from the requirement of a tolerance will also usually require an analytical method.

(vi) Data on the nature and level of residue in processed food/feed are required when detectable residues could concentrate on processing and thus require establishment of a food additive tolerance.

(vii) Livestock feeding studies are required whenever a pesticide occurs as a residue in any livestock feed. Direct application to livestock uses will require animal treatment residue studies.

(viii) Data on residues in potable water are required whenever a pesticide is to be applied directly to water, unless it can be determined that the treated water would not be used (eventually) for drinking purpose, by man or animals.

(ix) Data on residues in fish are required whenever a pesticide is to be applied directly to water.

(x) Data on residues in irrigated crops are required when a pesticide is to be applied directly to water that could be used for irrigation or to irrigation facilities such as irrigation ditches.

(xi) Data or residues in food/feed in food handling establishments are required whenever a pesticide is to be used in food/feed handling establishments.

(xii) Reduction of residue data are required when the assumption of tolerance level residues results in an unsafe level of exposure. Data on the level of residue in food as consumed will be used to obtain a more precise estimate of potential dietary exposure.

(xiii) The proposed tolerance must reflect the maximum residue likely to occur in crops and meat/milk/poultry/eggs.

(xiv) Residue data for outdoor domestic uses are required if home gardens are to be treated and the home garden use pattern is different from the use pattern on which the tolerances were established.

(c) *Biochemical pesticides toxicology data requirements*—(1) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the biochemical pesticides—toxicology data requirements and the substances to be tested.

Kind of data required	(2) Notes	General use patterns									Test substance		Guideline 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						
Tier I:													
Acute oral toxicity	(i)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* or EP dilution* and TGAI.	152–10
Acute dermal toxicity	(i), (ii)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* or EP dilution* and TGAI.	152–11

Acute inhalation	(xiv)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* and TGAI.	152–12
Primary eye irritation	(ii)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP	152–13
Primary dermal irritation.	(i), (ii)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP	152–14
Hypersensitivity study	(iii)	CR	CR	CR	CR	CR	CR	CR	CR	MP	EP	152–15
Hypersensitivity incidents.	(iv)	CR	CR	CR	CR	CR	CR	CR	CR	.....	.....	152–16
Studies to detect genotoxicity.	(v)	[R]	[CR]	[R]	[CR]	[R]	[CR]	[CR]	[CR]	TGAI	TGAI	152–17
Immune response	.....	[R]	R	[R]	R	[R]	R	R	R	TGAI	TGAI	152–18
90-day feeding (1 spp.).	(vi)	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152–20
90-day dermal (1 spp.).	(vii)	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152–21
90-day inhalation (1 spp.).	(viii)	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152–22
Teratogenicity (1 spp.).	(ix)	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152–23
Tier II:												
Mammalian mutagenicity tests.	(x)	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152–19
Immune response	(xi)	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152–24
Tier III:												
Chronic exposure	(xii)	CR	.....	CR	.....	.....	.....	.....	CR	TGAI	TGAI	152–26
Oncogenicity	(xiii)	CR	.....	CR	.....	.....	.....	.....	CR	TGAI	TGAI	152–29

Key: R=Required; CR=Conditionally Required; MP=Manufacturing-use product; EP*=End-use product (asterisk identifies those data requirements that end-use applicants (*i.e.*, "formulators") must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source); TGAI=Technical Grade of the Active Ingredient; [ ]=Brackets (*i.e.*, [R], [CR]) indicate data requirement that apply when an experimental use permit is being sought.

(2) NOTES. The following notes are referenced in column two of the table contained in paragraph (c)(1) of this section.

(i) Not required if test material is a gas or is highly volatile.

(ii) Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified toxicity category I on the basis of potential eye and dermal irritation effects.

(iii) Required if repeated contact with human skin results under condition of use.

(iv) Incidents must be reported, if they occur.

(v) Required to support non-food uses if use is likely to result in significant human exposure; or the active ingredient or its metabolites is (are) structurally related to a known mutagen, or belongs(s) to any chemical class of compounds containing known mutagens.

(vi) Required if the use requires a tolerance or an exemption from the requirement for a tolerance, or its use requires a food additive regulation; or the use of the product is otherwise likely to result in repeated human exposure by the oral route.

(vii) Required if pesticidal use will involve purposeful application to the human skin or will result in comparable prolonged human exposure to the product, (e.g., swimming pool algaecides, pesticides for impregnating clothing), and if either of the following criteria are met:

(A) Data from a subchronic oral study are not required.

(B) The active ingredient of the product is known or expected to be metabolized differently by the dermal route of exposure than by the oral route, and a metabolite of the active ingredient is the toxic moiety.

(viii) Required if pesticidal use may result in repeated inhalation exposure at a concentration which is likely to be toxic.

(ix) Required if any of the following criteria are met:

(A) Use of the product under widespread and recognized practice may reasonably be expected to result in significant exposure to female humans.

(B) Its use requires a tolerance or an exemption from the requirement for a tolerance, or its use requires issuance of a food additive regulation.

(x) Required if results from any one of the Tier I mutagenicity tests were positive.

(xi) Required if adverse effects are observed in the Tier I immune response studies.

(xii) Required if the potential for adverse chronic effects are indicated based on:

(A) The subchronic effect levels established in the Tier I subchronic oral toxicity studies, the Tier I subchronic dermal toxicity studies or the Tier I subchronic inhalation toxicity studies.

(B) The pesticide use pattern (e.g., rate, frequency, and site of application).

