UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

5730.1
Revision 1

6/21/23

RESPONSIBILITIES IN DUAL JURISDICTION ESTABLISHMENTS

I. PURPOSE

This directive provides instruction to FSIS inspection program personnel (IPP) about their roles and responsibilities regarding inspection, verification, documentation of findings, reporting and enforcement actions in establishments that operate under the jurisdiction of both FSIS and the U.S. Food and Drug Administration (FDA), (i.e., a dual jurisdiction establishment (DJE)). FSIS is revising this directive to reflect the updated Memorandum of Understanding (MOU) between FSIS and FDA and to provide instructions to IPP in establishments that harvest cells for cell-cultured meat and poultry food products.

KEYPOINTS:

- *Updates situations where FSIS will share information with FDA according to the MOU.*
- *Adds FSIS headquarters liaison responsibilities.*
- *Provides instructions for district offices (DOs) to include the headquarters liaison in certain situations.*

II. CANCELLATION

FSIS Directive 5730.1, *Responsibilities in Dual Jurisdiction Establishments*, 06/28/2005.

III. BACKGROUND

A. DJEs, as addressed in this directive, are those establishments subject to the jurisdiction of both FDA and FSIS. This includes establishments that produce and ship products regulated by FDA as well as products regulated by FSIS including establishments that harvest cells for cell-cultured meat and poultry food products amenable under the Acts. For example, the establishment produces and ships both a cooked bean chili and a beef chili or a spaghetti sauce with meat and a spaghetti sauce without meat. For another example, the establishment may process both fish of the order Siluriformes under FSIS inspection and other seafoods under FDA's jurisdiction. Establishments that harvest amenable cells for cell-cultured meat and poultry food products are also DJEs, because FDA has jurisdiction over the preharvest production areas of the establishment.

NOTE: An FSIS-regulated establishment that only manufactures meat and poultry products that incorporate FDA-regulated ingredients produced at another establishment is not a DJE. An FSIS-regulated establishment that only processes cell-cultured meat or poultry food products that were harvested at another establishment is not a DJE.

B. In an effort to increase cooperation among Federal agencies responsible for food safety, FSIS and FDA updated the MOU in 2021 regarding the exchange of information in DJEs. The MOU states that the Agencies will exchange information relevant to the other Agency's inspection of establishments under dual jurisdiction. This exchange of information will permit more efficient use of resources and will contribute to improved public health protection. FSIS and FDA agreed to communicate at the DO level about findings of

hazardous, contaminated, or misbranded foods, processes that may result in contamination, recalls, or evidence of tampering in DJEs, and awareness of whole genome sequencing (WGS) information indicating positive results in the DJEs. Additional instruction regarding the interagency communication and FSIS IPP and DO responsibilities in cell-cultured establishments are provided in FSIS Directive 7800.1, *FSIS Responsibilities in Establishments Producing Cell-Cultured Meat and Poultry Food Products*.

C. FDA and FSIS agreed to share test results in DJEs, which may provide information about sanitary conditions in those establishments or indicate serious adverse health consequences of products under either Agency's jurisdiction. For example, the Agencies will share WGS results from DJEs according to the agreed upon standard operating procedures.

D. FSIS agreed to notify FDA when it intends to withhold, suspend, or withdraw inspection from a DJE.

E. FDA agreed to notify FSIS when:

1. Any processing condition is observed in a DJE that could render foods bearing a USDA mark of inspection adulterated or misbranded; or

2. FDA plans to conduct an inspection of a DJE where physical inspection presence is not continuous, e.g., a patrol assignment, or an FSIS establishment that does not produce FSIS inspected product every day, during FSIS inspection coverage.

IV. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES

A. FSIS IPP are to focus inspection on the FSIS-regulated products. IPP are not to routinely enter or inspect an area of the establishment where nothing subject to FSIS jurisdiction and inspection occurs. In official meat, poultry, and egg products establishments, the extent of the official premises is defined in the grant of inspection. IPP are to limit their verification to these areas.

