MEMORANDUM OF UNDERSTANDING
BETWEEN THE
FOOD SAFETY AND INSPECTION SERVICE
UNITED STATES DEPARTMENT OF AGRICULTURE
AND THE
FOOD AND DRUG ADMINISTRATION
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

This agreement is entered into by the Food and Drug Administration (the FDA), United States Department of Health and Human Services (HHS) and the Food Safety and Inspection Service (FSIS), United States Department of Agriculture (USDA) (individually referred to as "Agency" and collectively referred to as "Agencies").

I. Purpose

The purpose of this Memorandum of Understanding (MOU) is to facilitate the exchange of information about dual jurisdiction establishments and operations (hereinafter referred to as "DJEs"). These establishments are subject to the jurisdiction of both Agencies. The DJEs under this MOU are limited to human food operations and exclude animal food operations, which are regulated by the FDA. This exchange of information will permit more efficient use of resources and will contribute to improved public health protection.

II. Authority

FSIS is responsible for implementing and enforcing the Federal Meat Inspection Act (21 U.S.C. 601, et seq.), the Poultry Products Inspection Act (21 U.S.C. 451, et seq.), and parts of the Egg Products Inspection Act (21 U.S.C. 1031, et seq.). In carrying out its responsibilities under these Acts, FSIS places inspectors in meat and poultry slaughterhouses and in meat, poultry, and egg product processing plants. FSIS also conducts inspections of warehouses, transporters, retail stores, restaurants, and other places where meat, poultry, and egg products are handled and stored. In addition, FSIS conducts voluntary inspections under the Agriculture Marketing Act (7 U.S.C. 1621, et seq.).

The FDA is responsible for implementing and enforcing the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 301, et seq.), the Public Health Service Act (42 U.S.C. 201, et seq.), the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.), and parts of the Egg Products Inspection Act. In carrying out its responsibilities under these Acts, the FDA conducts inspections of establishments that manufacture, process, pack, or hold foods, with the exception of certain establishments that are regulated exclusively by FSIS. The FDA also inspects vehicles and other conveyances, such as boats, trains, and airplanes, in which foods are transported or held in interstate commerce.

Nothing in this agreement shall lessen the responsibilities or authorities of FSIS and the FDA under their statutory authorities.

III. Background

In February 2014, the Agricultural Act of 2014 (2014 Farm Bill) directed USDA to execute a MOU[1] with the FDA for the following purposes:

1. To improve interagency cooperation on food safety and fraud prevention, building upon any other prior agreements.

2. To maximize the effectiveness of limited personnel and resources by ensuring that:

    a. Inspections conducted by FSIS satisfy requirements under the FD&C Act.

    b. Inspections of shipments and processing facilities for fish of the order Siluriformes are not duplicative; and

    c. Any information resulting from examination, testing, and inspections conducted is considered in making risk-based determinations, including the establishment of inspection priorities.

As a result, MOU 225-14-0009 was signed between the Agencies on April 30, 2014. Both agencies agree that the transition of regulatory oversight of Siluriformes outlined in that agreement has been completed. This MOU supersedes and replaces it.

In January 2018, the FDA and FSIS announced a formal agreement to make the oversight of food more efficient and effective by bolstering coordination between the two Agencies. That agreement outlined efforts to increase interagency collaboration and coordination on areas of mutual interest in order to achieve improved regulatory efficiency and effectiveness.

The Agencies determined that changes in inspectional activities, available resources, and food safety hazards necessitate updating this MOU, intended to facilitate the exchange of information between the Agencies about DJEs. Therefore, the FDA and FSIS have updated this MOU to address current public health needs.

IV. Substance of Agreement

The Agencies will exchange information relevant to the other Agency's inspection of establishments under dual-jurisdiction. The Agencies will also share relevant information about facilities that hold or distribute human food products regulated by both Agencies, but which are not considered DJEs for the purpose of this MOU.

Each Agency agrees to notify the other Agency of the following findings in a DJE inspection:

1. The finding of foods involved in outbreaks of foodborne illness, injuries, or adverse health consequences.

[1] The 2014 MOU was a result of the May 1997 Report to the President entitled, "Food Safety from Farm to Table – A National Food Safety Initiative," that recommended increased cooperation among agencies responsible for food safety.

2. The finding of adulterated or mislabeled foods such that there is a reasonable probability that the use of or exposure to such products will cause serious adverse health consequences.[2]
3. A processing condition or failure that is likely to result in food contamination leading to outbreaks of foodborne illness or serious adverse health consequences.
4. Significant findings in the facility of insanitary conditions such as rodent infestation.
5. Microbiological or other sampling findings in DJEs or products which may provide information about sanitary conditions in those establishments or indicate serious adverse health consequence of products under either Agency's jurisdiction. These results will include microbe characteristics (e.g., serotype, whole genome sequence, antimicrobial resistance profile, etc.) where applicable, and other information related to categorizing and tracking pathogens.
6. The initiation of a recall at a DJE.
7. Reports of tampering or threats of tampering.
8. A food handler diagnosed as having a communicable disease that is likely to result in food contamination or outbreaks of foodborne illness (e.g., hepatitis).
9. Convictions of a DJE, or any officer or key employee of a DJE, for any felony or more than one misdemeanor involving the DJE or any food prepared or packed in the DJE.
10. Convictions of an establishment preparing, packing, holding, or otherwise handling meat, poultry or egg products solely under state regulation and foods regulated by the FDA, or any officer or key employee of such an establishment, for any felony or more than one misdemeanor involving the establishment, or any food prepared or packed in the establishment.

