(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. m³/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/s the avian dietary LC50 or the avian single dose oral LD₅₀ (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 EC₅₀ or LC₅₀ 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.

					Gen	eral use pat	terns				Test su	bstance	Guide-
Kind of data required	(2) Notes	Terre	estrial	Aqu	latic	Greer	house		Domestic		Data to sup-	Data to sup-	lines ref-
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood	Forestry	outdoor		port MP	port EP	erence No.
Product identity manufac- turing 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
Analysis of samples	(iii)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	MP and TGAI.	EP* and TGAI.	151–23
Certification of limits Analytical methods		[R] R	R R	[R] R	R R	[R] R	R R	R R	R R	R R	MP	EP* EP*	151–25 151–25
Physical and chemical properties.		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* and TGAI.	151–26
Submittal of samples	(iv)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	MP and TGAI, PAI.	EP* TGAI and PAI.	151–27

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.*, "formula-tors") 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 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 scale production.

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(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 re-quired on a case-by-case basis. For pesticide in the production stage, a rudimentary product analytical method and data will suffice to support an experimental use permit. AAA(iv) Routinely required for products produced by an integrated formulation system. Required on a case-by-case basis for other products or materials.

(b) Microbial pesticides-residue data requirements-(1) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the microbial pesticides-residue data requirements and the substances to be tested.

					Gen	eral use pat	terns				Test su	bstance	Guide-
Kind of data required	(2) Notes	Terre	estrial	Aqu	latic	Green	house		Domestic		Data to sup-	Data to sup-	lines ref-
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood	Forestry	outdoor	Indoor	port MP	port EP	No.
Residue data	(i)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]			153–4

Key: CR=Conditionally required data; EP=End-use product; MP=Manufacturing-use product; []=Brackets (i.e., [CR]) indicate data requirements that apply when an experimental use per-(2) NOTES. The following notes are referenced in column two of the table contained in paragraph (b)(1) of this section.

(i) Residue data requirements shall apply to microbial pesticides when Tier II or Tier III toxicology data are required, as specified for microbial pesticides in (c)(1) of this section. (ii) Reserved)

(c) Microbial pesticides-toxicology data requirements-(1) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the microbial pesticides-toxicology data requirements and the substances to be tested.

					Gen	eral use pat	terns				Test su	bstance	Guide-
Kind of data required	(2) Notes	Terre	estrial	Aqu	latic	Greer	nhouse		Domostio	Indeer	Data ta aun	Data ta aun	lines ref-
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood	Forestry	Domestic outdoor	Indoor use	Data to sup- port MP	Data to sup- port EP	erence No.
Tier I: Acute oral		[R]	MP and TGAI.	EP* or EP* dilution and TGAI.	152–30								
Acute dermal		[R]	MP and TGAI.	EP* or EP dilution and TGAI.	152–31								
Acute inhalation	(i)	[R]	MP and TGAI.	EP* or EP Dilution* and TGAI.	152–32								
I.V., I.C., I.P. injection Primary dermal Primary eye Hypersensitivity study Hypersensitivity inci- dents.		[R] [R] [R] R CR	TGAI MP MP MP	TGAI EP* EP* EP*	152–33 152–34 152–35 152–36 152–37								
Immune response Tissue culture		[R] [R]	R R	[R] [R]	R R	[R] [R]	R R	R R	R R	R R	TGAI TGAI	TGAI TGAI	152–38 152–39

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					Gen	eral use pat	terns				Test su	bstance	Guide-
Kind of data required	(2) Notes	Terre	estrial	Aqu	latic	Greer	house		Domestic	Indoor	Data to sup-	Data to sup-	lines ref-
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood	Forestry	outdoor	use	port MP	port EP	No.
Tier II:													
Acute oral	(vi)	CR	CR	CR	CR	CR	CR	CR	CR	CR	MP	EP*	152-40
Acute inhalation	(vii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	MP	EP*	152-41
Subchronic oral	(viii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-42
Acute I.P., I.C	(ix)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-43
Primary dermal	(x)	CR	CR	CR	CR	CR	CR	CR	CR	CR		EP*	152-44
Primary eye	(xi)	CR	CR	CR	CR	CR	CR	CR	CR	CR		EP*	152-45
Immune response	(xii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-46
Teratogenicity	(xiii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-47
Virulence enhance-	(xiv)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-48
ment.													
Mammalian mutage- nicity.	(xv)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152–49
Tier III:													
Chronic feeding	(xvi)	CR		CR		CR				CR	TGAI	TGAI	152-50
Oncogenicity	(xvii)	CR		CR		CR				CR	TGAI	TGAI	151–51
Mutagenicity	(xviii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152–52
Teratogenicity	(xix)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152–53

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 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 (c)(1) of this section.

