

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

FSIS DIRECTIVE

10,240.3

12/9/2002

MICROBIAL SAMPLING OF READY-TO-EAT (RTE) PRODUCTS FOR THE FSIS VERIFICATION TESTING PROGRAM

PART 1 - GENERAL

I. PURPOSE

This directive provides inspection program personnel with instructions for when to sample ready-to-eat (RTE) meat and poultry products produced in official establishments as one aspect of the verification activities conducted by FSIS. **Part 1** provides the purpose, cancellation, references, reason for reissuance and terminology. **Part 2** outlines the type of verification testing FSIS will conduct in establishments, depending upon the risk of the product and operation. **Part 3** outlines the sample collection procedures and the regulatory actions that FSIS will follow should a sample of product test positive for a microbial hazard, including *Listeria monocytogenes* (*L. monocytogenes*), *Salmonella*, and *Escherichia coli* O157:H7 (*E. coli* O157:H7). Part 3 also outlines new Hazard Analysis and Critical Control Point (HACCP) and Sanitation Standard Operating Procedure (Sanitation SOP) verification steps that FSIS will take in establishments to ensure control of *L. monocytogenes* in certain RTE products through control of their processing environments. In particular, Part 3 outlines the regulatory actions FSIS will follow should a food contact surface sample test positive for a microbial contaminant.

II. CANCELLATION

FSIS Directive 10,240.2, Revision 1, Amendment 1, dated 1/24/01

III. REASON FOR REISSUANCE

A. To clarify the procedures that are to be followed by inspection program personnel in establishments that produce certain high, medium, or low risk RTE products, particularly those products subject to exposure to the environment after the lethality step.

B. To include sampling of food contact surfaces, and sampling of other surfaces in the RTE operation, by FSIS in establishments that produce certain RTE products. Such sampling will be conducted initially by specially trained inspection program personnel, including microbiologists.

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

OPI: OPPD

C. To provide the procedures that inspection program personnel will follow when establishments that produce certain RTE products incorporate pathogen and indicator organism testing into their HACCP plans, Sanitation SOPs, and prerequisite programs.

IV. REFERENCES

FSIS Directive 5000.1, dated 11/21/97
FSIS Directive 5400.5, dated 11/21/97
FSIS Directive 8080.1, Revision 3, dated 1/19/00
FSIS Directive 10,200.1 dated 07/19/01
FSIS Directive 10,210.1, Amend. 3, dated 07/01/02
FSIS Directive 11,000.1, dated 1/25/00
Title 9 Code of Federal Regulations (CFR) Part 416
Title 9 CFR Part 417
Title 21 United States Code (U.S.C.) Parts 453 and 601

V. TERMINOLOGY

Environmental Samples – Samples from surfaces that have:

- indirect or potential contact with exposed RTE product in the RTE production area (e.g., mop handles, outer garments, etc., that may be handled by a person who may touch RTE product), or
- no contact with RTE product in a RTE production area (e.g., floors, drains, walls, overhead structures).

Food Contact Surface – For purposes of this directive, a surface of equipment or a utensil with which exposed RTE product has direct contact (e.g., conveyor belt, tabletop, knife blade). A food contact surface does not include aprons, mop handles, gloves, and other items that may have indirect or potential contact with exposed RTE product.

Food Contact Surface Samples – A collection of samples (e.g., swabs) from food contact surfaces that represent the conditions under which the sampled lot was processed. The samples are collected during the production shift, not pre-operational, but without disrupting production, such as during breaks and at the end of a shift.

High or Medium Risk Operation – For purposes of this directive,

A. All establishments defined as large in the July 26, 1996 Pathogen Reduction/Hazard Analysis and Critical Control Point Systems (PR/HACCP) final rule that produce any amount of high or medium risk product;

B. Any establishment defined as a small or very small establishment in the July 26, 1996 final rule that:

1. Produces a large volume of high or medium risk products;
2. Produces any volume of high or medium risk products and has a

history of multiple or recurring sanitation (procedures 01B, 01C, 06D) noncompliance records (NRs) in the in the area of the facility where RTE product is exposed to the environment; or

3. Produces any volume of high or medium risk products and is operating under conditions that have historically been associated with findings of *L. monocytogenes* on product or in the environment (e.g., construction activity that may affect the presence of *Listeria*), but does not have a science-based control program to address this situation.

High or Medium Risk Products – For purposes of this directive, these RTE meat and poultry products are (1) deli-type products (high risk), which include, but are not limited to the following products that either are sliced in the establishment or likely will be sliced at retail (e.g., at a deli counter): cured ham, roast beef or turkey, bologna, luncheon meat, pastrami, and other cold cuts; (2) hot dog-type products (medium risk), which include any meat or poultry products that are cooked sausages -- such as wieners or frankfurters of the type specified in 9 CFR 319.180, 319.181, or a variation of these standardized products; and (3) deli- and hot dog-type products that **have not** been formulated or **are not** produced and distributed under conditions validated to prevent the growth of *L. monocytogenes*.¹

Indicator Organisms – For purposes of this directive, bacteria often used as an indicator for potential presence of a pathogen, not necessarily the pathogen itself. *Listeria spp.* and *Listeria*-like organisms are frequently used as an indicator organism for the potential presence of *L. monocytogenes* contamination.

Lethality Treatment – For purposes of this directive, lethality treatment refers to the necessary reduction in the number of pathogens to result in a product that is safe for consumption without further cooking or application of another lethality treatment to destroy pathogens.

***Listeria monocytogenes* (*L. monocytogenes*)** – A type of pathogenic bacteria often found in the environments in which food producing animals are raised and processed (e.g., in soil, water, and vegetation, and on the surfaces of equipment, floors, and walls).

Listeria spp. - The genus or group of microorganisms that include *L. monocytogenes*. *Listeria spp.* may be present in the processing environment but not all species are pathogens.

Low Risk Operation – For purposes of this directive, any establishment that produces low risk product and:

¹ These RTE meat or poultry products fit into the categories identified by the January 2001, Draft Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods, U.S. Department of Health and Human Services' Food and Drug Administration's Center for Food Safety and Applied Nutrition and the U.S. Department of Agriculture's Food Safety and Inspection Service.

A. Does not have a history of multiple or recurring sanitation (procedures 01B, 01C, 06D) noncompliance records (NRs) in the in the area of the facility where RTE product is exposed to the environment; and

B. Has a science-based control program to address conditions that have historically been associated with findings of *L. monocytogenes* on product or in the environment (e.g., construction activity that may affect the presence of *Listeria*).

