

Subpart D—Data Requirement Tables

§ 158.202 Purposes of the registration data requirements.

(a) *General.* The data requirements for registration are intended to generate data and information necessary to address concerns pertaining to the identity, composition, potential adverse effects and environmental fate of each pesticide.

(b) [Reserved]

(c) *Residue chemistry.* (1) Residue Chemistry Data are used by the Agency to estimate the exposure of the general population to pesticide residues in food and for setting and enforcing tolerances for pesticide residues in food or feed.

(2) Information on the chemical identity and composition of the pesticide product, the amounts, frequency and time of pesticide application, and results of test on the amount of residues remaining on or in the treated food or feed, are needed to support a finding as to the magnitude and identity of residues which result in food or animal feed as a consequence of a proposed pesticide usage.

(3) Residue chemistry data are also needed to support the adequacy of one or more methods for the enforcement of the tolerance, and to support practicable methods for removing residues that exceed any proposed tolerance.

(d) *Environmental fate—(1) General.* The data generated by environmental fate studies are used to: assess the toxicity to man through exposure of humans to pesticide residues remaining after application, either upon reentering treated areas or from consuming inadvertently-contaminated food; assess the presence of widely distributed and persistent pesticides in the environment which may result in loss of usable land, surface water, ground water, and wildlife resources; and, assess the potential environmental exposure of other nontarget organisms, such as fish and wildlife, to pesticides. Another specific purpose of the environmental fate data requirements is to help applicants and the Agency estimate expected environmental concentrations of pesticides in specific habitats where threatened or endan-

gered species or other wildlife populations at risk are found.

(2) *Degradation studies.* The data from hydrolysis and photolysis studies are used to determine the rate of pesticide degradation and to identify pesticides that may adversely affect nontarget organisms.

(3) *Metabolism studies.* Data generated from aerobic and anaerobic metabolism studies are used to determine the nature and availability of pesticides to rotational crops and to aid in the evaluation of the persistence of a pesticide.

(4) *Mobility studies.* These data requirements pertain to leaching, adsorption/desorption, and volatility of pesticides. They provide information on the mode of transport and eventual destination of the pesticide in the environment. This information is used to assess potential environmental hazards related to: contamination of human and animal food; loss of usable land and water resources to man through contamination of water (including ground water); and habitat loss of wildlife resulting from pesticide residue movement or transport in the environment.

(5) *Dissipation studies.* The data generated from dissipation studies are used to assess potential environmental hazards (under actual field use conditions) related to: reentry into treated areas; hazards from residues in rotational crop and other food sources; and the loss of land as well as surface and ground water resources.

(6) *Accumulation studies.* Accumulation studies indicate pesticide residue levels in food supplies that originate from wild sources or from rotational crops. Rotational crop studies are necessary to establish realistic crop rotation restrictions and to determine if tolerances may be needed for residues on rotational crops. Data from irrigated crop studies are used to determine the amount of pesticide residues that could be taken up by representative crops irrigated with water containing pesticide residues. These studies allow the Agency to establish label restrictions regarding application of pesticides on sites where the residues can be taken up by irrigated crops. These data also provide information that aids the Agency in establishing

any corresponding tolerances that would be needed for residues on such crops. Data from pesticides accumulation studies in fish are used to establish label restrictions to prevent applications in certain sites so that there will be minimal residues entering edible fish or shell fish. These residue data are also used to determine if a tolerance or action level is needed for residues in aquatic animals eaten by humans.

(e) *Hazard to humans and domestic animals.* Data required to assess hazards to humans and domestic animals are derived from a variety of acute, subchronic and chronic toxicity tests, and tests to assess mutagenicity and pesticide metabolism.

(1) *Acute studies.* Determination of acute oral, dermal and inhalation toxicity is usually the initial step in the assessment and evaluation of the toxic characteristics of a pesticide. These data provide information on health hazards likely to arise soon after, and as a result of, short-term exposure. Data from acute studies serve as a basis for classification and precautionary labeling. For example, acute toxicity data are used to calculate farmworker reentry intervals and to develop precautionary label statements pertaining to protective clothing requirements for applicators. They also: provide information used in establishing the appropriate dose levels in subchronic and other studies; provide initial information on the mode of toxic action(s) of a substance; and determine the need for child resistant packaging. Information derived from primary eye and primary dermal irritation studies serves to identify possible hazards from exposure of the eyes, associated mucous membranes and skin.

(2) *Subchronic studies.* Subchronic tests provide information on health hazards that may arise from repeated exposures over a limited period of time. They provide information on target organs and accumulation potential. The resulting data are also useful in selecting dose levels for chronic studies and for establishing safety criteria for human exposure. These tests are not capable of detecting those effects that have a long latency period for expression (e.g., carcinogenicity).

(3) *Chronic studies.* Chronic toxicity (usually conducted by feeding the test substance to the test species) studies are intended to determine the effects of a substance in a mammalian species following prolonged and repeated exposure. Under the conditions of this test, effects which have a long latency period or are cumulative should be detected. The purpose of long-term oncogenicity studies is to observe test animals over most of their life span for the development of neoplastic lesions during or after exposure to various doses of a test substance by an appropriate route of administration.

(4) *Teratogenicity and reproduction studies.* The teratogenicity study is designed to determine the potential of the test substance to induce structural and/or other abnormalities to the fetus as the result of exposure of the mother during pregnancy. Two-generation reproduction testing is designed to provide information concerning the general effects of a test substance on gonadal function, estrus cycles, mating behavior, conception, parturition, lactation, weaning, and the growth and development of the offspring. The study may also provide information about the effects of the test substance on neonatal morbidity, mortality, and preliminary data on teratogenesis and serve as a guide for subsequent tests.