(f) Required if 20 percent or more of the aerodynamic equivalent of the product (as registered or under conditions of use) is composed of particulates less than 10 microns in diameter. (ii) Data required in products as follows:
 (A) Intravenous ("IV") infectivity study for bacterial, and viral agents;
 (B) Intracerebral ("IC") infectivity study for fungal and protozoan agents; and
 (C) Intraperitoneal ("IP") infectivity study for fungal and protozoan agents.
 (iii) Required if commonly recognized use practices will result in repeated human contact by inhalation or dermal routes.

(iv) Hypersensitivity incidents must be reported, if they occur.

(v) Data required for products whose active ingredient is a virus.

(vi) Required if survival, replication, infectivity, toxicity, or persistence of the microbial agent (virus or protozoa) is observed in the test animals treated in the Tier I acute oral infectivity tests or the intraperitoneal or intracerebral injection test for protozoa.

(vii) Required if survival, replication, infectivity, toxicity, or persistence of the microbial agent (virus or protozoa) is observed in the test animals treated in the comparable Tier I acute inhalation tests.

(viii) Required if there is evidence of survival, replication, infectivity, or persistence of the protozoan agent in the Tier I oral infectivity test.

(ix) Required if in Tier I acute oral infectivity testing, Tier I dermal toxicity/infectivity testing, or Tier I intraperitoneal or intracerebral injection testing, the test microorganism (bacteria, fungi, or protozoa) survived for more than 2 weeks, caused toxic effects, or caused a severe illness response in an experimental animal as evidenced by irreversible gross pathology, severe weight loss, toxemia, or death.

(X) Required if infectivity or if marked edema or broad erythema was observed in the Tier I dermal irritation study.

(xi) Required if infectivity or if severe ocular lesions are observed in the Tier I primary eye irritation study.

(xii) Required if results of the Tier I immune response test indicate abnormalities.

(xiii) Required when Tier I tests on viral agents show replication of the virus in mammalian hosts and significant damage to mammalian cells. (xiv) Required when Tier I infectivity tests on bacteria or fungi indicate prolonged survival (including presence of viable microbial agents in test animal excreta) and/or multiplication (infectivity) of the bacteria or fungal agent, respectively. (xv) Required if any of the following criteria are met:

(A) Acute infectivity tests are positive in Tier I studies.

(B) Adverse effects are observed in immune response studies.

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(C) Positive results are obtained in tissue culture tests with viral agents.

(xvi) Required when the potential for chronic adverse effects (e.g., replication or persistence of viral or subviral constituents, protozoans, fungi, or bacteria) are demonstrated by any of the

(xvii) Required when the potential for chronic adverse effects (e.g., replication or persistence of viral or subviral constituents, protozoans, rungi, or bacteria) are demonstrated by any or the Tier II tests (except primary dermal, primary ocular, and mammalian mutagenicity tests).
 (xvii) Required when the potential for oncogenic effects is indicated (e.g., adverse cellular effects due to presence, replication, or persistence of viral or subviral constituents, or bacteria, fungi or protozoans; or mutagenic effects) by any of the Tier II tests except the primary dermal and primary ocular studies.
 (xviii) Required when the potential for mutagenic effects is indicated (e.g., adverse cellular effects due to presence, replication, or persistence of viral or subviral constituents, bacteria, fungi or protozoans; or mutagenic effects) by any of the Tier II tests except the primary dermal and primary ocular studies.
 (xviii) Required when the potential for mutagenic effects is indicated (e.g., adverse cellular effects due to presence, replication, or persistence of viral or subviral constituents, bacteria, fungi or protozoa) by any of the Tier II tests except primary dermal or primary ocular studies.
 (xix) Required when the potential for teratogenic effects is expected based on the presence of persistence of fungi, bacteria, viruses, or protozoa in mammalian species as a result of testing performed in Tier II, except primary dermal and primary ocular studies.

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

					Gen	eral use pat	terns				Test su	bstance	Guide-
Kind of data required	(2) Notes	Terre	estrial	Aqu	uatic	Greer	house		Domestic	Indoor	Data to sup-	Data to sup-	lines ref-
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood	Forestry	outdoor	use	port MP	port EP	No.
Tier I: Avian oral	(i), (ii), (iii)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154–16
Avian injection test	(i), (ii), (iii)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154–17
Wild mammal testing Freshwater fish test- ing.	(iv) (i)	CR [R]	CR [R]	CR [R]	CR [R]	 CR	CR	CR [R]	CR CR	CR	TGAI TGAI	TGAI TGAI	154–18 154–19
Freshwater aquatic invertebrate testing.	(i)	[R]	[R]	[R]	[R]	CR	CR	[R]	CR	CR	TGAI	TGAI	154–20
Estuarine and marine animal testing.	(v)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	154–2
Nontarget plant stud- ies.		[R]	[R]	[R]	[R]			[R]	[R]	CR	TEP	TEP	154–2
Nontarget insect test- ing.		[R]	[R]	[R]	[R]	CR	CR	[R]	[R]		TGAI	TGAI	154–23
Honey bee testing Tier II:		[R]	[R]	[R]	[R]	CR	CR	[R]	[R]		TGAI	TGAI	154–24
Terrestrial environ- mental testing.	(vi)	CR	CR	CR	CR			CR	CR		TGAI or TEP	TGAI or TEP	155–18
Freshwater environ- mental expression tests.	(vii)	CR	CR	CR	CR			CR	CR		TGAI or TEP	TGAI or TEP	155–19
Marine or estuarine environmental ex- pression tests. Tier III:	(xiii), (ix)	CR	CR	CR	CR			CR	CR		TGAI or TEP	TGAI or TEP	155–20
Terrestrial wildlife and aquatic organism testing.	(x)	CR	CR	CR	CR			CR	CR		TGAI or TEP	TGAI or TEP	154–25

