

Subpart O—Residue Chemistry

§ 158.1400 Definitions.

The following terms are defined for the purposes of this subpart:

Livestock, for the purposes of this section, includes all domestic animals that are bred for human consumption, including, but not limited to, cattle, swine, sheep, and poultry.

Plant or animal metabolite means a pesticide chemical residue that is the result of biological breakdown of the parent pesticide within the plant or animal.

Residue of concern means the parent pesticidal compound and its metabolites, degradates, and impurities of toxicological concern.

Tolerance, for the purposes of this section, includes the establishment of a new tolerance or tolerance exemption, or amended tolerance or tolerance exemption.

§ 158.1410 Residue chemistry data requirements table.

(a) *General*. Sections 158.100 through 158.130 describe how to use this table to determine the residue chemistry 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 in paragraph (e) of this section.

(b) *Use patterns*. (1) Data are required or conditionally required for all pesticides used in or on food and for residential outdoor uses where food crops are grown. 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) Data may be required for nonfood uses if pesticide residues may occur in food or feed as a result of the use. Data requirements for these nonfood uses will be determined on a case-by-case basis. For example, most products used in or near kitchens require residue data for risk assessment purposes even though tolerances may not be necessary in all cases.

(c) *Key*. R=Required; CR=Conditionally required; NR=Not required; TGAI=Technical grade of the active ingredient; PAI=Pure active ingredient; PAIRA=Pure active ingredient radio-labeled; Residue of concern= the active ingredient and its metabolites, degradates, and impurities of toxicological concern; TEP=Typical end-use product.

(d) *Table*. The following table list the data requirements for residue chemistry related to food uses. The table notes are shown in paragraph (e) of this section.

TABLE—RESIDUE CHEMISTRY DATA REQUIREMENTS FOR FOOD USES

Guideline Number	Data Requirement	Use Pattern					Test substance	Test Note No.
		Terrestrial Food or Feed	Aquatic Food	Greenhouse Food	Indoor Food	Residential Outdoor		
Supporting Information								
860.1100	Chemical identity	R	R	R	R	R	TGAI	--
860.1200	Directions for use	R	R	R	R	R	--	--
860.1550	Proposed tolerance	R	R	R	CR	NR	--	1
860.1560	Reasonable grounds in support of petition	R	R	R	CR	NR	--	1
860.1650	Submittal of analytical reference standards	R	R	R	CR	NR	PAI and residue of concern	1, 2, 25
Nature of the residue								
860.1300	Nature of the residue in plants	R	R	R	CR	CR	PAIRA	3, 4, 25

TABLE—RESIDUE CHEMISTRY DATA REQUIREMENTS FOR FOOD USES—Continued

Guideline Number	Data Requirement	Use Pattern					Test substance	Test Note No.
		Terrestrial Food or Feed	Aquatic Food	Greenhouse Food	Indoor Food	Residential Outdoor		
860.1300	Nature of the residue in livestock	CR	CR	CR	CR	NR	PAIRA or radiolabeled plant metabolite	1, 6, 25
860.1850	Confined rotational crops	CR	CR	NR	NR	NR	PAIRA	7
Analytical methods								
860.1340	Residue analytical methods	R	R	R	CR	CR	Residue of concern	1, 3, 8, 9, 10, 25
860.1360	Multiresidue method	R	R	R	CR	NR	Residue of concern	1, 11, 25
Magnitude of the residue								
860.1380	Storage stability	R	R	R	CR	CR	TEP or residue of concern	1, 3, 10, 12, 25
860.1500	Crop field trials	R	R	R	CR	CR	TEP	3, 10, 14, 24, 25
860.1520	Processed food or feed	CR	CR	CR	CR	NR	TEP	1, 15, 25
860.1480	Meat/milk/poultry/eggs	CR	CR	CR	CR	NR	TGAI or plant metabolite	1, 16, 17, 18, 25
860.1400	Potable water	NR	R	NR	NR	NR	TEP	19, 25
860.1400	Fish	NR	R	NR	NR	NR	TEP	5, 25
860.1400	Irrigated crops	NR	CR	NR	NR	NR	TEP	20, 25
860.1460	Food handling	NR	NR	NR	CR	NR	TEP	1, 21, 25
860.1540	Anticipated residues	CR	CR	CR	CR	NR	Residue of concern	1, 13, 22, 26
860.1900	Field rotational crops	CR	CR	NR	NR	NR	TEP	23, 25

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

1. Required if indoor use could result in pesticide residues in or on food or feed.

2. Material safety data sheets must accompany standards as specified by OSHA in 29 CFR 1910.1200.

3. Required for residential outdoor uses on food crops if the corresponding agricultural use is not approved or the residential use is

expected to produce higher residues based on the label directions.