(5) *Mutagenicity studies.* For each test substance a battery of tests are required to assess potential to affect the mammalian cell's genetic components. The objectives underlying the selection of a battery of tests for mutagenicity assessment are:

(i) To detect, with sensitive assay methods, the capacity of a chemical to alter genetic material in cells.

(ii) To determine the relevance of these mutagenic changes to mammals.

(iii) When mutagenic potential is demonstrated, to incorporate these findings in the assessment of heritable effects, oncogenicity, and possibly, other health effects.

(6) *Metabolism studies.* Data from studies on the absorption, distribution, excretion, and metabolism of a pesticide aid in the valuation of test results from other toxicity studies and in the extrapolation of data from animals

to man. The main purpose of metabolism studies is to produce data which increase the Agency's understanding of the behavior of the chemical in its consideration of the human exposure anticipated from intended uses of the pesticide.

(f) *Reentry Protection.* Data required to assess hazard to farm employees resulting from reentry into areas treated with pesticides are derived from studies on toxicity, residue dissipation, and human exposure. Monitoring data generated during exposure studies are used to determine the quantity of pesticide to which people may be exposed after application and to develop reentry intervals.

(g) *Pesticide Spray Drift Evaluation.* Data required to evaluate pesticide spray drift are derived from studies of droplet size spectrum and spray drift field evaluations. These data contribute to development of the overall exposure estimate and along with data on toxicity for humans, fish and wildlife, or plants are used to assess the potential hazard of pesticides to these organisms. A purpose common to all these tests is to provide data which will be used to determine the need for (and appropriate wording for) precautionary labeling to minimize the potential adverse effect to nontarget organisms.

(h) *Hazard to nontarget organisms—(1) General.* The information required to assess hazards to nontarget organisms are derived from tests to determine pesticidal effects on birds, mammals, fish, terrestrial and aquatic invertebrates, and plants. These tests include short-term acute, subacute, reproduction, simulated field, and full field studies arranged in a hierarchical or tier system which progresses from the basic laboratory tests to the applied field tests. The results of each tier of tests must be evaluated to determine the potential of the pesticide to cause adverse effects, and to determine whether further testing is required. A purpose common to all data requirements is to provide data which determines the need for (and appropriate wording for) precautionary label statements to minimize the potential adverse effects to nontarget organisms.

(2) *Short term studies.* The short-term acute and subchronic laboratory studies provide basic toxicity information which serves as a starting point for the hazard assessment. These data are used: to establish acute toxicity levels of the active ingredient to the test organisms; to compare toxicity information with measured or estimated pesticide residues in the environment in order to assess potential impacts on fish, wildlife and other nontarget organisms; and to indicate whether further laboratory and/or field studies are needed.

(3) *Long term and field studies.* Additional studies (i.e., avian, fish, and invertebrate reproduction, lifecycle studies and plant field studies) may be required when basic data and environmental conditions suggest possible problems. Data from these studies are used to: estimate the potential for chronic effects, taking into account the measured or estimated residues in the environment; and to determine if additional field or laboratory data are necessary to further evaluate hazards. Simulated field and/or field data are used to examine acute and chronic adverse effects on captive or monitored fish and wildlife populations under natural or near-natural environments. Such studies are required only when predictions as to possible adverse effects in less extensive studies cannot be made, or when the potential for adverse effects is high.

(i) *Product performance.* Requirements to develop data on product performance provide a mechanism to ensure that pesticide products will control the pests listed on the label and that unnecessary pesticide exposure to the environment will not occur as a result of the use of ineffective products. Specific performance standards are used to validate the efficacy data in the public health areas, including disinfectants used to control microorganisms infectious to man in any area of the inanimate environment and those pesticides used to control vertebrates (such as rodents, birds, bats and skunks) that may directly or indirectly transmit diseases to humans.

[49 FR 42881, Oct. 24, 1984. Redesignated and amended at 53 FR 15993, May 4, 1988]

§ 158.240 Residue chemistry data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the residue chemistry data requirements and the substances to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food corp	Nonfood	Food corp	Nonfood						
Chemical identity	(1)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI	TGAI	171-2
Directions for use	(2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	171-3
Nature of the residue:													
Plants	(13), (14)	[R]	[R]	[R]	[CR]	[CR]	PAIRA	PAIRA	171-4
Livestock	(3), (13), (14)	[CR]	[CR]	[CR]	[CR]	[CR]	PAIRA and plant metabolites.	PAIRA and plant metabolites.	171-4
Residue analytical method.	(4), (13), (14), (15)	[R]	[R]	[R]	[CR]	[CR]	TGAI and metabolites.	TGAI and metabolites.	171-4
Magnitude of the residue:													
Crop field trials	(13), (14)	[R]	[R]	[R]	[CR]	[CR]	TEP	TEP	171-4
Processed food/feed.	(5), (14)	[CR]	[CR]	[CR]	[CR]	EP	EP	171-4
Meat/milk/poultry/eggs.	(6), (14)	[CR]	[CR]	[CR]	[CR]	TGAI or plant metabolites.	TGAI or plant metabolites.	171-4
Potable water	(7)	[R]	[R]	EP	EP	171-4
Fish	(8)	[R]	[R]	EP	EP	171-4
Irrigated crops	(9)	[CR]	[CR]	EP	EP	171-4
Food handling	(10), (14)	[CR]	EP	EP	171-4
Reduction of residue	(11), (14)	[CR]	[CR]	[CR]	[CR]	Residue of concern.	Residue of concern.	171-5
Proposed tolerance	(12), (14)	[R]	[R]	[R]	[CR]	Residue of concern.	Residue of concern.	171-6
Reasonable grounds in support of the petition.	(14)	[R]	[R]	[R]	[CR]	171-7
Submittal of analytical reference standards.	(14)	[R]	[R]	[R]	[CR]	PAIRA	PAIRA	171-13

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

- (b) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.
- (1) The same chemical identity data as required under subpart C of this part are required, with emphasis on impurities that could constitute a residue problem.
 - (2) Required information includes crops to be treated, rate of application, number and timing of applications, preharvest intervals, and relevant restrictions.
 - (3) Data on metabolism in livestock are required when residues occur on a livestock feed, or the pesticide is to be applied directly to livestock.

