

- (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 residues in fish are required whenever a pesticide is to be applied directly to water that could be used for irrigation or to irrigation facilities such as irrigation ditches.
- (9) Data on residues in irrigated crops are required when a pesticide is to be applied directly to water that could be used in food/feed handling establishments. Disinfectants and sanitizers used in food or feed handling establishments are exempt from this requirement if their residues are regulated by the Food and Drug Administration at 21 CFR 178.1010.
- (10) Data on residues in food/feeds 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.
- (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]

**§ 161.290 Environmental fate data requirements.**

(a) *Table.* Sections 161.100 through 161.102 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]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	161-1
Photodegradation:																		
In water		R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	161-2
On soil	(1)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	161-3
In air	(2)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	161-4
Metabolism studies-lab																		
Aerobic soil		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	162-1
Anaerobic aquatic																		162-3
Aerobic aquatic																		162-4
Mobility studies																		
Leaching and adsorption/desorption.		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	163-1

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							
Volatility: (Lab) (Field)	(2) (2)	CR CR				CR CR	CR CR				TEP TEP	TEP TEP	163-2 163-3	
Dissipation studies-field														
Soil		R						R			TEP	TEP	164-1 164-2	
Aquatic (sediment)			R								TEP	TEP	164-2 164-3	
Forestry								R			TEP	TEP	164-3 164-4	
Combination and tank mixes.	(2)													
Soil, long-term	(4)	CR									TEP	TEP	164-5	
Accumulation studies														
Rotational crops:														
(Confined)	(5)	[CR]									PAIRA	PAIRA	165-1	
(Field)	(6)	CR									TEP	TEP	165-2	
Irrigated crops	(7)										TEP	TEP	165-3	
In fish	(8)	[CR]									TEP or PAIRA	TEP or PAIRA	165-4	
In aquatic non-target orga- nisms.	(8), (9)										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; TGA=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 accu-  
 mulation 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]

§ 161.340 Toxicology data requirements.

(a) Table. Sections 161.100 through 161.102 describe how to use this table to determine the toxicology data requirements and the substance to be tested.