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

FSIS DIRECTIVE

10,240.4, Revision 2 | 2/3/09

VERIFICATION PROCEDURES FOR CONSUMER SAFETY INSPECTORS FOR THE *Listeria monocytogenes* (*Lm*) REGULATION AND *Lm* SAMPLING PROGRAMS

I. PURPOSE

This directive is being reissued to provide directions to Consumer Safety Inspectors (CSIs) on submitting ready-to-eat (RTE) product samples under the ALLRTE and RTE001 sampling projects to the laboratory after the establishment has completed all interventions, except for any intervention based on microbiological test results. In addition, this directive changes the products sampled under the ALLRTE project code and instructs CSIs to collect samples under both sampling programs when CSIs receive forms (see attachments). This directive also provides CSIs with verification instructions for RTE products when establishment product disposition occurs off-site. In addition, this directive provides CSIs with instructions for verifying whether establishments are complying with the regulatory requirements in 9 CFR Part 430, *Requirements for Specific Classes of Product*.

Key Points Covered

- *CSI verification of 9 CFR part 430*
- *Sample collection responsibilities of the CSI for the ALLRTE and RTE001 sample projects*
- *Enforcement*
- *Verification of Corrective Actions*
- *Disposition of RTE product occurring off-site*

II. CANCELLATION

FSIS Directive 10,240.4, Revision 1, Verification Procedures For Consumer Safety Inspectors For The *Listeria monocytogenes* (*Lm*) Regulation and Introduction Of Phase 2 Of The *Lm* Risk-Based Verification Testing Program

III. REASON FOR REISSUANCE

This directive is being reissued to provide direction to CSIs regarding:

1. the removal of the requirement to submit intact samples after pre-shipment review;

2. the need to collect all *Lm* samples scheduled at the same establishment over the same time period (i.e., RLm, ALLRTE and RTE001); and

3. the issuance of Noncompliance Records (NRs) based on FSIS results, depending on whether the establishment also found the positive product and held affected product.

IV. REFERENCES

21 U.S.C. section 453 et seq. and 601 et seq.
9 CFR parts 416, 417, 430, 500
FSIS Directive 5000.1, Verifying an Establishment's Food Safety System
FSIS Directive 7355.1, Use of Sample Seals for Program Samples and Other Applications
FSIS Directive 8080.1, Recall of Meat and Poultry Products
FSIS Directive 10,200.1, Accessing Laboratory Sample Information via LEARN
FSIS Directive 10,210.1, Unified Sampling Form
FSIS Form 7350-1, Request and Notice of Shipment of Sealed Meat/Poultry

V. BACKGROUND

On June 6, 2003, FSIS published an interim final rule (68 FR 34207) that amended its regulations to require that official establishments that produce certain RTE meat and poultry products prevent product adulteration by the pathogenic environmental contaminant *Lm*. In particular, 9 CFR 430.1 sets out definitions of terms. 9 CFR 430.4(a) states that *Lm* is a hazard that an establishment producing a RTE product that is exposed to the post-lethality environment must control through its HACCP plan or prevent in the processing environment through a Sanitation Standard Operating Procedure (Sanitation SOP) or other prerequisite program.

The interim final rule also states that RTE product is adulterated if it contains *Lm,* or if it comes into direct contact with a food contact surface that is contaminated with *Lm.* 9 CFR 430.4(b) sets out three alternatives that establishments producing post-lethality exposed RTE product are to choose from in order to meet the requirements of 9 CFR 430.4(a). CSIs are to verify establishment compliance with the regulatory requirements of 9 CFR 430.4(b).

Under the previous version of FSIS Directive 10,240.4, Verification Procedures for Consumer Safety Inspectors for the *Listeria monocytogenes* (*Lm*) Regulation and Introduction of Phase 2 of the *Lm* Risk-Based Verification Testing Program and under the previous version of FSIS Directive 10,240.5, Enforcement, Investigations, and Analysis Officer (EIAO) Assessment of Compliance with the Listeria monocytogenes (*Lm*) Regulation and Introduction of

Phase 2 of the *Lm* Risk-Based Verification Testing Program, CSIs were not to send RTE product samples to the laboratory until the establishment completed pre-shipment review for the sampled lot. The policy allowed CSIs to collect RTE product samples from an establishment before the establishment completed pre-shipment review. However, if the establishment collected a sample from the same production lot that CSIs sampled, and the establishment found its sample positive for *Lm*, the establishment likely would not complete pre-shipment review for the product until there had been proper disposition of the product. Consequently, under the former policy, CSIs spent work time collecting samples that FSIS laboratories did not analyze, and for which FSIS did not obtain *Lm* test results.