(4) A residue method 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. Analytical methods used to enforce residue limits for emergency exemptions, temporary tolerances and permanent tolerances must be available for use by enforcement agencies and thus may not be claimed as confidential business information.

(5) 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.

(6) Livestock feeding studies are required whenever a pesticide occurs as a residue in a livestock feed. Use involving direct application to livestock, including poultry, will require animal treatment residue studies.

(7) 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.

(8) Data on residue in fish are required whenever a pesticide is to be applied directly to water inhabited by fish.

(9) 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.

(10) Data on residues in food/feed in food handling establishments are required whenever a pesticide is to be used in food/feed handling establishments. Disinfectants and sanitizers used in food or feed handling establishment are exempt from this requirement if their residues are regulated by the Food and Drug Administration at 21 CFR 178.1010.

(11) Reduction of residue data are required when the assumption of tolerance level residues would result in predicted exposure at an unsafe level. Data on the level of residue in food as consumed will be used to obtain a more precise estimate of potential dietary exposure. The Agency recommends that such data be generated to support all pesticides requiring a tolerance in case new data are revealed which indicates the pesticide is more toxic than initially determined.

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

(13) 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 tolerance was established.

(14) Required to support registration of an indoor use pesticide if such a use could result in residues in food or feed.

(15) For all food uses, data on whether the FDA/USDA multiresidue methodology would detect and identify the pesticide are required.

[49 FR 42881, Oct. 24, 1984. Redesignated and amended at 53 FR 15993, 15999, May 4, 1988; 58 FR 34203, June 23, 1993]

§ 158.290 Environmental fate data requirements.

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

Kind of data required	(b) Notes	General use patterns									Test substance		Guide-lines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Degradation studies-lab													
Hydrolysis		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]		TGAI or PAIRA.	TGAI or PAIRA.	161-1
Photodegradation:													
In water		R	R	R	R			R			TGAI or PAIRA.	TGAI or PAIRA.	161-2
On soil	(1)	CR						CR			TGAI or PAIRA.	TGAI or PAIRA.	161-3
In air	(2)	CR									TGAI or PAIRA.	TGAI or PAIRA.	161-4
Metabolism studies-lab													
Aerobic soil		[R]	[R]			R	R	[R]	R		TGAI or PAIRA.	TGAI or PAIRA.	162-1
Anaerobic aquatic				R	R			R			TGAI or PAIRA.	TGAI or PAIRA.	162-3

Aerobic aquatic				[R]	[R]						TGAI or PAIRA.	TGAI or PAIRA.	162-4
Mobility studies													
Leaching and adsorption/desorption.		[R]	[R]	R	R	R	R	[R]	R		TGAI or PAIRA.	TGAI or PAIRA.	163-1
Volatility:													
(Lab)	(2)	CR				CR	CR				TEP	TEP	163-2
(Field)	(2)	CR				CR	CR				TEP	TEP	163-3
Dissipation studies-field													
Soil		R	R						R		TEP	TEP	164-1
Aquatic (sediment)				R	R						TEP	TEP	164-2
Forestry								R			TEP	TEP	164-3
Combination and tank mixes.	(2)												164-4
Soil, long-term	(4)	CR		CR							TEP	TEP	164-5
Accumulation studies													
Rotational crops:													
(Confined)	(5)	[CR]		[CR]							PAIRA	PAIRA	165-1
(Field)	(6)	CR		CR							TEP	TEP	165-2
Irrigated crops	(7)			[CR]	CR						TEP	TEP	165-3
In fish	(8)	[CR]	[CR]	[CR]	[CR]			[CR]			TGAI or PAIRA.	TGAI or PAIRA.	165-4
In aquatic non-target organisms.	(8), (9)				CR			CR			TEP	TEP	165-5

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

(b) Notes.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Not required if use involves application to soils solely by injection of the product into the soil or by incorporation of the product into the soil upon application.

AAA(2) Required on case by case basis depending on product use pattern and other pertinent factors.

AAA(3) Not required if anaerobic aquatic metabolism study has been conducted.

AAA(4) Required if pesticide residues do not readily dissipate in soil.

AAA(5) Confined accumulation study is required when it is reasonably foreseeable that any food or feed crop may be subsequently planted on the site of pesticide application.

AAA(6) Field accumulation study is required if significant pesticide residue is likely to be present in soil at time of plant crop, as evidenced by residue data obtained from confined accumulation study.

AAA(7) Required if it is reasonably foreseeable that water at treated site may be used for irrigation purposes.

AAA(8) Required if significant concentrations of the active ingredient and/or its principal degradation products are likely to occur in aquatic environments and may accumulate in aquatic organisms.

AAA(9) Required unless tolerance or action level for fish has been granted.

[49 FR 42881, Oct. 24, 1984. Redesignated at 53 FR 15993, May 4, 1988]

§ 158.340 Toxicology data requirements.