(C) The frequency and level of repeated human exposure that is expected.
(xiii) Required if the product meets either of the following criteria:
(A) The active ingredient(s) or any of its (their) metabolites, degradation products, or impurities produce(s) in Tier I subchronic studies a morphologic effect (e.g., hyperplasia, metaplasia) in any organ that potentially could lead to neoplastic change.
(B) If adverse cellular effects suggesting oncogenic potential are observed in Tier I or Tier II immune response studies or in Tier II mammalian mutagenicity assays.
(xiv) Required if the product consists of, or under conditions of use results in, an inhalable material (e.g., gas, volatile substance, or aerosol/particulate).

(d) *Nontarget organism, fate and expression data requirements*—(1) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the biochemical pesticides non-target organism, fate and expression data requirements and substances to be tested.

Kind of data required	(2) Notes	General use patterns									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						
Tier I:													
Avian acute oral	(i), (ii)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154–6
Avian dietary	(i), (ii), (vi)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154–7
Freshwater fish LC_{50}	(i), (ii), (v)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154–8
Freshwater invertebrate LC_{50}.	(i), (ii), (vii)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154–9
Nontarget plant studies.	(iii)		R		R			R			TGAI	TGAI	154–10
Nontarget insect testing.	(iv), (v)	CR	CR	CR	CR	CR	CR	CR	CR		TGAI	TGAI	154–11
Tier II:													
Volatility	(viii)	CR	CR	CR	CR			CR	CR		TEP	TEP	155–4
Dispenser-water leaching.	(ix)	CR	CR	CR	CR			CR	CR		EP	EP	155–5
Adsorption-desorption	(x)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155–6
Octanol/Water Partition.	(x)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155–7
U.V. absorption	(xi)	CR	CR	CR	CR			CR	CR		PAI	PAI	155–8
Hydrolysis	(x)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155–9
Aerobic soil metabolism.	(x)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155–10
Aerobic aquatic metabolism.	(x)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155–11
Soil photolysis	(x)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155–12
Aquatic photolysis	(x)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155–13
Tier III:													
Terrestrial wildlife testing.	(xii)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	15–12
Aquatic animal testing	(xiii)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	154–13
Nontarget plant studies.	(xiv)										TGAI	TGAI	154–14

Nontarget insect testing.	(xv)	CR	CR	CR	CR	.....	.....	CR	CR	.....	TGAI	TGAI	154–15

Key: R=Required; CR=Conditionally reguired; [ ]=Brackets (*i.e.*, [R], [CR]) indicates data requirements that apply to products for which an experimental use permit is being sought; MP=Manufacturing-use product; TEP=Typical end-Use product; TGAI=Technical grade of the active ingredient; EP=End-use product, PAI="Pure" active ingredient.

(2) NOTES. The following notes are referenced in column two of the table contained in paragraph (d)(1) of this section.

(i) Tests for pesticides intended solely for indoor application will be required on a case-by-case basis, depending on use pattern, production volume, and other pertinent factors.

(ii) Preferable test species are: bobwhite quail or mallard for avian acute oral and avian dietary studies: rainbow trout for freshwater fish studies; and *Daphnia* for freshwater invertebrate studies on biochemicals.

(iii) Data are required for pesticides to be used in forests and natural grasslands. For herbicides used in forest site preparation; the aquatic plant growth tests will be required. Data are required when to support products to be used in other locations when any of the following conditions are met.

(A) Phytotoxicity problems arise and open literature data are not available.

(B) The product may pose hazards to endangered or threatened species.

(C) A rebuttable presumption against registration Special Review has been initiated on the product.

(iv) Required depending on pesticide mode of action and results of any available product performance data.

(v) Biochemicals introduced directly into an aquatic environment when used as directed shall be tested as specified in §158.145.

(vi) Not required if pesticide is highly volatile (estimated volatility greater than 5×10^{-5} atm. m^3/mol).

(vii) If the pesticide will be introduced directly into an aquatic environment when used as directed, then it must be tested as indicated in §158.145.

(viii) Required when results of any one or more of the Tier I tests indicate potential adverse effects on nontarget organisms and the biochemical agent is to be applied on land.

(ix) Required when results of any one or more of the Tier I tests indicate potential adverse effects on nontarget organisms and the biochemical agent is to be applied on land in a passive dispenser.

(x) Required on a case-by-case basis when results of Tier I tests indicate environmental fate data are needed.

(xi) Required when results of Tier I tests indicate potential adverse effects on beneficial insects and the intended route of exposure of the pesticide is through vapor phase contact.

(xii) Required if either of the following criteria are met:

(A) Environmental fate characteristics indicate that the estimated concentration of the biochemical pesticide in the terrestrial environment is equal to or greater than 1/5 the avian dietary LC50 or the avian single dose oral LD_{50} (converted to ppm).

(B) The pesticide or any of its metabolites or degradation products are stable in the environment to the extent that potentially toxic amounts may persist in the avian feed.

(xiii) Required if environmental fate characteristics indicate that the estimated environmental concentration of the biochemical agent in the aquatic environment is equal to or greater than 0.01 of any EC_{50} or LC_{50} determined in testing required by Tier I aquatic tests.

(xiv) Required if the product is expected to be transported from the site of application by air, soil, or water. The extent of movement will be determined by the Tier II environmental fate tests.

(xv) Required when results of Tier I tests indicate potential adverse effects on nontarget insects and results of Tier II tests indicate exposure of nontarget insects.

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

§ 158.740 Microbial pesticides—Product analysis data requirements.

(a) *Microbial pesticides product analysis data requirements*—(1) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the microbial pesticides—product analysis data requirements and the substance to be tested.

Kind of data required	(2) 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						
Product identity manufacturing process.		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	151–20
	(i)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* and TGAI.	151–21
Discussion of formation of unintentional ingredients.	(ii)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* and TGAI.	151–22