profiles demonstrate that the antimicrobial is likely to readily degrade either microbially or via redox reactions (chemically) and no transformation/degradate/leachate products of concern (as described under §158.2280(a)(2)) are produced.

11. Analytical methods used to generate data associated with this study must include results of a successful confirmatory method trial by an independent laboratory.

12. Protocols must be approved by the Agency prior to the initiation of the study.

13. For industrial processes and water systems, wood preservatives, and the all other use patterns category (as specified in §158.2280(a)(3)), data are required based on the potential for aquatic exposure and if the weight-of-evidence indicates that the active ingredient or principal transformation products are likely to have the potential for persistence, mobility, nontarget aquatic toxicity, or bioaccumulation.

14. Data are required if the weight-of-evidence indicates that the active ingredient or principal transformation products are likely to occur in nontarget freshwater, estuarine, or marine waters such that human or environmental exposures are likely to occur. In making that determination, the Agency takes into account other factors such as the toxicity of the chemical(s), available monitoring data and the vulnerability of the freshwater, estuarine, or marine water resources in the antimicrobial use area.

15. For wood preservatives, an aquatic leaching study is required. A soil leaching study is required if human or environmental exposures are likely to occur from leachates that contain the active ingredient or principal transformation products from wood treated with a preservative product. Protocols must be approved by the Agency prior to the initiation of the study.

16. For antifoulant paints and coatings, a leaching study is required. Protocols must be approved by the Agency prior to the initiation of the study.

17. Protocols, which include the residues of concern (such as parent, degradate/transformation product, and/or leachate residues) that would be monitored, must be approved by the Agency prior to the initiation of the study.

18. A biodegradation study is not required if the antimicrobial meets one or more of the following criteria:

i. Classified as a metal,

ii. Relatively volatile, but not hydrophobic,

iii. Highly reactive,

iv. Both the parent and all transformation/degradate products (as described under §158.2280(a)(2)) have half-lives of less than 3 hours,

v. None of the registered or proposed product uses would result in transport of the parent and its transformation/degradate products (as described under §158.2280(a)(2)) to a wastewater treatment plant.

19. The activated sludge sorption isotherm test is not required if the antimicrobial is:

i. Relatively volatile, but not hydrophobic;

ii. Highly reactive; or

iii. The log K_{ow} is less than 3.0.

20. If the criteria of test note 19 of this paragraph are not met, then the activated sludge sorption isotherm test is required if one or more of the following criteria are also met:

i. The antimicrobial is a metal,

ii. The log K_{ow} is greater than or equal to 3.0,

iii. The antimicrobial is positively charged or polycationic,

iv. The EC_{50} in the activated sludge, respiration inhibition test is less than or equal to 20 mg/L,

v. The EC_{50} in the activated sludge, respiration inhibition test is greater than 20 mg/L, and the antimicrobial fails the ready biodegradability study.

21. The activated sludge respiration inhibition study is not required if none of the registered or proposed product uses would result in transport of the parent and its transformation/degradate products (as described under §158.2280(a)(2)) to a wastewater treatment plant.

§158.2290 Residue chemistry.

(a) *General.* Subpart B of this part and §158.2201 describe how to use the table in paragraph (h) of this section to determine the residue chemistry data

requirements for antimicrobial pesticide products. Notes that apply to an individual test including specific conditions, qualifications, or exceptions are listed in paragraph (i) of this section.

(b) Residue chemistry data are required for:

(1) Antimicrobial end-use products with uses that may result in residues in or on food, including but not limited to:

(i) Products that require a tolerance, tolerance exemption, or food additive regulation or clearance.

(ii) Products that may be used to treat livestock or poultry drinking water, for food egg washing, or for fruit and vegetable rinses.

(iii) Products that may be applied to a surface or incorporated into a material that may contact food or feed. Data are required regardless of whether the antimicrobial is applied or impregnated for the purpose of imparting antimicrobial protection to external surfaces of the substance or article, or for the purpose of protecting the substance or article itself.

(iv) Products that may be applied to water that have the potential to result in residues in potable water, or in water used for livestock and poultry drinking water, irrigation of crops, or water containing fish that may be used for human food.

(v) Wood preservative or antifoulant products intended for treating submerged materials that may result in food contact (e.g., lobster pots, fish cages on fish farms).

(2) Each manufacturing-use product bearing directions for formulation into an end-use product bearing uses described in paragraph (b)(1) of this section.

