



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2023-0445; FRL-11370-01-OCSP]

Pesticides; Concept for a Framework to Assess the Risk to the Effectiveness of Human and Animal Drugs Posed by Certain Antibacterial or Antifungal Pesticides; Notice of Availability and Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of and soliciting public comment on the concept for developing a framework to improve assessments of potential risks to human and animal health where the use of certain pesticides could potentially result in antimicrobial resistance (AMR) that compromises the effectiveness of medically important antibacterial and antifungal drugs. EPA is also seeking feedback on research gaps and other information to help inform the risk assessment and mitigation processes. The concept document was developed in collaboration with the U.S. Department of Health and Human Services (HHS), the U.S. Department of Agriculture (USDA), and offices within the White House Executive Office of the President. A pesticide must be registered with the EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) before it can be legally sold or distributed in the United States. During the registration process, EPA considers whether the pesticide will cause unreasonable adverse effects on people or the environment. Because resistance is considered an adverse effect under FIFRA, the U.S. government is working to develop a structured and coordinated approach to assess and manage these risks. EPA is seeking public comment on a concept document for a proposed framework and on potential solutions, research, or mitigation approaches to reduce the spread of AMR. The agencies will consider feedback in developing a proposed framework that will also be shared for public review and comment.

DATES: Submit your comments on or before **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2023-0445, 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 and visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Jennings, Immediate Office (7501M), Office of Pesticide Programs, Environmental Protection Agency, 1201 Constitution Ave. NW., Washington, DC 20004; telephone number: (706) 355-8574; email address: jennings.susan@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What is the Agency's authority for taking this action?

This action is being taken under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*).

B. What action is the Agency taking?

EPA is announcing the availability of and soliciting public comment on a document that describes the concept for developing a proposed framework to improve assessments of potential risks to human and animal health where the use of certain pesticides could potentially result in antimicrobial resistance that compromises the effectiveness of medically important antibacterial and antifungal drugs. EPA is also seeking feedback on research gaps and other information to help inform the risk assessment and mitigation processes. The concept document was developed in collaboration with the U.S. Department of Health and Human Services (HHS), the U.S.

Department of Agriculture (USDA), and offices within the White House Executive Office of the President. A pesticide must be registered with the EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) before it can be legally sold or distributed in the United States. During the registration process, EPA considers whether the pesticide will cause unreasonable adverse effects on people or the environment. Because resistance is considered an adverse effect under FIFRA, the U.S. government is working to develop a structured and coordinated approach to assess and manage these risks. EPA is seeking public comment on a concept document for a proposed framework and on potential solutions, research, or mitigation approaches to reduce the spread of AMR. The agencies will consider feedback in developing a proposed framework that will also be shared for public review and comment.

C. Why is the Agency taking this action?

In the United States, more than 2.8 million antimicrobial-resistant infections occur each year, resulting in more than 35,000 annual deaths. Some antibacterial and antifungal pesticides used in agriculture as well as some pesticides used in other settings, belong to the same class as or share mechanisms of action with medically important antimicrobial drugs used in human and veterinary medicine. Recent evidence indicates that the use of some antifungal pesticides can select for resistant organisms that pose a potential risk to human and animal health. As new pesticides and uses are proposed, the potential exists for these pesticides to select for pathogenic bacteria or fungi that are resistant to medically important antimicrobial drugs, including both FDA-approved drugs and those still undergoing clinical trials.

D. 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 may be interested in assessments of potential risks to human and animal health where the use of certain pesticides could potentially result in antimicrobial resistance that compromises the effectiveness of medically important antibacterial and antifungal drugs. Since other entities may also be interested, the Agency has not attempted to describe all

the specific entities that may be interested in 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**.

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

1. Submitting CBI.

Do not submit CBI information 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 and instructions at <https://www.epa.gov/dockets/commenting-epa-dockets>.

II. Request for Comments

EPA is seeking comment on the document entitled “Soliciting Feedback from Stakeholders on the Structure of a Proposed Framework to Assess the Risk to the Effectiveness of Human and Animal Drugs Posed by Certain Antibacterial or Antifungal Pesticides” (also referred to as the concept document), a copy of which is available in the docket. EPA is also requesting public comments on potential solutions, research, or mitigation approaches to reduce the spread of AMR, and is specifically seeking public comment on the following questions for the proposed framework:

- Is the concept for the proposed framework (see Figure 1 in the concept document) appropriately defined and clear to stakeholders?
- Are there specific types of pesticides that should be evaluated under the framework,

either by class or function?

- What factors that should be considered in determining if a proposed pesticide use constitutes a potential risk to human or animal health due to AMR?
- How to determine which human and animal antimicrobial drugs should be considered ‘medically important’ and how should this term be defined?
- What mitigation strategies are currently available to address the risk of AMR developing because of pesticide use?

Comment is also requested on the list of research gaps that could help inform risk assessment and mitigation addressed in this framework, including agricultural methods or other processes that could minimize the potential for these pesticides to select for resistant organisms and strategies to prevent infection or colonization related to pathogen exposure, including:

- How do organisms that might have developed resistance by exposure to these pesticides come into contact with and cause illness in humans or animals (e.g., through direct contact, inhalation, ingestion, healthcare-associated transmission), and which human or animal populations are most affected (e.g., agricultural workers, persons handling compost, persons with immunocompromising conditions, persons living near treated fields, animals for food production, companion animals)?
- What are effective strategies to reduce the potential for these pesticides to select for antimicrobial-resistant bacteria and fungi? For example, which agricultural practices are effective in reducing the potential for these pesticides to select for AMR, including strategies to reduce the need for pesticide use and practices that reduce the likelihood that pesticide use will result in resistance emergence (e.g., crop rotations, specific pesticide formulations)?
- By which mechanisms do human or animal pathogenic bacteria and fungi spread through populations after becoming resistant through selection by these pesticides?
- What are the best approaches to determine the potential for pesticides to select for antimicrobial-resistant pathogens, and do chemical criteria exist that could help determine

whether pesticides are more or less likely to pose health risks to humans or animals?

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

Dated: September 21, 2023.

Michal Freedhoff,

Assistant Administrator,

Office of Chemical Safety and Pollution Prevention.

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