

## Environmental Protection Agency

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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.

(4) *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 pesticide 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 shellfish. These residue data are also used to determine if a tolerance or action level is needed for residues in aquatic animals eaten by humans.

### Subpart C—Experimental Use Permits

#### § 158.200 Experimental use permit data requirements tables.

Sections 158.200 through 158.270 describe how to use these tables to determine the experimental use permit data

requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed at the end of each table. Refer to 40 CFR part 172 for further information on experimental use permits.

#### § 158.210 Experimental use permit data requirements for product chemistry.

All product chemistry data, as described in §158.310, must be submitted to support a request for an experimental use permit.

#### § 158.220 Experimental use permit data requirements for product performance.

All product performance data, as described in paragraph (c) of this section, must be submitted to support a request for an experimental use permit.

(a) *Use patterns.* (1) The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop and terrestrial nonfood crop. The aquatic use pattern includes products classified under the general use patterns of aquatic food crop and aquatic nonfood crop. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. The indoor use pattern includes products classified under the general use patterns of indoor food and indoor nonfood use.

(2) Data are also required for forestry and residential outdoor uses.

(b) *Key.* CR=Conditionally required; NR=Not required; R=Required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product.

(c) *Table.* The following table shows the experimental use data requirements for product performance. The test notes are shown in paragraph (d) of this section.

TABLE—EXPERIMENTAL USE PERMIT DATA REQUIREMENTS FOR PRODUCT PERFORMANCE

Guideline No.	Data Requirement	Use Pattern										Test substance to support		Test Note No.	
		Terrestrial		Aquatic		Greenhouse		Forestry	Residential Outdoors	Indoor	MP	EP			
		Food Crop	Nonfood Crop	Food Crop	Nonfood Crop	Food Crop	Nonfood Crop								
Efficacy of antimicrobial agents															
91-8	Products for treating water systems	NR	NR	CR	NR	NR	NR	NR	NR	NR	NR	NR	NR	EP	1
Efficacy of fungicides and nematocides															
93-16	Products for control of organisms producing mycotoxins	CR	NR	CR	NR	CR	NR	NR	NR	NR	NR	NR	NR	EP	1
Efficacy of vertebrate control agents															
96-5	Avian toxicants	R	R	NR	NR	NR	NR	NR	NR	R	R	NR	NR	EP	1
96-6	Avian repellents	R	R	NR	NR	NR	NR	NR	NR	R	R	NR	NR	EP	1
96-7	Avian frightening agents	R	R	NR	NR	NR	NR	NR	NR	R	R	NR	NR	EP	1
96-9	Bat toxicants and repellents	NR	NR	NR	NR	NR	NR	NR	NR	R	R	NR	NR	EP	1
96-10	Commensal rodenticides	R	R	NR	NR	NR	NR	NR	NR	R	R	TEP	NR	EP	1
96-12	Rodenticides on farm and rangelands	R	R	NR	NR	NR	NR	NR	NR	R	R	NR	NR	EP	1
95-13	Rodent fumigants	R	R	NR	NR	NR	NR	NR	NR	R	R	NR	NR	EP	1
95-16	Rodent reproductive inhibitors	R	R	NR	NR	NR	NR	NR	NR	R	R	NR	NR	EP	1
95-17	Mammalian predacides	R	R	NR	NR	NR	NR	NR	NR	R	R	NR	NR	EP	1

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(d) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (c) of this section.

1. The Agency has waived the requirement 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 product is 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]

[72 FR 60957, Oct. 26, 2007, as amended at 73 FR 75596, Dec. 12, 2008]

**§ 158.230 Experimental use permit data requirements for toxicology.**

All toxicology data, as described in paragraph (c) of this section, must be

submitted to support a request for an experimental use permit.

(a) *Use patterns.* (1) Food use patterns include products classified under the general use patterns of terrestrial food crop use, terrestrial feed crop use, aquatic food crop use, greenhouse food crop use, and indoor food use.

(2) Nonfood use patterns include products classified under the general use patterns of terrestrial nonfood crop use, aquatic nonfood outdoor use, greenhouse nonfood crop use, forestry use, residential outdoor use, indoor nonfood use, and indoor residential use.

(b) *Key.* CR=Conditionally required; NR=Not required; R=Required; EP=End-use product; MP=Manufacturing-use product; PAIRA=Pure active ingredient radio-labeled; TGAI=Technical grade of the active ingredient.

(c) *Table.* The following table shows the experimental use data requirements for toxicology. The test notes are shown in paragraph (d) of this section.

TABLE—EXPERIMENTAL USE PERMIT TOXICITY DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern		Test substance to support		Test Note No.
		Food	Nonfood	MP	EP	
<b>Acute Testing</b>						
870.1100	Acute oral toxicity - rat	R	R	MP and TGAI	TGAI, EP	1
870.1200	Acute dermal toxicity	R	R	MP and TGAI	TGAI, EP	1, 2
870.1300	Acute inhalation toxicity - rat	R	R	MP and TGAI	TGAI and EP	3
870.2400	Primary eye irritation - rabbit	R	R	MP	TGAI and EP	2
870.2500	Primary dermal irritation	R	R	MP	TGAI and EP	1, 2
870.2600	Dermal sensitization	R	R	MP	TGAI and EP	2, 4
870.6100	Delayed neurotoxicity (acute) - hen	CR	CR	TGAI	TGAI	5
<b>Subchronic Testing</b>						
870.3100	90-day Oral - rodent	R	NR	TGAI	TGAI	--
870.3150	90-day Oral - non-rodent	R	NR	TGAI	TGAI	--
<b>Chronic Testing</b>						