(c) Residue chemistry data are not required under paragraph (b) of this section if no adverse effects (no toxicity endpoints) are associated with dietary exposure to the active ingredient or if theoretical (high-end) dietary exposure estimates combined with the applicable toxicity endpoint result in acute and chronic dietary risks that are below the Agency levels of concern.

(d) For purposes of this section, Magnitude of the Residue Studies include the following: Food-handling, migration studies, potable water, fish, irrigated crops, meat/milk/poultry/eggs, crop field trails, processed food or feed, and anticipated residues.

(e) If the antimicrobial chemical may be applied to a field crop, then the residue chemistry data requirements of §158.1410 apply.

(f) The following term is defined for the purposes of this section:*Residue of concern* means the parent pesticidal compound and its metabolites, degradates, and impurities of toxicological concern.

(g) *Key*. R = Required; CR = Conditionally required; NR = Not required; TGAI = Technical grade of the active ingredient; TEP = Typical end-use product; PAI = Pure active ingredient; PAIRA = Pure active ingredient radiolabeled; ROC = Residue of concern.

(h) *Antimicrobial residue chemistry data requirements table*. The following table shows the data requirements for residue chemistry. The test notes appear in paragraph (i) of this section.

TABLE—ANTIMICROBIAL RESIDUE CHEMISTRY DATA REQUIREMENTS

Guideline No.	Data requirement	Uses				Test substance	Test note No.
		Agricultural premise	Indirect food	Direct food	Aquatic		
Supporting Information							
860.1100	Chemical identity	R	R	R	R	TGAI.	
860.1200	Directions for use	R	R	R	R	.	
860.1550	Proposed tolerance/tolerance exemption	R	R	R	R		1
860.1560	Reasonable grounds in support of petition	R	R	R	R		1
860.1650	Submittal of analytical reference standards	R	R	R	R	PAI/ROC	2
Food-Contact Surfaces or Impregnated Materials							
860.1460	Food-handling	CR	CR	CR	CR	TEP	3
None	Nature of residue on surfaces	CR	CR	CR	CR	PAIRA or TGAI	4
None	Migration studies	CR	CR	CR	CR	TEP	5
860.1340	Residue analytical method for data collection	CR	CR	CR	CR	ROC	6
860.1380	Storage stability	R	R	R	R	TEP or ROC	7
Higher tiered							
860.1300	Nature of the residue in plants	CR	CR	CR	CR	PAIRA	8
860.1300	Nature of the residue in livestock	CR	CR	CR	CR	PAIRA	9
860.1340	Residue analytical methods for tolerance/tolerance exemption enforcement.	CR	CR	CR	CR	ROC	10
860.1360	Multiresidue method testing	CR	CR	CR	CR	ROC	11
860.1400	Potable water	CR	CR	CR	CR	TEP	12
860.1400	Fish	CR	CR	CR	CR	TEP	13
860.1400	Irrigated crops	CR	CR	CR	CR	TEP	14
860.1480	Meat/milk/poultry/eggs	CR	CR	CR	CR	TGAI or ROC	15
860.1500	Crop field trials	CR	CR	CR	CR	TEP	16
860.1520	Processed food or feed	CR	CR	CR	CR	TEP	17
None	Anticipated residues	CR	CR	CR	CR	ROC	18

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

1. A petition proposing a numerical tolerance or a tolerance exemption is required for any food or feed use subject to section 408 of FFDCA if the use is not covered by an existing tolerance or tolerance exemption. If the use is subject to FFDCA section 409, the applicant must identify to EPA an applicable section 409 food additive regulation or clearance, or submit a copy of a petition to FDA requesting a section 409 food additive regulation or clearance for the food or feed use.

2. An analytical reference standard is required for any food or feed use requiring a numeric tolerance or exemption. Material safety data sheets as specified by the Occupational Safety and Health Administration in 29 CFR 1910.1200 must accompany analytical standards.

3. Data are required if a pesticide may be used in a food-handling establishment unless data including, but not limited to, theoretical (high-end) estimates, radiolabeled laboratory data, or the nature of the residue on surfaces study show that residues will not occur in food or feed.

4. If an antimicrobial pesticide may be applied to a food-contact surface or impregnated into a food-contact material and if theoretical (high-end) estimates of exposure exceed EPA's risk level of concern, then the nature of the residue on surfaces study is required. Protocols must be approved by the Agency prior to the initiation of the study.

