Secretary Brooke L. Rollins

MEMORANDUM OF UNDERSTANDING

between the

Food Safety and Inspection Service, U.S. Department of Agriculture

and the

Food and Drug Administration, U.S. Department of Health and Human Services

and the

U.S. Environmental Protection Agency

on

Drug Residues, Pesticide Residues, and Chemical Contaminants in Meat, Poultry, and Egg Products

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I. Purpose

The purpose of this Memorandum of Understanding (MOU) is to promote effective, efficient, and coordinated Federal activities concerning drug residues,[1] pesticide residues,[2] and chemical contaminants[3] (collectively, "chemical residues and contaminants") that have the potential to adulterate meat, poultry, or egg products. Because the Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture; the Food and Drug Administration (FDA), U.S. Department of Health and Human Services; and the U.S. Environmental Protection Agency (EPA), collectively "Signatory Agencies," have common and related objectives in carrying out their Agency missions and statutory responsibilities in the area of chemical residues and contaminants in food, it is in the public interest to set forth, in a memorandum of understanding, the working arrangements adopted to effectively discharge these responsibilities. Through this MOU, the Signatory Agencies intend to establish a structure for interagency information exchange, mutual consultation on scientific and regulatory issues, and resolution of disagreements.

II. Authority

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[1] "Drug residues" are residues of animal drugs, as defined by 21 CFR 530.3.

[2] "Pesticide residues" are residues of pesticides, as defined by FIFRA.

[3] For purposes of this MOU, "Chemical contaminants" are chemicals, other than drug and pesticide residues, that are present in meat, poultry, or egg products and that are of potential public health concern. This includes environmental contaminants.

FDA's authority for cooperating with FSIS and EPA as contemplated in this MOU derives from its responsibilities to regulate food, including animal food, and animal drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. §§ 301 *et seq.*].

EPA's authority for cooperating with FSIS and FDA as contemplated in this MOU derives from its responsibilities to regulate pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) [7 U.S.C. § 136t(b)] and the FD&C Act [21 U.S.C. § 346a].

III. Background

The monitoring and regulation of chemical residues and contaminants is an essential aspect of the safety of meat, poultry, and egg products. In the United States at the Federal level, the responsibility for evaluating and approving agricultural chemicals, for monitoring and testing food for chemical residues and contaminants, and for responding to findings is shared among several U.S. Government agencies, most notably the Signatory Agencies.

Under the FMIA, the PPIA, and the EPIA, FSIS has primary responsibility over the safety and regulation of meat, poultry, and egg products from the slaughter establishment (or egg processing establishment) to the consumer. FSIS also has regulatory authority over meat, poultry, and egg products imported into the United States. FSIS inspects products at slaughter, processing, and import and samples and tests edible tissue and products for a variety of microbial and chemical hazards. Part of its regulatory approach is the U.S. National Residue Program for Meat, Poultry, and Egg Products (NRP) which coordinates sampling and testing for chemical residues and contaminants.

Under the FD&C Act, FDA has primary responsibility over most food, including products not regulated by FSIS, such as live food-producing animals (until they are presented for slaughter at an FSIS-inspected establishment), most fish and seafood, shell eggs, nonamenable meats, and animal food. Additionally, FDA reviews and approves animal drugs for use in food-producing animals and sets maximum levels (tolerances) for animal drug residues in edible tissues, including meat, milk, and eggs. FDA conducts investigations of FSIS-reported residues to determine the party responsible for causing the tissue residue violation and the party responsible for introducing the adulterated food into interstate commerce.

Under FIFRA and the FD&C Act, EPA regulates the sale, distribution, and use of pesticides (including insecticides, herbicides, rodenticides, disinfectants, sanitizers, and more) in the United States and establishes maximum levels (tolerances) or exemptions from the requirement of tolerances for pesticide chemical residues in food, including food for food-producing animals.

IV. Scope

This MOU applies to the Signatory Agencies' activities concerning chemical residues and contaminants that are related to meat, poultry, and egg products under FSIS jurisdiction, food-producing animals while under FSIS or FDA jurisdiction, and food for food-producing animals. For purposes of this MOU, "food-producing animals" are limited to animal species that are amenable under the FMIA or PPIA, as well as animals subject to voluntary inspection by FSIS.

V. Governance

Senior Executive Council. The interagency activities falling under this MOU shall be governed by a Senior Executive Council (SEC). Each Signatory Agency shall designate at least one representative to serve on the SEC. These representatives should be Senior Executive Service (SES) members, Senior Leaders (SLs), or equivalent individuals or designees, and should have a portfolio that includes activities that fall within the scope of the MOU. The SEC should meet at least once per year, and any Signatory Agency may call for additional *ad hoc* meetings of the SEC. Decisions within the SEC shall be made by consensus among the Signatory Agencies.

Other interagency committees, task forces, or groups. The SEC may decide to create, modify, or terminate additional interagency committees, task forces, or groups under the umbrella of this MOU. Currently existing entities that fall under this MOU are the Interagency Residue Control Group (IRCG) and the Surveillance Advisory Team (SAT). Each entity may have its own charter outlining, at a minimum, the entity's purpose and membership. In addition to the representation from the Signatory Agencies, these entities may also invite other relevant Federal agencies to join on an *ad hoc* or regular basis.

