

§ 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	Guideline reference No.			
		Terrestrial Food crop	Nonfood	Aquatic Food crop	Nonfood	Greenhouse Food crop	Nonfood	Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP
Product identity manufacturing process.	(i) [R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*
Discussion of formation of unintentional ingredients.	(ii) [R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	151–21
Analysis of samples	(iii) [CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	MP and TGAI; EP* and TGAI.	151–22
Certification of limits	(iv) [R]	R	R	R	R	R	R	R	R	R	MP and TGAI; EP* and TGAI.	151–23
Analytical methods	[R]	R	R	R	R	R	R	R	R	R	MP	151–25
Physical and chemical properties.	[R]	R	R	R	R	R	R	R	R	R	MP	151–26
Submittal of samples	(iv) [CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	TGAI; EP* and TGAI; 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., "formulators") must satisfy, provided that their active ingredients(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 scale production. 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.

(ii) 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 pesticide in the production stage, a rudimentary product analytical method and data will suffice to support an experimental use permit.

(iii) AAAl(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.

Kind of data required	(2) Notes	General use patterns						Test substance	Guideline reference No.			
		Terrestrial Food crop	Nonfood	Aquatic Food crop	Nonfood	Greenhouse Food crop	Nonfood	Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP
Residue data	(i) [CR]	[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 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 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.

Kind of data required	(2) Notes	General use patterns						Test substance		Guide-lines reference No.	
		Terrestrial Food crop	Nonfood	Aquatic Food crop	Food Nonfood	Greenhouse Food crop	Nonfood	Forestry	Domestic outdoor	Indoor use	
Tier I:		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	EP* or EP* dilution and TGAI.
Acute oral	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	152–30
Acute dermal	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	EP* or EP* dilution and TGAI.
Acute inhalation	(i)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	152–31
I.V., I.C., I.P. injection	(ii)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	EP* or EP* dilution and TGAI.
Primary dermal	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	152–32
Hyper sensitivity study	(iii)	R	R	R	R	R	R	R	R	R	Dilution* and TGAI.
Hyper sensitivity inci- dents.	(iv)	CR	CR	CR	CR	CR	CR	CR	CR	CR	152–33
Immune response	R	R	R	R	R	R	R	R	R	TGAI
Tissue culture	(v)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	152–34
Tier II:											152–35
Acute oral	(vi)	CR	CR	CR	CR	CR	CR	CR	CR	CR	EP*
Acute inhalation	(vii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	EP*
Subchronic oral	(viii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	EP*
Acute I.P., I.C.	(ix)	CR	CR	CR	CR	CR	CR	CR	CR	CR	152–41
Primary dermal	(x)	CR	CR	CR	CR	CR	CR	CR	CR	CR	152–42
Primary eye	(xi)	CR	CR	CR	CR	CR	CR	CR	CR	CR	152–43
Immune response	(xii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	152–44
Teratogenicity	(xiii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	152–45
Virulence enhance- ment.	(xiv)	CR	CR	CR	CR	CR	CR	CR	CR	CR	152–46
Mammalian mutage- nicity.	(xv)	CR	CR	CR	CR	CR	CR	CR	CR	CR	152–47
Tier III:											152–48
Chronic feeding	(xvi)	CR	CR	CR	CR	CR	CR	CR	CR	CR	152–50
Oncogenicity	(xvii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	151–51
Mutagenicity	(xviii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	152–52

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Kind of data required	(2) Notes	General use patterns										Test substance	Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Domestic outdoor		Indoor use			
		Food crop	Nonfood crop	Food crop	Nonfood crop	Food crop	Nonfood	CR	CR	CR	CR	TGAI	152-53
Teratogenicity	(xix) CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	152-53
Key: R=Required; CR=Conditionally required; MP=Manufacturing-use product; EP=End use product (assterisk 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.													
(i) 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 for products as follows:													
(A) Intravenous ("IV") infectivity study for bacterial, and viral agents;													
(B) Intracerebral ("IC") infectivity study for fungal and protozoan agents;													
(C) Intraperitoneal ("IP") infectivity study for viral and protozoan agents;													
(D) Hypersensitivity incidents 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 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 (infection) 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.													
(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 Tier I 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 protozoa; 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.													