VI. NEW POLICY

With the issuance of this directive, CSIs are not to wait until the establishment completes pre-shipment review before submitting RTE product samples to the laboratory for testing. Instead, CSIs are to submit the RTE product samples to the laboratory after the establishment has completed all interventions. If an establishment has any intervention based on microbiological test results, CSIs are not to wait for the establishment to receive microbiological test results before sending the sample to the laboratory. CSIs, in many cases, will be collecting and submitting FSIS samples to the laboratory before the establishment completes pre-shipment review.

VII. CSI RESPONSIBILITIES FOR VERIFYING COMPLIANCE WITH 9 CFR PART 430

The establishment is not required to comply with 9 CFR part 430 if the RTE products produced in the establishment are not exposed to the environment after the lethality step.

A. What are the regulatory requirements of 9 CFR 430.4(b)(1), Alternative 1?

Use of a post-lethality treatment (which may also be the antimicrobial agent) that reduces or eliminates microorganisms on the product and an antimicrobial agent or process that suppresses or limits the growth of Lm.

B. How do CSIs verify compliance with the requirements in Alternative 1?

To verify compliance, CSIs are to follow the methodology in FSIS Directive 5000.1 when seeking answers to the following questions and any necessary follow-up questions that CSIs may identify:

1. Is the post-lethality treatment (which may be an antimicrobial agent) incorporated in the HACCP plan?

2. Does the establishment have validation data for the post-lethality

treatment in accordance with 9 CFR 417.5?

3. Is the establishment implementing the post-lethality treatment as described in the HACCP plan?

4. Has the establishment documented in its HACCP plan or its Sanitation SOPs or other prerequisite program the effectiveness of the antimicrobial agent or process in suppressing or limiting the growth of *Lm*?

5. Is the establishment using the antimicrobial agent or process as described in its HACCP plan, its Sanitation SOPs, or a prerequisite program?

NOTE: If CSIs have questions regarding the validation data, they are to contact the Policy Development Division (PDD) or an EIAO through supervisory channels.

C. What are the regulatory requirements of 9 CFR 430.4(b)(2), Alternative 2?

Use of either a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product or an antimicrobial agent or process that suppresses or limits the growth of Lm.

Choice 1 - An establishment that produces post-lethality exposed product that selects this alternative and chooses to use a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product:

or

Choice 2 - An establishment that produces post-lethality exposed product and that selects this alternative and chooses to use an antimicrobial agent or process that suppresses or limits the growth of *Lm*.

D. How do CSIs verify compliance with the requirements in Alternative 2?

When verifying compliance with Alternative 2, CSIs are to seek answers to the questions from paragraph B. Alternative 2 is based on the same requirements as Alternative 1 except that the establishment can choose to have just a post-lethality treatment that meets the requirements of B. 1-3 above (Choice 1) or to use just an antimicrobial agent or process to suppress or limit the growth of *Lm* throughout the shelf life of the product that meets the requirements of B. 4 above (Choice 2). Also, if the establishment chooses Choice 2, the CSI should seek answers to the following questions and any necessary follow-up questions that the CSI may identify:

Does the establishment's sanitation program:

1. provide for testing of food contact surfaces in the post-lethality

processing environment to ensure that the surfaces are sanitary and free of *Lm* or of an indicator organism?

2. identify the conditions under which the establishment implements hold-and-test procedures following a positive test of a food-contact surface for *Lm* or an indicator organism?

NOTE: If CSIs have questions regarding the validation data, they are to contact the PDD or an EIAO through supervisory channels.

3. state the frequency with which testing is done?

4. identify the size and location of the sites that are sampled?

5. include an explanation of why the testing frequency is sufficient to ensure that effective control of *Lm*, or an indicator organism, is maintained?

E. What *are the regulatory requirements of 9 CFR 430.4(b)(3),* Alternative 3?

Use of sanitation measures only.

