11. Data are required on estuarine/marine species if the product is intended for direct application to the estuarine or marine environment, or the product is expected to enter this environment in significant concentrations because of its expected use or mobility patterns.

12. Data are required on freshwater species if the end-use product is intended to be applied directly to water, or is expected to be transported to water from the intended use site, and when one or more of the following conditions apply:
   i. When based on deterministic modeling results: If the Estimated Environmental Concentration (EEC) in water is equal to or greater than 0.1 of the no-observed-adverse-effect concentration or no-observed-adverse-effect level (NOAEC/NOAEL) in the fish early-life stage or invertebrate life cycle tests.
   ii. When based on probabilistic modeling results: If the estimated 10th percentile 7Q10 Surface Water Concentration based on probabilistic modeling exceeds for 20 days or more the chronic concentration of concern (i.e., one-tenth the NOAEC or NOAEL) determined in the fish early-life stage or invertebrate life cycle tests.
   iii. If studies of other organisms indicate that the reproductive physiology of fish may be affected.

13. Not required when:
   i. The octanol/water partition coefficients of the pesticide and its major degradates are less than 1,000;
   ii. There are no potential exposures to fish and other nontarget aquatic organisms; or
   iii. The hydrolytic half-life is less than 5 days at pH 5, 7, and 9.

14. Environmental chemistry methods used to generate data associated with this study must include results of a successful confirmatory method trial by an independent laboratory. Test standards and procedures for independent laboratory validation are available as addenda to the guideline for this test requirement.

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

16. Data are required if the intended use pattern, and the physical/chemical properties and environmental fate characteristics of the antimicrobial indicate significant potential exposure, and, based on the results of the acute and chronic aquatic organism testing, significant impairment of nontarget aquatic organisms could result.

17. Data are required if the half-life of the pesticide in the sediment is equal to or less than 10 days in either the aerobic soil or aquatic metabolism studies, and if one or more of the following conditions are met:
   i. The soil partition coefficient (K_d) is equal to or greater than 50 L/kg.
   ii. The log K_ow is equal to or greater than 3.
   iii. The K_oc is equal to or greater than 1,000.

18. Data are required if the EEC in sediment is greater than 0.1 of the acute LC_{50}/EC_{50} values and if one or more of the following conditions are met:
   i. The soil partition coefficient (K_d) is equal to or greater than 50 L/kg.
   ii. The log K_ow is equal to or greater than 3.
   iii. The K_oc is equal to or greater than 1,000.

19. Sediment testing with estuarine/marine test species is required if the product is intended for direct application to the estuarine or marine environment or the product is expected to enter this environment in significant concentrations either by runoff or erosion, because of its expected use or mobility pattern.

20. For the all other use patterns category (as specified in §158.2240(a)(5)), data are required only for beehive applications when the beehive (empty or occupied) may be treated.

21. A study similar to “Honey Bee Toxicity of Residues on Foliage” is required using treated wood instead of the foliage. Protocols must be approved by the Agency prior to the initiation of the study.

§ 158.2250 Nontarget plant protection.

(a) Subpart B of this part and §158.2201 describe how to use the table
§ 158.2250

in paragraph (f) of this section to determine the nontarget plant protection data requirements for a particular antimicrobial pesticide product. Notes that apply to an individual test including specific conditions, qualifications, or exceptions are listed in paragraph (g) of this section.

(b) Data on transformation/degradation products or leachate residues of the parent compound are also required to support registration, if the transformation/degradation products or leachate residues meet one of the following criteria:

(1) More toxic, persistent, or bioaccumulative than the parent;

(2) Have been shown to cause adverse effects in mammalian or aquatic reproductive studies; or

(3) The moiety of concern (i.e., functional group in the parent chemical molecule that imparts adverse effects) remains intact.

(c) For the purpose of determining data requirements, the all other use patterns category includes the following use patterns:

(1) Agricultural premises and equipment.

(2) Food-handling/storage establishments, premises, and equipment.

(3) Commercial, institutional and industrial premises and equipment.

(4) Residential and public access premises.

(d) If an antimicrobial may be applied to a field crop, horticultural crop, or turf, then the data requirements in §158.660 apply.

(e) Key. MP = Manufacturing use product; EP = End-use product; R = Required; CR = Conditionally required; NR = Not required; TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.

