Ready To Eat Sampling Programs Introduction

RTE Sampling-Key Points

FSIS sampling programs are designed to verify:

- The establishment food safety systems are effective.
- FSIS performance standards/regulations are met.
- Identify pathogens of concern associated with sampling of RTE products.
- Describe the conditions for RTE product to be considered adulterated.
- Explain the RTEPROD sampling project code.
- Understand why it is important to notify establishment management prior to taking a sample.
- How to verify corrective actions for a positive RTE sample.
- Understand the two sampling programs that EIAOs may perform at an RTE establishment.

RTE Sampling

Terminology

Introduction

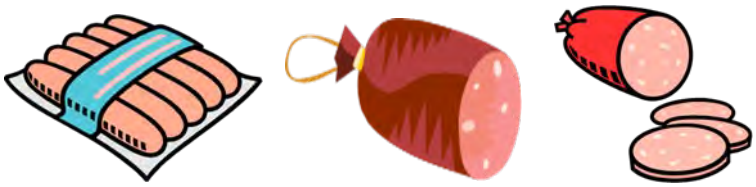
FSIS sampling programs verify that food safety systems are effective and FSIS performance standards/regulations are met.

Pathogens of concern that FSIS samples for in RTE products:

- *Listeria monocytogenes (Lm)*
- *Salmonella* - usually indicates inadequate lethality step

Introduction

- RTE product is adulterated if it:
- Contains *Lm*, *Salmonella* or any pathogen known to cause illness, including *E. coli* O157:H7
- Comes into contact with a food contact surface positive for *Lm*



Terminology

Aseptic - Free from pathogenic organisms. An aseptic technique implies that you do not add any microorganisms, pathogenic or not, to the sample when it is collected.

Environmental samples- Samples from surfaces that have indirect or potential contact with exposed RTE product in the RTE production area (mop handles, outer garments, etc.), that may be handled by a person who may touch RTE product, or non-contact surfaces in a RTE production area (e.g., floors, drains, walls, overhead structures).

Terminology

Food contact surface - The equipment or utensil surface with which exposed RTE product has direct contact (for example, conveyor belt, tabletop, knife blade).

A food contact surface does not include items that may have indirect or potential contact with exposed RTE product.

Terminology

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.

Terminology

Final Package - Product in the final packaged form in which it will be shipped. The lab receives the sample in the same immediate container as the consumer at retail, so the tested product is exactly the same as the product the consumer purchased.

Terminology

Recall - An establishment's voluntary removal of distributed meat or poultry products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA). Product that is adulterated and has left the establishment's control may be subject to a recall.

The recall would involve at least the sampled lot, but it could be expanded depending upon a review by the Recall Management Staff (RMS) of all factors in the situation. FSIS Directive 8080.1 gives additional details on recalls.

Terminology

RTE Production Area - Area in an establishment 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 *Lm* or indicator organisms.

Sample - A collection of product that represents a larger group of product (i.e. the sampled lot).

Terminology

Short-weight or S lack Filled - A short-weight or slack-filled container meets the definition of final packaging, but with less product (e.g., a liner from a bulk package which contains approximately one pound of product, folded down and sealed in the same manner as the bulk package under normal production conditions.

Terminology

Sampled Lot - The amount of product represented by the sample.

Subsequent Production - Product produced after the sampled lot is produced. It is not usually part of the sampled lot, but it may or may not be affected product.

Implicated Lot - Product that may be connected to a sampled lot that tested positive through common resource material or other root cause findings.

Review Question

When do you think RTE product is adulterated? (check all that apply)

- If the establishment is not executing proper sanitation
- If it contains a pathogen of public health concern
- If it comes into contact with a sampled positive surface

RTE Sampling - Sampling Steps #1 - 3

RTE/SS Course

Sample Initiation

- Directed Sampling Task

- Displayed in the PHIS Task List

- If IPP have concerns they may request additional directed tasks through the supervisory chain of command.

- If justified, District Office personnel will contact OPARM (Office of Planning, Analysis & Risk Management) to request additional directed tasks through PHIS.

Steps in Sampling

1. Determine which product to sample and schedule in PHIS.
2. Notify establishment management.
3. Collect the sample.
4. Document the sample in PHIS.
5. Pack & ship the sample and form.
6. Respond to the results.

Steps to Sampling

Step 1 - Determine which product to sample and schedule in PHIS.

RTEPROD_RAND

- Randomly collect **any** RTE product.
- Includes post-lethality exposed products **and** those that are not.
- Rotate through different products.

RTEPROD_RISK

- Follow risk-based priority list.
- **ONLY** products that are post-lethality exposed.