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					Gen	eral use pat	terns				Test su	bstance	Guide-
Kind of data required	(2) Notes	Terre	estrial	Aqu	uatic	Greer	house		Demotio	la da an	Data ta ave	Data ta ave	lines ref-
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood	Forestry	Domestic outdoor	Indoor use	Data to sup- port MP	Data to sup- port EP	erence No.
Avian pathogenicity/ reproduction test.	(xi)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	154–26
Definitive aquatic ani- mal tests.	(xii)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	154–27
Aquatic embryo lar- vae and life cycle studies.	(xiii)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	154–28
Aquatic ecosystem test.	(xiv)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	154–29
Special aquatic tests (reserved).													154–30
Nontarget plant stud- ies.	(xv)	CR	CR	CR	CR			CR	CR		TGAI	TEP	154–31
Tier IV:	(xvi)												
Simulated and actual field tests (birds, mammals).	(xiii)	CR	CR	CR	CR			CR	CR		TEP	TEP	154–33
Simulated and actual field tests (aquatic	(xvii), (xviii)	CR	CR	CR	CR			CR	CR		TEP	TEP	154–34
organisms). Simulated and actual field tests (insect													154–35
predators, parasites) (re- served). Simulated and actual field tests (insect pollinators) (re- served).													154–36

AAAKey: R=Required; CR=Conditionally required; []=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. AAA(2) NOTES. The following notes are referenced in column two of the table contained in paragraph (d)(1) of this section.

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

AAA(iii) Preferable test species are: bobwhite quail or mallard for avian acute oral and avian dietary studies; rainbow trout for freshwater fish studies. AAA(iii) Data from *either* the avian acute oral *or* the avian injection study are required to support an experimental use permit. AAA(iv) Required on a case-by-case basis if results of tests required by paragraph (c)(1) of this section are inadequate or inappropriate for assessment of hazards to wild animals. AAA(v) Required when product is intended for direct application into the estuarine or marine environment or expected to enter this environment in significant concentrations because of expected use or mobility pattern. AAA(v) Required when toxic or pathogenic effects are observed in any of the following Tier I tests for microbial pest control agents: AAA(a) Avian single dose oral toxicity and pathogenicity tests. AAA(B) Avian injection pathogenicity tests. AAA(B) Avian injection pathogenicity test. AAA(D) Plant studies—terrestrial.

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AAA(E) Honey bee toxicity/pathogenicity test. AAA(F) Testing for toxicity/pathogenicity to insect predators and parasites.

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AAA(vii) Required when toxic or pathogenic effects are observed in any of the following Tier I test for microbial pest control agents:

AAA(A) Freshwater fish toxicity and pathogenicity testing. AAA(B) Freshwater aquatic invertebrate toxicity and pathogenicity test.

AAA(C) Plant studies—aquatic. AAA(viii) Required if product is applied on land or in fresh water and toxic or pathogenic effects are observed in any of the following Tier I tests for microbial pest control agents: AAA(A) Estuarine and marine animal toxicity and pathogenicity test.

AAA(B) Plant studies-estuarine or marine

AAA(ix) Required if product is applied in marine or estuarine environments and toxic or pathogenic effects are observed in any of the following Tier I tests:

AAA(A) Avian single dose oral toxicity and pathogenicity test.

AAA(B) Avian injection pathogenicity test.

AAA(C) Estuarine and marine animal toxicity and pathogenicity test.

AAA(x) Required when toxic effects on nontarget terrestrial wildlife or aquatic organisms are reported in one or more Tier I tests and results of Tier II tests indicate exposure of the mocrobial agent to the affected nontarget terrestrial wildlife or aquatic organisms.

AAA(xi) Required when:

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AAA(A) Pathogenic effects are observed in Tier I avian tests at a level equal to the adjusted host equivalent amount.

AAA(B) Chronic, carcinogenic, or teratogenic effects are reported in tests required by paragraph (c)(1) of this section for evaluating hazard to humans and domestic animals.

AAA(C) Tier II Environmental expression testing indicates that exposure of terrestrial animals to the microbial agent is likely.