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

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.	
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP		
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood							
Acute testing														
Acute oral toxicity—rat	(1)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* or EP dilution* and TGAI.	81-1
Acute dermal toxicity	(1), (2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* or EP dilution* and TGAI.	81-2
Acute inhalation toxicity—rat.	(16)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* and TGAI.	81-3
Primary eye irritation—rabbit.	(2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	81-4
Primary dermal irritation ...	(1), (2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	81-5
Dermal sensitization	(3)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	81-6
Acute delayed neurotoxicity—hen.	(4)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI	TGAI	81-7
Subchronic testing														
90-day feeding studies—rodent and nonrodent.	(17)	[R]	CR	[R]	CR	[R]	CR	CR	CR	CR	CR	TGAI	TGAI	82-1
21-day dermal	(18)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI and EP*.	82-2
90-day dermal	(5), (19)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82-3
90-day inhalation—rat	(6)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82-4
90-day neurotoxicity:														
Hen	(7)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82-5
Mammal	(8)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82-5
Chronic testing														
Chronic feeding—2 spp. rodent and nonrodent.	(9), (13), (20)	[R]	CR	[R]	CR	[R]	CR	CR	CR	CR	CR	TGAI	TGAI	83-1
Oncogenicity study—2 Spp. rat and mouse preferred.	(9), (21)	R	CR	R	CR	R	CR	CR	CR	CR	CR	TGAI	TGAI	83-2
Teratogenicity—2 species	(10), (15)	[R]	CR	[R]	CR	[R]	CR	CR	CR	CR	CR	TGAI	TGAI	83-3
Reproduction, 2-generation.	(11), (14)	[R]	CR	[R]	CR	[R]	CR	CR	CR	CR	CR	TGAI	TGAI	83-4
Mutagenicity testing														
Gene mutation	(22)	[R]	R	[R]	R	[R]	R	R	R	R	R	TGAI	TGAI	84-2
Structural chromosomal aberration.	(22)	[R]	R	[R]	R	[R]	R	R	R	R	R	TGAI	TGAI	84-2
Other genotoxic effects	(22)	[R]	R	[R]	R	[R]	R	R	R	R	R	TGAI	TGAI	84-4

Special testing														
General metabolism	(23)	R	CR	R	CR	R	CR	CR	CR	CR	CR	PAI or PAIRA.	PAI or PAIRA.	85-1
Dermal penetration	(24)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	Choice	Choice	85-2
Domestic animal safety	(12)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	Choice	Choice	86-1

AAKey: R=Required data; CR=Conditionally required; []=Brackets (ie [R], [CR]) indicate data requirements that apply when an experimental use permit is being sought; 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; PAI="Pure" active ingredient; PAIRA="Pure" active ingredient, radio-labeled; Choice=choice of several test substances, depending on studies required.

(b) Notes.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

- (1) Not required if test material is a gas or highly volatile.
- (2) 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 as toxicity category I on the basis of potential eye and dermal irritation effects.
- (3) Required unless repeated dermal exposure does not occur under conditions of use.
- (4) Not required unless test material, is an organophosphate, or a metabolite or degradation product thereof which causes acetyl cholinesterase depression or is structurally related to a substance that causes delayed neurotoxicity.
- (5) Required if use involves purposeful dermal application to, or prolonged exposure of, human skin.
- (6) Required if use may result in repeated inhalation exposure at a concentration likely to be toxic. A test with duration of 21 days is required if pesticide is used on tobacco.
- (7) Required if acute delayed neurotoxicity test showed neuropathy or neurotoxicity or if closely related structural to a compound which can induce these effects.
- (8) Required if acute oral, dermal, or inhalation studies showed neuropathy or neurotoxicity.
- (9)(i) Studies designed to simultaneously meet the requirements of both the chronic feeding and oncogenicity studies (i.e., a combined study) can be conducted.
- (ii) Minimum acceptable test durations for chronic feeding and oncogenicity studies are as follows:
 - (A) Chronic rodent feeding study (food use pesticides)—24 months.
 - (B) Chronic rodent feeding study (non-food pesticides)—12 months is usually sufficient.
 - (C) Chronic nonrodent (i.e., dog) feeding study—12 months.
 - (D) Mouse oncogenicity study—18 months.
 - (E) Rat oncogenicity study—24 months.
- (10) Required to support products intended for food uses and to support products intended for non-food uses if significant exposure of human females of child bearing age may reasonably be expected.
 - (11) Required to support products intended for food uses and to support products intended for non-food uses if use of the product is likely to result in human exposure over a portion of the human lifespan which is significant in terms of the frequency of exposure, magnitude of exposure, or the duration of exposure (for example; pesticides used in treated fabrics for wearing apparel, diapers, or bedding; insect repellents applied directly to human skin; swimming pool additives; constant-release indoor pesticides which are used in aerosol form).
 - (12) Required on a case by case basis.
 - (13) In most cases, where theoretical maximum residue contribution (TMRC) exceeds 50 percent of the maximum permitted intake (MPI), a one year (or longer) interim report on a chronic feed study is required to support a temporary tolerance.
 - (14) In most cases, where theoretical maximum residue contribution (TMRC) exceeds 50 percent of the maximum permitted intake (MPI), a first generation (or longer) interim report on a multigeneration reproduction study is required to support a temporary tolerance.
 - (15) A teratology study in one species is required to support a temporary tolerance.
 - (16) Required if the product consists of, or under conditions of use will result in, an inhalable material (e.g., gas volatile substances, or aerosol/particulate).
 - (17) Required if intended use(s) of the pesticide product is expected to result in human exposure to the product, under the following conditions:
 - (i) Human exposure is via the oral route.
 - (ii) Expected human exposure is over a limited portion of the human lifespan, yet is significant in terms of the frequency of exposure, magnitude of exposure, or the duration of exposure (for example, products requiring a temporary tolerance to support an experimental use permit or emergency exemption).
 - (18) Required if intended use(s) of the pesticide product is expected to result in human exposure to the product, under the following conditions:
 - (i) Human exposure is via skin contact.
 - (ii) Expected human skin contact is not purposeful, and such exposure is of limited frequency and duration (for example, such exposure could result from use of certain disinfectant, liquid fumigant or agricultural or home/garden pesticide products, and other circumstances where the Agency determines that more than acute dermal exposure is involved).
 - (iii) Data from a subchronic 90-day dermal toxicity study are not required.
 - (19) Required if pesticidal use will involve purposeful application to the human skin or will result in comparable human exposure to the product, (e.g., swimming pool algacides, pesticides for impregnating clothing), and if either of the following criteria are met:
 - (i) Data from a subchronic oral study are not required.
 - (ii) 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.
 - (20) Required if either of the following criteria are met:
 - (i) Use of the pesticide product is likely to result in repeated human exposure to the product, over a significant portion of the human life-span (for example, products intended for use in and around residences, swimming pools, and enclosed working spaces or their immediate vicinity).

