(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 frequence 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 algaecides, 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 structually 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 abberations, 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

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						
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/m^3 (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.