4. Required for indoor uses where the pesticide is applied directly to food, in order to determine metabolites and/or degradates. Not required when only indirect contact with food would occur (e.g., crack and crevice treatments).

5. Data for fish are required for all pesticides applied directly to water inhabited, or which will be inhabited, by fish that may be caught or harvested for human consumption.

6. Required when a pesticide is to be applied directly to livestock, to livestock premises, to livestock drinking water, or to crops used for livestock feed. If results from the plant metabolism study show differing metabolites in plants from those found in animals, an additional livestock metabolism study involving dosing with the plant metabolite(s) may also be required.

7. Required when the Agency determines that it is reasonably foreseeable that a food or feed crop could be subsequently planted on the site of pesticide application after harvest or failure of the treated crop. Typically not required for pesticide uses in permanent food crops (e.g., various tree crops, vines) or semi-permanent crops (e.g., asparagus, pineapples).

8. A residue analytical method suitable for enforcement purposes is required whenever a numeric tolerance (including temporary and time-limited tolerances) is proposed.

9. New analytical methods to be used for enforcement purposes must include results from an independent laboratory validation.

10. A residue method, storage stability data, and crop field trials are required for the nonfood crop tobacco (green, freshly harvested). Depending on the level of residues found on the green tobacco, additional data may be required on cured/dried tobacco and pyrolysis products.

11. Data are required to determine whether FDA/USDA multiresidue methodology would detect and identify the pesticides and any metabolites.

12. Data are required for any magnitude of the residue study unless analytical samples are stored frozen for 30 days or less, and the active ingredient is not known to be volatile or labile.

13. Studies using single serving samples of a raw agricultural commodity may be needed for acutely toxic pesticides and/or their metabolites. These residue studies must be conducted using a statistical design accepted by the Agency.

14. Required for indoor uses which are direct postharvest treatments of raw agricultural commodities (e.g., fungicidal waxes or stored grain fumigants).

15. Data on the nature and level of residues in processed food/feed are required if residues could potentially concentrate on processing thus requiring the establishment of a separate tolerance higher than that of the raw agricultural commodity.

16. Required when the pesticide use is a direct application to livestock.

17. Data are required if pesticide residues are present in or on livestock feed items or intentionally added to drinking water. These studies, however, may not be required in cases where the livestock metabolism studies indicate negligible transfer of the pesticide's residues of concern to tissues, milk,

and eggs at the maximum expected exposure level for the animals.

18. If results from the plant metabolism study show differing metabolites in plants from those found in animals, an additional livestock feeding study involving dosing with the plant metabolite(s) may also be required.

19. Data are required whenever a pesticide may be applied directly to water, unless it can be demonstrated that the treated water would not be available for human or livestock consumption.

20. Data 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.

21. Data are required whenever a pesticide may be used in a food handling or feed handling establishment.

22. Required when residues at the tolerance level may result in a risk of concern. These data may include washing, cooking, processing or degradation studies as well as market basket surveys for a more precise residue determination.

23. Typically required if pesticide residues of concern greater than 0.01 ppm are found in crops at the appropriate plant back intervals (taking into account plant back restrictions on product labels) in the confined rotational crop study. If residues of concern in the confined study are greater than 0.01 ppm but less than the limit of quantitation of the analytical method to be used on field trial samples, the Agency will consider not requiring, on a case-by-case basis, the limited field trials. If there are particular toxicological concerns with the parent pesticide or any metabolites, limited field studies may be needed if such residues are identified at levels below 0.01 ppm in the confined study.

24. Crop field trials are required to establish tolerances on rotational crops when quantifiable residues of concern are observed in the field rotational crops study.

25. Not required for an exemption from a tolerance provided that dietary exposure estimates are not needed due to low toxicity or that theoretical estimates of exposure are adequate to assess dietary risk.

26. Not required for an exemption from a tolerance.

Subparts P–T [Reserved]

§§ 158.1500–158.1900 [Reserved]

Subpart U—Biochemical Pesticides

SOURCE: 72 FR 61002, Oct. 26, 2007, unless otherwise noted.