- (ii) The use requires a tolerance for the pesticide or an exemption from the requirement to obtain a tolerance, or requires issuance of a food additive regulation.
- (21) Required if any of the following criteria are met:
 - (i) The active ingredient(s) or any of its (their) metabolites, degradation products, or impurities:
 - (A) Is structurally related to a recognized carcinogen.
 - (B) Is a substance that cause mutagenic effect as demonstrated by *in vitro* or *in vivo* testing.
 - (C) Produces in subchronic studies a morphologic effect (e.g., hyperplasia, metaplasia) in any organ that may lead to neoplastic change.
 - (ii) The use requires a tolerance for the pesticide or exemption from the requirement to obtain a tolerance, or requires the issuance of a food additive regulation.
 - (iii) Use of the pesticide product is likely to result in human exposure over a portion of the human lifespan which is significant in terms of either the time the exposure occurs or the duration of exposure (for example; pesticides used in treated fabrics for wearing apparel, diapers, or bedding; insect repellents applied directly to human skin; swimming pool additives; constant-release indoor pesticides which are used in aerosol form).
- (22)(i) The required battery of mutagenicity tests must include tests appropriate to address the following three categories in accordance with the objectives set forth in § 158.202:
 - (A) Gene mutations.
 - (B) Structural chromosomal aberrations.
 - (C) Other genotoxic effects as appropriate for the test substance, e.g., numerical chromosome aberrations, direct DNA damage and repair, mammalian cells transformation, target organ/cell analysis.
- (ii) Currently recognized tests for each of these categories are listed with the National Technical Information Service (NTIS). Applicants shall explain their reasons for selecting specific tests from the battery of currently recognized tests. Because of the rapid improvements in this field, applicants are encouraged to discuss with the Agency: test selection, protocol design and results of preliminary testing.
- (iii) Not required if the pesticide use pattern precludes human exposure (e.g., nonvolatile pesticides packaged and used in enclosed bait boxes).
- (23) Required if chronic feeding or oncogenicity studies are required.
- (24) Dermal absorption studies required for compounds having a serious toxic effect as identified by oral or inhalation studies, for which a significant route of human exposure is dermal and for which the assumption of 100 percent absorption does not produce an adequate margin of safety. Registrants should work closely with the Agency in developing an acceptable protocol and performing dermal absorption studies.

[49 FR 42881, Oct. 24, 1984. Redesignated and amended at 53 FR 15993, 15999, May 4, 1988; 58 FR 34203, June 23, 1993]

§ 158.390 Reentry protection data requirements.

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

Kind of data required	(b) 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						
Foliar dissipation	(1)	CR	CR	CR	CR	CR	TEP	TEP	132-1
Soil dissipation	(1), (4)	CR	CR	CR	CR	CR	TEP	TEP	132-1
Dermal exposure	(1), (2), (3)	CR	CR	CR	CR	CR	TEP	TEP	133-3
Inhalation exposure	(1), (2), (3)	CR	CR	CR	CR	CR	TEP	TEP	133-4

- Key: CR=Conditionally required; TEP=Typical end-use product.
- (b) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.
- (1) Data are required if the following conditions are met:
 - (i)(A) The acute dermal toxicity of the technical grade of active ingredient is less than 200 mg/kg (body weight); or
 - (B) The acute inhalation toxicity of the technical grade of active ingredient is less than 200 mg/m³ (for a one-hour exposure); or
 - (C) The acute oral toxicity of the technical grade of active ingredient is less than 50 mg/kg (body weight); or
 - (D) Neurotoxic, teratogenic, or oncogenic effects or other adverse effects as evidenced by subchronic, chronic, and reproduction studies would be expected from entry of persons into treated sites; or
 - (E) The Agency receives other scientifically validated toxicological or epidemiological evidence that a pesticide or residue of a pesticide could cause adverse effects on persons entering treated sites. In the last situation, reentry intervals and supporting data may be required on a case-by-case basis.
 - (ii) And if: end-use product is to be registered for:
 - (A) Application to growing crops, such as to or around horticultural and agronomic crops that are field- or orchard-grown.

- (B) Application to outdoor tree nursery and forestry operations.
- (C) Application to turf crops and commercial applications to turf.
- (D) Application to parks and arboretums; or (E) application to aquatic crops.
- (iii) And if: human exposure to residues of the pesticide can be reasonably foreseen. This applies primarily to pesticides that will be used on crops where human tasks will involve substantial exposure to residues of the pesticide.
- (2) Data required if appropriate surrogate data are not available.
- (3) Data required if the applicant chooses to use the allowable exposure level method for proposal of a reentry interval.
- (4) Soil dissipation data required if agricultural practice involves human tasks that would cause substantial exposure to residues sorbed to soil.

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

§ 158.440 Spray drift data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the aerial spray drift data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Droplet size spectrum	(1)	CR	CR	CR	CR	CR	TEP	TEP	201-1
Drift field evaluation	(1)	CR	CR	CR	CR	CR	TEP	TEP	202-1

Key: CR=Conditionally required; TEP=Typical end use product.