F. How do CSIs verify compliance with the requirements in Alternative 3?

To determine compliance, CSIs are to seek answers to questions that include the following and any necessary follow-up questions that CSIs may identify:

Does the establishment that produces post-lethality exposed product and that selects this alternative have on-going verification testing procedures of food contact surfaces that are designed to:

1. have sanitation measures incorporated in its HACCP plan or Sanitation SOPs or other prerequisite program?

2. test food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or of an indicator organism?

3. identify the conditions under which the establishment implements hold-and-test procedures following a positive test of food contact surfaces *for Lm* or an indicator organism?

4. state the frequency with which the testing is done?

5. identify the size and location of the sites that are sampled?

6. include an explanation of why the testing frequency is sufficient to ensure that effective control of *Lm,* or of an indicator organism, is maintained?

Also, does an establishment producing a deli, hotdog, or pate product:

1. verify that the corrective actions it implemented with respect to sanitation after an initial positive test for *Lm* or an indicator organism on a food contact surface in the post-lethality processing environment are effective by follow-up testing that includes a targeted test of the specific site on the food contact surface area and other sites as are necessary to ensure the effectiveness of corrective actions?

2. hold lots of product, during follow-up testing, if the establishment obtains a second positive test for *Lm,* or an indicator organism for product that may have become contaminated by contact with the food contact surface until the establishment corrects the problem indicated by the test result?

3. sample and test the lots for *Lm* or an indicator organism using a sampling method and frequency that provides a level of statistical confidence that ensures that each lot is not adulterated with *Lm,* in order to release into commerce the lots of product that may have been contaminated with *Lm*?

4. document the results of the testing?

5. rework the held product using a process that is destructive of *Lm*?

G. How do CSIs document noncompliance and verify corrective actions?

If the answers to any questions in B, D, or F above or similar questions are "no", CSIs are to issue a Noncompliance Record (NR) under the appropriate 03 or 01 procedure code as described in FSIS Directive 5000.1 and reference 9 CFR 430.4(b)(1), (2), or (3) and the appropriate sections of 9 CFR 417 or 416, if applicable. CSIs are to verify that the establishment takes corrective action to bring itself into compliance with 9 CFR Part 430. Such actions may include, but are not limited to, a reassessment of the HACCP plan and the establishment's choosing of another alternative or determining that the decisions it made in the hazard analysis regarding the use of a prerequisite program remain valid.

VIII. CSI RESPONSIBILITIES IN VERIFYING 9 CFR 430.4(e*)*

A. What does 9 CFR 430.4(e) state?

An establishment that controls Lm by using a post-lethality treatment or an antimicrobial agent or process that eliminates or reduces, or suppresses or limits the growth of the organism may declare this fact on the product label provided that the establishment has validated the claim.

B. How do CSIs verify compliance if an establishment takes advantage of this regulatory provision?

The CSI is to verify that the establishment's records demonstrate that the

labeling claim is accurate, that the establishment has data to support the claim, and that the establishment has a sketch label approval on file.

If the establishment does not have data to support the claim, the CSI is to document the noncompliance on an NR using the appropriate HACCP procedure code and referencing 430.4(e) and 417.5(a).

IX. CSI RESPONSIBILITIES FOR COLLECTING SAMPLES OF RTE PRODUCTS UNDER THE RTE PROJECT CODES ALLRTE AND RTE001

NOTE: Collecting RLm samples will no longer take precedence over the other RTE sampling programs (i.e., ALLRTE and RTE001). If FSIS *Lm* sampling projects are scheduled at the same establishment over the same time period, all samples are to be collected as scheduled. If a CSI receives sample request forms for sampling products under both ALLRTE and RTE001 for the same time frame, the CSI is to collect samples for both projects. CSIs are not to collect samples for ALLRTE and RTE001 from the same lot of product. If possible, CSIs are to collect samples for ALLRTE and RTE001 from different weeks of production. Collecting samples for all the projects provides FSIS overall verification of an establishment's process.

A. How Do CSIs Collect Samples of RTE Products for the RTE001 and ALLRTE Sampling Projects?

1. The CSI is to collect a RTE product sample within the sampling window timeframes denoted on FSIS Form 10,210-3, Requested Sample Programs, from the Office of the Chief Information Officer, Laboratory Information Technology Branch (OCIO-LITB) (See attachment 3 for additional shipping instructions).