Low Risk Products – For purposes of this directive, these RTE meat and poultry products are deli-type products (i.e., products that either are sliced in the establishment or will be sliced at retail) and hot dog type-products (i.e., 9 CFR 319.180-type) that **have been** formulated or **are** produced and distributed under conditions validated to prevent the growth of *L. monocytogenes*. These products are stable with respect to growth of *L. monocytogenes* by any of the following means:

- pH < 4.5
- pH < 5.0 + refrigerated storage
- $a_w < 0.90$ (NOTE: a_w refers to water activity)
- $a_w < 0.92$ + refrigerated storage
- $a_w < 0.95$ + pH < 5.5
- the presence of an antimicrobial agent (e.g., sodium or potassium lactate, sodium diacetate) that has been validated through scientific studies to inhibit growth of *L. monocytogenes*
- Product that is held at or below 0°C (32°F) and is labeled “Keep Frozen” and does not meet the criteria for Not-RTE (see Attachment 2), or
- Product that has received a post-lethality treatment that has been validated to be lethal for *L. monocytogenes*.

Pathogen of Public Health Concern – Any microorganism or other biological agent that has the ability to cause disease in humans. For purposes of this directive, these pathogens include *E. coli* O157:H7, *L. monocytogenes*, and *Salmonella*.

Post Lethality Exposure – Exposure of RTE product directly to a food contact surface after the lethality treatment. Such exposures generally are the result of slicing, peeling, or re-bagging product that previously underwent a lethality treatment to result in RTE status.

Post Lethality Treatment – A lethality treatment after post lethality exposure that is applied to the final product or sealed package and is intended to further reduce the level of potential pathogens, such as *L. monocytogenes*, in RTE products.

Prerequisite Program - For purposes of this directive, prerequisite programs are procedures other than Sanitation SOPs that are designed to provide the basic environmental and operating conditions necessary for the production of safe, wholesome food and to control *L. monocytogenes*. Because of its prerequisite program, an establishment may decide that a food safety hazard (e.g. *L. monocytogenes*) is not reasonably likely to occur in its operation. The establishment would need to document this determination in its Hazard Analysis and include the

procedures (e.g., regular auditing and documentation) it employs to ensure that the program is working and that the hazard is not likely to occur (9 CFR 417.5(a)(1)).

Ready-to-Eat (RTE) Product – Product that is intended to be consumed without any further safety preparation steps. FSIS will sample and test RTE products produced under the following processing categories:

- A. not heat treated—shelf stable (9 CFR 417.2(b)(v), ISP HACCP process 03E)
- B. heat treated—shelf stable (9 CFR 417.2(b)(vi), ISP HACCP process 03F)
- C. fully cooked—not shelf stable (9 CFR 417.2(b)(vii), ISP HACCP process 03G)
- D. product with secondary inhibitors—not shelf stable, (9 CFR 417.2(b)(ix), ISP HACCP process 03I).

NOTE: FSIS is aware that establishments may produce RTE and Not-RTE products under A, B, and D. Attachment 2 provides further guidance regarding how establishments and inspection program personnel may determine whether a product is RTE or Not-RTE. When collecting samples from these categories, inspection program personnel should only collect samples associated with RTE product or production. Also, for products that can be RTE or Not-RTE, inspection program personnel are to collect samples as RTE if the establishment does not follow the guidance for a Not-RTE product as described in Attachment 2.

RTE Product Samples – A collection of sampled RTE product that represents the sampled lot. The samples are taken from product that has passed the establishment's pre-shipment HACCP review. The sampled product should be in its consumer-ready package whenever possible. When this is not possible (e.g., only bulk product is being produced and the immediate container is too large to ship), inspection program personnel may permit the establishment to short-weight or slack-fill the immediate container. In such cases, the sample must be produced and packaged in the same way as the product that it represents; the only difference would be that the contents of the package would be less than the contents of the packages that it represents. Minimum sample sizes for analysis are defined in FSIS Directive 10,210.1 or are provided in block 18 of the sample request form, FSIS Form 10,230-3.

RTE Production Area - An RTE production area is one where exposed RTE products are stored, further processed, or packaged. This is the area from which food contact surface samples and environmental samples are taken and analyzed for indicator organisms or *L. monocytogenes*.

Sampled Lot – Based on the establishment's definition of a lot, the sampled lot would be the amount of product represented by one or more product and food contact surface samples. As a guide, FSIS considers all product produced under a single HACCP plan between performance of complete cleaning and sanitizing procedures (clean-up to clean-up, including start to finish under extended clean-ups) to be an appropriate definition of a sampled lot. In situations where recall, retention, or seizure is necessary, FSIS may determine that more product or less product than that

produced from clean-up to clean-up under the HACCP plan is represented by the sample. In making this determination, FSIS will consider such factors as the establishment's history of practices for setting lot size and the definition of lot size as defined in the establishment's sampling program; coding of product; the pathogen of concern; the processing and packaging; the equipment; the decision-making documents that the establishment is required to maintain under 9 CFR 417.5(a)(2); the establishment's testing under its HACCP plan; the establishment's HACCP plan monitoring and verification activities performed in accordance with 9 CFR 417.2 and 417.4; the establishment's Sanitation SOP records as required in 9 CFR 416.16; and whether some or all of the products controlled by the same or substantially similar HACCP plans have been affected, including whether the establishment has documentation to support that potential contamination would be limited to individual production lines and for individual products.

PART 2 - LISTERIA STATEMENT OF POLICY

GENERAL POLICY REGARDING *LISTERIA* IN HIGH, MEDIUM, or LOW RISK PRODUCTS

This section defines how FSIS will decide the frequency of the verification testing that it will perform in operations that produce deli-type products and hot dog-type products. FSIS inspection program personnel must determine the following: Whether the establishment is producing high or medium risk product or is producing low risk product; whether the establishment has a written science-based program that is part of the HACCP plan, Sanitation SOP, or prerequisite program; and whether the establishment makes available to FSIS all data collected as part of its validation and on-going monitoring and verification activities. See attachments 3 and 4 for flowcharts regarding the type of verification testing program for these products, and for determining the risk category associated with these products.

