



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2023-0430; FRL-11382-01-OCSP]

Pesticides; Draft Guidance and Proposed Method for Antimicrobial Product Efficacy Claims Against Planktonic *Legionella Pneumophila* in Cooling Tower Water; Notice of Availability and Request for Comments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of and soliciting public comment on a draft guidance document and proposed method for adding efficacy claims to antimicrobial products for use in cooling tower water to reduce the level of planktonic *Legionella pneumophila*. The draft guidance document describes efficacy testing for antimicrobial products to support claims for the reduction of planktonic *L. pneumophila* in water within cooling tower systems and how to prepare an application for registration. The proposed method is for evaluating the efficacy of antimicrobial products in water of cooling towers against planktonic *L. pneumophila*. The draft guidance does not address adherent or sessile bacteria that attach to a surface (e.g., biofilm) of the cooling tower system or any other microorganism other than *L. pneumophila* which may be found in the water of cooling tower systems.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2023-0430, through the Federal eRulemaking Portal at <https://www.regulations.gov>.

Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the

docket, along with more information about dockets generally, is available at

<https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For information on the proposed method contact:* Lisa S. Smith, Microbiology Laboratory Branch (7503M), Biological and Economic Analysis Division, Office of Pesticide Programs, Environmental Protection Agency, Environmental Science Center, 701 Mapes Road Ft. Meade, MD 20755-5350; telephone number: (410) 305-2637; email address: smith.lisas@epa.gov.

For information on the draft guidance contact: César E. Cordero, Efficacy Branch (7510M), Antimicrobials Division, Office of Pesticide Programs, Environmental Protection Agency, William Jefferson Clinton East Building, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (202) 564-3716; email address: cordero.cesar@epa.gov.

SUPPLEMENTARY INFORMATION:

I. 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 efficacy testing of chemical substances under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What should I consider as I prepare my comments for EPA??

1. *Submitting CBI.* Do not CBI to EPA through <https://www.regulations.gov> or email. If you wish to include CBI in your comment, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the part or all of the information that you claim to be CBI. In addition to one complete version of the comment

that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

II. Background

Legionella pneumophila is a bacterium that is often identified as the causative agent of Legionnaires' Disease, which is a disease acquired by inhaling water droplets contaminated with *Legionella* bacteria. *Legionellae* are found naturally in freshwater environments but can become a health concern when they grow and spread in human-made building water systems like cooling towers. Cooling towers are a potential breeding ground for *L. pneumophila* and subsequent aerosolization of *L. pneumophila* can occur if cooling towers are not properly disinfected and maintained. Following a Legionnaires' disease outbreak in New York City in 2015, New York State began requiring cooling towers to be registered with the state and monitored and treated for *L. pneumophila*. However, EPA currently does not have guidance providing a framework for those seeking to register antimicrobial products with public health claims to reduce *Legionella* in cooling tower water. EPA received requests to develop a test method and guidance for registration of antimicrobial products intended to reduce *L. pneumophila* in water used in cooling tower systems. There is significant interest from stakeholders and the public in the availability of antimicrobial products with these claims.

III. Guidance Documents Do Not Contain Binding Requirements

As guidance, these documents are not binding on the Agency or any outside parties, and the Agency may depart from these documents 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 documents and any statute, regulation, or other legally binding document, the guidance documents will not be controlling.

Authority: 7 U.S.C. 136 *et seq.*

Dated: September 26, 2023.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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