MEMORANDUM OF UNDERSTANDING AMONG THE U.S. ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDE PROGRAMS, THE U.S. DEPARMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION AND CENTERS FOR DISEASE CONTROL AND PREVENTION, AND THE U.S. DEPARTMENT OF AGRICULTURE

I. Purpose

This Memorandum of Understanding (MOU) is made and entered into among the U.S. Environmental Protection Agency's (EPA) Office of Pesticide Programs (OPP), the Department of Health and Human Services' Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC), and the U.S. Department of Agriculture's (USDA), (the "Participants") to facilitate the sharing of information to inform EPA's regulation of pesticides that could potentially compromise the effectiveness of human or animal drugs. EPA works with confidential business information (CBI)[a] and FDA works with confidential commercial information (CCI)[b]. Under this MOU, EPA and FDA may share non-public information that may be exempt from public disclosure with participating agencies, subject to applicable limitations below.

II. Background

Antifungal and antibacterial resistance is a growing global health threat. The use of antifungal and antibacterial pesticides can potentially lead to resistance in human and animal pathogens that may compromise the effectiveness of medically important antibacterial[c] and antifungal drugs. Because the health of humans, animals, and the environment are intricately connected, it is important that a One Health approach is used to promote the judicious use of antibacterial and antifungals in all sectors, and to mitigate any risks from the development of resistance. Preserving the effectiveness of antibacterial and antifungal drugs is essential to prolonging their effectiveness and subsequently protecting the health of humans, animals, and plants. Resistance develops when pathogens such as bacteria or fungi acquire the ability to defeat the drugs designed to kill them. The use of antibacterial or antifungal compounds across settings (such as in hospitals, at veterinary clinics, or on farms, either to treat animals or crops)

---

[a] Confidential Business Information (CBI): Any business information received by EPA that is claimed or may be claimed as confidential in accordance with 40 CFR 2.203, 40 CFR 2.204 (c)(2), or any other applicable provision in Title 40, Code of Federal Regulations, and is not otherwise available to the public.

[b] Confidential Commercial Information (CCI): is commercial or financial information that is privileged or confidential means valuable data or information, which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs. 21 CFR 20.61(b).

[c] Defining "medically important" as it pertains to this framework will depend on a variety of factors, such as the drug's role in human medicine, the potential for cross resistance, and the availability of alternatives. An example of such a list for antimicrobial drugs is available from Appendix A of the Food and Drug Administration Guidance for Industry #152. Fungicides will be evaluated on a case-by-case basis. A list of antifungal drugs is contained in Appendix B.

can contribute to the emergence of antimicrobial-resistant organisms and possibly increase the difficulty of treating future infections in humans, animals, and plants.

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), a pesticide must—in most circumstances—be registered with EPA 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 human health, animal health, or the environment. EPA assesses the potential for antifungal or antibacterial resistance developing from the pesticidal use of certain compounds when EPA evaluates the risks of the pesticide. The potential for pesticidal use of a compound contributing to resistance in medically important drugs is considered a risk under FIFRA. Pesticides that share a drug class or mechanism of action with a medically important drug could potentially promote resistance and adversely impact the effectiveness of these therapies when they are used in humans or animals. EPA currently has an incomplete understanding of the factors that contribute to resistance in various settings.

Best practices continue to evolve for evaluating the risks to human and animal health posed by pesticides whose use may lead to, or increase the possibility for, resistant bacteria or fungi. Substantial scientific uncertainties exist related to this issue. Further, optimal approaches to risk mitigation, should mitigation be determined to be necessary based on the risk assessment and underlying science, may be unknown or vary substantially depending on the characteristics of a pesticide and its proposed use. Combining the Participants' expertise will provide EPA with as much information as possible about the potential for pesticide actions to compromise the effectiveness of human or animal drugs as it evaluates applications for registration of certain antibacterial and antifungal pesticide products.

III. Authorities

EPA has authority to enter into this agreement pursuant to section 22 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136t(b), and section 102(2)(G) of the National Environmental Protection Act, 42 U.S.C. 4332(2)(G).