Duties of the SEC. The SEC shall discuss overarching policy issues that are relevant to the purpose of this MOU and shall provide guidance and leadership to the interagency committees, task forces, and groups created under this MOU, including the IRCG and SAT. The SEC shall resolve disagreements between agencies that have been elevated to the SEC because they could not be resolved within such an interagency committee, task force, or group. Finally, the SEC may adopt sub-agreements under this MOU, provided the content of such sub-agreements is not in conflict with this MOU or any applicable statute or regulation.

Liaison officer and other staff. Each Signatory Agency shall designate a liaison officer who shall be responsible for implementing the MOU and for being the primary contact for matters concerning this MOU. In addition, each Signatory Agency shall assign appropriate personnel to interagency committees, task forces, or groups established under this MOU.

VI. Activities

This MOU is applicable to all interagency activities between the Signatory Agencies that fall within the scope outlined in Section IV, above. This includes, but is not limited to:

1. Sampling, Analytical Testing, and Method Development

- The Signatory Agencies agree to collaborate regarding the planning and execution of testing programs for chemical residues and contaminants in meat, poultry, and egg products.
- FSIS agrees to provide FDA with weekly residue reports. In addition, FSIS agrees to keep FDA and EPA informed of all FSIS sampling and testing programs for chemical residues and contaminants and to provide periodic reports of sampling plans and testing results. FDA and EPA agree to provide input and recommendations to FSIS on sampling frequency, production classes sampled, and chemical compounds tested on an annual basis, at a minimum.

- FDA and EPA agree to share information with each other and FSIS obtained from any other sampling or monitoring program for chemical residues and contaminants that may be relevant to activities under this MOU.
- The Signatory Agencies agree to collaborate with each other, as appropriate, and with other Federal agencies, in the development of analytical methods for chemical residues and contaminants in food, and in the acquisition and analysis of samples for special projects that fall within the National Residue Program.

2. Tolerances, Action Levels, and Screening Levels

- FDA and EPA agree to notify FSIS whenever FDA or EPA establish or amend a tolerance, an exemption from a tolerance, an action level, or a safe level for a drug, pesticide, or chemical contaminant that may relate to FSIS' responsibilities under the FMIA, PPIA, or EPIA.
- The Signatory Agencies agree to coordinate and, if appropriate, collaborate in the development of action levels or screening levels for chemical residues and contaminants in meat, poultry, and egg products.

3. Regulatory Actions

- The Signatory Agencies agree to notify each other of any information related to the actual, suspected, or anticipated presence of chemical residues and contaminants in meat, poultry, egg products, or food-producing animals that may constitute or could result in a violation of the FMIA, PPIA, EPIA, or FD&C Act.
- When requested and appropriate, the Signatory Agencies agree to assist one another in making regulatory decisions related to chemical residues and contaminants in meat, poultry, and egg products by sharing information, expertise, and analytical methodologies. The Signatory Agencies further agree to assist each other, when requested and appropriate, to conduct safety assessments, health hazard evaluations, or other evaluations of a chemical's toxicity or exposure aimed at determining whether meat, poultry, egg products, or food-producing animals have been adulterated.
- FDA agrees to review reports from FSIS or EPA of food potentially adulterated by the presence of any chemical residues and contaminants, and if deemed appropriate by FDA, to investigate the circumstances that may have caused the associated food-producing animals to be exposed prior to slaughter. When appropriate, FDA agrees to notify FSIS and EPA of the results of any review or investigation.
- EPA agrees to review reports from FSIS or FDA of pesticide misuse or other possible violations of FIFRA or the FD&C Act, and if deemed appropriate by EPA, to investigate the matter or to refer the matter for investigation to the appropriate State enforcement authority. When appropriate, EPA agrees to notify FSIS and FDA of the results of any review or investigation.

VII. Information Sharing

Access to the confidential and non-public information shared under this MOU shall be restricted to authorized FDA, FSIS, and EPA 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**. 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 must be used to protect against unauthorized use and disclosure of the non-public information exchanged under this MOU. Proper safeguards shall include the use of policies and procedures to ensure that the information shared under this MOU shall be shared and used consistent with the confidentiality provisions of 7 USC §8791 of the Food, Conservation, and Energy Act of 2008 (formerly Section 1619 of the 2008 Farm Bill), the Trade Secrets Act [18 U.S.C. § 1905], the FD&C Act [21 U.S.C. 301 *et seq.*], the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 *et seq.*], the Privacy Act of 1974, as amended [5 U.S.C. § 552a], the Freedom of Information Act (FOIA) [5 U.S.C. § 552], and any other applicable Federal law and regulations. Pursuant to FD&C Act section 301(j) [21 U.S.C. 331(j)], the FDA will not reveal to FSIS or EPA any method or process which is entitled to protection as a trade secret. Where appropriate, the Signatory Agencies will utilize appropriate methods for transfer or sharing relevant confidential information in accordance with established procedures and governing authority, e.g., 40 CFR 2.209(c) and 2.307(h). Any Signatory Agency may decide not to share information or expertise in response to a particular request for information, or to limit the scope of information and expertise shared in response to a particular request. See *Process for Information Sharing* under *Appendix A*.