AAA(xii) Required when product is intended for use in water or expected to be transported to water from the intended use site, and when pathogenicity or infectivity was observed in Tier I tests.

AAA(xiii) Required when both of the following conditions are met:

AAA(A) Pathogenic effects at actual or expected field residue exposure levels are reported in Tier III. AAA(B) The agency determines that quarantine methods will prevent the microbial pest control agent from contaminating areas adjacent to the test area. AAA(xiv) Required if, after an analysis of the microbial agent's properties, the individual use patterns, and the results of previous nontarget organism and environmental expression tests, it is determined that use of the microbial agent may result in adverse effects on the nontarget organisms in aquatic environments, including those of the water column and bottom sediments. When a microbial pest control agent is used in or is expected to transport to water from the intended use site, major considerations for requiring these intendedivity tests include, but are not limited to:

AAA(A) Infectivity or pathogenicity demonstrated in previous testing.

AAA(B) Viability of the microorganism in natural waters as demonstrated in Tier II tests.

AAA(xý) Required if the product is transported from the site of application by air, soil, or water or transmission by other animals. The extent of movement will be determined by the environmental expression tests in Tier II.

AAA(xv) The Agency expects that Tier IV requirements would be imposed retrospectively—after product registration as post registration monitoring, since it is unlikely a registrant would pursue registration of a microbial agent posing potential hazards such that testing beyond Tier III is required.

AAA(xvii) Short term simulated or actual field studies are required when it is determined that the product is likely to cause adverse short-term or acute effects, based on consideration of available laboratory data, use patterns, and exposure rates.

AAA(xviii) Data from a long-term simulated field test (e.g., where reproduction and growth of confined populations are observed) and/or an actual field test (e.g., where reproduction and growth of natural populations are observed) are required if laboratory data indicate adverse long-term, cumulative, or life-cycle effects may result from intended use.

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

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APPENDIX A TO PART 158-DATA RE-QUIREMENTS FOR REGISTRATION: USE PATTERN INDEX

How to use this Index:

1. Identify the Pesticide Use Site Group listed below (e.g., agricultural crops, forests, ornamental plants) that covers the specific use pattern of interest to you.

2. Find your specific use pattern under the appropriate Pesticide Use Site Group.

3. Identify the general use pattern that corresponds to your specific use pattern. 4. Use the general use pattern in deter-

mining applicable data requirements on the Data Requirements tables presented in §§158.120 through 153.170.

Pesticide use site group 1. Agricultural Crops.

2. Ornamental Plants and Forest Trees.

3. General Soil Treatment and Composting.

4. Processed or Manufactured Products,

and food or feed containers or dispensers.

 5. Pets and Domestic Animals.
 6. Agricultural Premises and Equipment. 7. Household.

8. Wood or Wood Structure Protection Treatments.

9. Aquatic sites.

10. $\bar{\text{Noncrop}},$ wide area, and general indoor/ outdoor treatments.

11. Antifouling treatments.

Commercial and Industrial Uses.
 Domestic and Human Use.
 Miscellaneous Indoor Uses.

Specific use patterns—listed according to use site group	Corresponding gen- eral use pattern
1. Agricultural crops Small fruits Caneberries (e.g., raspberry, dew- berry) Bushberries (e.g., blueberry, cur-	Terrestrial food crop
rant) Vine fruits (e.g., grape, kiwi fruit) Strawberry Cranberry Pome fruits (e.g., apple, quince) Stone fruits (e.g., peach, cherry) Nut crops—tree & shrub (e.g., pecan, filbert) Other temperate fruits (e.g., per-	
simmon, pawpaw) Tropical and subtropical fruits Citrus Banana and plantain Palm fruits and nuts (e.g., date, co- conut) Pineapple Other fruits and nuts	
Beverage crops Woody—cocoa, coffee, tea Herbaceous—chicory, mint Flavoring and spice crops Woody—leaf/stem, root, seed and pod Herbac.—leaf/stem, root, seed and pod	
Vegetables—leaf/stem, root, seed and pod, fruiting vegetables, cucurbits	

