

Status of Missing or Inapplicable OCSPP Test Guidelines – August 2012 Update

[Excerpted from the main body of comments from the ACC Biocides Panel comments submitted to EPA docket EPA-HQ-OPP-2008-0110 on 9 April 2009. See Pp. 17-19.]

The following is a listing of OCSPP Guidelines cited in the 158 W proposal that the Panel has been able to identify as not having been issued or finalized by the Agency. Some of these were released as “drafts” in early 1996. Some of these guidelines have been provided as draft guidelines for comment whereas select guidelines have been finalized and have been made available by the Agency. Please see the chart below for updated information on the status of the guidelines for select Sections of the Proposed Rule. **This chart was initially presented to the Agency in 2010 and any Test Guidelines that have been made final since that time are found below in “strikethrough” text.** Additional text has been added to the Comments section in some cases to reflect the most recent EPA activity.

<i>Section of Proposed Rule</i>	<i>Data Requirement</i>	<i>Referenced but Not Available</i>	<i>Comment</i>
158.2220 Product performance	Hard surface products Confirmatory data Fabrics and textiles Air sanitizers Treatment of drinking water	91-2 (810.2100/2200) 91-3 (810.2200/2300) 91-4 (810.2400) 91-5 (810.2500) 91-8 (810.2600)	On March 16, 2012 (77 FR 15750), EPA announced availability of the following final 810 test guidelines: 810.2000 (Public Health Uses of Antimicrobial Agents); 810.2100 (Sterilants); 810.2200 (Disinfectants); and 810.2300 (Sanitizers). On June 27, 2012 (77 FR 38280), EPA announced availability of the following final 810 test guidelines: 810.2400 (Disinfectants and Sanitizers for Use of Fabrics and Textiles); 810.2500 (Air Sanitizers); and 810.2600 (Disinfectants and Sanitizers for Use in Water).
158.2230 Toxicology	Companion animal safety	870.7200	870.7200 is <i>inapplicable</i> to antimicrobial pesticides as application of these compounds to animals removes these uses from the FIFRA definition of “pesticide.”

<p>158.2240 Non-target organisms</p>	<p>Avian acute oral Acute freshwater invertebrate Acute freshwater fish Avian dietary Avian reproduction Acute estuarine and marine Acute estuarine and marine Acute estuarine and marine Acute estuarine and marine Acute estuarine and marine Fish early-life stage Aquatic invertebrate life cycle Aquatic invertebrate life cycle Fish life cycle Aquatic organism bioconc Aquatic organism bioconc Aquatic organism biomagnif Aquatic organism field test Whole sediment acute freshwater Whole sediment acute marine Whole sediment chronic both Honeybee acute Honeybee foliage residue toxicity</p>	<p>850.2100 850.1010 850.1075 850.2200 850.2300 850.1025 850.1035 850.1045 850.1055 850.1075 850.1400 850.1300 850.1350 850.1500 850.1710 850.1730 850.1850 850.1950 850.1735 850.1740 NONE 850.3020 850.3030</p>	<p>On June 27, 2012 (77 FR 38282), EPA announced the availability of multiple final 850 test guidelines, along with reorganization of the tests, renaming and renumbering and modifications to several of the now final test guidelines. The new “Group B – Terrestrial Wildlife” series now contains final versions of 850.2100 (Avian Acute Oral); 850.2200 (Avian Dietary); and 850.2300 (Avian Reproduction). The new “Group C – Terrestrial Beneficial Insects, Invertebrates and Soil and Wastewater Micrororganisms” series now contains final versions of 850.3020 (Honey Bee Acute Contact) and 850.3030 (Honey Bee Residue).</p> <p><u>No final guidance is available for these remaining requirements</u>, although there are draft versions available from April 1996. <u>No guidance is available</u>, even in draft form, for the chronic whole sediment study.</p>
<p>158.2250 Non-target plants</p>	<p>Seedling emergence Tier II Vegetative vigor Tier II Aquatic plant growth Tier II Aquatic plant growth Tier II Terrestrial field Aquatic field</p>	<p>850.4225 850.4250 850.4400 850.5400 850.4300 850.4450</p>	<p>On June 27, 2012 (77 FR 38282), EPA announced the availability of multiple final 850 test guidelines, along with reorganization of the tests, renaming and renumbering and modifications to several of the now final test guidelines. The new “Group D – Terrestrial and Aquatic Plants, Cyanobacteria and Terrestrial Soil Core Microcosm” now contains final versions of 850.4100 (Seedling Emergence; which combines former 850.4100 and 850.4225); 850.4150 (Vegetative</p>