CDC has authority to enter into this agreement pursuant to the Public Health Service Act (PHSA) § 301 (42 U.S.C. § 241), and the Consolidated Appropriations Act of 2023 (42 U.S.C. 300hh-37).

FDA has the authority to enter into this agreement pursuant to the following provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C 355, a360b, and 393(c) and the following provisions of the Public Health Service Act, 42 U.S.C 262 and 264.; FDA is authorized to share certain non-public information with other federal agencies under 21 CFR 20.85.

USDA has authority to enter into this agreement pursuant to the Agricultural Research, Extension and Education Reform Act, 7 U.S.C. § 7653(c).

IV. Roles and Responsibilities

Substance of Agreement. EPA and FDA intend to share, on an as-needed basis and consistent with their applicable statutory and regulatory obligations, non-public information related to the two agencies' respective programs regulating pesticide and medical human and animal drugs, where the use of the pesticide has the potential to adversely impact the efficacy of the drug. CDC, EPA, FDA, and USDA agree to protect the confidentiality of the non-public information that EPA and FDA may share pursuant to this MOU. To ensure appropriate protection of non-public information, EPA and FDA agree to identify non-public information shared under this MOU. Disclosure of confidential and other non-public information

to Participants' employees pursuant to this MOU is provided with the understanding that those employees are not considered members of the public for purposes of disclosure of such designated information and thus such disclosure does not constitute a waiver of any FOIA exemption protection.

Confidential or nonpublic information includes but is not limited to: (1) confidential commercial information, such as the information that would be protected from public disclosure pursuant to Exemption 4 of the Freedom of Information Act (FOIA); (2) personal privacy information, such as the information that would be protected from public disclosure pursuant to Exemption 6 or 7(c) of the FOIA; or (3) information that is otherwise protected from public disclosure by Federal statues and their implementing regulations (e.g. Trade Secrets Act (18 U.S.C. 1905)), the Privacy Act (5 USC 552a), other Freedom of Information Act exemptions not mentioned above (5 USC 552(v)), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Insecticide, Fungicide, and Rodenticide Act, and the Health Insurance Portability and Accountability Act (HIPAA), Pub. L. 104-191).

Subject to Paragraphs A., and B. below, an agency shall not further disclose non-public information received under this MOU except with the written permission of the agency from which the non-public information originated. An agency in receipt of a judicial or legislative mandate ordering disclosure of non-public information provided by another agency will promptly notify the agency that provided this information and will take all appropriate legal measures in accordance with its regulations to advise the requesting authority of the need to protect the information from public disclosure. If an agency that has received non-public information under this MOU receives a Freedom of Information Act (FOIA) request for which there are responsive records of such non-public information that originated with the other agency, it will refer that request to the other agency for it to respond directly to the requestor regarding the release of the non-public information. In such cases, the agency making the referral will notify the requestor that a referral has been made to the agency from which the non-public information originated and that a response will issue directly from that other agency.

Actions Arising from MOU. EPA intends to work with its interagency partners to establish a new workgroup—the Interagency Drug and Pesticide Resistance and Efficacy Workgroup (IDPREW). IDPREW's goal would be to provide member agency scientific and policy opinions, when requested by EPA on resistance issues involving antifungal or antibacterial pesticides, potential interactions with medically important human or animal drugs, and risk management options. EPA would chair this workgroup. Initially, the workgroup could be comprised of several members with appropriate subject matter expertise from EPA, CDC, FDA, and USDA.

As a first step, when it is considering taking regulatory action on a pesticide, EPA will examine available information and consider whether interagency discussion is warranted about the potential for the pesticide to compromise the effectiveness of a human or animal drug. If so, EPA will consult with FDA's Center for Drug Evaluation and Research (CDER), and FDA's Center for Veterinary Medicine (CVM) through the IDPREW. The IDPREW will discuss the potential for resistance to medically important human or animal drugs to develop in human or animal pathogens from the use of the antifungal or antibacterial pesticide, using a weight-of-evidence approach, based on the current state of science. IDPREW will document its opinion in a memorandum from the meeting. This memorandum will only include non-confidential information.