Specific use patterns—listed according to use site group Corresponding general use pattern Commercial annual (e.g., tomato, bean) Corresponding general use pattern Commercial perennial (e.g., aspar- agus, rhubath) Greenhouse food crop Greenhouse (commercial) Greenhouse non- food crop Mushrooms Greenhouse non- food crop Forage crops Greenhouse non- food crop Cotton Others—(e.g., flax) Forage crops Greenhouse non- food crop Typical grasses—perennial (e.g., bromegrass) Typical grasses—perennial (e.g., bromegrass) Typical grasses—perennial (e.g., bromegrass) Aquatic food crop Corn and sorghum Small grains for forage (e.g., rye) Perensial food crop Annual legumes (e.g., crotalaria, soy- bean) Corn and sorghum Sorghum Aftalfa Other nongrains (e.g., squash, pumpkin) Greenhouse Buckwheat Seeame Peanut Sunflower Sorghum Aftalfa, etc. Nonlegume crops (e.g., wheat, rad- ish, black mustard) Indoor Crops grown exclusively for seed for planting Sugar crops Indoor Stored raw agricultural commodities Honey (principal nectar-producing crops) Indoor Sugarcane Sugarcane Sugarcane Sapodilla (for chewing gum) Terrestrial nonfood crop Oil crops Annual herbaceous crops Perennial herbaceous crops Perennial herbaceous crops Perennial herbaceous crops Perennial herbaceous crops Perennial herbaceo		
bean) Commercial perennial (e.g., aspar- agus, rhubarb) Greenhouse (commercial) Mushrooms Nursery/seed crop/medical crop/to- bacco Fiber crops Cotton Others—(e.g., flax) Forage crops Cottal grasses—annual (e.g., sudan grass) Typical grasses—perennial (e.g., bromegrass) Corn and sorghum Small grains for forage (e.g., rye) Perennial legumes (e.g., white clo- ver) Annual legumes (e.g., crotalaria, soy- bean) Crop harvest residue (peanut vines, bet tops, etc.) Grain and edible seed crops Corn Rice Wheat, barley, rye, oats Sorghum Affaffa Other grains Other nongrains (e.g., squash, pumpkin) Buckwheat Seeame Peanut Sunflower Seed sprout crops Mung bean, red clover, soybean, affaffa, etc. Nonlegume crops (e.g., wheat, rad- ish, black mustard) Crops grown exclusively for seed for planting Sugar crops Stored raw agricultural commodities Honey (principal nectar-producing crops) Sugar beet Sugar cane Sugar maple Sorghum (for sugar) Crops for smoking and chewing —field —shade —greenhouses Sapodilla (for chewing gum) Oil crops Annual herbaceous crops Perennial herbaceous crops Temperate woody crops Drug and medicinal crops Temperate woody crops		Corresponding gen- eral use pattern
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Environmental Protection Agency

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Specific use patterns—listed according to use site group	Corresponding gen- eral use pattern	Specific use patterns—listed according to use site group	Corresponding gen- eral use pattern
2. Ornamental plants and forest trees		Seeds (sesame, sunflower)	
Ornamental plants	Terrestrial nonfood	Dried processed Fruits	
Annual garden plants	crop	Vegetables	
Temperate perennial nonfood gar-		Tobacco	
den herbs	Creambauran	Beverages (tea, coffee)	
Commercial greenhouse crops	Greenhouse nonfood crop	Herbs and spices Animal Feeds	
Houseplants	Indoor	Cattle (beef)	
Home and retail greenhouse and		Cattle (dairy)	
conservatory plants Public display plantings	Terrestrial nonfood	Goat (nondairy) Goat (dairy)	
Public display plantings	crop	Horse, mule, donkey	
Bulb, corm, and tuber ornamentals		Poultry (chicken, turkey, etc.)	
Subtropical/tropical garden ever-		Sheep (meat)	
green plants (dry—e.g., agave) Subtropical/tropical garden ever-		Sheep (wool) Swine	
green plants (moist—e.g., ferns)		Dog	
Groundcovers		Cat	
Aquatic plants (e.g., waterlilies)	Aquatic nonfood use	Other pets (including birds) Fur-bearing stock	
Ornamental trees, shrubs, and vines	Terrestrial nonfood	Other meat-producing stock (e.g.,	
(woody) Deciduous temperate broadleaf	crop	rabbit) Fish food (commercial)	
Evergreen temperate broadleaf		Fish food (pet)	
Deciduous temperate conifer		Birdseed	
Evergreen temperate conifer		Processed grain products for human consumption	
Tropical/subtropical broadleaf Tropical/subtropical conifer		Corn	
Tropical/subtropical miscellaneous		Soybean	
(e.g., cycad, tree fern, bamboo)		Wheat	
Lawn and turf grasses—ornamental	Terrestrial nonfood crop or domestic	Other grains (rice, barley, etc.) Cereal foods	
	outdoor	Flour	
Cool season Winter grasses (bent,		Baked goods	
bluegrass, fescue, etc.) Summer grasses (zoysia,		Farinaceous products	
Summer grasses (zoysia, bermudagrass, etc.)		Processed animal products for human consumption	
Ornamental bunch grasses		Cheese	
(pampasgrass, blue fescue)		Egg yolks	
Forest trees—nonornamental—trees forests, plantings	Forestry	Meats, including fish and poultry Milk	
Deciduous temperate (broadleaf)		Processed plant products for human	
Evergreen temperate (broadleaf)		consumption	
Deciduous and evergreen conifers		Chocolate	
Tropical/subtropical broadleaf Tropical/subtropical conifer		Candy Sugar	
Forest tree nurseries—Temperate		Yeast	
broadleaf trees		Citrus pulp	
Temperate conifer trees Forest trees: dead trees/logs/stumps in		Chewing gum Cigarettes, etc.	
the forest or in plantings		Herbs and spices	
3. General soil treatment and		Pickles	
composting	To manufacture of the set	Glazed fruits	
General soil treatments	Terrestrial nonfood crop	Jellies Seed oils	
Soil application with no mention of	Ciop	Fruit syrups (e.g., cola)	
crops to be grown (potting soil,		Fruit juices	
top soil).		Fermentation beverages (wine,	
Manure Composts		beer, whiskey, vinegar) Processed or manufactured	
Cull piles		nonfood plant and animal prod-	
Mulches		ucts	
4. Processed or manufactured prod- ucts, and food or feed containers or		Textiles, fabrics, fibers Fur and hair products	
dispensers		Leather products	
Processed vegetables, fruits, and nuts	Indoor	Food and feed containers, dispensers,	
Fruits		and processing equipment	
Leafy vegetables Root vegetables		Airtight storages—large (empty/full) Airtight storages—small (empty/full)	
Fruited vegetables		Fumigation chambers	
i fulleu vegelables			
Nuts Peanuts		Bins Elevators	

