

§ 161.240 Residue chemistry data requirements.

(a) Table. Sections 161.100 through 161.102 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		Guide-lines 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]	[R]	TGAI	TGAI	171-2
Directions for use	(2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI	TGAI	171-3
Nature of the residue:														
Plants	(13), (14)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	PAIRA	PAIRA	171-4
Livestock	(3), (13), (14)	[CR]	[CR]	[CR]	[CR]	[CR]	[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]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI and metabolites.	TGAI and metabolites.	171-4
Magnitude of the residue:														
Crop field trials	(13), (14)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TEP	TEP	171-4
Processed food/feed.	(5), (14)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	EP	EP	171-4
Meat/milk/poultry/eggs.	(6), (14)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	TGAI or plant metabolites.	TGAI or plant metabolites.	171-4
Potable water	(7)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	EP	EP	171-4
Fish	(8)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	EP	EP	171-4
Irrigated crops	(9)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	EP	EP	171-4
Food handling	(10), (14)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	EP	EP	171-4
Reduction of residue	(11), (14)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	Residue of concern.	Residue of concern.	171-5
Proposed tolerance	(12), (14)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	Residue of concern.	Residue of concern.	171-6
Reasonable grounds in support of the petition.	(14)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	PAIRA	PAIRA	171-7
Submital of analytical reference standards.	(14)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	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 requirements 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 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/feed in food handling establishments 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]

**§ 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]	TGAI or PAIRA.	TGAI or PAIRA.		161-1	
Photodegradation:																		
In water		R	R	R	R	R	R	R	R	R	R	R	R	TGAI or PAIRA.	TGAI or PAIRA.		161-2	
On soil	(1)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI or PAIRA.	TGAI or PAIRA.		161-3	
In air	(2)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI or PAIRA.	TGAI or PAIRA.		161-4	
Metabolism studies-lab																		
Aerobic soil		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI or PAIRA.	TGAI or PAIRA.		162-1	
Anaerobic aquatic														TGAI or PAIRA.	TGAI or PAIRA.		162-3	
Aerobic aquatic														TGAI or PAIRA.	TGAI or PAIRA.		162-4	
Mobility studies																		
Leaching and adsorption/desorption.		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI or PAIRA.	TGAI or PAIRA.		163-1	