B. If conditions in the area of the establishment that is only under FDA's jurisdiction may lead to, or are creating, insanitary conditions or product adulteration in the FSIS inspected areas of the establishment as described in 9 CFR 416.2, *Establishment grounds and facilities*, IPP are to:

1. Take the appropriate action with respect to FSIS-regulated products as set forth in FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System*, Chapter II, Sanitation and Chapter V, Documentation and Enforcement; and

2. Notify the DO of the situation through supervisory channels.

C. If the production of FDA products and FSIS products is separated by time, IPP are to verify the Sanitation Performance Standards (SPS), Sanitation Standard Operating Procedures (Sanitation SOPs), and Hazard Analysis and Critical Control Point (HACCP) requirements by following the instructions in FSIS Directive 5000.1, when the establishment starts its operation under FSIS jurisdiction.

D. IPP are not to take any regulatory control action or other administrative enforcement action against the FDA-regulated products or the production of the FDA products.

E. IPP are to request instructions from their supervisor when FDA investigators invite FSIS IPP to accompany the FDA investigator prior to inspecting a DJE.

F. IPP are to communicate through the supervisory chain of command when they are contacted by FDA or when they are made aware of FDA involvement in the establishment.

V. DISTRICT OFFICE RESPONSIBILITIES

A. The DOs are to maintain and update annually a list of DJEs and send the current list of DJEs to the FSIS headquarters liaison (formtad@usda.gov) when requested.

NOTE: The Office of Field Operations (OFO) Recall Management and Technical Analysis Division (RMTAD) is the FSIS headquarters liaison for the FSIS-FDA MOU and can be contacted by e-mail: formtad@usda.gov.

B. The DOs are to report to the FSIS headquarters liaison (formtad@usda.gov), the appropriate FDA field office, and the FDA headquarters liaison the following situations in a DJE:

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

2. The finding of adulterated or misbranded foods such that there is a reasonable probability that the use of or exposure to such products will cause serious adverse health consequences;

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. Any positive microbiological or other sampling project results. These results are to include microbial characteristics (e.g., serotype, whole genome sequence, antimicrobial resistance profile) where applicable, and other information related to categorizing and tracking pathogens, such as findings of harborage or cross-contamination from *Listeria* WGS reports;

6. All for-cause sampling results, including both positive and negative results;

7. The initiation of a recall;

8. Reports of tampering or threats of tampering;

9. 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);

10. 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; or

11. FSIS has acted to withhold the mark of inspection or to suspend or withdraw the grant of inspection.

C. The DOs are to direct IPP to conduct appropriate follow-up verification or investigation activities when FDA notifies the FSIS DO or headquarters liaison about the following situations:

1. Any processing condition is observed in a DJE that could render foods bearing a USDA mark of inspection adulterated or misbranded;

2. FDA plans to conduct an inspection of a DJE where physical inspection presence is not continuous, e.g., a patrol assignment, or an FSIS establishment that does not produce FSIS inspected product every day, during FSIS inspection coverage; or

3. FDA shares sampling information that there are matching *Listeria monocytogenes* isolates found

over time in a DJE, which may or may not match *Listeria monocytogenes* isolates collected by FSIS.

D. The DO is to schedule a for-cause public health risk evaluation (PHRE) as directed in FSIS Directive 5100.4, *Public Health Risk Evaluation Methodology,* when FDA testing results in a DJE indicates a potential food safety concern that could impact the FSIS production. During the PHRE, the Enforcement, Investigation, and Analysis Officers are to consider whether the FDA test results are from areas of the establishment where the FSIS product could become contaminated.

E. The DOs are to contact the FSIS headquarters liaison (formtad@usda.gov) if they have questions concerning the information they receive from FDA. For example, if they have a question about FSIS isolates included in an FDA WGS report.

VI. FSIS HEADQUARTERS LIAISON RESPONSIBILITIES

The FSIS headquarters liaison is to develop and maintain a contact list of field and headquarters contacts designated for the purpose of the USDA-FDA MOU. The liaison is to include OFO District Managers and Deputy District Managers, Office of Investigation, Enforcement and Audit, Regional Directors and Deputy Regional Directors, OFO headquarters and RMTAD contacts along with the corresponding FDA counterparts on the contact list. The FSIS headquarters liaison is to share the contact list with the pertinent FSIS and FDA contacts. The FSIS headquarters liaison is to update the contact list annually or whenever there is a change to the list. The FSIS headquarters liaison is to request a list of current DJEs from the DOs within three months of the issuance of this directive and before the end of each calendar year. They are to develop, maintain, and share the list of FSIS DJEs with the FDA liaison annually or whenever they are made aware of a change to the list.

VII. QUESTIONS

Refer questions through supervisory channels.

Assistant Administrator
Office of Policy and Program Development