

10230.1SpeciesIdentSmplgforCkdPrd101487

OPI: MPIO

SPECIES IDENTIFICATION SAMPLING
FOR COOKED PRODUCT

I. PURPOSE

This directive prescribes procedures for FSIS inspectors, and guidelines for plant operators regarding:

A. FSIS policy for sampling cooked products for species identification.

B. Actions to take when undeclared species are found.

II. (RESERVED)

III. (RESERVED)

IV. REFERENCES

MPI Regulations Sections 301.2(aa) and (ii), 317.2, 317.4, 317.6, 318.2, 318.7, 319.1, 381.1(4) and (31), 381.146; 381.147, 381.155, FSIS Directives 10,625.1 and 8080.1.

V. FORMS AND ABBREVIATIONS

The following will appear as abbreviated in this directive:

MPIO	Meat and Poultry Inspection Operations
AS	Area Supervisor
IIC	Inspector in Charge
CS	Circuit Supervisor
CP	Compliance Program
QC	Quality Control
EPS	Emergency Programs Staff
SIFT	Species Identification Field Test
FSIS Form 10,600-1	Chemical Laboratory Analysis

VI. DEFINITIONS

A. Cooked Products. Formulated, chopped/comminuted or chunked and formed products, e.g., frankfurters, bologna, ham, corned beef, poultry rolls and other similarly prepared products.

B. Like Products. Products that are processed using the same raw materials (species), processing procedures, and are identified with the same name. Examples: Ace Beef Franks and Ace Jumbo Beef Franks would be considered "like" products. Ace

Beef Bologna and Ace Beef Franks would not be considered "like" products.

C. Initial Sample. An in-plant sample collected in accordance with the most recent program monitoring request.

D. Suspect Product Sample. A sample collected from products due to the suspicion that it may contain undeclared species.

E. Verification Sample. Samples collected from cooked product retained as a result of positive Species Identification Field Test (SIFT) results.

F. Species Identification Field Test (SIFT). A rapid method test of officially held product to identify the species of raw materials. Officially held product should continue to be processed; however, it may not leave the official premises until test results indicate acceptable findings.

G. Letter of "Notification". Letter from the Regional Director to plant management regarding sample results of undeclared species and the need for immediate action.

H. Corrective Action Letter. A letter from a plant operator to the Area Supervisor describing in-plant process control checks being made to guard against the inclusion of undeclared species in cooked products.

I. Subsequent Production Sample. A sample collected from retained product prepared following receipt of positive verification sample results and/or positive suspect sample results.

J. Sample Size. Three 1-pound units of finished product for each production lot which are collected using random sampling techniques. Exception: When sampling uncooked product, only collect three 1/4-pound units of emulsion.

K. Hold. Withholding marks of inspection of cooked product until inspection is completed by use of SIFT on raw emulsion.

VII. POLICY

A. Inspection program employees inspect products as often as they deem necessary to ascertain that they are not adulterated or misbranded when they leave the establishment and that they comply with the requirements of the regulations. Product suspected of being adulterated or misbranded shall be retained by the employee for further inspection and, if found to be adulterated or misbranded, is subject to condemnation and

disposal under the regulations (318.2 and 381.145), and may result in criminal prosecutions. The presence in a meat food product or poultry product of animal tissue that purchasers would not reasonably expect to be in the product will result in the product being adulterated and/or misbranded. The meat/poultry portion of meat food products and poultry products is a valuable ingredient and, for purposes of inspection, usually characterizes the product, and the substitution of any of that ingredient with other substances is prohibited by the FMIA and the PPIA. All ingredients must be declared and approved for such use by FSIS (318.7, 319.1, 381.147 and 381.155.) The identity of the finished product and its ingredients must be described on the label approved for that product by FSIS (317.2, 317.4, 317.6, 381.115, 381.118 and 381.132.) Product suspected of being adulterated and/or misbranded due to the presence of undeclared animal tissue shall be sampled and tested to ascertain whether such tissue is present, and shall be further inspected as specified in this directive.

B. FSIS has developed laboratory procedures to identify species tissues in formulated cooked meat and poultry products. The test, an Enzyme Linked Immunosorbent Assay (ELISA), is accurate and, as all immunoassays, is based on antibody-antigen reactions. The test was developed after Agency scientists were able to isolate an antigen that was still reactive after the product had been heated. This test gives FSIS the means to check products' species identification. Further, FSIS has developed in-plant testing procedures capable of identifying pork, poultry, and beef in uncooked, formulated meat and poultry products. The test sample is taken, in-plant, from mixed product formulas just prior to stuffing and cooking. The test, an immunodiffusion plant procedure (SIFT), is accurate, and is also based on antibody-antigen reactions. The SIFT test gives FSIS the means to check uncooked products when there is suspicion of illegal species substitution, and is considered part of the inspection process.

C. The IIC shall discuss the contents of this directive with plant management to assure that they are aware of and understand the FSIS intent and purpose regarding cooked product sampling for species identification.

VIII. PROCEDURES; RESPONSIBILITIES

A. Inspectors shall closely monitor a plant's cooked product activities at all critical control points during processing. For the concerns relative to possible undeclared species determinations, inspectors will emphasize the following and assure that plant operators meet their responsibilities in these areas:

1. The receipt and use of acceptable raw materials at the first point where visual characteristics of these materials can no longer be determined, e.g., after grinding or chopping.

2. The accumulation, identification, and ultimate use of rework materials.

3. The cleanup of equipment and/or acceptable production sequences/time separations between different product formulas.

4. In some operations, an undeclared species could be introduced into products via use of an all-beef rework contained in pork casings or the use of animal source materials, e.g., extracts, stocks, dried blood, hydrolyzed pork skins, non-fat dry milk or powdered eggs as flavorings or binders.