(b) NOTES.—The following are referenced in column two of the table contained in paragraph (a) of this section.

(1) This study is required when aerial applications (rotary and fixed winged) and mist blower or other methods of ground application are proposed and it is estimated that the detrimental effect level of those nontarget organisms expected to be present would be exceeded. The nontarget organisms include humans, domestic animals, fish and wildlife, and nontarget plants. This requirement may be satisfied by submittal of published or unpublished information regarding spray drift patterns that would be expected to be similar to the proposed product.

(2) [Reserved]

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

§ 158.490 Wildlife and aquatic organisms data requirements.

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

Kind of data required	(b) Notes	General use patterns									Test substance		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						
Avian and mammalian testing													
Avian oral LD ₅₀ (preferably mallard or bobwhite).	(1)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	71-1

Kind of data required	(b) Notes	General use patterns									Test substance		Guide-lines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food Crop	Nonfood	Food crop	Nonfood						
Avian dietary LC ₅₀ (preferably mallard and bobwhite).	(1)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	71-2
Wild mammal toxicity	(2)	CR	CR	CR	CR	CR	CR	TGAI	TGAI	71-3
Avian reproduction (preferably mallard and bobwhite).	(3)	CR	CR	CR	CR	CR	CR	TGAI	TGAI	71-4
Simulated and actual field testing—mammals and birds.	(2)	CR	CR	CR	CR	CR	CR	TEP	TEP	71-5
Aquatic organism testing													
Freshwater fish LC ₅₀ (preferably rainbow and bluegill).	(1), (7)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	72-1
Acute LC ₅₀ freshwater invertebrates (preferably <i>Daphnia</i>).	(1), (7)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	72-2
Acute LC ₅₀ estuarine and marine organisms.	(4), (7)	CR	CR	CR	CR	CR	CR	TGAI	TGAI	72-3
Fish early life stage and aquatic invertebrate life-cycle.	(5)	CR	CR	CR	CR	CR	CR	TGAI	TGAI	72-4
Fish—life-cycle	(6)	CR	CR	CR	CR	CR	CR	TGAI	TGAI	72-5
Aquatic organism accumulation.	(8)	CR	CR	CR	CR	CR	CR	TGAI, PAI, or degradation product.	TGAI, PAI, or degradation product.	72-6
Simulated or actual field testing—aquatic organisms.	(2)	CR	CR	CR	CR	CR	CR	TEP	TEP	72-7

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

(b) Notes.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1)(i) Data are required as follows to support manufacturing use products and those end-use products for indoor use for which there is no registered manufacturing use product:

(A) Solid formulation indoor use products require avian oral LD₅₀ (bobwhite), avian dietary LC₅₀ (bobwhite), freshwater fish LC₅₀ (rainbow trout) and acute LC₅₀ freshwater invertebrate (*Daphnia*).

(B) Liquid formulation indoors use products require all tests listed under (b)(1)(i) of this section except the avian oral LD₅₀.

(ii) Data are not required to support:

(A) Indoor end-use products consisting of a gas/highly volatile liquid or a highly reactive solid.

(B) Indoor end-use products for which there is a manufacturing use product registration.

(2) Tests required on a case-by-case basis depending on the results of lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics.

(3) Data required if one or more of the following criteria are met:

- (i) Birds may be subjected to repeated or continued exposure to the pesticide or any of its major metabolite degradation products, especially preceding or during the breeding season.
- (ii) The pesticide or any of its major metabolites or degradation products are stable in the environment to the extent that potentially toxic amounts may persist in avian feed.
- (iii) The pesticide or any of its major metabolites or degradation products is stored or accumulated in plant animal tissues, as indicated by its octanol/water partition coefficient, accumulation studies, metabolic release and retention studies, or as indicated by structural similarity to known bioaccumulative chemicals.
- (iv) Any other information, such as that derived from mammalian reproduction studies that indicates the reproduction in terrestrial vertebrates may be adversely affected by the anticipated use of the pesticide product.

NOTE: Prior to conducting this test to support the registration of an avicide, the applicant should consult the Agency.
 (4) Data required if the product is intended for direct application to the estuarine or marine environment, or the product is expected to enter this environment in significant concentrations because of its expected use or mobility pattern.

(5) Data from fish early life-stage tests or life-cycle tests with aquatic invertebrates (on whichever species is most sensitive to the pesticide as determined from the results of the acute toxicity tests) are required if the product is applied directly to water or expected to be transported to water from the intended use site, and when any one or more of the following conditions apply:

- (i) If the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity.
- (ii) If any LC₅₀ or EC₅₀ value determined in acute toxicity testing is less than 1 mg/l; or
- (iii) If the estimated environmental concentration in water is equal to or greater than 0.01 of any EC₅₀ or LC₅₀ determined in acute toxicity testing.
- (iv) If the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any EC₅₀ or LC₅₀ determined in acute toxicity testing and any of the following conditions exist:

- (A) Studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected.
 - (B) Physicochemical properties indicate cumulative effects.
 - (C) The pesticide is persistent in water (e.g., half-life in water greater than 4 days).
- (6) Data are required if end-use product is intended to be applied directly to water or expected to transport to water from the intended use site, and when any of the following conditions apply:

- (i) if the estimated environmental concentration is equal to or greater than one-tenth of the no-effect level in the fish early life-stage or invertebrate life-cycle test.
- (ii) If studies of other organisms indicate the reproductive physiology of fish may be affected. NOTE: The applicant should consult the Agency prior to these tests to support the registration of a pesticide.