After meeting with the IDPREW, EPA will consider the consultative scientific and policy information provided by the other agencies and generate its own assessment of the resistance potential for the

pesticide. As appropriate, EPA will distribute its draft assessment to the IDPREW for their review and comment. EPA will make the IDPREW meeting memorandum and agenda available to the public in the docket when it releases its decision, along with its resistance assessment and any other chemical specific assessments and supporting information.

A. Non-public Information Provided by EPA

EPA may share non-public information, including sensitive and/or confidential business information relevant to the requirements of FIFRA and the FD&C Act. EPA may only share confidential business information with other Federal agencies in accordance with 40 CFR 2.209(c).

CDC, FDA, and USDA will share non-public information provided by EPA only with employees from their respective agencies who have been granted access to confidential information by the Director of EPA/OCSPP/OPP or their designate via the FIFRA Access Authorization Agreement form. Each year, not later than October 30th and during the year as needs change due to the nature of a specific regulatory issue being considered and due to personnel actions such as retirements, transfers, and resignations, CDC, FDA and USDA employees who have a need for access to EPA non-public information will complete the FIFRA Access Authorization Agreement form in accordance with the FIFRA Confidential Business Information Security Manual. The EPA Liaison Officer will maintain a current list of people from each agency who are eligible to view EPA confidential information and each year, not later than November 15th and when the list changes, the EPA Liaison Officer will provide the CDC, FDA and USDA Liaison Officers updated lists of people from their respective agencies who have been granted access to non-public information provided by EPA, and a description of the information disclosed.

Each individual who will be authorized access to non-public information provided by EPA will (1) read the required documentation annually; (2) sign the FIFRA Access Authorization Agreement annually; and (3) sign the Affirmation of Non-multinational Status. Annually is defined as 365 days after the person's last signature of these forms. The forms must be forwarded via EPA/OCSPP/OPP Immediate Office Security Officer to the FIFRA Security Officer.

No state, county, local official, or CDC, EPA, USDA or FDA grantee or contractor will be permitted to have access to non-public information provided by EPA.

B. Non-public Information Provided by FDA

FDA may share non-public information, such as confidential commercial information, related to FDA's regulatory oversight of human or animal drugs, with designated employees from the other federal agency party to this MOU, consistent with the terms of this MOU).

Access to the confidential and non-public information shared under this MOU shall be restricted to authorized EPA, USDA and CDC employees, agents, and officials who require access to perform their official duties in accordance with the uses of the information as authorized in this MOU and any such non-public information is shared by FDA pursuant to **21 C.F.R 20.85**, and the signed authorization to share such information. Such personnel shall be advised of (1) the confidential nature of the information; (2) safeguards against the unauthorized disclosure of confidential information, and (3) the administrative and civil penalties contained in applicable Federal laws for the unauthorized disclosure of confidential information.

Proper safeguards shall include the adoption of policies and procedures to ensure that the information shared under this MOU shall be used consistent with the Trade Secrets Act [18 U.S.C. § 1905], the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. 301 et seq.], the Privacy Act of 1974, as amended [5 U.S.C. § 552a], the Freedom of Information Act [5 U.S.C. § 552], any other applicable Federal law and their implanting regulations. Pursuant to FDCA section 301(j) [21 U.S.C. § 331(j)], FDA will not reveal to EPA or USDA any method or process which is entitled to protection as a trade secret. In certain circumstances, and if appropriate and consistent with applicable laws and regulations, FDA will consider whether masked or aggregated information may be provided to the designated employees of the federal partners to this MOU.