Both Agencies will also:

1. Develop, maintain, share, and annually update a list of DJEs including establishment name, applicable Agency identification number, and establishment address. These establishments are limited to those that prepare or pack foods regulated by both Agencies. This list, which will be updated yearly, will be organized by state and territory, and distributed to the field and headquarters contacts of both Agencies. When updating this list, each Agency agrees to identify all DJEs under its jurisdiction, and remove those that have discontinued operations.
2. Develop, maintain, share, and annually update a list of field and headquarters contacts designated for the purpose of this MOU. This list will also include the offices responsible for each state and territory. In addition to the annual updates to this list, each Agency agrees to promptly inform its counterpart of any changes.

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[2] The following hazards constitute adulteration or mislabeling: pathogenic organisms; foreign materials; undeclared allergens in human food (e.g., peanuts, peanut butter, peanut flour, hydrolyzed peanut protein, pecans, walnuts, hazelnuts, filberts, cashews, Brazil nuts, eggs, egg whites, egg yolk, egg albumen, powdered eggs, shrimp, crab, crayfish, lobster, oysters, clams, scallops, mussels, almonds, pistachios, cow milk, cream, dry milk, whey, other proteins from cow's milk, soy, soybeans, soy protein, soy flour, fish, wheat); undeclared color additives (e.g. FD&C Yellow No. 5 and FD&C Yellow No. 6); and undeclared sulfites.

The FDA will:

1. Notify the FSIS field and headquarters level designees when:
    a. Any processing condition is observed in a DJE that could render foods bearing a USDA mark of mandatory or voluntary inspection adulterated or mislabeled.
    b. There is reason to believe that an FDA-regulated ingredient sent to or received by an FSIS-regulated establishment could adulterate a meat, poultry, or egg product if used in it.
2. Notify the appropriate FSIS liaison contact prior to conducting an inspection of a DJE that is not under continuous FSIS inspection.
3. Notify and invite the FSIS inspector to accompany the FDA investigator prior to inspecting a DJE that is under continuous inspection.

FSIS will:

Notify the FDA field and headquarters level designees of an FSIS action to withhold the mark of inspection or to suspend or withdraw the grant of inspection at a DJE.

V. Information Sharing

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 Trade Secrets Act [18 U.S.C. § 1905], the FD&C Act [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 regulations implementing it. Pursuant to FD&C Act section 301(j) [21 U.S.C. 331(j)], the FDA will not reveal to FSIS any method or process which is entitled to protection as a trade secret. Either 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 sharing in response to a particular request. *See Process for Information Sharing under Appendix A.*

Access to the non-public information shared under this MOU shall be restricted to the FDA and FSIS authorized 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. It may not be further disclosed or shared in any manner without the express written consent of the originating Agency. In cases where further disclosure may be required by law, the FDA and/or FSIS will respond promptly to a request seeking such permission. For example, the requesting party will 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. Employees, agents and officials shall be advised 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 an Agency that has received information under this MOU receives a Freedom of Information Act (FOIA) request for which there are responsive records that originated with the other Agency,

to the extent practicable, it will refer that request to the other Agency for it to respond directly to the requestor regarding the release of the information. In such cases, the Agency making the referral will notify the requestor that a referral has been made and that a response will issue directly from the other Agency.

VI. General Provisions

The provisions of this MOU are not intended to add to, nor detract from, any of the statutory authorities of each Agency or the regulations promulgated by each Agency under such authorities. Each Agency reserves the authority to review, independently of the other, matters of concern to their respective authorities.

VII. Previous Agreements

This version supersedes the earlier MOU 225-99-2001.

This agreement supersedes MOU 225-14-0009, related to examination and inspection of Siluriformes fish and fish products, signed by the Agencies on April 30, 2014.

This MOU does not modify any other existing agreements between USDA and the FDA.

VIII. Liaison Officers

All notices and other communication must be in writing and may be by personal delivery, registered or certified United States mail, electronic mail, facsimile, to the other Agency as provided below. Notices will be deemed delivered upon receipt.

FSIS
Lisa Volk
Program Manager
Office of Field Operations
Food Safety and Inspection Service, USDA
Room 3153 South Building
Washington, DC 20250
Phone: (202) 720-4863
Lisa.volk@usda.gov

FDA
Martha Myrick
Program Expert
Office of Regulatory Affairs
Divisions of Domestic Human and Animal Foods Operation Branch
Phone: (240) 402-5840
martha.myrick@fda.hhs.gov

IX. Term, Termination, and Modification:

This agreement is effective upon signing by both Agencies and shall remain in effect from the latest signature date unless modified or terminated. This MOU will continue in effect unless modified or terminated by mutual written consent of the Agencies upon a 30-day advance written concurrence to the other Agency. The Agencies agree that they will review this MOU every five years to determine whether it should be modified or terminated.

IN WITNESS WHEREOF, the Agencies hereto have executed this MOU as follows:

Food Safety and Inspection Service, United States Department of Agriculture

07/28/2021

Food Safety and Inspection Service
1400 Independence Ave., S.W.
Washington, D.C. 20250-3700

Date

Food and Drug Administration, United States Department of Health and Human Services

7/26/2021

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Date

APPENDIX A

Process for Information Sharing

Pursuant to Section V of the Memorandum of Understanding (MOU) entered into by the Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS), either Agency "may decide not to share information or expertise in response to a particular request for information made according to the procedures established under Section IV, or to limit the scope of information and expertise sharing in response to a particular request." Nothing in the process described below changes Section V.

When, under the current MOU, authorized FDA and FSIS 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 informal 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 FDA-FSIS MOU. 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 informal 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 FDA-FSIS Memorandum of Understanding, this communication may contain privileged and/or confidential information exempt from public disclosure. 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.