A. If the establishment produces high or medium risk products and does not have a science-based program addressing *L. monocytogenes* in product, food contact surfaces, and the environment (i.e, in a HACCP plan, Sanitation SOP, or prerequisite program), or has these programs and does not make data from its testing available to FSIS inspection program personnel, FSIS will place this operation into its intensified verification program (Part 3, I.A.).

B. If the establishment produces high or medium risk products and does have a science-based program addressing *L. monocytogenes* in product, food contact surfaces, and the environment, and does make data from its testing available to FSIS inspection program personnel, FSIS will place this operation into its targeted verification program (Part 3, I.B.). If such establishments receive a positive test result for *L. monocytogenes* from FSIS testing, FSIS will consider placing them into the intensified verification program until corrective actions are successful.

C. If the establishment produces low risk products and does not have a science-based program addressing *L. monocytogenes* in product, food contact surfaces, and the environment (i.e, in a HACCP plan, Sanitation SOP, or prerequisite program), FSIS will place this operation into its intensified verification program (Part 3, I.A.).

D. If the establishment produces low risk products and:

1. Does have a science-based program addressing *L. monocytogenes* in product, food contact surfaces, and the environment, and does make data from its testing available to FSIS inspection program personnel, FSIS will place this operation into its low-targeted verification program (Part 3, I.C.).

2. Does have the science-based program identified in D.1 above but does not make data from its testing available to FSIS inspection program personnel, FSIS will place this operation into its targeted verification program. If this establishment receives a positive test result for *L. monocytogenes* from FSIS testing, FSIS will consider placing this operation into the intensified verification program until corrective actions are successful.

PART 3 – RTE PRODUCT, FOOD CONTACT SURFACE, AND ENVIRONMENTAL SAMPLING

I. VERIFICATION TESTING BY FSIS

A. Intensified verification testing program. This program includes, but is not limited to, high, medium, and low risk products produced in establishments that operate under the conditions specified in Part 2 for establishments placed into the intensified verification testing program. When samples of RTE product are scheduled for collection, this program may include instructions to inspection program personnel to collect multiple product, food contact surface, and environmental samples which are intended to be collected on the same day. As a general matter, FSIS will focus its testing in high and medium risk operations. Intensified verification testing will include:

1. Increased frequency and number of samples taken of product for testing (as compared to targeted verification testing) for pathogens of public health concern, and the collection of food contact surface and environmental samples for testing for *L. monocytogenes*, and

2. Increased FSIS record verification checks regarding the implementation of the food safety system, as directed by the frontline supervisor.

B. Targeted verification testing program. This program includes high, medium, and low risk products produced in establishments that operate under the conditions specified in Part 2 for establishments placed into the targeted verification testing program. This program also includes all other RTE products except those under the low-targeted verification testing program described in paragraph C and those under the non-targeted verification testing program listed in paragraph D. FSIS randomly collects one sample of product at a time from an individual establishment and tests for pathogens of public health concern.

C. Low-targeted verification testing program. This program includes low risk products produced in establishments that operate under the conditions specified in Part 2 for establishments placed into the low-targeted verification testing program. In addition, this program includes RTE products other than low risk products that have been formulated or are produced and distributed under conditions validated to prevent the growth of *L. monocytogenes* (see Low Risk Products for a listing of the means by which products are stable with respect to growth). These products, particularly those from low risk operations, will be scheduled at a decreased frequency for product testing (as compared to targeted verification testing) for pathogens of public health concern. FSIS randomly collects one sample of product at a time from an individual establishment and tests for pathogens of public health concern.

D. Non-targeted verification testing program. FSIS will direct inspection program personnel to collect product samples, as necessary, in operations that exclusively produce the types of products listed below:

- a. Lard,
- b. Margarine,
- c. Lard margarine,
- d. Mixtures of rendered animal fats,
- e. Popped pork skins,
- f. Pork rinds,
- g. Dried soup bases,
- h. Concentrated (high salt content) soup mixes,
- i. Pickled pig's feet, or
- j. Product labeled "For Further Processing" in which the product is expected to receive a lethality treatment

II. **SAMPLING**

A. Product and pathogen selection. FSIS Directive 10,210.1 Amendment 3, Unified Sampling Form, lists the products and pathogens for which FSIS may test samples. For example, FSIS may analyze a not heat treated, not shelf stable RTE meat and poultry product for *Salmonella* AND *L. monocytogenes*, and if the product is a dry or semi-dry fermented beef sausage, the product will also be analyzed for *E. coli* O157:H7.

B. Notification of sample request. When the Office of Public Health and Science (OPHS) schedules a sample from a lot of RTE product to be taken at an establishment, the Inspector-in-Charge (IIC) receives FSIS Form 10,210-3, "Requested Sample Programs" from OPHS. Generally, only one sample request form will be sent to the IIC. The District Office (DO) will coordinate the random sampling of a lot of high, medium, or low risk product and the collection of environmental samples. When the forms are sent, certain blocks will be preprinted with information specific to the sample to be collected. Using the project code in Block 14 of the forms, follow the corresponding instructions found in FSIS Directive 10,210.1, Amend. 3 for collecting and shipping samples.

C. Informing the establishment regarding sample collection. Inspection

program personnel should provide the establishment management enough time to hold all product that the establishment determines to be represented by the sample (i.e., the sampled lot). In some cases, inspection program personnel may need to inform the establishment a number of hours or days in advance, such as for establishments operating under an extended clean-up or because of the production process involved (e.g., the production of dry and semi-dry fermented sausages).

D. Informing the establishment about holding product. Establishments are not required to hold product represented by the sampled lot. However, to reduce the risk of a recall, FSIS recommends that establishments should hold product represented by the sample until the test results confirm that a pathogen of public health concern is not present in product or food contact surface samples.

E. Personnel collecting samples. Inspection program personnel will collect product samples. However, trained program personnel other than the in-plant inspection employees may be directed to collect food contact surface and environmental samples (i.e., the samples from the food contact surface, the indirect food contact surface, and the surfaces that do not contact food). The collection of food contact surface and environmental samples is not intended to replace product sampling by FSIS. These non-product samples will provide helpful information to FSIS regarding the sanitary conditions in the RTE production area of the establishment, but special skills and training are required in order to collect these non-product samples.

