

# FSIS DIRECTIVE

10,240.2  
Revision 1

12/1/2000

## MICROBIAL SAMPLING OF READY-TO-EAT (RTE) PRODUCTS

### I. PURPOSE

This directive provides inspection program personnel with instructions for sampling ready-to-eat (RTE) meat and poultry products produced in official establishments. Additionally, it outlines the regulatory actions FSIS will initiate when a sample of such product tests positive for a microbial hazard, such as *Salmonella*, *Listeria monocytogenes*, *E. coli* O157:H7, and *staphylococcal enterotoxin*. **NOTE: DO NOT IMPLEMENT THE INSTRUCTIONS IN THIS DIRECTIVE UNTIL DECEMBER 1, 2000.**

### II. CANCELLATION

FSIS Directive 10,240.2, Amendment 1, dated 12-18-98  
FSIS Directive 10,240.1, Revision 1, dated 8-30-90

### III. REASON FOR RE-ISSUANCE

A. to clarify the role of FSIS microbiological sampling of RTE product under HACCP.

B. to provide the procedures inspection program personnel follow when an establishment that produces RTE product incorporates pathogen testing into its Sanitation SOP's and HACCP plans.

### IV. REFERENCES

Part 417 of the Federal meat and poultry products inspection regulations  
FSIS Directive 10,210.1, Amend. 2, dated 10/16/00  
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

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

**OPI: OPPDE**

## V. TERMINOLOGY

*What terms will we use in this directive?*

**Ready-to-Eat (RTE) Product** – Product that is intended to be consumed without any further safety preparation steps. Attachment 2 provides further guidance regarding how establishments and inspection program personnel may determine whether a product is RTE or not. 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 activity number 03E)
- B. heat treated—shelf stable (9 CFR 417.2(b)(vi), ISP activity number 03F)
- C. fully cooked—not shelf stable (9 CFR 417.2(b)(vii), ISP activity number 03G)
- D. product with secondary inhibitors—not shelf stable, (9 CFR 417.2(b)(ix), ISP number 03I). **NOTE:** Establishments may produce RTE and Not-RTE products under this category. However, when collecting samples from this category, inspection program personnel should only collect RTE product.

**Sample** – A collection of product that represents a larger group (the sampled lot) that has passed the establishment's pre-shipment HACCP review. The sample should be in its consumer-ready package state whenever possible. When this is not possible (e.g., the shipping container is too large to mail), inspection program personnel may permit the establishment to short-weight or slack-fill a container. In such cases, the sample must be produced in the same way as the rest of the product it represents; the only difference would be the size of the package. 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.

**Sampled Lot** - This is the amount of product represented by the sample. The establishment defines the sampled lot. 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 coding of product; the pathogen of concern; the processing and packaging; the equipment; the establishment's testing under its HACCP plan; the establishment's HACCP plan monitoring and verification activities performed in accordance with 417.2 and 417.4; Sanitation SOP records as required in 416.16; and whether some or all of the products controlled by the same or substantially similar HACCP plans have been affected.

## VI. POLICY

A. FSIS verifies the adequacy of an establishment's HACCP system by determining whether HACCP plans meet the requirements of 9 CFR Part 417 and all other applicable regulations, and whether the system is being operated as planned. Verification activities include, but are not limited to, collecting and testing RTE products for microbial hazards. FSIS Directive 10,210.1 Amendment 2, Unified Sampling Form, lists the products and pathogens and toxins for which FSIS may test samples. For example, FSIS may analyze a not heat treated, shelf stable ready-to-eat meat and poultry product for *Salmonella* AND *Listeria monocytogenes*, and if the product is a dry or semi-dry fermented sausages, the product will also be analyzed for *E. coli* O157:H7 and staphylococcal enterotoxin.

B. If a sample tests positive for a microbial hazard, FSIS expects establishments to: (1) take corrective and preventive measures and conduct reassessments in accordance with 9 CFR Part 417 and (2) recall from commerce any product represented by that sample. Inspection program personnel will follow the instructions in FSIS Directive 5000.1 to verify that the establishment complied with 9 CFR part 417. The Recall Management Division (RMD) will coordinate any recall activity as outlined in FSIS Directive 8080.1, Revision 3. Note: The cause of a positive finding in RTE product varies from case to case, based on the pathogen or toxin found, and the type of processing involved. Before making its determination, FSIS will consider the entire situation. This includes whether some or all products produced under the same or a substantially similar HACCP plan have been affected, what pathogens or toxins are involved, whether there have been any other incidents of contamination in the establishment associated with the pathogen or toxin, and whether there have been persistent and recurring noncompliances in the establishment.