CDC will share confidential information provided by FDA only with CDC employees who have been designated by the CDC Director and identified to FDA by the CDC Liaison Officer as having a need for access to such information. EPA will share confidential information provided by FDA only with EPA employees who have been designated by the Director of EPA/OPP and identified to FDA by the EPA Liaison Officer as having a need for access to such information. USDA will share confidential information provided by FDA only with USDA employees designated by the Director of USDA and identified to FDA by the USDA Liaison Officer as having a need for access to such information. Each year, not later than October 30th and during the year as needs change due to the nature of a specific regulatory issue being considered and due to personnel actions (such as retirements, transfers, or resignations), the CDC, EPA and USDA liaison officers will provide the FDA Liaison Officer an updated list of people from their respective agencies who have a need for access to FDA non-public information. Each year, not later than November 15th and during the year as needs change due to personnel actions such as retirements, transfers, or resignations, the FDA Liaison Officer will provide to the CDC, EPA, and USDA liaison officers updated lists of people from their respective agencies who have been granted access to FDA confidential information. CDC, EPA and USDA employees designated for access to non-public information provided by FDA must first be authorized access to non-public information relevant to the requirements of their respective statutes and regulations, as appropriate, within their respective organizations.

V. Other Understandings and Agreements

This MOU is intended to serve as an overarching statement of the intention of the Participants to engage in information sharing among and between the Participants to help inform EPA's regulation of pesticides that could potentially compromise the effectiveness of human or animal drugs.

This MOU does not nullify or negate any existing understandings or agreements among or between the Participants.

This MOU does not preclude any Participant from entering into additional, separate understandings or agreements with another Participant.

The Participants and their respective agencies and offices will handle their own activities and utilize their own resources, including the expenditure of their own funds, in pursuing these objectives. Each Participant will carry out its separate activities in a coordinated and mutually beneficial manner.

VI. No Private Right of Action Created

This MOU is a voluntary, internal government agreement and does not explicitly or impliedly create, confer, grant, or authorize any rights, privileges, benefits, or obligations, substantive or procedural, enforceable at law or otherwise, by any Party against any other or by any third party against the Parties; their parent agencies; the United States; or the officers, employees, agents, or other associated people thereof and is not intended, nor should be construed, as creating any such right, privilege, benefit, or obligation.

VIII. Administrative Liaison Officers

Each agency will identify a primary point of contact who will be responsible for maintaining a list of that agency's staff who will share and receive information under this agreement.

Each Participant may designate new liaisons/points of contact at any time by notifying the other Participant's administrative liaison in writing. If, at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the Participant will name a new liaison within 30 days and notify the other Participant through the designated administrative liaison.

VII. Duration of Agreement, Amendments or Termination

This MOU will become effective on the date of the last signatory to the agreement.

This MOU may be extended or modified, at any time per the mutual written consent of the parties.

A party may terminate this participation in this MOU at any time by providing written notice to the other parties, at least ninety (90) days in advance of the desired termination date.

VIII. Approval

MICHAL FREEDHOFF

Digitally signed by MICHAL FREEDHOFF
Date: 2024.09.24 16:02:20 -04'00'

Dr. Michal I Freedhoff

Assistant Administrator

Office of Chemical Safety and Pollution Prevention

U.S. Environmental Protection Agency

Date: _____

NAMANDJE N. BUMPUS -S

Digitally signed by NAMANDJE N. BUMPUS -S
Date: 2024.09.20 16:50:47 -04'00'

Dr. Namandjé Bumpus

Principal Deputy Commissioner

U.S. Food and Drug Administration

Date: 9/20/24

Daniel Jernigan -S

Digitally signed by Daniel Jernigan -S
Date: 2024.09.22 12:17:06 -04'00'

Dr. Daniel Jernigan

Director, National Center for Emerging and

Zoonotic Infections Diseases

U.S. Centers for Disease Control and Prevention

Date: _____

CHAVONDA JACOBS YOUNG

Digitally signed by CHAVONDA JACOBS YOUNG
Date: 2024.09.23 14:56:04 -04'00'

Dr. Chavonda Jacobs-Young

Under Secretary,

Research, Education, and Economics

U.S. Department of Agriculture

Date: _____