F. Sample collection and submittal timeframes. If possible, **only** collect and mail the samples from the establishment's current day's production that has passed the establishment's pre-shipment record review (see 9 CFR 417.5(c)). If not possible, such as in establishments where production is held off-site prior to completion of the pre-shipment record review, or the pre-shipment record review is performed at a later date, collect samples of the current day's production, refrigerate or freeze them, keep them in a secure location, and postpone mailing the samples until the pre-shipment record review is complete, and the product is eligible for shipment. After the establishment completes the pre-shipment record review, inspection program personnel should prepare the samples to be sent to the laboratory on the next available Federal Express pickup day.

G. Sample collection decisions. Any in-plant sampling for *L. monocytogenes* to be performed under the intensified verification testing program will be coordinated through the DO. Any sampling of establishments under the targeted, low-targeted, and non-targeted verification testing program is performed by the in-plant inspection program personnel as per the sample request form. If a change in operations or conditions at an establishment results in a need to change the establishment to the intensified verification testing program (e.g., type of product produced changes; construction), the in-plant inspection program personnel would notify their frontline supervisor. The inspection program personnel in the plant would have a first-hand knowledge about the operations in that establishment. FSIS may direct the inspection program personnel to pull additional samples, but such instructions would come from the DO and specially trained inspection program personnel would collect any food contact or environmental samples in these situations.

H. Completion of sample request form and inspection procedure. Sample request form. Complete all requested information in Part 2 of the FSIS Form 10,210-3, as described in FSIS Directive 10,210.1, Amend. 3. The FSIS laboratories will discard any samples with incomplete forms.

III. FSIS ACTIONS WHEN PRODUCT, FOOD CONTACT SURFACE, OR ENVIRONMENTAL SAMPLES ASSOCIATED WITH HIGH, MEDIUM, OR LOW RISK PRODUCT TEST POSITIVE FOR *LISTERIA*

A. Product Testing by FSIS or the Establishment for *L. monocytogenes*

When an FSIS or establishment product sample tests positive for *L. monocytogenes*, the sampled lot is adulterated and inspection program personnel take the appropriate action as set out in FSIS Directive 5000.1, FSIS Directive 11,000.1, and FSIS Notice 29-02. FSIS will request a recall if any product in the sampled lot has been shipped.

B. Food Contact Surface Testing by FSIS or the Establishment for *L. monocytogenes*

When an FSIS or establishment food contact surface sample tests positive for *L. monocytogenes*, product from the sampled lot is adulterated, and inspection program personnel take the appropriate action as set out in FSIS Directive 5000.1, FSIS Directive 5400.5, FSIS Directive 11,000.1, and FSIS Notice 29-02. FSIS will request a recall if any product in the sampled lot has been shipped. (NOTE: On a case-by-cases basis, for low risk products that have a post-lethality treatment subsequent to contact with the implicated food contact surface, and the treatment has been validated to be lethal for *L. monocytogenes*, FSIS will determine whether to request a recall).

C. Environmental Testing by FSIS for *L. monocytogenes*

When an indirect or a non-food contact surface sample from the RTE production area collected by FSIS tests positive for *L. monocytogenes*, inspection program personnel are to take the appropriate action as set out in FSIS Directive 5400.5 and FSIS Directive 11,000.1 and inform the establishment so that the establishment can take corrective actions as described in its HACCP Plan, Sanitation SOP, or prerequisite program, or to reassess these programs if they do not include corrective actions for the presence of this pathogen in the environment. Trained inspection program personnel may be directed to take additional environmental samples, as well as food contact surface and product samples.

D. Food Contact Surface Testing by the Establishment for Indicator Organisms

1. If a food contact surface sample tests positive for indicator organisms (the establishment is not testing for *L. monocytogenes*; thus, FSIS would not have a basis to definitively conclude that the product is adulterated) in an establishment's testing program, inspection program personnel are to verify that the establishment takes the corrective actions it has developed, whether as part of a HACCP plan, Sanitation SOP,

or prerequisite program as specified in FSIS Directive 5000.1, FSIS Directive 5400.5, FSIS Directive 11,000.1, and FSIS Notice 29-02.

2. FSIS expects that a properly designed, science-based preventative program for *L. monocytogenes* will include features such that the establishment takes additional steps to thoroughly clean and sanitize potentially contaminated food contact surfaces and increase the number of food contact surface samples that it takes, particularly of the areas represented by the initial positive, in an effort to find the source of the contamination and to prevent harborage. If any of these follow-up samples are positive as a consequence of this intense searching for potential sources of contamination, inspection program personnel are to verify that the establishment takes the corrective actions it has developed. A properly designed, science-based preventative program may include procedures such as holding and testing product after corrective actions in order to verify that harborage has been prevented. In such cases, inspection program personnel are to verify that the establishment has identified and implemented the conditions in which hold and test procedures for affected product will be initiated by the establishment and the conditions in which hold and test procedures for affected product will be terminated by the establishment.

3. On an ongoing basis, inspection program personnel are to review the laboratory results of the establishment's food contact surface testing program. If multiple positive samples for indicator organisms are detected, either within consecutive samples or non-consecutive samples within a relatively short time span, and the establishment did not take the corrective and preventative action outlined in the establishment's plan, inspection program personnel should immediately contact their frontline supervisor. A CSO may be assigned by the DO to review the control measures included in HACCP plans, Sanitation SOPs, or prerequisite programs. The CSO will assess the establishment's total system to verify that the establishment has designed its testing procedures so that if indicator organisms or *L. monocytogenes* are detected, the establishment has in place procedures to effectively address their presence. The CSO will review written procedures, assess decision-making documents for completeness and rationale, and review laboratory results.

E. Environmental Testing by the Establishment for Indicator Organisms or *L. monocytogenes*

When an indirect or a non-food contact surface sample from the RTE production area collected by the establishment tests positive for an indicator organism or *L. monocytogenes*, inspection program personnel are to verify that the establishment has taken corrective actions as described in the establishment's HACCP Plan, Sanitation SOP, or prerequisite program. Trained FSIS inspection program personnel may be directed to take environmental samples, as well as food contact surface and product samples.

IV. FSIS ACTIONS WHEN PRODUCT SAMPLES ASSOCIATED WITH ANY RTE PRODUCT OTHER THAN HIGH, MEDIUM, OR LOW RISK PRODUCT TEST POSITIVE FOR A PATHOGEN OF PUBLIC HEALTH CONCERN

When an FSIS or establishment product sample tests positive for a pathogen of a

public health concern, including *L. monocytogenes*, the sampled lot is adulterated and inspection program personnel take the appropriate action as set out in FSIS Directive 5000.1, FSIS Directive 11,000.1, and FSIS Notice 29-02. FSIS will request a recall if any product in the sampled lot has been shipped.