2. If a CSI does not collect a sample, then he or she is to check the appropriate code in block 33 on the unused form. If code 53, other, is checked, briefly describe in block 33 the reason why the sample was not collected and return the unused form to the laboratory identified in block 9. The Office of Public Health Science laboratories will enter this data into the Lab Sample Flow System (LSFS).

3. If a specific product is not pre-selected for sampling in Block 18 of the sample request form, the CSI is to sample product using the instructions in attachment 1 for the RTE001 project code or attachment 2 for the ALLRTE project code. Under the ALLRTE sampling code, IPP are to make every effort to sample all the RTE products produced at an establishment by rotating through the products when IPP receive sample request forms.

4. Safeguard the security of samples during preparation, storing, packaging, and submission for testing (See FSIS Directive 7355.1).

5. Follow the directions in FSIS Directive 10,200.1 for obtaining test results through the LEARN System. CSIs should provide this information to

establishment management even if the establishment receives e-mail notifications from OCIO-LITB.

X. CSI RESPONSIBILITIES REGARDING ENFORCEMENT ACTIONS FOR POSITIVE SAMPLE RESULTS

A. RLm Sampling Program

The CSI is to document an NR at the completion of the food safety assessment (FSA) conducted by an EIAO. The CSI bases the NR on the determinations of the EIAO's FSA including positive sample results from the RTE RLm Sampling Program. The CSI is to issue an NR under the appropriate 03 code using the verification trend indicator and referencing 9 CFR 417.4(a) and 301.2 or 381.1 for product or food contact surface results. If the determination of the EIAO's FSA is to document an NR related to the design or execution of environmental sampling, the CSI is to issue an NR under the 06D01 procedure code using the product-based trend indicator and referencing 9 CFR 416.4(b).

B. RTE001 and ALLRTE Sampling Projects

If the CSI collects a RTE product sample under the RTE001 or ALLRTE sampling projects, then the CSI is to make the following determinations regarding adulteration based on the circumstances:

1. If any RTE product sample collected by the CSI under the RTE001 or ALLRTE sampling projects tests positive for *Lm*, product in the sampled lot is adulterated.

a. If FSIS finds the product positive, and the establishment tested the product, CSIs are to check establishment *Lm* test results to determine whether the establishment also found the sampled product positive for *Lm.*

b. If the establishment held the product or maintained control of the product (e.g., the establishment moved the product off site but did not complete preshipment review or transfer ownership of the product to another entity) pending its own test results, and FSIS and the establishment found the product positive for *Lm*, CSIs are not to issue an NR. CSIs are to verify that the establishment performs the appropriate corrective actions.

c. The CSI is to issue an NR using the appropriate 03 procedure code and the verification trend indicator referencing 9 CFR 417.4(a) and 301.2 or 381.1 when the establishment either did not find the product positive and did not hold the affected product or did not take the appropriate corrective actions.

d. The CSI is to contact the District Recall Officer (DRO) following the directions in FSIS Directive 8080.1 if any adulterated product in the sampled lot has entered commerce.

C. CSI Responsibilities Regarding Establishment Testing

1. Product and Food Contact Surface Testing

a. When an establishment does its own sampling of product for *Lm*, the product represented by the sample is adulterated if:

i. the sample of RTE product is positive; or

ii. there is a positive result for a post-lethality RTE food contact surface if no subsequent and adequate post-lethality treatment was applied to the product represented by the sample.

If the establishment held the affected product, CSIs are not to issue an NR unless the establishment fails to meet the requirements of 9 CFR 417.3 if *Lm* is addressed in the HACCP plan or a prerequisite program, or the requirements of 9 CFR 416.15 and 417.3 if *Lm* is addressed in the Sanitation SOPs.

b. When an establishment does its own sampling of a post-lethality food contact surface for *Listeria* species, CSIs are to verify that the establishment addresses the positive *Listeria* species sample results in its corrective actions.