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Kind of data required	(2) Notes	General use patterns						Test substance		Guideline reference No.
		Terrestrial Food crop	Terrestrial Nonfood	Aquatic Food crop	Aquatic Nonfood	Greenhouse Food crop	Greenhouse Nonfood	Domestic outdoor	Indoor use	
Tier I:										
Avian oral	(i), (ii), (iii), (iv)	[R]	[R]	[R]	CR	CR	[R]	CR	TGAI	154-16
Avian injection test	(i), (ii), (iii)	[R]	[R]	[R]	CR	CR	[R]	CR	TGAI	154-17
Wild mammal testing		CR	CR	CR	CR	CR	CR	CR	TGAI	154-18
Freshwater fish testing	(i)	[R]	[R]	[R]	CR	CR	[R]	CR	TGAI	154-19
Freshwater aquatic invertebrate testing	(i)	[R]	[R]	[R]	CR	CR	[R]	CR	TGAI	154-20
Estuarine and marine invertebrate testing.	(v)	CR	CR	CR	CR	CR	CR	CR	TGAI	154-2
Nontarget plant studies.	[R]	[R]	[R]	CR	CR	[R]	CR	TEP	154-2
Nontarget insect testing.	[R]	[R]	[R]	CR	CR	[R]	CR	TEP	154-23
Honey bee testing	[R]	[R]	[R]	CR	CR	[R]	CR	TEP	154-24
Tier II:										
Terrestrial environmental testing.	(vi)	CR	CR	CR	CR	CR	CR	CR	TGAI or TEP	155-18
Freshwater environmental expression tests.	(vii)	CR	CR	CR	CR	CR	CR	CR	TGAI or TEP	155-19
Marine or estuarine environmental expression tests.	(xiii), (ix)	CR	CR	CR	CR	CR	CR	CR	TGAI or TEP	155-20
Tier III:										
Terrestrial wildlife and aquatic organism testing.	(x)	CR	CR	CR	CR	CR	CR	CR	TGAI or TEP	154-25
Avian pathogenicity/ reproduction test	(xi)	CR	CR	CR	CR	CR	CR	CR	TGAI	154-26
Definitive aquatic animal tests.	(xii)	CR	CR	CR	CR	CR	CR	CR	TGAI	154-27
Aquatic embryo larvae and life cycle studies.	(xiii)	CR	CR	CR	CR	CR	CR	CR	TGAI	154-28
Aquatic ecosystem test.	(xiv)	CR	CR	CR	CR	CR	CR	CR	TGAI	154-29
Special aquatic tests (reserved).	154-30
Nontarget plant studies.	(xv)	CR	CR	CR	CR	CR	CR	CR	TEP	154-31

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Kind of data required	(2) Notes	General use patterns						Test substance	Guideline reference No.
		Terrestrial Food crop	Terrestrial Nonfood	Aquatic Food crop	Aquatic Nonfood	Greenhouse Food crop	Greenhouse Nonfood		
Tier IV: Simulated and actual field tests (birds, mammals). Simulated and actual field tests (aquatic organisms). Simulated and actual field tests (insect predators, parasites) (reserved). Simulated and actual field tests (insect pollinators) (reserved).	(xvi) (xvii)	CR CR	CR CR	CR CR	CR CR	CR CR	TEP TEP	154-33 154-34 154-35 154-36

AAA Key: R=Required; CR=Conditionally required; []=Brackets (i.e., [R]) indicate data requirements that apply to products for which an experimental use permit is being sought; MP=Manufacturing-use Product; TEP=typical end-use product; TAG=t=technical grade of the active ingredient; EP=E=nd-use product; PA=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) 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(vi) Required when toxic or pathogenic effects are observed in any of the following Tier I tests for microbial pest control agents:

AAA(A) Avian injection pathogenicity tests.