V. FSIS ACTIONS WHEN FOOD CONTACT SURFACE SAMPLES ASSOCIATED WITH ANY POST-LETHALITY EXPOSED RTE PRODUCT OTHER THAN HIGH, MEDIUM, OR LOW RISK PRODUCT TEST POSITIVE FOR *L. MONOCYTOGENES*

When an FSIS or establishment food contact surface sample tests positive for *L. monocytogenes*, the sampled lot is adulterated and inspection program personnel take the appropriate action as set out in FSIS Directive 5000.1, FSIS Directive 11,000.1, and FSIS Notice 29-02. FSIS will request a recall if any product in the sampled lot has been shipped. (NOTE: On a case-by-case basis, for RTE products that have a post-lethality treatment subsequent to contact with the implicated food contact surface, and the treatment has been validated to be lethal for *L. monocytogenes*, FSIS will determine whether to request a recall).

Refer technical questions to the Technical Service Center.

Philip S. Derfler /s/

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QUESTIONS AND ANSWERS

(Attachment 1)

SAMPLE COLLECTION

1. **Question:** Are establishments required to hold the lot that is sampled?

Answer: No. Establishments are not obligated to hold any product when inspection program personnel collect samples. As has been FSIS policy and practice as instructed in FSIS Directive 10,210.1, inspection program personnel are to notify establishments sufficiently early to provide them the opportunity to hold the entire lot represented by the sample. Establishments' willingness to hold sampled lots becomes an important public health benefit if a sampled lot is found to be positive for a pathogen. Inspection program personnel will ensure that plants are appropriately notified.

2. **Question:** When should inspection program personnel submit samples?

Answer: The pre-shipment review must be completed before the samples are sent to the laboratory for analysis.

3. **Question:** If a sample is collected on a Friday but not picked up by Federal Express on that day, and if the next scheduled pick up is Monday, can the sample be kept in the cooler or freezer until Monday and then shipped?

Answer: Inspection program personnel should try to avoid holding samples over the weekend whenever possible because the establishment would most likely be holding the sampled lot. If Federal Express cannot pick up the sample on the day of collection, inspection program personnel can refrigerate or freeze the sample until it can be picked up. However, inspection program personnel should not hold samples for more than three days (i.e., Friday to Monday) prior to shipping.

4. **Question:** If inspection program personnel already have sample request forms issued under FSIS 10,240.2, what should they do?

Answer: With the issuance of FSIS Directive 10,240.3, Directive 10,240.2 (including Section VIII of that Directive) was canceled. With Directive 10,240.3, there no longer is any condition in which establishments can get "exempted" from FSIS verification testing. Therefore, inspection program personnel should collect samples according to the timeframes identified on the sample request forms and regardless of whether the form was issued before or after implementation of FSIS Directive 10,240.3.

5. **Question:** Will existing RTE sample request projects (HV03E, HV03F, HV03G, and HV03I) be terminated?

Answer: At this time, FSIS expects to terminate these specific programs and identify new project codes with new names. Although the December 2002 forms have already been generated and distributed with these project codes, FSIS now expects to issue the January 2003 and subsequent sample request forms with the project code "Targeted." December 2002 forms should be collected as normal following the instructions on the form and FSIS Directive 10,210.1. The forms for January 2003 and subsequent months should be collected following the new instructions on the form and referencing FSIS Directive 10240.3. If you have any questions on collecting RTE samples, please contact the Technical Service Center for assistance.

SAMPLE RESULTS

6. **Question:** If an establishment delivered product from a sampled lot to a customer but retrieved all of it before the report of the FSIS sample result, will the product be deemed to have been shipped?

Answer: Yes, once an establishment completes its pre-shipment record review, the product is considered as "shipped" or "eligible for shipment." Upon report of a positive result, establishments are expected to prevent product from entering commerce in accordance with sections 9 CFR 417.3(a)(4) or (b)(3) of the regulations and to treat it in a manner that will make it no longer adulterated. Product adulterated with a pathogen that is not treated in such a manner will be condemned. Inspection program personnel are not to take any regulatory control actions unless the establishment fails to control product as specified in 9 CFR 417.3(a)(4) or (b)(3).

7. **Question:** If an FSIS product or food contact surface sample tests positive, what is the status of product(s) produced on days subsequent to the day the sample was collected?

Answer: In general, FSIS does not consider product that is produced on days subsequent to the day of sampling and that is coded differently from the sampled lot to be represented by the sample, and under most circumstances not subject to retention, detention, or voluntary recall. A positive sample does call into question the adequacy of an establishment's process for producing safe product. Upon report of a positive sample, inspection program personnel will perform the appropriate HACCP 02 procedure on the product's HACCP plan, and an 01B01 and an 01C01 procedure on the establishment's Sanitation SOPs covering the time period from when the sample was collected to the present. If the findings of these procedures indicate that the establishment shipped adulterated product other than the sampled lot, this additional product would be subject to detention, voluntary recall, or seizure. For example, if inspection program personnel found that the establishment failed to meet the critical limit at the cooking CCP and took no corrective action on subsequent lots, all product affected by this failure is subject to retention, detention, voluntary recall, or seizure.

8. **Question:** Does a sample test result that is positive for *Listeria* spp. microorganisms indicate that the product is adulterated?

Answer: No. However, FSIS considers a finding of *Listeria* spp. microorganisms on product or a food contact surface to be an indication that the process may not be appropriately controlled. In high or medium risk operations, FSIS intends to conduct intensified verification reviews of the establishment's food safety system when *Listeria* spp. or *Listeria*-like results are found and there is no scientifically-based procedure in place to address this sanitation concern. This may include taking new verification samples of product and of the environment.

9. **Question:** If a RTE product tested by FSIS is found positive for a pathogen, is the HACCP plan automatically inadequate, and should the inspector immediately take a withholding action?

Answer: Not necessarily. As noted in the directive, the Agency will take into account all available information and consider the entire situation before making a determination of HACCP plan inadequacy. The cause and significance of a positive result varies from case to case based on the pathogen found, and the circumstances of processing involved. FSIS will consider whether some or all products produced under the same or a substantially similar HACCP plan are affected, whether there have been other incidents of product contamination with the pathogen, and whether incidents of product contamination have been persistent or recurring. Establishments are required to take corrective and preventive actions in accordance with 9 CFR 417.3. In regard to a withholding action, inspection program personnel will follow the procedures in FSIS Directive 5000.1, Part II and III, and 9 CFR Part 500. If the IIC determines, based on the available information, that the establishment is continuing to produce and ship product that may be injurious to health, he or she should withhold the marks of inspection and inform the DO.