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Specific use patterns—listed according to use site group	Corresponding gen- eral use pattern	Specific use patterns—listed according to use site group	Corresponding ge eral use pattern
Storage areas—(empty/full)		Fish	
Processing or handling equipment		Amphibians	
and machinery (other than food		Reptiles	
processing)		Primates	
. Pets and domestic animals—animals		Other vertebrates	
and their man-made premises		6. Agricultural premises and equipment	
,	Indoor	Egg handling facilities and equipment	Indoor
airy cattle-nonlactating		Egg washers Egg rooms	
airy cattle—heifers, calves bats—lactating		Hatching egg treatments	
bats—nonlactating		Hatching egg rooms	
bats—voung (kids)		Hatching egg equipment	
r- and wool-bearing animals		Egg packing plants and hatcheries	
Goats		Milk handling facilities and equipment	
Sheep		Milk storage rooms	
Mink		Milking stalls and parlors	
Chinchilla		Milking machines, milk tanks, etc.	
Rabbit		Teat cups, liners, etc.	
Fox		Milk processing equipment	
Nutria eat animals (mammals)		7. <i>Household</i> Non-food area and sites	Indoor
Cattle (and calves)		Closets, storage areas	
Goats (and kids)		Basements, cellars	
Horses		Bedrooms	
Rabbits		Attics	
Sheep (and lambs)		Recreation rooms	
Swine		Living rooms	
Bison		Baseboards, window sills, etc.	
Reindeer		Plumbing fixtures	
ultry (meat, eggs)		Sickrooms	
Chickens		Food-handling and food storage areas	
Turkeys		Kitchens	
Ducks, geese		Dining rooms	
Guineas, pheasants, quail, etc.		Pantry and food storage shelving Household contents and space	
Bees		Air	
Beehives		Beds	
Honeycombs		Rugs	
	Aquatic food use	Book cases	
Hatchery buildings	•	Furs, fabrics, blankets	
Culture ponds, containers		Play pens	
	Indoor	Sickroom utensils	
ng, lab use, etc.		Filters for air vents, air condi-	
Dogs		tioners, furnaces, etc.	
Horses, donkeys, mules		Outdoor areas (Noncommercial home-	Domestic outdoor
Guinea pigs		owner use)	or terrestrial for
Mice Rats		Homo gardon, orchards	crop
Gerbils		Home garden, orchards Porches	Domestic outdoor
Hamsters		Patios	
Monkeys		Foundations	
Cats		Steps	
Chickens, birds		Eaves	
Wild rodents		Yards, lawn, turf	
Alfalfa leafcutting bee (pollinator)		Domestic ornamental plantings	
Alkaline bee (pollinator)		8. Wood or Wood Structure Protection	
Zoo ruminants		Treatments	
Zoo ungulates		Buildings (for termite, powderdust bee-	Domestic outdoor
Zoo canines		tle controls, etc.)	or indoor
Zoo felines		Unseasoned forest products	
Zoo primates		Seasoned forest products	
Zoo reptiles Zoo amphibians		Finished wood products Wood pressure treatments	
Zoo birds		Plant-growing wood structures and con-	
Zoo—others		tainers	
Aquarium fish		Wood containers for nonfood, nonfeed	
mals for pets, including their cages,		uses	
bedding, nests, etc.		9. Aquatic sites	
Dogs		Food processing water systems	Aquatic food crop
Cats		Poultry and livestock drinking water	
		Pulp and papermill systems	Aquatic noncrop
Birds			/ iquallo nonorop
		Swimming pool water Industrial disposal systems	