			Vigor; which combines former 850.4150 and 850.4250); 850.4300 (Terrestrial Field Studies; which combines former 850.4025 and 850.4300); and 850.4500 (Algal Toxicity; which replaces former 850.5400 and combines 850.4500 and 850.4550)
158.2260 Applicator exposure	Product Use Information	875.1700	No guidance is available for this requirement, even in draft form. Registrants are encouraged to combine the response to 875.1700 with 875.2700 and 875.2800, which also do not have final guidance. The Panel is currently working with the Antimicrobials Division to develop Test Guidelines.
158.2270 Post-application exposure	Indoor surface residue dissipation Product use information Post-application activity	875.2300 875.2700 875.2800	No final guidance is available for any of these requirements. Registrants are directed to materials submitted to a March 1998 SAP for draft guidance: http://www.epa.gov/scipoly/sap/meetings/1998/march/contents.htm 875.2800 is <i>inapplicable</i> to antimicrobial pesticides as this guidance is only relevant for determining re-entry intervals following crop treatment. The Panel is currently working with the Antimicrobials Division to develop a Test Guideline.
158.2280 Environmental fate	Aerobic soil metabolism Anaerobic soil metabolism Aerobic aquatic metabolism Anaerobic aquatic metabolism Aquatic field (sediment) Monitoring US waters Special leaching	835.4100 835.4200 835.4300 835.4400 835.6200 NONE NONE	The 835 Series metabolism and aquatic field studies are <i>inapplicable</i> to many uses of antimicrobial pesticides as these are relevant for application to soil and/or water. No guidance is available, even in draft form, for the water monitoring and leaching studies.

158.2290 Residue Chemistry	Meat/Milk/Poultry/Eggs Crop field trials Anticipated residues Nature of residue on surfaces Migration studies	860.1480 860.1500 860.1540 NONE NONE	<u>No guidance is available</u> , even in draft form, for 860.1540 as well as the surface residue and migration studies. 860.1480 is <i>inapplicable</i> to antimicrobial pesticides as this guidance is relevant only for direct application to livestock or addition to feed. 860.1500 is <i>inapplicable</i> to antimicrobial pesticides as this guidance is only relevant for direct application on crops.
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Note: The above Table was last updated August 7, 2012.

Select Provisions of FIFRA, Section 3(h)
REGISTRATION REQUIREMENTS FOR ANTIMICROBIAL PESTICIDES

(1) EVALUATION OF PROCESS.—To the maximum extent practicable consistent with the degrees of risk presented by an antimicrobial pesticide and the type of review appropriate to evaluate the risks, the Administrator shall identify and evaluate reforms to the antimicrobial registration process that would reduce review periods existing as of the date of enactment of this subsection [Aug. 3, 1996] for antimicrobial pesticide product registration applications and applications for amended registration of antimicrobial pesticide products...

(2) REVIEW TIME PERIOD REDUCTION GOAL.—Each reform identified under paragraph (1) shall be designed to achieve the goal of reducing the review period following submission of a complete application, consistent with the degree of risk...

(3) IMPLEMENTATION—

(A) PROPOSED RULEMAKING—

(i) ISSUANCE.—Not later than 270 days after the date of enactment of this subsection [Aug. 3, 1996], the Administrator shall publish in the Federal Register proposed regulations to accelerate and improve the review of antimicrobial pesticide products designed to implement, to the extent practicable, the goals set forth in paragraph (2).

(ii) REQUIREMENTS.—Proposed regulations issued under clause (i) shall—(I) define the various classes of antimicrobial use patterns, including household, industrial, and institutional disinfectants and sanitizing pesticides, preservatives, water treatment, and pulp and paper mill additives, and other such products intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms, or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; (II) differentiate the types of review undertaken for antimicrobial pesticides; (III) conform the degree and type of review to the risks and benefits presented by antimicrobial pesticides and the function of review under this Act, considering the use patterns of the product, toxicity, expected exposure, and product type; (IV) ensure that the registration process is sufficient to maintain antimicrobial pesticide efficacy and that antimicrobial pesticide products continue to meet product performance standards and effectiveness levels for each type of label claim made; and (V) implement effective and reliable deadlines for process management.

(iii) COMMENTS.—In developing the proposed regulations, the Administrator shall solicit the views from registrants and other affected parties to maximize the effectiveness of the rule development process.

(B) FINAL REGULATIONS—...

(iii) REQUIREMENTS.—In issuing final regulations, the Administrator shall—(I) consider the establishment of a certification process for regulatory actions involving risks that can be responsibly managed, consistent with the degree of risk, in the most cost-efficient manner; (II) consider the establishment of a certification process by approved laboratories as an adjunct to the review process; (III) use all appropriate and cost-effective review mechanisms, including—(aa) expanded use of notification and nonnotification procedures; (bb) revised procedures for application review; and (cc) allocation of appropriate resources to ensure streamlined management of antimicrobial pesticide registrations; and (IV) clarify criteria for determination of the completeness of an application.