## VII. SAMPLING

*What are the sampling procedures?*

A. When a sample is scheduled to be taken at an establishment, the Inspector-in-Charge (IIC) receives FSIS Form 10,210-3, "Requested Sample Programs" from the Office of Public Health and Science (OPHS). When the form is sent, certain blocks will be pre-printed with information specific to the sample to be collected. Using the project code in **Block 14** of the form, follow the corresponding instructions found in FSIS Directive 10,210.1, Amend. 2 for collecting and shipping samples. **NOTE:** OPHS has changed the project code numbers in **Block 14** to correspond to the 03 HACCP processing categories (see definition of RTE products).

B. Unless the establishment meets the criteria in section VIII, randomly collect a sample from a RTE product produced under the project number listed in **Block 14** of FSIS Form 10,210-3. The IIC will oversee the sample collection to ensure that different products are sampled each time sample request forms are received.

C. Provide the establishment management enough time to hold all product the establishment determines to be represented by the sample, i.e., the sampled lot. Coordinate with the establishment management to determine at what time to provide the notification. 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. 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 § 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 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 review, inspection program personnel should prepare the samples to be sent to the laboratory on the next available Federal Express pickup day.

E. Complete all requested information in Part II of the FSIS Form 10,210-3, as described in FSIS Directive 10,210.1, Amend. 2. The FSIS laboratories are to discard any samples with incomplete forms.

F. Record the sample collection as a performed, unscheduled 05B02 on FSIS Form 5400-5.

## **VIII. Verification of Establishment Testing**

### *When should samples not be collected?*

Unless otherwise instructed via the FSIS Form 10,210-3, inspection program personnel should not collect samples at an establishment that:

A. At a minimum, tests one RTE product per HACCP plan for the pathogens and toxins listed in **Block 13** of FSIS Form 10,210-3 once a month; or

B. At a minimum, tests one RTE product per HACCP plan for the

pathogens and toxins listed in **Block 13** of FSIS Form 10,210-3 once every 3 months provided that the establishment:

1. conducts on-going food contact surface and non-food contact surface testing for indicator organisms such as *Listeria spp.*, and
2. conducts targeted product testing for *L. monocytogenes*, when there is a positive result of *Listeria spp.* on a food-contact surface.

NOTE: FSIS expects that the protocol for such testing will address issues such as the frequency of sampling, randomness of sampling, the recording of results, and actions the establishment will take in the event of a positive finding. FSIS is not prescribing the frequency of the on-going *Listeria spp.* testing or the targeted product testing. Establishments will need to develop a scientifically based frequency for this testing. The scientific basis can include: recommendations from scientific experts; scientific journal articles; FSIS guidance materials; and establishment history. Inspection program personnel should contact the Technical Service Center when they have questions. FSIS also expects the protocol to include the laboratory methodology. The laboratory detection methods for environmental samples should be AOAC-validated for that specific application or, alternatively, validated to be equivalent or greater in sensitivity when compared to the current FSIS *Listeria* method. The laboratory detection methods for product testing should be validated to be equivalent or superior in sensitivity when compared to the current FSIS *Listeria* method. The FSIS methodology can be found in the Microbiology Laboratory Guidebook, 3rd Edition/1998, Chapter 8, "Isolation and Identification of *Listeria monocytogenes* from Red Meat, Poultry, Eggs, and Environmental Samples" (Revision 2; 11-08-99).

For an establishment conducting the testing above, under the correct ISP activity code verify as appropriate that:

1. the testing protocol for product samples is incorporated into the establishment's validated HACCP plan as specified in 9 CFR 417.2 as an on-going verification activity.
2. the testing protocol for food contact and non-food contact surface is incorporated into the establishment's Sanitation SOP's as specified in 9 CFR 416.12. NOTE: An establishment may choose to incorporate this testing into a validated HACCP plan.
3. the appropriate documentation is present to support the establishment's testing protocol in its facility (see 9 CFR 416.16 and 417.5).