(f) Nontarget plant protection data requirements table. The following table shows the data requirements for nontarget plant protection. The test notes appear in paragraph (g) of this section.
### TABLE—NONTARGET PLANT PROTECTION DATA REQUIREMENTS

<table>
<thead>
<tr>
<th>Guideline No.</th>
<th>Data requirement</th>
<th>Use pattern</th>
<th>Test note No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>850.4225 ...</td>
<td>Seedling emergence, Tier II—dose response.</td>
<td>CR ............ CR ............ CR ............ CR ............ CR ............ TEP ........ TEP ........</td>
<td>1, 2</td>
</tr>
<tr>
<td>850.4250 ...</td>
<td>Vegetative vigor, Tier II—dose response.</td>
<td>CR ............ NR ............ CR ............ CR ............ CR ............ TEP ........ TEP ........</td>
<td>1, 3</td>
</tr>
<tr>
<td>850.4400 ...</td>
<td>Aquatic plant growth (aquatic vascular plant) Tier II—dose response.</td>
<td>R ............ R ............ R ............ R ............ CR ............ TGAI, TEP TGAI, TEP</td>
<td>4, 10</td>
</tr>
<tr>
<td>850.5400 ...</td>
<td>Aquatic plant growth (algae) Tier II (dose response).</td>
<td>R ............ R ............ R ............ R ............ R ............ TGAI, TEP TGAI, TEP</td>
<td>4, 5, 6</td>
</tr>
<tr>
<td>850.4300 ...</td>
<td>Terrestrial field.</td>
<td>CR ............ CR ............ CR ............ CR ............ CR ............ TEP ........ TEP ........</td>
<td>7, 8, 9</td>
</tr>
<tr>
<td>850.4450 ...</td>
<td>Aquatic field</td>
<td>CR ............ CR ............ CR ............ CR ............ CR ............ TEP ........ TEP ........</td>
<td>7, 8, 9</td>
</tr>
</tbody>
</table>
(g) Test notes. The following test notes apply to the data requirements in the table to paragraph (f) of this section:

1. Data on only one plant species (rice, *Oryza sativa*) are required.

2. Data are required if the risk quotient from any aquatic plant growth Tier II study exceeds a level of concern for aquatic plants.

3. Not required when:
   a. There are no potential exposures to plants;
   b. The hydrolytic half-life is less than 5 days at pH 5, 7, and 9; or
   c. The results of a biodegradation study indicate that the active ingredient or principal degradation products are not biodegradable in 28 days, i.e., the biodegradation curve has not reached a plateau for at least three determinations within the 28 days.

4. For TEP testing, data are required for the applicant’s end-use product if an ingredient in the end-use product, other than the active ingredient, is expected to enhance the toxicity of the active ingredient.

5. One Tier II (dose response) study, conducted with *Selenastrum capricornutum*, is required for the all other use patterns category (as specified in §158.2250(c)). If the results of this study exhibit detrimental effects (EC50 less than 1.0 ppm or mg/L), then additional Tier II (dose response) studies are required on three species (*Anabaena flos-aquae*, *Navicula pelliculosa*, and *Skeletonema costatum*).

6. For industrial processes and water systems, antifoulant coatings and paints, wood preservatives, and aquatic areas, Tier II (dose response) studies are required on four species (*Anabaena flos-aquae*, *Navicula pelliculosa*, *Skeletonema costatum*, and *Selenastrum capricornutum*).

7. Environmental chemistry methods used to generate data must include the results of a successful confirmatory method trial by an independent laboratory.

8. Tests are required on a case-by-case basis based on the results of lower tier plant protection studies, adverse incident reports, intended use pattern, and environmental fate characteristics that indicate potential exposure.

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

10. For the all other use patterns category (as specified in §158.2250(c)), data are required if the aquatic (algal) plant growth Tier II study demonstrates detrimental effects at less than 1.0 ppm or mg/L.

§ 158.2260 Applicator exposure.

(a) General. Subpart B of this part and §158.2201 describe how to use the table in paragraph (d) of this section to determine the applicator exposure data requirements for antimicrobial pesticide products. Notes that apply to an individual test including specific conditions, qualifications, or exceptions are listed in paragraph (e) of this section.

1. The Agency may accept surrogate exposure data estimations and/or modeling estimations from other sources to satisfy exposure data requirements. The surrogate data must meet the basic quality assurance, quality control, good laboratory practice, and other scientific requirements set by EPA. To be acceptable, the Agency must find that the surrogate exposure data estimations have adequate information to address the applicable exposure data requirements and contain adequate monitoring events of acceptable quality. The data must reflect the specific use prescribed on the label and the activity of concern, including formulation type, application methods and rates, type of activity, and other pertinent information.

2. Occupational uses include not only handlers, mixers, loaders, and applicators, but also commercial applications to residential sites. Residential uses are limited to non-professional, i.e., non-professional, antimicrobial applications. Both occupational and residential applicator data may be required for the same product.

(b) Criteria for testing. Applicator exposure data described in the table to paragraph (d) of this section are required based on toxicity and exposure criteria. Data are required if at least one of the toxicity criteria in paragraph (b)(1) of this section, and at least one of the exposure criteria in paragraph (b)(2) of this section are met.