(7) Data from testing with the applicant's end-use product or a typical end-use product is required to support the registration of each end-use product which meets any one of the following conditions:

- (i) The end-use pesticide will be introduced directly not an aquatic environment when used as directed.
- (ii) The LC₅₀ or EC₅₀ of the technical grade of active ingredient is equal to or less than the maximum expected environmental concentration (MEEC) or the estimated environmental concentration (EEC) in the aquatic environment when the end-use pesticide is used as directed.
- (iii) An ingredient in the end-use formulation other than the active ingredient is expected to enhance the toxicity of the active ingredient or to cause toxicity to aquatic organisms.
- (8) Required if significant concentrations of the active ingredient and/or its principal degradation products are likely to occur in aquatic environments and may accumulate in aquatic organisms.

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

§ 158.540 Plant protection data requirements.

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

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Target area phytotoxicity .. Nontarget area phytotoxicity.	(1)	EP	EP	121-1
Tier I: Seed germination/ seedling emergence.	(2)	R	R	R	TGAI	TGAI	122-1
Vegetative vigor	(2)	R	R	R	TGAI	TGAI	122-1

Kind of data required	(b) Notes	General use patterns									Test substance		Guide-lines 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						
Aquatic plant growth	(2)	R	R	R	TGAI	TGAI	122-2
Tier II: Seed germination/ seedling emergence.	(3)	CR	CR	CR	TGAI	TGAI	123-1
Vegetative vigor	(3)	CR	CR	CR	TGAI	TGAI	123-1
Aquatic plant growth	(4)	CR	CR	CR	TGAI	TGAI	123-2
Tier III: Terrestrial field	(3)	CR	CR	CR	TEP	TEP	124-1
Aquatic field	(4)	CR	CR	CR	TEP	TEP	124-2

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

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

§ 158.590 Nontarget insect data requirements.

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

Kind of data required	(b) Notes	General use pattern									Test substance		Guide-lines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Nontarget insect testing— pollinators													
Honey bee acute contact LD ₅₀ .	(1)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	TGAI	TGAI	141-1
Honey bee—toxicity of residues on foliage.	(1), (2)	CR	CR	CR	CR	CR	CR	TEP	TEP	141-2
Honey bee subacute feeding study.	(3)	141-4
Field testing for pollinators	(4)	CR	CR	CR	CR	CR	CR	TEP	TEP	141-5

Nontarget insect testing— aquatic insects	(5)	142-1
Acute toxicity to aquatic insects.	(5)	142-1
Aquatic insect life-cycle study.	(5)	142-3
Simulated or actual field testing for aquatic in- sects.	(5)	143-1 thru 143-3

Key: CR=Conditionally required; []=Brackets (ie, [CR]) indicate data requirements that apply to products for which an experimental use permit is being sought; TGA=Technical grade of the active ingredient; 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) Required only if proposed use will result in honey bee exposure.
- (2) Required only when formulation contains one or more active ingredients having an acute LD₅₀ of less than 1 microgram/bee.
- (3) This requirement is reserved pending development of test methodology.
- (4) May be required under the following conditions:
 - (i) Data from the honey bee subacute feeding study indicate adverse effects on colonies, especially effects other than acute mortality (reproductive, behavioral, etc.).
 - (ii) Data from residual toxicity studies indicate extended residual toxicity.
 - (iii) Data derived from studies with organisms other than bees indicate properties of the pesticide beyond acute toxicity, such as the ability to cause reproductive or chronic effects.
- (5) This requirement is reserved pending further evaluation to determine what and when data should be required, and to develop appropriate test methods.

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

§ 158.640 Product performance data requirements.

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

Kind of data required	(b) Notes	General use patterns									Test substance		Guide- lines ref- erence No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to sup- port MP*	Data to sup- port EP*	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Efficacy of antimicrobial agents													
Products for use on hard surfaces.	(1)	CR	EP*	91-2
Products requiring con- firmatory data.	(1)	CR	EP*	91-3
Products for use on fab- rics and textiles.	(1)	CR	EP*	91-4
Air sanitizers	(1)	CR	EP*	91-5
Products for control of mi- crobial pests associated with human and animal wastes.	(1)	CR	EP*	91-7

Kind of data required	(b) Notes	General use patterns									Test substance		Guide-lines 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						
Products for treating water systems.	(1)	[CR]	CR	EP*	91-8
Efficacy of fungicides and nematocides													
Products for control of organisms producing mycotoxins.	(1)	[CR]	[CR]	[CR]	EP*	93-16
Efficacy of Vertebrate Control Agents													
Avian toxicants	(1)	(R)	(R)	(R)	(R)	EP*	96-5
Avian repellents	(1)	(R)	(R)	(R)	EP*	96-6
Avian frightening agents ..	(1)	(R)	(R)	(R)	EP*	96-7
Bat toxicants and repellents.	(1)	(R)	EP*	96-9
Commensal rodenticides ..	(1)	(R)	(R)	(R)	(R)	TEP	EP*	96-10
Rodenticides on farm and rangelands.	(1)	(R)	(R)	(R)	EP*	96-12
Rodent fumigants	(1)	(R)	(R)	(R)	(R)	EP*	96-13
Rodent reproductive inhibitors.	(1)	(R)	(R)	(R)	(R)	EP*	96-16
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		Guide-lines 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 through 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		Guide-lines 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

Kind of data required	(2) Notes	General use patterns									Test substance		Guide-lines 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						
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
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 expressible 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 a 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		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:														
Acute oral toxicity	(i)	[R]	[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]	[R]	MP and TGAI.	EP* or EP dilution* and TGAI.	152-11
Acute inhalation	(xiv)	[R]	[R]	[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]	[R]	[R]	MP	EP	152-13
Primary dermal irritation.	(i), (ii)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP	152-14
Hypersensitivity study	(iii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	MP	EP	152-15
Hypersensitivity incidents.	(iv)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	152-16
Studies to detect genotoxicity.	(v)	[R]	[CR]	[R]	[CR]	[R]	[CR]	[CR]	[CR]	[CR]	[CR]	TGAI	TGAI	152-17
Immune response	[R]	R	[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	CR	CR	TGAI	TGAI	152-20
90-day dermal (1 spp.).	(vii)	CR	CR	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	CR	CR	TGAI	TGAI	152-22
Teratogenicity (1 spp.).	(ix)	CR	CR	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	CR	CR	TGAI	TGAI	152-19
Immune response	(xi)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-24
Tier III:														
Chronic exposure	(xii)	CR	CR	CR	CR	TGAI	TGAI	152-26
Oncogenicity	(xiii)	CR	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 algacides, 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 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.