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Specific use patterns—listed according to use site group	Corresponding gen- eral use pattern	Specific use patterns—listed according to use site group	Corresponding gen eral use pattern
Industrial ponds Human drinking water Cooling water towers Agricultural irrigation water, and ditches Agricultural drainage water and ditches Sewage systems and drainfields Dishwashing water Domestic and commercial nonpotable water Lakes, ponds, impounded water Streams, rivers, canals Swamps, marshes, wetlands	Aquatic food crop Aquatic noncrop Aquatic food crop Aquatic noncrop Indoor Aquatic noncrop	Nonagricultural areas for public health treatments Bird roosting, nesting areas Bird feeding areas 11. Antifouling Treatments Sites for marine exposures Boat bottoms and other submersed structures Steel Fiberglass Aluminum Wood	Aquatic noncrop
Air conditioner water Humidifier water Air washer water systems Secondary oil recovery injection water		Plastic Other substances and mate- rials Crab pots and lobster pots	
Heat exchange water system Polluted water Bait boards (floating—for vertebrate control) Catch basins, puddles, tree holes Estuaries, tidal marshes		Sites for fresh water exposures Cooling tower influent conduits 12. Commercial and Industrial Uses Transportation Facilities Bus Truck and Trailer	Indoor
Commercial and sport fish-bearing wa- ters 10. Noncrop, wide area, and general indoor/outdoor treatments	Aquatic food crop	Containerized units Railroad cars Aircraft Ships/barges	
Uncultivated agricultural areas (nonfood producing) Farmyards Fuel storage areas Fence rows Rights-of-way	Terrestrial noncrop	Auto, taxis Recreational vehicles Shipping containers Food and feed processing plants Bakeries Bottlers Canneries	
Fallow land Soil bank land	Terrestrial food crop Terrestrial noncrop	Dairies, creameries, milk proc- essing plants Feed mills, feed stores	
Barrier strips Uncultivated nonagricultural areas (out- door) Airports Recreation areas, fairgrounds, race tracks, tennis courts, etc. Campgrounds Recreation area structures Highway rights-of-way Railroad rights-of-way Utility rights-of-way Sewage disposal areas Industrial sites (lumberyards, tank		Fresh fruit packing and processing Meat processing Poultry processing Wineries, wine cellars Flour mills, machinery, ware- houses, bins, elevators Egg processing Candy and confectionary plants Sugar processing, cane mills, etc. Cider mills Dry food products plants Tobacco processing Air treatment for processing and	
farms, etc.) Paved areas Private roads and walks Fencerows and hedgerows (non- agricultural) Directed Pest Control to Pests' Nests,	Townshiel account	transportation of foods Beverage processing Nut processing Cereal processing Seafood processing	
etc., and for Traps Diseased beehives Nuisance bee nests Ant mounds, hills, dens Termite mounds Insect traps (chemical lures) Repellents and irritants to pests (when not covered by other sites)	Terrestrial noncrop or indoor	Vegetable oil processing Spice mills Vinegar processing Farinaceous processing (noodles, etc.) Mushroom processing Dried fruit processing Pickle processing Ice plants Chocolate processing	
Wide area and general indoor/outdoor treatments Rural areas (unspecified) Urban areas (unspecified) Public buildings and structures Animal burrow entrances, dens, tunnels Animal nests Animal nests Animal trails Mammal feeding areas		Fruit juice processing Eating establishments (all) Food handling areas Food serving areas Eating establishment nonfood areas Air treatment for eating establish- ments Food storage equipment (coolers, refrigerators, etc.)	

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Specific use patterns—listed according to use site group Corresponding gen-eral use pattern Eating and serving utensils (spoons, etc.) Food marketing, storage, and distribution Food dispensing and vending equipment Food stores, markets, stands Meat and fish markets Food catering facilities Food marketing, storage, and distribution equipment and utensils Hospitals and related institutions and facilities Critical premises (e.g., burn wards, etc.) Hospital patient premises (wards, emergency rooms, etc.) Noncritical premises (labs, lounges, lobbies, storage) Critical items (hypodermic needles, dental instruments, catheters, etc.) Noncritical items (bedpans, carpets, furniture, etc.) Air treatment (also to ambulances) Janitorial equipment Barber and beauty shop instruments and equipment Morgues, mortuaries, and funeral homes Premises (embalming rooms, etc.) Equipment (tables, etc.) Instruments Burial vaults, mausoleums Air treatment Commercial, institutional, and industrial Maintenance, Buildings, and Structures Locker rooms, equipment Gyms, bowling alleys, and equipment Telephones and booths Shower rooms, mats, and equipment Cotton mill premises and equipment Auditoriums and stadiums Factories Rendering plants Loading areas, ramps School buildings and equipment Office buildings Laundries Fuels from Crops (alcohol, methane) Fossil fuels (e.g., oils, jet fuel) Seed oils Paper Pesticide materials preservation and protection Rodenticide baits (protection against insects) Dried plant parts (pyrethrum, red squill, rotenone, sabadilla) Paints Preservatives and protectants Grains Hay, silage Adhesives Coatings (asphalt and lacquer) Fuels Leather and leather products Leather processing liquors Metalworking cutting fluids Oil recovery drilling muds and packer fluids