2. Environmental Sampling

An establishment may or may not conduct environmental sampling, other than on food contact surfaces, under its HACCP plan or Sanitation SOPs or other prerequisite program. If the establishment is conducting such sampling, and it receives positive results for *Lm* or an indicator organism, e.g., *Listeria* species, then CSIs are to verify that the establishment takes the appropriate action as outlined in the program under which the establishment did the sampling. If the establishment is conducting such sampling but is not addressing the sampling under its HACCP, or Sanitation SOP, or other prerequisite programs, and CSIs find that such sampling is resulting in repetitive positive results, CSIs are to notify the District Office (DO).

D. CSI Verification of Corrective Actions

When an FSIS RTE product sample or post-lethality exposed RTE food contact surface sample tests positive for *Lm,* and there was no subsequent and adequate post-lethality treatment applied to the product represented by the sample, the CSI is to issue an NR.

If an establishment RTE product sample or a post-lethality exposed RTE food contact surface sample tests positive for *Lm* and there is no subsequent and adequate post-lethality treatment applied to the product, the product represented by the sample is adulterated, and the establishment must implement corrective actions that meet the requirements of 9 CFR 417.3 or of 9 CFR 417.3 and 9 CFR 416.15.

1. As soon as possible after the establishment has implemented its

corrective actions, the CSI is either:

a. to perform a HACCP 02 procedure for the specific production for a NR written for a FSIS sampling result that tested positive for *Lm* and verify that the establishment implements corrective action that meets the requirements of 9 CFR 417.3 if *Lm* is addressed in the HACCP plan or prerequisite program, or 9 CFR 416.15 and 417.3 if *Lm* is addressed in the Sanitation SOPs; or

NOTE: A verification plan is developed to assist the CSI in verifying the effectiveness of the establishment's corrective measures and lists the activities that CSIs are to perform. A verification plan is developed when a decision is made to defer enforcement following the issuance of a NOIE, or a decision is made to hold a suspension in abeyance following the suspension of the assignment of inspection program personnel that resulted from an FSA. The EIAO has the primary responsibility for preparing the written verification plan. However, the EIAO is to work with the in-plant inspection team, including the Frontline Supervisor, in the development of the verification plan.

b. to perform the activities in the verification plan if an enforcement action was taken.

2. CSIs are to verify the establishment's disposition of the sampled product lot by verifying that:

a. the establishment has documentation to support that potential contamination is limited to individual production lines for individual products; and

b. the establishment has destroyed the sampled lot or has reworked the sampled lot with a process that is destructive of *Lm*.

3. If an establishment chooses Alternative 3, CSIs are to verify all the factors for the testing in Alternative 2, Choice 2 (see section VII. D). In addition, in establishments that produce a deli, hotdog, or paté product, CSIs are to verify the adequacy of how the establishment:

a. verifies the corrective actions that the establishment takes with respect to sanitation after an initial positive test for *Lm* or an indicator organism on a food contact surface in the post-lethality processing environment are effective by conducting follow-up testing that includes a targeted test of the specific site on the food contact surface area that is the most likely source of contamination by the organism; and

b. holds lots of product that may have become contaminated by contact with the food contact surface during follow-up testing after the establishment obtains a second positive test. The CSI should seek answers to the following questions to assist in determining if all affected product has been held by the establishment:

i. has the establishment held all the affected product?

ii. have ingredients or solutions (e.g., brine) been re-used in the

process in the post-lethality environment?

iii. has the same equipment been used in the production of the product in the post-lethality environment?

4. Establishments that choose Alternative 3 and produce a deli, hotdog, or pate product have 2 different options for salvaging contaminated product:

a. the establishment samples and tests the lots of product that may have been contaminated with *Lm* for *Lm* or for an indicator organism using a sampling method and frequency that provides statistical confidence that each lot is not adulterated with *Lm* before releasing the lots into commerce and documents the results of testing; or

b. the establishment reworks the held product using a process that is destructive of *Lm* or the indicator organism.

If the establishment salvages the product, CSIs are to verify the establishment meets the requirements in either X. D. 4. a. or b. above.

NOTE: The DO is to schedule an EIAO to conduct an FSA in conjunction with collecting product, food contact, and environmental (non-food contact) samples (INTPROD, INTCONT, and INTENV, respectively) using the Intensified Verification Testing (IVT) methodology within 30 days of being notified of an FSIS RTE product sample for ALLRTE, RTE001 that tested positive for *Lm*, *E. coli* O157:H7, or *Salmonella*.