5. Based on the results of the nature of the residue on surfaces study, if residues of concern are identified, then the migration study will be required. Protocols must be approved by the Agency prior to the initiation of the study.

6. If a magnitude of the residue study, as specified in §158.2290(d), is required, then a residue analytical method suitable for collecting data is also required. The method must be capable of determining all residues of concern, to permit calculation of dietary risk or to establish a tolerance or tolerance exemption.

7. If a magnitude of the residue study, as specified in §158.2290(d), is required, then storage stability data are also required, unless analytical samples are stored for 30 days or less. If, during hazard characterization, a residue has been identified as ''of concern'' and is known to be volatile or labile, then storage stability data are required regardless of sample storage time.

8. If crop plants or metabolically active raw agricultural commodities of food crops may be directly or indirectly exposed to an antimicrobial, plant metabolism studies are required to determine the transformation products that may enter the human diet. Such exposure could include, but is not limited to:

i. Treatment of storage or shipping containers,

ii. Postharvest fruit and vegetable treatment prior to shipping or storage,

iii. Use of antimicrobial-treated water for irrigation, and

iv. Any direct food contact use.

9. If livestock may be exposed to an antimicrobial, then hen and ruminant metabolism studies are required to determine the identities of residues of concern that may enter the human diet from consumption of livestock commodities. Livestock may be exposed via the oral, dermal, or inhalation route following treatment or contamination of sites including, but not limited to, livestock premises, feed, and drinking water. Shell eggs and other metabolically active livestock products may also be treated. If livestock may be exposed to one or more residues of concern differing from those found in animals, then one or more additional livestock metabolism studies involving dosing with these residues may be required.

10. If there is a numerical tolerance or tolerance exemption level to enforce, then a residue analytical method suitable for enforcement purposes is required. The method must be supported by an independent laboratory validation.

11. If there is a numerical tolerance or tolerance exemption level to enforce, then testing is required to determine whether the Food and Drug Administration/United States Department of Agriculture multiresidue methodology would detect and identify

the antimicrobial and its residues of concern, as part of programs to monitor pesticides in the U.S. food supply.

12. Data are required if an antimicrobial may be applied directly to water or if there is the potential that the antimicrobial-treated water could be used directly for drinking water purposes by humans or animals or that contaminated water could run-off, leach, or be discharged from treated sites or materials and make its way into potable water.

13. Data are required if an antimicrobial may be applied directly to water inhabited by fish or that will be inhabited by fish or if contaminated water could run-off, leach, or be discharged from treated sites or materials and make its way into bodies of water containing fish that may be used for human consumption.

14. Data are required if an antimicrobial may be applied directly to water used for irrigation of food crops or such that contaminated water could run-off, leach, or be discharged from treated sites or materials to make its way into water used for irrigation of food crops.

15. If the antimicrobial may be applied directly to livestock, metabolically-active livestock commodities (e.g., eggs), livestock feed or drinking water, or livestock premises, or a livestock metabolism study indicates that residues of the antimicrobial may result in livestock commodities, studies are required to determine the magnitude of the residues of concern in fat, meat, meat by-products, milk, poultry, and eggs that may be consumed by humans. These studies, however, may not be required in cases where the livestock metabolism studies indicate that transfer of pesticide residues of concern to tissues, milk, and eggs is not expected to occur at the maximum expected exposure level for the animals.

16. If food crops or raw agricultural commodities of food crops may be exposed to an antimicrobial, then residue studies are required to determine the magnitude of the residues of concern that may enter the human diet. Such exposures include, but are not limited to, postharvest fruit and vegetable treatments and application of antimicrobial chemicals to field crops, mushroom houses, empty or occupied beehives, or wood used to construct beehives.

17. Data on the nature and magnitude of residues in processed food or feed are required if antimicrobial residues could potentially concentrate on processing. If so, the establishment of a separate tolerance higher than that in the raw agricultural commodity may be required.

18. Data are required when dietary exposure values at the tolerance level or screening-level (high-end) result in estimates of dietary or aggregate risk that meet or exceed the Agency's level of concern. These data may include, but are not limited to, washing, cooking, processing, or degradation studies as well as market basket surveys for a more realistic residue determination. Protocols must be approved by the Agency prior to the initiation of the study.

Subparts X–Z [Reserved]

§§ 158.2300–158.2500 [Reserved]

PART 159—STATEMENTS OF POLICIES AND INTERPRETATIONS

Subparts A–C [Reserved]

Subpart D—Reporting Requirements for Risk/Benefit Information

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