B. Sampling Collection. The IIC will receive computer generated requests from Headquarters to collect monitoring samples of cooked products from particular establishments. However, an inspector may collect additional samples as deemed necessary, e.g., where it is suspected that a product contains undeclared species.

NOTE: IIC will inform plant management immediately prior to any such sample collection.

1. Initial sample collections. The IIC will collect the sample from a single production lot of finished cooked product on hand at the establishment.

2. Subsequent productions will be tested or sampled as instructed in the Attachment.

C. Sample Submission.

1. Individual samples, other than the monitoring samples, shall be accompanied by FSIS Form 10,600-1 (formerly FSIS Form 6200-1).

2. Each FSIS Form 10,600-1 shall contain all required information and shall also include the internal temperature achieved when the product was cooked.

3. Unless otherwise instructed by supervision, IICs will submit all samples for species determinations to the FSIS Microbiology Laboratory servicing their area.

4. When sampling cooked products, the IIC shall specifically identify each sample with the production lot it

represents.

5. The IIC shall inform plant management of all sample results.

D. Actions by IIC Based on Sample Results.

1. Monitoring

a. Initial samples.

(1) Negative findings. Continue in-plant monitoring program sampling.

(2) Positive findings. See Attachment.

b. Subsequent production testing and sample collection actions. See Attachment.

c. Verification samples actions. See Attachment.

2. Suspect product sample collection and actions. See Attachment.

Guidelines for Agency Action in Response to Positive Results of Species Identification Test

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Attachment (See hard copy of the directive for the flow charts.)

FSIS DIRECTIVE 10230.1
ATTACHMENT 1

GUIDELINES FOR AGENCY ACTION IN RESPONSE TO
POSITIVE RESULTS OF SPECIES IDENTIFICATION TEST

I. Samples submitted for species identification determination will be gathered by MPIO as part of a regular in-plant monitoring program.

A. Upon notification of an initial positive sample result, the Regional Director will:

1. Issue a "letter of notification" to the plant operator identifying the problem and actions to be taken. Copies of this letter will be sent to the AS, CS, IIC, and CP.

2. Instruct the IIC to:

a. Sample each lot of "like" product on hand in the plant. (In lieu of sampling, plant may rework or relabel product.) If samples are taken, request the plant to select one of the two following voluntary options:

(1.) To voluntarily hold and segregate all "like" product on hand pending sample results. If results are negative, product may move freely.

(2.) To agree to voluntarily recall all "like" product shipped from the plant which is represented by the sample(s) found positive for undeclared species.

If neither voluntary option is selected, IIC shall notify the Circuit Supervisor as soon as possible.

NOTE: Products found to contain undeclared species from sampling of "like" product on hand at the establishment must either be reworked or relabeled. If product is later found to be adulterated, it may be subject to retention, detention, or seizure actions.

b. Increase surveillance over critical control point areas of the questionable processing procedures.

3. Request that the IIC contact plant operators to:

a. Evaluate product formulations, manufacturing procedures and employee habits and practices related to preparation of "like" product.

b. Request that they prepare a letter to the Area Supervisor identifying the precautions taken to guard against the inclusion of undeclared species in subsequent productions.

c. Advise them that subsequent productions of their products will be tested and held pending results using the SIFT procedures. Individual production lot(s) with negative SIFT results will be released.

4. Inform the IIC that any sample and retain actions as listed in I, A, 3, c above for subsequent productions will continue until products from 5 consecutive production days are

reported as being negative. (See Sample Flow Chart #1.)

B. The IIC shall take the following actions on positive SIFT results:

1. Retain production lot(s) of questionable "like" products from the same day of production of the positive sample and submit verification sample(s) of cooked products to the FSIS laboratory.

a. If verification sample results are negative, release the retained individual lots. The negative verification result will count towards the 5 consecutive production days required in I, A, 4 above.

b. If verification sample results are positive, rework or relabel retained product. Sample and retain subsequent production of "like" product and submit samples to the FSIS laboratory.

2. Continue to sample and retain subsequent productions until 5 consecutive days of negative results have been received.

3. Positive results received during the sample and retain mode shall generate the following actions:

a. Rework or relabel retained "like" product represented by positive findings.

b. Sample and retain other cooked products prepared with the same species.

c. Sample all other cooked products prepared at the plant. Permit these products to move in commerce. Positive tests results on these products will initiate notification and SIFT procedures identified in I, A, 1 through 4 above. (See Sample Flow Chart #2.)

II. The IIC shall take the following actions when it is suspected that a product contains undeclared species.

A. Retain questionable production lot(s) and contact CS for guidance.

B. With concurrence by CS, continue to retain questionable lot(s) and submit samples to the FSIS laboratory. (See Sample Flow Chart #3.)

NOTE: CS contacts the officer in charge, CP, with preliminary information.

1. If sample result is negative, release individual lot.
 2. If verification sample result is positive:
 - a. Rework or relabel retained product.
 - b. Sample and retain subsequent production of "like" product and submit samples to the FSIS laboratory or accredited laboratory.
 - c. Issue a "letter of notification" from the Regional Director to the plant operator identifying the problem and actions to be taken. Copies of this letter will be sent to the AS, CS, IIC, and CP.
- C. Continue to sample and retain subsequent productions until 5 consecutive days of negative results have been received.
- D. Positive results received during the sample and retention mode shall generate the following actions:
1. Rework or relabel retained "like" product represented by positive findings.
 2. Sample and retain other cooked products prepared with same species.
 3. Sample all other cooked products prepared at the plant. Permit these products to move in commerce. Positive test results on these products will initiate notification and SIFT procedures identified in I, A, 1 through 4 above. (See Sample Flow Chart #2.)