While the DO is to schedule an FSA or IVT within 30 days of the notification, the FSA or IVT need not take place within 30 days of this notification. The FSA or IVT should take place as soon as practicable. If the DO personnel are unable to schedule an FSA or IVT within 30 days of the notification above, then the District Manager (DM) is to document the reason in the case file.

DMs are to contact the OCIO-LITB through the IVT Sample Scheduling Mailbox to request the forms for sampling. This sampling should not be initiated until the corrective and preventive measures have been put in place.

E. Disposition of Product Occurring Off-site

1. If the establishment transports positive product to another site for appropriate disposition, IPP are to verify that the establishment has met all corrective action requirements by verifying that the establishment:

a. maintained records identifying the official establishment, renderer, or landfill operation that received positive product;

b. maintained control of product that was destined for a landfill operation or renderer while the product was in transit (e.g., through company seals);

c. maintained control of product that was destined for an official establishment while the product was in transit (e.g., through company seals) or ensured that such product moved under FSIS control (e.g., under USDA seal or

accompanied by FSIS Form 7350-1);

d. maintained records showing that positive product received the proper disposition, including documentation showing proper disposal of the product from the official establishment, renderer, or landfill operation where disposition occurred; and

e. completed pre-shipment review for the positive product only after it has received the records described above for that particular product.

2. If the product is shipped to another official establishment for disposition, IPP at that establishment are periodically to verify that the receiving establishment disposes of the product in an appropriate manner.

3. If IPP find that there is not compliance with the corrective action requirements, they are to document the noncompliance in accordance with FSIS Directive 5000.1.

If an establishment ships adulterated product to renderer or landfill operation, IPP are to verify the establishment denatures the product before the product leaves the establishment (9 CFR 314).

In situations where the establishment has not properly moved the product, IPP are to notify their DO through supervisory channels.

Refer questions regarding this directive to the PDD through *askFSIS* at http://askfsis.custhelp.com or by telephone at 1-800-233-3935.

Assistant Administrator
Office of Policy and Program Development

Attachment 1

PROJECT CODE AND NAME	**RTE001** - Risk-based Verification Testing of only Post-lethality Exposed RTE Meat and Poultry Products
PRODUCT TO SAMPLE	Select the highest risk post-lethality exposed RTE product produced at the time of collection 1) Deli-meats that are sliced in the federal establishment 2) Deli-meats shipped whole from the federal establishment (this does not include cook-in-bag products; only those exposed post-lethality) 3) Hotdog Products 4) Deli salads, patés, and meat spreads 5) Fully cooked type products (other than cooked products in 1-4 above) 6) Fermented products 7) Dried products 8) Salt-cured products 9) Products labeled as "Keep Frozen" **NOTE:** DO NOT sample the same lot of a product for more than one sample collection project (RLm, ALLRTE, and RTE001).
ANALYZED FOR	*Listeria monocytogenes* AND *Salmonella*. If product is a dry or semi-dry fermented sausage or fully cooked meat patties, it will also be analyzed for *Escherichia coli* O157:H7.
SPECIAL COLLECTION INSTRUCTIONS	Randomly select a day, shift, and time within the sample collection time frame indicated in block 4 of the FSIS form 10,210-3. Collect enough INTACT product so that at least 2 pounds of meat or poultry is submitted to the laboratory for analysis. If an intact sample of the product is too large to submit to the laboratory, ask the establishment to slack fill or short weight a package to 2 pounds without any changes to its processing operations. If this is not possible, contact the laboratory to see if a larger shipping container is available.
SAMPLE REQUEST FORM	Complete part II of the 10,210-3 form. Blocks 19, 20, 22, and 28-32 are required. Place the sample request form and a copy of the label in a plastic bag and place the plastic bag into the shipping container with the sample. If no sample is collected, complete Block 33 and mail the form to the laboratory listed in Block 9.
SAMPLE SECURITY	Identify sample and seal shipping container per FSIS Directive 7355.1, Rev. 2.
SPECIAL SHIPPING INSTRUCTIONS	Ship immediately after product represented by the sample has passed all establishment interventions except microbiological testing. Ship refrigerated or frozen, using sufficient frozen coolant to keep samples cold during transit. Ship samples Monday through Friday so that they arrive at the laboratory overnight. Do not ship samples on Saturdays or on the day before a Federal holiday.
REFERENCES	FSIS Directive 7355.1 Rev. 2