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Specific use patterns—listed according	Corresponding get
to use site group	eral use pattern
Paints (latex) Paper and paper products	
Plastic products	
Resin emulsions	
Rubber (natural) products	
Specialty products (polishes,	
cleansers, dyes, etc.) Textiles, textile fibers, and cordage	
Wet-end additives, etc. (pulp	
sizing, alum, casein, printing	
pastes)	
Disposable diapers	
Wool, hair, mohair, furs, felt, feath- ers, etc.	
Electrical supplies, cables, and	
equipment	
13. Domestic and Human Use	
Human Body and Hair	Indoor
Fiber product protection (Moth, mildew-proofing)	
Clothing	
Upholstery	
Ornamental fabrics (draperies, tap-	
estries)	
Ropes Sail cloth	
Human articles and materials	
Bedding, blankets, mattresses	
(Treatments to) hair, body, clothing	
(while being worn)	
Clothing	
Face gear (goggles, face masks, etc.)	
Headgear (safety helmets, head-	
phones, etc.)	
Wigs	
Contact lenses Dentures, toothbrushes, mouth-	
pieces to musical instruments,	
etc.	
Brick, asbestos, etc.	
Wood surfaces	
Leather surfaces Fabric surfaces	
Paper/paperboard surfaces	
Specialty uses	
Museum collectors (preserved ani-	
mal and plant specimens)	
Military uses—not specified Quarantine uses—not specified	
Quarantine uses—not specified DHHS/FDA uses—not specified	
Filters (air conditioning, air, and	
furnace)	
Biological specimens	
Underground cables Cuspidors, spittoons	
Vomitus	
Human wastes	
Air sanitizers	
Diapers	
Laundry equipment (carts, chutes, tables, etc.)	
Dust control—products and equip-	
ment (mops, etc.)	
Dry cleaning	
Carpets	
Upholstery	
Detherson tollate the test of the test	
Bathrooms, toilets bowls, and related	
sites	
sites Bathroom premises	
sites	

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Specific use patterns—listed according to use site group	Corresponding gen- eral use pattern
Vehicular holding tanks Bathroom air treatment Diaper pails Refuse and solid waste Refuse and solid waste containers Refuse and solid waste transpor- tation and handling equipment Garbage dumps Household trash compactors Garbage disposal units, food dis- posals Incinerators 14. <i>Miscellaneous Indoor Uses</i> Surface Treatments Hard nonporous surfaces (painted, tile, plastic, metal, glass, etc.) Hard porous surfaces (cement, plaster) Camping equipment and gear Grooming instruments (brushes, clippers, razors, etc.)	Indoor

PART 159—STATEMENTS OF POLICIES AND INTERPRETATIONS

Subparts A-C [Reserved]

Subpart D—Reporting Requirements for Risk/Benefit Information

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- 159.153 Definitions.
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- gation of the rule.
- 159.160 Obligations of former registrants.159.165 Toxicological and ecological studies.
- 159.167 Discontinued studies.
- 159.170 Human epidemiological and expo-
- sure studies. 159.178 Information on pesticides in or on
- food, feed, or water. 159.179 Metabolites, degradates, contami-
- nants, and impurities.
- 159.184 Toxic or adverse effect incident reports.

159.188 Failure of performance information.159.195 Reporting of other information.

AUTHORITY: 7 U.S.C. 136-136y.

 $\ensuremath{\texttt{SOURCE:}}$ 63 FR 49388, Sept. 19, 1997, unless otherwise noted.

Subparts A-C [Reserved]

Subpart D—Reporting Requirements for Risk/Benefit Information

§159.152 What the law requires of registrants.

(a) Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) states: "If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator."

(b) Section 152.50(f)(3) of this chapter requires applicants to submit, as part of an application for registration, any factual information of which he is aware regarding unreasonable adverse effects of the pesticide on humans or the environment, which would be required to be reported under section 6(a)(2) if the product were registered.

(c) Compliance with this part will satisfy a registrant's obligations to submit additional information pursuant to section 6(a)(2) and will satisfy an applicant's obligation to submit additional information pursuant to § 152.50(f)(3) of this chapter.

§159.153 Definitions.

(a) For the purposes of reporting information pursuant to FIFRA section 6(a)(2), the definitions set forth in FIFRA section 2 and in 40 CFR part 152 apply to this part unless superseded by a definition in paragraph (b) of this section.

(b) For purposes of reporting information pursuant to FIFRA section 6(a)(2), the following definitions apply only to this part:

Established level means a tolerance, temporary tolerance, food additive regulation, action level, or other limitation on pesticide residues imposed by law, regulation, or other authority.

Formal Review means Special Review, Rebuttable Presumption Against Registration (RPAR), FIFRA section 6(c)suspension proceeding, or FIFRA section 6(b) cancellation proceeding, whether completed or not.

Hospitalization means admission for treatment to a hospital, clinic or other health care facility. Treatment as an