(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. 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 1/5 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 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.

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
Analysis of samples	(iii)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	MP and TGAI.	EP* and TGAI.	151–23
Certification of limits		[R]	R	[R]	R	[R]	R	R	R	R	MP	EP*	151–25
Analytical methods		R	R	R	R	R	R	R	R	R	MP	EP*	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., "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 (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.
 - (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 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.

Kind of data required	(2) Notes	General use patterns									Test substance		Guide-lines 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						
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 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		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	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* or EP* dilution and TGAI.	152-30
Acute dermal	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* or EP dilution and TGAI.	152-31
Acute inhalation	(i)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* or EP Dilution* and TGAI.	152-32
I.V., I.C., I.P. injection	(ii)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI	TGAI	152-33
Primary dermal	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	152-34
Primary eye	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	152-35
Hypersensitivity study	(iii)	R	R	R	R	R	R	R	R	R	MP	EP*	152-36
Hypersensitivity incidents.	(iv)	CR	CR	CR	CR	CR	CR	CR	CR	CR	152-37
Immune response	[R]	R	[R]	R	[R]	R	R	R	R	TGAI	TGAI	152-38
Tissue culture	(v)	[R]	R	[R]	R	[R]	R	R	R	R	TGAI	TGAI	152-39
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

Kind of data required	(2) Notes	General use patterns									Test substance		Guide-lines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
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 enhancement.	(xiv)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-48
Mammalian mutagenicity.	(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.
- (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 viral 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.
 - (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 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 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.

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 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	(iv)	CR	CR	CR	CR	CR	CR	TGAI	TGAI	154–18
Freshwater fish testing.	(i)	[R]	[R]	[R]	[R]	CR	CR	[R]	CR	CR	TGAI	TGAI	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 studies.	[R]	[R]	[R]	[R]	[R]	[R]	CR	TEP	TEP	154–2
Nontarget insect testing.	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	TGAI	TGAI	154–23
Honey bee testing	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	TGAI	TGAI	154–24
Tier II:													
Terrestrial environmental testing.	(vi)	CR	CR	CR	CR	CR	CR	TGAI or TEP	TGAI or TEP	155–18
Freshwater environmental expression tests.	(vii)	CR	CR	CR	CR	CR	CR	TGAI or TEP	TGAI or TEP	155–19
Marine or estuarine environmental expression tests.	(xiii), (ix)	CR	CR	CR	CR	CR	CR	TGAI or TEP	TGAI or TEP	155–20
Tier III:													
Terrestrial wildlife and aquatic organism testing.	(x)	CR	CR	CR	CR	CR	CR	TGAI or TEP	TGAI or TEP	154–25
Avian pathogenicity/reproduction test.	(xi)	CR	CR	CR	CR	CR	CR	TGAI	TGAI	154–26
Definitive aquatic animal tests.	(xii)	CR	CR	CR	CR	CR	CR	TGAI	TGAI	154–27
Aquatic embryo larvae 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

Kind of data required	(2) Notes	General use patterns									Test substance		Guide-lines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Special aquatic tests (reserved). Nontarget plant studies.	(xv)	CR	CR	CR	CR			CR	CR		TGAI	TEP	154-31
Tier IV: Simulated and actual field tests (birds, mammals).	(xvi) (xiii)	CR	CR	CR	CR			CR	CR		TEP	TEP	154-33
Simulated and actual field tests (aquatic organisms).	(xvii), (xviii)	CR	CR	CR	CR			CR	CR		TEP	TEP	154-34
Simulated and actual field tests (insect predators, parasites) (reserved).													154-35
Simulated and actual field tests (insect pollinators) (reserved).													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) 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 single dose oral toxicity and pathogenicity tests.
- AAA(B) Avian injection pathogenicity tests.
- AAA(C) Wild mammals toxicity and pathogenicity test.
- AAA(D) Plant studies—terrestrial.
- AAA(E) Honey bee toxicity/pathogenicity test.
- AAA(F) Testing for toxicity/pathogenicity to insect predators and parasites.

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 microbial agent to the affected 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 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 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 II 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 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 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.

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

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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>	Indoor
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	Indoor
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		Air	
Hatchery buildings	Aquatic food use	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)	Domestic outdoor or terrestrial food crop
Gerbils		Home garden, orchards	
Hamsters		Porches	Domestic outdoor
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.)	Domestic outdoor or indoor
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	Aquatic food crop
Animals for pets, including their cages, bedding, nests, etc.		Poultry and livestock drinking water	
Dogs		Pulp and papermill systems	Aquatic noncrop
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
<p>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, cleansers, dyes, etc.)</p>		<p>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 Vomitus 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</p>	<p>Indoor</p>

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 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	Indoor

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.
- 159.153 Definitions.
- 159.155 When information must be submitted.
- 159.156 How information must be submitted.
- 159.158 What information must be submitted.
- 159.159 Information obtained before promulgation of the rule.
- 159.160 Obligations of former registrants.
- 159.165 Toxicological and ecological studies.
- 159.167 Discontinued studies.
- 159.170 Human epidemiological and exposure studies.
- 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.