10. **Question:** If an establishment tests for indicator organisms and has a second positive result for indicator organisms does this mean that the establishments control and testing programs that are incorporated into their Sanitation SOPs or prerequisite programs are automatically invalid?

Answer: No. FSIS will take into consideration how the establishment responds to the positives, the type of intensified testing the establishment conducts, and the conditions that may have led to the second positive. In some cases, the second positive may have occurred from lack of proper execution of control programs and in other cases may indicate a design problem. In cases that involve a design problem such that there are repetitive positive findings, FSIS may place the establishment into the intensified testing program until FSIS determines that the establishment has implemented the proper corrective and preventive measures.

11. **Question:** Can establishments use product that tested positive for a pathogen as "re-work?" Are there special restrictions?

Answer: The regulations do not prohibit the use of product that tested positive for a pathogen as “re-work.” An establishment is expected to address the use of such product in its HACCP plan. The plan must address any hazards presented by the practice such as the potential hazard of increased tolerance of bacteria that survived a “kill” step. If the practice of re-working such product is done all the time, then critical limits and CCPs need to account for any potential added hazards. If the practice is done occasionally, the plan may only need to address the procedures, critical limits, and CCPs to be met when lots containing re-work are processed. When product that tested positive is identified after it has left an establishment, it may be moved under control to an establishment where it can be further processed.

FOLLOW-UP SAMPLING

12. **Question:** During follow-up verification sampling that may be scheduled from headquarters, must the samples be collected on consecutive production days?

Answer: The form should come with a note that instructs the inspection program employee to collect the samples within 60 days, if possible. Samples do not have to be collected on consecutive production days. The purpose of the follow-up sampling is to verify the effectiveness of the establishment’s corrective and preventive measures.

INSPECTION ACTIVITIES

13. **Question:** When an environmental sample (indirect or non-food contact) taken in an RTE production area by FSIS under the intensified verification program results in a positive finding of *L monocytogenes*, how do inspection program personnel document the finding?

Answer: Inspection program personnel should document the sample result on an NR using procedure code 06D01, with the trend indicator Facility/Product Based. In addition, the NR should reference 416.4(b) as the regulatory citation.

14. **Question:** When a food contact surface sample taken in an RTE production area by FSIS under the intensified verification program results in a positive finding of *L monocytogenes*, how do inspection program personnel document the result?

Answer: Inspection program personnel should document the sample result on an NR using procedure code 01C02, with the trend indicator Sanitation SOP/Implementation. In addition, the NR should reference 416.14 as the regulatory citation.

15. **Question:** If an establishment has a science-based environmental sampling program incorporated into its HACCP plan, Sanitation SOP, or prerequisite program and its sample of a food contact surface results in a positive finding of *L monocytogenes*, what should inspection program personnel do?

Answer: Inspection program personnel should verify that the establishment has taken the appropriate corrective action, as outlined within the establishment's environmental sampling program, and all regulatory requirements have been met. If the program is contained within the establishment's HACCP plan, inspection program personnel should verify that the requirements within 417.3 (a) are met. If the program is contained within the establishment's Sanitation SOPs, inspection program personnel should verify that the requirements within 416.15 are met. If the program is contained within a prerequisite program, inspection program personnel should verify that all procedures outlined within the program are followed.

16. **Question:** If an establishment's food contact surface sample results in a positive finding of *L monocytogenes* and the establishment does not take corrective action as outlined in their science-based environmental sampling program, how do inspection program personnel document this?

Answer: The type of documentation will depend on where in the establishment's food safety system the environmental sampling procedure is addressed.

- If the establishment's sampling program is addressed within their Sanitation SOPs, inspection program personnel should write an NR using procedure 01B01 or 01C01, whichever is appropriate, with the trend indicator Sanitation SOP/implementation. In addition, the NR should reference 416.14 as the regulatory citation.
- If the establishment's sampling program is addressed within their HACCP plan, inspection program personnel should write an NR using the appropriate HACCP 03 procedure with the trend indicator HACCP/Corrective Action. In addition, the NR should reference 417.3(a) or (b), whichever is appropriate, as the regulatory citation.
- If the establishment's sampling program is addressed outside of their HACCP plan or Sanitation SOPs, as a prerequisite program supporting their hazard analysis, inspection program personnel should write an NR using the appropriate HACCP 03 procedure with the trend indicator HACCP/Recordkeeping. In addition, the NR should reference 417.5 (a)(1) as the regulatory citation.

17. **Question:** Are there situations in which inspection program personnel may submit an inspector-generated sample?

Answer: Yes, depending on situations taking place within the establishment, inspection program personnel may feel that it is necessary to request permission for collecting and submitting an inspector-generated sample. For example, an establishment produces a low risk product and is in the low-targeted verification testing program. Inspection program personnel observe that the establishment has modified the production process for this product and it no longer satisfies the conditions for low risk; the product now is a high risk product but the establishment has not modified its environmental control program to address this situation. In this situation, after consulting with his or her frontline supervisor, inspection program personnel obtain permission to collect the sample, and obtain FSIS 10,210-3 Requested Sample Form through channels from the Office of Public Health and

Science prior to collecting a “for cause” sample. Remember, inspection program personnel are to consult with his or her frontline supervisor before taking any inspector-generated sample.

18. **Question:** If inspection program personnel have not received a sample request form in a number of months, should he or she take an inspector-generated sample?

Answer: No, inspector-generated samples should not be submitted solely because the inspector has not received a generated sample request in the past few months. Under its sampling programs, FSIS will concentrate its resources on high or medium risk operations that do not have science-based programs or that do not share their data. Consequently, there may be times when certain products and operations will be sampled less frequently than in the past.

19. **Question:** If an establishment is utilizing sliced deli meats or hot dogs in a Heat Treated, but not Fully Cooked, Not Shelf-Stable product (Not-ready-to-eat) multi-component product such as a frozen meal, dinner, entree, or hot sandwich, are the finished products or in-process deli-meats or hot dogs categorized as a high or medium risk product and subject to the intensified verification testing program?