AAA(B) Wild mammals toxicity and pathogenicity tests.

AAA(C) Plant studies—terrestrial.

AAA(D) Honey bee toxicity/pathogenicity test.

AAA(E) Testing for toxicity/pathogenicity to insect predators and parasites.

AAA(F) 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(VII) Required if product is applied on land or in fresh water and toxic or pathogenic effects are observed on land and marine animal toxicity and pathogenicity test.

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

AAA(B) Plant studies—estuarine or marine.

AAA(X) 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.

AAA(XI) Required when:

- 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 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 infectivity 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 I tests.

AAA(xv) 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(xvi) 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 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 REQUIREMENTS 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 determining 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. Noncrop, wide area, and general indoor/outdoor treatments.
11. Antifouling treatments.
12. Commercial and Industrial Uses.
13. Domestic and Human Use.
14. Miscellaneous Indoor Uses.

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Specific use patterns—listed according to use site group	Corresponding general use pattern
Commercial annual (e.g., tomato, bean) Commercial perennial (e.g., asparagus, rhubarb) Greenhouse (commercial)	Greenhouse food crop
Mushrooms Nursery/seed crop/medical crop/tobacco Fiber crops	Greenhouse non-food crop Terrestrial food crop
Cotton Others—(e.g., flax) Forage crops	
Typical 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 clover) Annual legumes (e.g., crotalaria, soybean) Crop harvest residue (peanut vines, beet tops, etc.) Grain and edible seed crops	
Corn Rice Wheat, barley, rye, oats	Aquatic food crop Terrestrial food crop
Sorghum Alfalfa Other grains Other nongrains (e.g., squash, pumpkin) Buckwheat Sesame Peanut Sunflower Seed sprout crops	
Mung bean, red clover, soybean, alfalfa, etc. Nonlegume crops (e.g., wheat, radish, black mustard) Crops grown exclusively for seed for planting Sugar crops Stored raw agricultural commodities	Indoor
Honey (principal nectar-producing crops) Sugar beet Sugarcane Sugar maple Sorghum (for sugar) Crops for smoking and chewing	
—field —shade —storage —greenhouses Sapodilla (for chewing gum)	Terrestrial nonfood crop
Oil crops	Terrestrial food crop
Annual herbaceous crops Perennial herbaceous crops Tropical/subtropical woody crops	
Drug and medicinal crops	Terrestrial nonfood crop
Annual herbaceous crops Perennial herbaceous crops Temperate woody crops Tropical/subtropical wood crops	

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

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

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Specific use patterns—listed according to use site group	Corresponding general use pattern	Specific use patterns—listed according to use site group	Corresponding general use pattern
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 Air conditioner water Humidifier water Air washer water systems Secondary oil recovery injection water Heat exchange water system Polluted water Bait boards (floating—for vertebrate control) Catch basins, puddles, tree holes Estuaries, tidal marshes Commercial and sport fish-bearing waters 10. Noncrop, wide area, and general indoor/outdoor treatments Uncultivated agricultural areas (nonfood producing) Farmyards Fuel storage areas Fence rows Rights-of-way Fallow land Soil bank land Barrier strips Uncultivated nonagricultural areas (outdoor) 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 farms, etc.) Paved areas Private roads and walks Fencerows and hedgerows (non-agricultural) Directed Pest Control to Pests' Nests, 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) 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 trails Mammal feeding areas Nonagricultural areas for public health treatments	Aquatic food crop Aquatic noncrop Aquatic food crop Aquatic noncrop Indoor Aquatic noncrop Aquatic food crop Terrestrial noncrop Terrestrial food crop Terrestrial noncrop Terrestrial noncrop or indoor	Bird roosting, nesting areas Bird feeding areas 11. Antifouling Treatments Sites for marine exposures Boat bottoms and other submersed structures Steel Fiberglass Aluminum Wood Plastic Other substances and materials Crab pots and lobster pots Sites for fresh water exposures Cooling tower influent conduits 12. Commercial and Industrial Uses Transportation Facilities Bus Truck and Trailer Containerized units Railroad cars Aircraft Ships/barges Auto, taxis Recreational vehicles Shipping containers Food and feed processing plants Bakeries Bottlers Canneries Dairies, creameries, milk processing plants Feed mills, feed stores Fresh fruit packing and processing Meat processing Poultry processing Wineries, wine cellars Flour mills, machinery, warehouses, 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 transportation of foods Beverage processing Nut processing Cereal processing Seafood processing Vegetable oil processing Spice mills Vinegar processing Farinaceous processing (noodles, etc.) Mushroom processing Dried fruit processing Pickle processing Ice plants Chocolate processing Fruit juice processing Eating establishments (all) Food handling areas Food serving areas Eating establishment nonfood areas Air treatment for eating establishments Food storage equipment (coolers, refrigerators, etc.) Eating and serving utensils (spoons, etc.) Food marketing, storage, and distribution	Aquatic noncrop Indoor

