

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

FSIS DIRECTIVE	5730.1	6/28/05
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RESPONSIBILITIES IN DUAL JURISDICTION ESTABLISHMENTS

I. PURPOSE

This directive provides instruction to Food Safety and Inspection Service (FSIS) inspection program personnel about their roles and responsibilities with regard to inspection, verification, documentation of findings, and enforcement actions in establishments that operate under the jurisdiction of both FSIS and the Food and Drug Administration (FDA), (i.e., a Dual Jurisdiction Establishment (DJE)).

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

Federal Meat Inspection Act (21 U.S.C. 601, et. seq.)
Poultry Products Inspection Act (21 U.S.C. 451, et. seq.)
Egg Products Inspection Act (21 U.S.C. 1031, et seq.)
9 CFR parts 300 to end

V. BACKGROUND

A. DJEs, as addressed in this directive, are those establishments that produce and ship products regulated by FDA as well as products regulated by FSIS. For example, the plant produces and ships both a cooked bean product and a Beef Chili or spaghetti sauce with meat and a spaghetti sauce without meat. The directive does not address situations that involve the manufacture of FSIS products that incorporate ingredients produced under FDA jurisdiction.

B. In an effort to increase cooperation among Federal agencies responsible for food safety, FDA and FSIS entered into a Memorandum of Understanding (MOU) in 1998 regarding the sharing of information in a DJE. The MOU states that each Agency's resources and experience will be used efficiently, and duplication of inspection effort is to be avoided. FSIS and FDA agreed to communicate at the district office level about findings of hazardous, contaminated, or mislabeled foods and about processes that may result in contamination, recalls, or evidence of tampering in DJEs.

DISTRIBUTION: Inspection Offices; T/A Inspectors; Plant Mgt.; T/A Plant Mgt.; TRA; ABB; TSC; Import Offices

OPI: OPPED

C. FSIS also agreed to notify FDA when it intends to withhold, suspend or withdraw

inspection from a DJE. In addition, FSIS committed to notifying FDA of the following findings:

1. Any processing condition in a DJE that would render foods bearing the USDA mark of inspection adulterated or mislabeled (e.g., presence of pathogenic bacteria or undeclared allergens).

2. Reason to believe that an FDA regulated ingredient that would adulterate a meat, poultry, or egg product if the ingredient were used had been sent to or received by an FSIS regulated establishment.

VI. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES

A. FSIS inspection program personnel are not to routinely enter or inspect an area of the establishment in which nothing that is subject to FSIS jurisdiction occurs. Inspection program personnel are to focus inspection toward the USDA regulated products. There may be situations where an FDA product is processed in close proximity to or on the same line as a FSIS regulated product, and, therefore, inspection personnel may be in the same area. In meat and poultry establishments the inspected facility is defined in the grant of inspection, and in egg products establishments the entire premises includes all buildings on the property.

B. If conditions in the area of the establishment that is only under FDA's jurisdiction may lead to, or are creating, insanitary conditions in the FSIS inspected areas of the establishment as described in 9 CFR 416.2, *Establishment grounds and facilities*, or in 9 CFR 590,

1. Inspection program personnel in meat and poultry establishments are to:

- a. take the appropriate action with respect to FSIS regulated products as set forth in FSIS Directive 5000.1, Revision 1, Chapter I, Sanitation and Chapter IV, Enforcement , and

- b. notify the District Office of the situation through supervisory channels.

2. Inspection program personnel in egg facilities are to take the appropriate actions (e.g., retain egg products or reject equipment) and are to record the findings with a memorandum to the file.

NOTE: Inspection program personnel are not to take any control action or other administrative enforcement action against the FDA products or the production of the FDA products.

VII. DISTRICT OFFICE RESPONSIBILITIES

A. Each FSIS District Office will maintain and keep current a list of dual jurisdiction establishments in its District.

B. District Offices will report to the appropriate FDA liaison a finding that:

1. foods produced in a DJE are implicated in outbreaks of foodborne illness, injuries or adverse reactions,

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2. foods produced in a DJE are found to be contaminated or mislabeled in situations where there is a reasonable likelihood that consumption of such products will cause serious adverse health consequences,

3. processing conditions or failures in a DJE are likely to result in food contamination that may lead to outbreaks of foodborne illness, injuries, or adverse reactions,

4. foods in a DJE have been recalled,

5. foods in a DJE have been tampered with or there have been threats of tampering,

6. a food handler at a DJE has been diagnosed as having a communicable disease that is likely to result in food contamination outbreaks of food borne illness (e.g., hepatitis),

7. a DJE or any officer or key employee of a DJE has been convicted of any felony or for more than one misdemeanor involving the DJE or any food prepared, packed, held, or otherwise handled by the DJE,

8. FSIS has acted to withhold the mark of inspection or to suspend or withdraw the grant of inspection from a DJE.

Direct all questions related to this directive through supervisory channels.

Philip S. Derfler /s/

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