Answer: If the meat or poultry component received an adequate lethality treatment for pathogens; cooking and preparation instructions on the product are sufficient to destroy pathogens; instructions are realistic for the intended consumer and proper caution statements such as those described in Attachment 2, ISP 0H3 are utilized, the finished product as well as the sliced deli meat portion or hot dogs would not be categorized as high or medium risk product and are not subject to the intensified verification testing program.

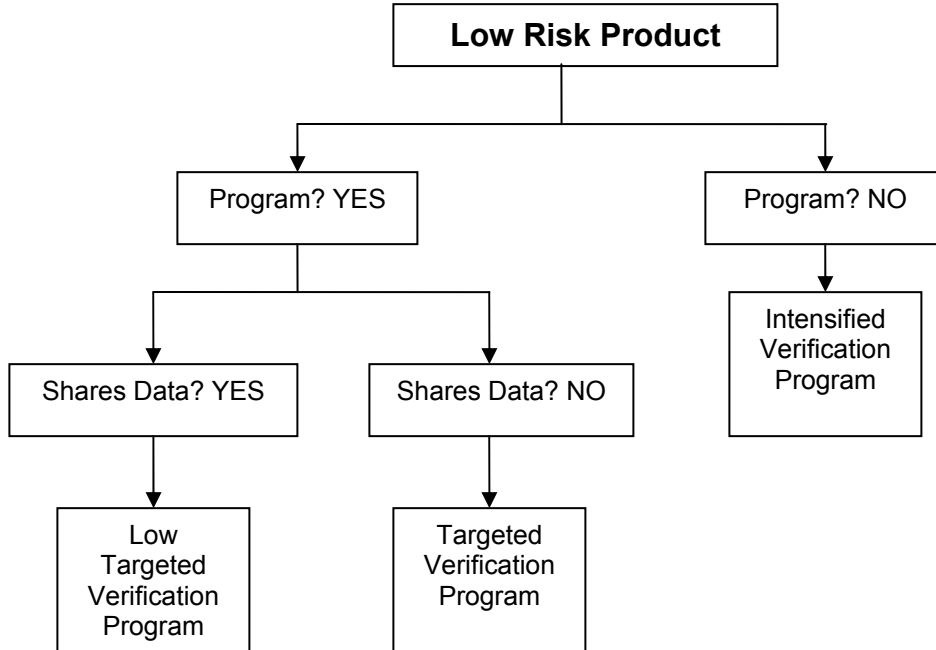
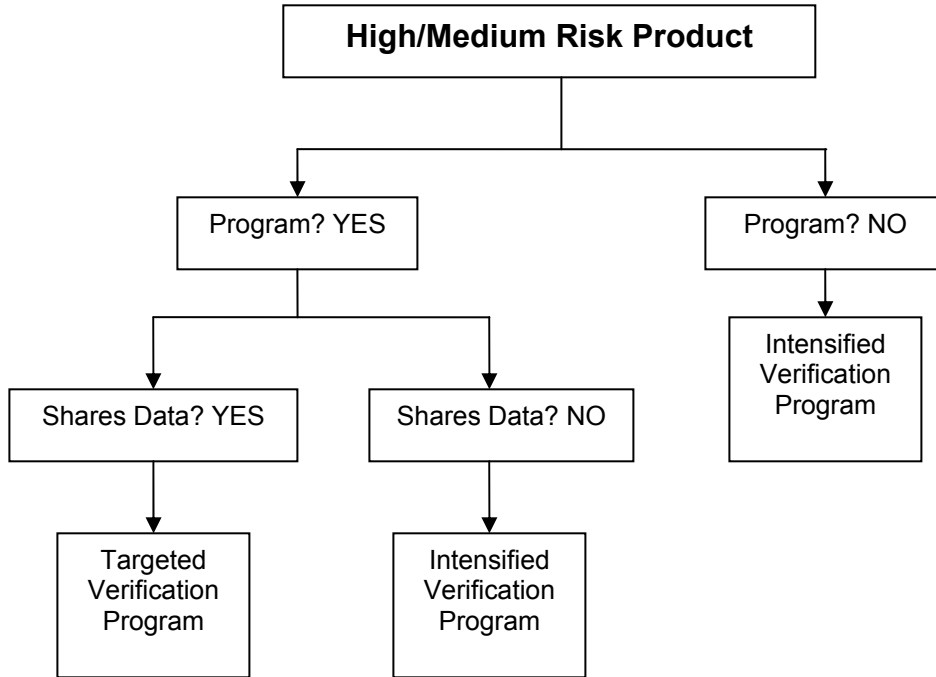
20. **Question:** What are the expectations regarding environmental testing for low risk products that receive a post-packaging lethality treatment validated to destroy any *L. monocytogenes* that might be present?

Answer: The FSIS public health focus is on products that have a greater likelihood of becoming contaminated after the lethality step, and on products that support the growth of *L. monocytogenes*. Products that receive a lethality treatment after they are in their final packaging, validated to be effective under the operational conditions in the establishment, are unlikely to become further contaminated. In addition, such establishments may not routinely test food contact surfaces or the environment where these products are produced.