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Specific use patterns—listed according to use site group	Corresponding general use pattern	Specific use patterns—listed according to use site group	Corresponding general use pattern
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 Paints (latex) Paper and paper products Plastic products Resin emulsions Rubber (natural) products Specialty products (polishes, cleaners, dyes, etc.)		Textiles, textile fibers, and cordage Wet-end additives, etc. (pulp sizing, alum, casein, printing pastes) Disposable diapers Wool, hair, mohair, furs, felt, feathers, etc. Electrical supplies, cables, and equipment 13. <i>Domestic and Human Use</i> Human Body and Hair Fiber product protection (Moth, mildew-proofing) Clothing Upholstery Ornamental fabrics (draperies, tapestries) 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, headphones, etc.) Wigs Contact lenses Dentures, toothbrushes, mouthpieces to musical instruments, etc. Brick, asbestos, etc. Wood surfaces Leather surfaces Fabric surfaces Paper/paperboard surfaces Specialty uses Museum collectors (preserved animal and plant specimens) Military uses—not specified Quarantine uses—not specified DHHS/FDA uses—not specified Filters (air conditioning, air, and furnace) Biological specimens Underground cables Cuspidors, spittoons Vomit Human wastes Air sanitizers Diapers Laundry equipment (carts, chutes, tables, etc.) Dust control—products and equipment (mops, etc.) Dry cleaning Carpets Upholstery Bathrooms, toilets bowls, and related sites Bathroom premises Toilet bowls and urinals Toilet tanks Portable toilets, chemical toilets Vehicular holding tanks Bathroom air treatment Diaper pails Refuse and solid waste Refuse and solid waste containers Refuse and solid waste transportation and handling equipment Garbage dumps Household trash compactors	Indoor

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Specific use patterns—listed according to use site group	Corresponding general use pattern
Garbage disposal units, food disposals	
Incinerators	
14. <i>Miscellaneous Indoor Uses</i>	
Surface Treatments	Indoor
Hard nonporous surfaces (painted, tile, plastic, metal, glass, etc.)	
Hard porous surfaces (cement, plaster)	
Camping equipment and gear	
Grooming instruments (brushes, clippers, razors, etc.)	
Laundry, cleaning, and dry cleaning	

PART 159—STATEMENTS OF POLICIES AND INTERPRETATIONS**Subparts A–C [Reserved]****Subpart D—Reporting Requirements for Risk/Benefit Information**

Sec.

- 159.152 What the law requires of registrants.
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159.158 What information must be submitted.
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159.160 Obligations of former registrants.
159.165 Toxicological and ecological studies.
159.167 Discontinued studies.
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159.178 Information on pesticides in or on food, feed, or water.
159.179 Metabolites, degradates, contaminants, 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.

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 out-patient is not considered to be hospitalization.

Maximum contaminant level (MCL) means the maximum permissible level, established by EPA, for a contaminant in water which is delivered to any user of a public water system.

Non-target organism means any organism for which pesticidal control was either not intended or not legally permitted by application of a pesticide.