It is the intention of this MOU that access to the non-public information shared under this MOU be restricted to authorized employees, agents, and officials of the Signatory Agencies who require access to perform their official duties in accordance with the uses of the information as authorized in this MOU. It may not be further disclosed or shared in any manner without the express written consent of the originating Agency, unless required by law. In cases where further disclosure may be required by law, each Signatory Agency intends to respond promptly to a request seeking such permission. For example, the requesting party would notify the sharing party before responding to any judicial order that compels the release of shared non-public information, so that the parties may determine the appropriate measures to take, including, where appropriate, legal action. The Signatory Agencies resolve to advise employees, agents and officials of (1) the confidential nature of the information; (2) safeguards against unauthorized disclosure of confidential information; and (3) the administrative, civil and criminal penalties contained in applicable Federal laws for the unauthorized disclosure of confidential information.

If a FOIA request is received for any shared information, the Receiving Participant will: (a) if the request implicates documents from the Sharing Participant in their original form, refer the request to the Sharing Participant for that Participant to respond directly to the requester, and notify the FOIA requester of the referral and that a response will issue directly from the Sharing Participant regarding the releasability of the information; and (b) if the request implicates documents authored by the Receiving Participant that incorporates information from shared documents, consult with the Sharing Participant about how to respond to the FOIA request. The Receiving Participant will not indicate to the

FOIA requester whether the Sharing Participant has responsive or releasable records. All actions taken under this paragraph must be in compliance with 45 C.F.R. 5.25 and 9 CFR Part 390.

VIII. Other Provisions

1. *Term, Termination, and Modification.* This MOU is effective upon signing by all Signatory Agencies and shall remain in effect unless modified or terminated. This MOU may be modified or terminated by mutual written consent by the Signatory Agencies or terminated by any Signatory Agency upon a 30-day advance written notice to the other Signatory Agencies.

2. *Previous Agreement.* Once signed by all Signatory Agencies, this MOU supersedes the MOU on the subject of "regulatory activities concerning residues of drugs, pesticides, and environmental contaminants in foods," which was referred to as MOU # FSIS 12-37-MU-330 and FDA MOU 225-85-8400 with an effective date of December 7, 1984. This MOU does not otherwise modify any existing agreements among the Signatory Agencies.

3. *Rights and Benefits.* Nothing in this MOU is intended to diminish or otherwise affect the authority of any agency to carry out its statutory, regulatory, or other official functions, nor does it create any right or benefit, substantive or procedural, enforceable at law by any party against the United States, its agencies or officers, State agencies or officers carrying out programs authorized under Federal law, or any other person.

4. *Agreement Does Not Involve Funding.* All commitments made in this MOU are subject to the availability of appropriated funds and budget priorities. Nothing in this MOU, in and of itself, obligates the Signatory Agencies to expend appropriations or to enter into any contract, assistance agreement, interagency agreement, or incur other financial obligations. This MOU, in and of itself, does not result in the transfer of funds or in the incurrence of other financial obligations between the Signatory Agencies. Funding arrangements, if any, shall be the subject of separate agreements that will be subject to the availability of funds.

IX. Signatories

Brooke L. Rollins
Secretary
U.S. Department of Agriculture

Robert F Kennedy Jr.
Secretary
U.S. Department of Health and Human Services

Lee Zeldin
Administrator
U.S. Environmental Protection Agency

APPENDIX A – Process for Information Sharing

Pursuant to Section VII of this MOU, any Signatory Agency "may decide not to share information or expertise in response to a particular request for information, or to limit the scope of information and expertise shared in response to a particular request." Nothing in the process described below changes Section VII.

When, under this MOU, authorized Signatory Agency employees, agents, and officials who require access to perform their official duties request from the other Agency information that may contain non-public material, the request should be in writing, which includes an email, and need only identify the subject for which information is requested. Although a more specific description of the information asked for may be helpful, it would not be required for purposes of making a request. However, the following language should be included in the request:

"Information that is shared under this request will be under the FSIS-FDA-EPA MOU # 225-26-005. Unless otherwise required by law, we agree not to disclose any shared information in any manner without your express prior written permission." With the inclusion of this statement, requestors would not have to use a particular format or include other pre-specified text.

A response to a request should also be in writing, but it, too, can be an email that acknowledges transmission of information in response to the request. Although identifying each piece of information/document provided may be helpful, it would not be required for purposes of responding to a request. However, the following language should be included in the response:

"Pursuant to the FSIS-FDA-EPA MOU # 225-26-005, this communication may contain privileged and/or confidential information exempt from public disclosure. Unless otherwise required by law, it may not be disclosed or shared in any manner without our express prior written consent."

With the inclusion of this statement, responders would not have to use a particular format or include other pre-specified text.