4. the appropriate preventive and corrective actions are taken in accordance with 9 CFR 416.15 and 417.3 (See FSIS Directive 5000.1 Part II, Section III, Paragraph B.3 and Part III, Section III Paragraph B.2.). **Note:** Do not issue a Noncompliance Record (NR)(FSIS Form 5400-4) just because there has been a positive sample result under an establishment's sampling protocol. The preventive and corrective actions should address the procedures the establishment will follow. Non-compliance occurs when the establishment fails to address the positive result or to implement the corrective and preventive actions.

5. If the establishment does not meet the criteria above, collect the sample.

## IX. FSIS Test Results

*What happens when an FSIS sample tests positive?*

A. If an FSIS sample tests positive for microbial hazards, the DO provides the IIC with the information necessary to complete a NR. The IIC documents the procedure as unscheduled on the Procedure Schedule and, in **Block 8** on the NR, records the appropriate O3 ISP code and checks the "verification" trend indicator. In **Block 10** on the NR, the IIC includes:

- a. the sample collection date,
- b. the product name,
- c. the production or lot code,
- d. the organism or toxin found,
- e. sample request form number,
- f. whether the establishment shipped product from the sampled lot.

B. The IIC provides a copy of the NR to the establishment and files another copy in the government office.

*What actions will inspection program personnel take when the sample result is positive?*

A. Perform an O2 procedure on the product's HACCP plan and procedures O1B01 and O1C01 on the establishment's Sanitation SOP covering the time period from when the sample was collected to the present (see FSIS Directive 5400.5).

1. If the establishment has not stopped producing and shipping adulterated product, inspection program personnel should follow the instructions in FSIS Directive 5000.1, Part II, Paragraph III, C., 1.

2. If the establishment has stopped producing and shipping adulterated product, inspection program personnel should follow the instructions in FSIS

Directive 5000.1, Part II, Paragraph III, C. 2.

B. Inspection program personnel are to verify that the establishment takes corrective and preventive actions in accordance with 9 CFR 416.15 and 417.3. NOTE: If there is a positive for *L. monocytogenes* and the HACCP plan does not already provide for the control of *L. monocytogenes*, absent substantial, scientifically supportable reasons, the Agency would expect the establishment to modify the HACCP plan in question to incorporate appropriate controls for *L. monocytogenes*.

C. The DO will make a determination, based on consideration of the policy issues discussed in paragraph VI. regarding the necessity of enforcement actions and instruct inspection and enforcement personnel as needed (see 9 CFR Part 500).

## **X. FSIS FOLLOW-UP SAMPLING**

*When and how are follow-up samples taken?*

A. If an FSIS sample of an establishment's RTE product tests positive for a pathogen or toxin, inspection program personnel may conduct follow-up sampling to verify the continued effectiveness of the establishment's corrective and preventive action in accordance with 9 CFR 417.3. OPHS will send the IIC sample request forms that will indicate that they are for follow-up sampling. To verify the continued effectiveness of the establishment's corrective and preventive actions, inspection program personnel should begin collecting these HACCP verification samples after the establishment has implemented its appropriate corrective and preventive actions in accordance with 9 CFR 417.3.

B. To determine the number of samples to collect, inspection program personnel should consider what caused the positive result and the corrective and preventive actions taken. For example, in some situations the reason for a positive result may be directly linked to the fact that the product tested had been undercooked because of a mechanical malfunction. In this case, inspection program personnel may decide that the reason is obvious, the establishment's corrective and preventive actions are sufficient, and to collect only one or two follow-up samples. In other situations, the reason for a positive result may be less obvious and the effectiveness of the corrective and preventive actions less clear.

In such cases, inspection program personnel may decide to collect follow-up samples for each sample request form. For technical assistance in making a

determination, contact the District Manger.

Direct questions regarding this directive through supervisory channels.

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## QUESTIONS AND ANSWERS (Attachment 1)

### SAMPLE COLLECTION

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

**Answer:** No. Establishments are not obligated to hold any product when inspection program personnel collect samples. As has been our policy and practice as instructed in FSIS Directive 10,210.1, inspection program personnel are to notify establishments sufficiently early in order 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 or toxin. Inspection personnel will ensure that plants are appropriately notified.

2. **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.

### SAMPLE RESULTS

3. **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 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 or toxin that is not treated in such a manner will be condemned.