Attachment 2

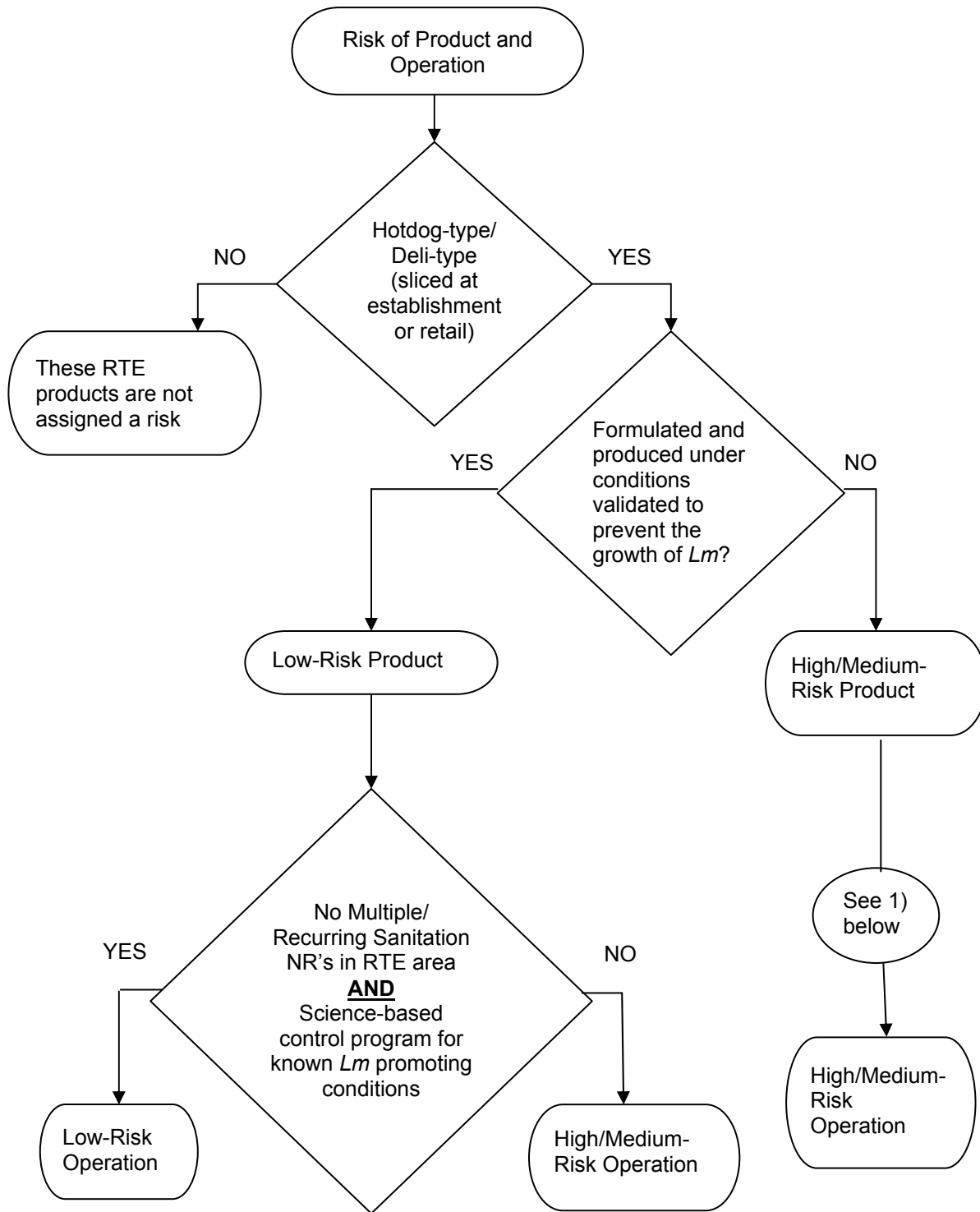
TYPE	CLASS	PROCESSING CATEGORY ISP CODE	REG REQUIRED SAFETY LABELING	WHAT THE HAZARD ANALYSIS/HACCP PLAN MAY ADDRESS
A product containing a meat/poultry product (in whole or in part) which has not received an adequate lethality treatment for pathogens (i.e. raw or partially cooked product).	Not-ready-to-eat	<ul style="list-style-type: none"> • Raw Product Ground – ISP 03B • Raw Product Not Ground – ISP 03C • Not Heat Treated Shelf Stable – ISP 03E • Heat Treated –shelf stable – ISP 03F • Heat Treated but not Fully Cooked Not Shelf Stable - ISP 03H • Products with secondary inhibitors Not Shelf Stable – ISP 03I • 	Product must be labeled with statements such as keep refrigerated, keep frozen, or refrigerate leftovers. Use of Safe Handling Instruction (SHI) labeling required.	<ul style="list-style-type: none"> • Use of SHI labeling (Some establishments may have a CCP for SHI labeling application). <p>If it is not obvious that the product is raw and needs to be cooked:</p> <ul style="list-style-type: none"> • Features on labeling are conspicuous so that intended user is fully aware that product must be cooked for safety. This is best conveyed through the product name (e.g., “Cook and Serve”) but may also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel, or by a burst stating such things as “needs to be fully cooked,” “see cooking instructions,” or “cook before eating.” • Validation that: <ol style="list-style-type: none"> a. Cooking and preparation instructions on the product are sufficient to destroy pathogens. b. Instructions are realistic for the intended consumer.
A product containing a meat/poultry component that has received a lethality treatment for pathogens in combination with non-meat/poultry components that need to receive a lethality treatment by the intended user. This includes meals, dinners, and frozen entrees.	Not-ready-to-eat	<ul style="list-style-type: none"> • Heat Treated but not Fully Cooked Not Shelf Stable - ISP 03H 	Product must be labeled with statements such as keep refrigerated or frozen. Use of SHI labeling is recommended.	<ul style="list-style-type: none"> • Validation that: <ol style="list-style-type: none"> a. The meat/poultry component received an adequate lethality treatment for pathogens. b. Cooking and preparation instructions on the product are sufficient to destroy pathogens. c. Instructions are realistic for the intended consumer. • Features on labeling are conspicuous so that intended user is fully aware that product must be cooked for safety. This is best conveyed through the product name (e.g., “Cook and Serve”) but may also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel, or by a burst stating such things as “needs to be fully cooked,” “see cooking instructions,” or “cook before eating.” • If necessary, hazard analysis should address whether instructions on the label are needed related to cross-contamination (e.g., avoid contact of contents) and prevention of pathogenic growth (e.g., promptly refrigerate leftovers). <p>NOTE: Inspection program personnel are to collect samples as RTE if the establishment does not follow the guidance above.</p>
A product containing a meat/poultry component that has received a lethality treatment for pathogens that may or may not be in combination with a non-meat/ poultry component that does not need to receive a lethality treatment by the intended user.	Ready-to-eat	<ul style="list-style-type: none"> • Not Heat Treated Shelf Stable – ISP 03E • Heat Treated Shelf Stable – ISP 03F • Fully Cooked Not Shelf Stable – ISP 03G • Products with secondary inhibitors Not Shelf Stable – ISP 03I 	If the product is not shelf stable labeling such as keep refrigerated or frozen is required.	<ul style="list-style-type: none"> • See part 417 of the meat and poultry regulations.

Attachment 3
Flowchart: Verification Testing Program for High, Medium, and Low Risk Products



Attachment 4

Flowchart: Determining Risk of Product and Operation



1) Establishment size, volume of product, history of sanitation NR's, and operating under conditions known to promote growth of Lm (e.g., construction), are factors FSIS takes into consideration when scheduling sampling. These are not factors in-plant personnel currently need to consider for the purposes of this issuance.