



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2017-0693 and EPA-HQ-OPP-2019-0161; FRL-10019-54]

Final Test Guidelines; OCSPP Series 810 – Product Performance Test Guidelines; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of the final product performance test guidelines for fire ants and invertebrate pests of pets. These test guidelines are part of a series of test guidelines established by the Office of Chemical Safety and Pollution Prevention (OCSPP) for use in testing pesticides and chemical substances. The test guidelines serve as a compendium of accepted scientific methodologies and protocols for testing that are intended to provide data to inform regulatory decisions. These test guidelines, which are identified as OCSPP Test Guideline 810.3100 and 810.3300, provide guidance for conducting a study to determine pesticide product performance against fire ants and invertebrate pests of pets, respectively, and are used by EPA, the public, and companies that submit data to EPA.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

EPA is announcing the availability of the following final test guidelines: OCSPP Test Guideline 810.3100: Treatments for Imported Fire Ants and 810.3300: The Efficacy of Topically Applied Pet Products Against Certain Invertebrate Pests.

These test guidelines are part of a series of test guidelines established by OCSPP for use

in testing pesticides and chemical substances to develop data for submission to the Agency under the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408 (21 U.S.C. 346a), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*), and the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601 *et seq.*). The test guidelines serve as a compendium of accepted scientific methodologies and protocols that are intended to provide data to inform regulatory decisions under TSCA, FIFRA, and/or FFDCA.

The test guidelines are used by EPA, the public, and companies that are subject to data submission requirements under TSCA, FIFRA, and/or FFDCA. As guidance documents, the test guidelines are not binding on either EPA or any outside parties, and EPA may depart from the test guidelines where circumstances warrant and without prior notice. At places in this guidance, the Agency uses the word “should.” In this guidance, use of “should” with regard to an action means that the action is recommended rather than mandatory. The procedures contained in the test guidelines are recommended for generating the data that are the subject of the test guideline, but EPA recognizes that departures may be appropriate in specific situations. You may propose alternatives to the recommendations described in the test guidelines, and the Agency will assess them for appropriateness on a case-by-case basis.

II. General Information

A. Does this action apply to me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who are or may be required to conduct testing of pesticides and chemical substances for submission to EPA under TSCA, FIFRA, and/or FFDCA, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How can I get copies of this document and other related information?

1. *Docket for this document.* The dockets for this action, identified by docket identification (ID) numbers EPA-HQ-OPP-2017-0693 and EPA-HQ-OPP-2019-0161, are available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public

Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Due to the public health emergency, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

2. *Electronic access to the OCSPP test guidelines.* To access OCSPP test guidelines electronically, please go to <http://www.epa.gov/ocspp/pubs/frs/home/testmeth.htm>. You may also access the test guidelines in <http://www.regulations.gov>, grouped by series under docket ID numbers: EPA-HQ-OPPT-2009-0150 through EPA-HQ-OPPT-2009-0159 and EPA-HQ-OPPT-2009-0576.

III. Overview

A. What action is EPA taking?

EPA is announcing the availability of final test guidelines under Series 810.3100 entitled “Treatments for Imported Fire Ants” and identified as OCSPP Test Guideline 810.3100, and Series 810.3300 entitled “The Efficacy of Topically Applied Pet Products Against Certain Invertebrate Pests” and identified as OCSPP Test Guideline 810.3300. These revised guidelines replace the original versions published in 1998. The guidelines provide recommendations for the design and execution of studies to evaluate the performance of pesticide products intended for use against fire ants and invertebrate pests of pests, such as fleas, ticks, and mosquitoes, in connection with registration of pesticide products under the FIFRA (7 U.S.C. 136, *et seq.*).

B. How were these final test guidelines developed?

EPA-registered pesticide products are an important part of pest management programs for pests of pets and premises. The Agency developed the product performance test guidelines to

standardize the approaches to testing methods to ensure the quality and validity of the efficacy data for these types of products. The Agency attended entomology conferences, consulted with leading academics, and reviewed peer-reviewed scientific journal articles on topics related to the guideline to draft the original document. Further, EPA sought advice and recommendations from FIFRA Scientific Advisory Panels (SAPs) and the public. The SAP meetings, held on May 8-10, 2018, and June 11-14, 2019, were announced in the *Federal Register* issues of January 26, 2018 (83 FR 3704) (FRL-9972-65) and April 15, 2019 (84 FR 15214) (FRL-9991-80), respectively. These guidelines have been revised based on comments from the SAPs and the public. The revisions to the fire ant guideline include the expansion of the guideline applicability to other ants in the *Solenopsis saevissima* complex, removal of the need to test in multiple geographically distinct locations and with both social forms of fire ants, inclusion of additional options for both field and laboratory test designs, and decreasing the number of ants needed for laboratory tests. The revisions to the pet product guideline include decreasing the number of animals used for tick testing, simplifying the tick test data collection categories, removing dead pest counts in favor of live pest counts, and revising the negative control for shampoo treatments from a placebo control to an untreated control. The Agency is also making available in the dockets the Response to Comments documents that address issues raised in the public comment submissions.

C. Do Guidance Documents Contain Binding Requirements?

As guidance, the test guidelines are not binding on the Agency or any outside parties, and the Agency may depart from it where circumstances warrant and without prior notice. While EPA has made every effort to ensure the accuracy of the discussion in the guidance, the obligations of EPA and the regulated community are determined by statutes, regulations, or other legally binding documents. In the event of a conflict between the discussion in the guidance document and any statute, regulation, or other legally binding document, the guidance document will not be controlling.

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>. This unit addresses those requirements that apply to a guidance document.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

The Office of Management and Budget (OMB) determined that the final test guideline documents are not significant regulatory actions under Executive Order 12866 (58 FR 51735, October 4, 1993). The final guidelines were not, therefore, submitted to OMB for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

These test guidelines do not create paperwork burdens that require additional approval by OMB under the PRA, 44 U.S.C. 3501 *et seq.* The information collection activities associated with pesticide registration are already approved by OMB under OMB Control No. 2070-0060.

Authority: 7 U.S.C. 136 *et seq.*; 15 U.S.C. 2601 *et seq.*; 21 U.S.C. 301 *et seq.*

Dated: March 10, 2021.

Michal Freedhoff,

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