4. **Question:** If an FSIS 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 personnel will perform a 02 procedure on the products' HACCP plan, and procedures 01B01 and 01C01 on the establishment's Sanitation SOP 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 retention, 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. If no evidence of product adulteration is found, no further action would be necessary.

5. **Question:** If a RTE product tested by FSIS is found positive for a pathogen or toxin, is the HACCP plan automatically inadequate, and should the inspector immediately withhold inspection?

**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 or toxin 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 or toxin, and whether incidents of product contamination have been consistent or recurring. Establishments are required to take corrective and preventive actions in accordance with 9 CFR 417.3. In regard to withholding of inspection, FSIS 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.

6. **Question:** If an establishment or its customers conduct their own testing on RTE products and find a pathogen or toxin, is this a noncompliance for which inspection program personnel would complete a Noncompliance Record (NR)?

**Answer:** No. In and of itself, an establishment or its customers' finding of a pathogen or toxin in RTE product is not a noncompliance. Establishments are required to ensure that their HACCP plan is producing product in accordance with Part 417 of the regulations and that adulterated product is not produced and shipped. FSIS will make a determination based on the information provided by the establishment or its customers as to whether adulterated product entered commerce and is subject to retention, detention, voluntary recall, or seizure.

7. **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 critical control points 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 critical control points 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

8. **Question:** During follow-up sampling, must the samples be collected on consecutive production days?

**Answer:** Block 4 of FSIS Form 10,210-3 will show the timeframe for collecting the follow-up samples. Samples do not have to be collected on consecutive production days. The purpose of the follow-up sampling is to verify the effectiveness of establishment's corrective and preventive measures.

NOT-READY-TO-EAT/READY-TO-EAT TABLE

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 <b>has not</b> received an adequate lethality treatment for pathogens (i.e. raw or partially cooked product).	NRTE	<ul style="list-style-type: none"> <li>• Raw Product Ground - ISP 03B</li> <li>• Raw Product Not Ground – ISP 03C</li> <li>• Heat Treated but not Fully Cooked Not Shelf Stable - ISP 03H</li> <li>• Products with secondary inhibitors Not Shelf Stable – ISP 03I</li> </ul>	Product must be labeled with statements such as keep refrigerated or frozen. Use of Safe Handling Instruction (SHI) labeling required.	<ul style="list-style-type: none"> <li>• Use of SHI labeling (Some establishments may have a CCP for SHI labeling application).</li> <li>If it is not obvious that the product is raw and needs to be cooked:</li> <li>• 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.”</li> <li>• Validation that:               <ol style="list-style-type: none"> <li>a. Cooking and preparation instructions on the product are sufficient to destroy pathogens.</li> <li>b. Instructions are realistic for the intended consumer.</li> </ol> </li> </ul>
A product containing a meat/poultry component that <b>has</b> received a lethality treatment for pathogens in combination with non-meat/poultry components that <b>need</b> to receive a lethality treatment by the intended user. This includes meals, dinners, frozen entrees.	NRTE	<ul style="list-style-type: none"> <li>• Heat Treated but not Fully Cooked Not Shelf Stable - ISP 03H</li> </ul>	Product must be labeled with statements such as keep refrigerated or frozen. Use of SHI labeling is recommended.	<ul style="list-style-type: none"> <li>• Validation that:               <ol style="list-style-type: none"> <li>a. The meat/poultry component received an adequate lethality treatment for pathogens.</li> <li>b. Cooking and preparation instructions on the product are sufficient to destroy pathogens.</li> <li>c. Instructions are realistic for the intended consumer.</li> </ol> </li> <li>• 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.”</li> <li>• 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).</li> </ul>
A product containing a meat/poultry component that <b>has</b> received a lethality treatment for pathogens that may or may not be in combination with a non-meat/poultry component that does <b>not</b> need to receive a lethality treatment by the intended user.	RTE	<ul style="list-style-type: none"> <li>• Not Heat Treated Shelf Stable – ISP 03E</li> <li>• Heat Treated Shelf Stable – ISP 03F</li> <li>• Fully Cooked Not Shelf Stable – ISP 03G</li> <li>• Products with secondary inhibitors Not Shelf Stable – ISP 03I</li> </ul>	If the product is not shelf stable labeling such as keep refrigerated or frozen is required.	<ul style="list-style-type: none"> <li>• See FSIS Notice 17-99, Listeria Monocytogenes Reassessment.</li> </ul>