PROJECT CODE AND NAME	**ALLRTE** – Random Verification Sampling of RTE Meat and Poultry Products
PRODUCT TO SAMPLE	Randomly select the product to sample from all RTE products produced at the establishment, with the exception of product labeled "For Further Processing" in which the product is expected to receive a lethality treatment at another federally-inspected establishment. (9 CFR 430.4 still applies to these products if they are post-lethality exposed). CSIs should make every effort to sample all the RTE products produced at an establishment by rotating through the products when CSIs receive sample request forms.
ANALYZED FOR	*Listeria monocytogenes* and *Salmonella.* If product is a dry or semi-dry fermented sausage or fully cooked meat patties, it will also be analyzed for *Escherichia coli* O157:H7.
SPECIAL COLLECTION INSTRUCTIONS	Randomly select a day, shift, and time within the sample collection time frame. Collect enough intact product so that at least 2 pounds of product are submitted to the laboratory for analysis. If an intact sample of the product is too large to submit to the laboratory, ask the establishment to slack fill or short weight a package to 2 pounds. If this is not possible, contact the laboratory to see if a larger shipping container is available.
SAMPLE REQUEST FORM	Place the sample request form and a copy of the label in a plastic bag. Place the plastic bag into the shipping container with the sample and seal per FSIS Directive 7355.1, rev. 2. If no sample is collected, complete Block 33 and mail the form to the laboratory listed in Block 9.
ESTABLISHMENT NOTIFICATION	Give establishment management sufficient notification of sampling so that the product represented by the sample may be held. Holding product is at the option of the establishment.
SPECIAL SHIPPING INSTRUCTIONS	Ship immediately after product represented by the sample has passed all establishment interventions except microbiological testing. Complete all requested information in block 28 of the sample request form. Identify sample and seal according to FSIS Directive 7,355.1, rev. 2. Ship refrigerated or frozen. Use sufficient frozen coolant to keep samples cold during transit. Ship samples Monday through Friday so that they arrive at the laboratory overnight. Do not ship samples on Saturdays or on the day before a Federal holiday.
REFERENCES	FSIS Directive 10,240.4, Revision 2; FSIS Directive 7355.1 Rev. 2

Attachment 3

Additional information CSIs are to consider when submitting a short-weighted or slack-filled RTE meat and poultry product.

1. CSIs are to submit all RTE samples to the laboratory for microbiology analysis in intact packages. If an intact product or product container is too large, heavy, or costly to ship to the laboratory, CSIs can ask the establishment to slack-fill or short-weight a product for a 1 or 2 lb. sample and send it in the usual establishment packaging such as the container liner. Refer to Directive 10,210.1 for additional product sampling details.

2. CSIs are to place one check mark in Block 28 next to either "Intact sample is short-weight/slack-filled" or "Retail package (Intact)" on the sampling request form to insure that a sample is not discarded as a non-intact sample by the laboratory.

3. The laboratory does not supply sterile bags or gloves for sampling because the CSIs are not to have direct contact with the exposed, unpackaged product.

4. If the intact package is an unsealed bag, tie it off (e.g., twist tie or rubber band) so smaller particles (i.e., shredded meat pieces) do not spill into the shipping container. Place in secondary bag. The laboratory will discard spilled or leaking products.

5. Do not use any laboratory supplied bag as the primary wrap for the sample. Laboratory supplied bags provided by the laboratory are for secondary containment only. The laboratory supplied bag protects the box in case the primary container leaks.

6. If CSIs cannot collect an intact or short-weighted/slack-filled sample and the establishment is not producing any other type of RTE product that the CSI could collect, CSIs are to use code 53 in block 33 on FSIS Form 10,210-3, Requested Sample Programs and explain why CSIs could not collect the sample. Examples of inappropriate samples for short-weight/slack-filled include a sample that would have to be cut to fit inside the shipping container and samples that are packed in a waxed box without a liner bag that is too large to fit inside a laboratory shipping box.

NOTE: The laboratory will discard samples deemed non-intact without the accompanying appropriately marked form.