Determining Which Product to Sample

Production Volume Categories (by Product Groups)	Risk Level
Other Fully Cooked Sliced Product	1
Hot Dog Products	2
Salad/Spread/Pate	3
Diced/Shredded	4
Meat + Nonmeat Components	5
Sausage Products	6
Patties/Nuggets	7
Other Fully Cooked Not Sliced Product	8

Risk Declines

Scheduling Sample Collection Date

- Randomly select the day, shift, and time within the sample window timeframe.
- Do not wait until the end of the window to schedule the sample.
- Allows more time to ensure available product.

* IPP are to collect samples from all shifts the establishment produces.

When Scheduling a Sampling Task

- Refer to the collection date range
- Use knowledge of establishment operations
- Consider the priority of sampling tasks relative to other tasks
- Ensure sampling tasks are scheduled so that they can be completed within the timeframe for collection.

Step #2 to Sampling

Steps 2 - Notify Establishment Management

- Advance notice to allow product to be held but not to allow altering the process.
  - 1 day generally is sufficient
  - More time may be given if necessary
  - May provide less time if establishment alters its practices

- Refer questions about notice time to your supervisor or AskFSIS

Step #2 to Sampling

Steps 2 - Notify Establishment Management

- Inform establishment about altering its practices when sampling is scheduled
- Notify FSIS so sampling can be rescheduled
- Justifiable reasons for altering practices:
    - Limiting lot size so all product can be held
    - Changes in customer orders
    - Documented changes in SSOP or HACCP

Step #2 to Sampling

Steps 2 - Notify Establishment Management

- Inform establishment it is responsible for defining the sampled lot and holding or controlling the product represented by the sampled lot.
- IPP will verify this and notify District Office personnel through their supervisor if it is not done.

Step #3 to Sampling

Step #3: Collect the sample:

- Collect sample from current day's production after all interventions except any microbiological testing intervention.
- Collect sample on any shift.
- **Do not** wait for the establishment to perform the pre-shipment review.
- Ship the sample the next FedEx pick-up day.

Step #3 to Sampling

Step #3: Collect the sample:

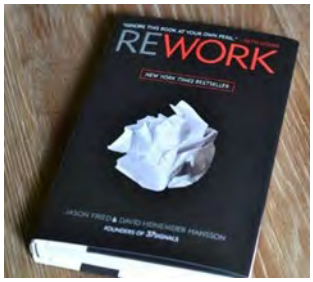
- Collect a 1 lb. sample in the final consumer-ready package.
- Must be intact or slack-filled or short-weighted to ensure product is not contaminated during collection.
- For packages < 1 lbs. collect multiple packages.
- 3 hours or more into production, if possible.
- Vary the shifts, if possible.

Step #3 to Sampling

Step #3: Collect the sample: REWORK

Any process that removes product from the package and exposes it to the environment such as re-cooking, re-processing or re-packaging.

Sample rework as part of production lot in the final package after all interventions are complete (e.g. recooking) as long as adequate notice was given to hold affected product.



Step #3 to Sampling

Step #3: Collect the sample:

Some products contain meat or poultry and other ingredients.

- If meat or poultry and other ingredients <u>are</u> commingled (in contact) in the final package:
    - Collect 1 lb. sample of the commingled product
- If meat or poultry and other ingredients <u>are not</u> commingled (in contact) in the final package:
    - Collect 1 lb. sample of the meat or poultry component only

Step #3 to Sampling

Step #3: Collect the sample:

If intact product is too large request slack-fill or short-weight package for 1 lb. sample:

- Inform lab through PHIS that sample is short weight or slack-filled.
- If a slack-filled or short-weight package is not possible and no other RTE product is available, contact the lab.

Step #3 to Sampling

Step #3: Collect the sample:

If slack filled package is an unsealed bag:

- IPP should place it in a secondary bag and tie it off (lab discards if contents leaking or spilled).
- Do not use lab-supplied bag as primary wrap.
- Secondary containment only (not sterile).
- Protects box in case of leak in primary container.

Steps #4 - #6 to Sampling

Step #4 - Document Sample Collection in PHIS

Step #5 - Pack & Ship the Sample

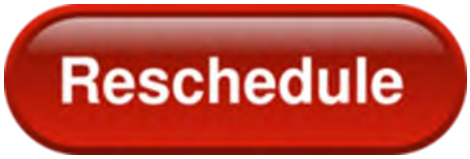
Step #6 - Respond to Results

- Notify the establishment of all results
- Negative Results? Complete the task in PHIS

Step #3 to Sampling

Step #3: Collect the sample:

- If sample cannot be collected on original date:
    - Reschedule sampling task in the timeframe allowed.
    - If not possible to reschedule - cancel and provide justification.



Intervention Considerations

If product is treated with an intervention: Review HACCP documentation to determine the purpose of the treatment.

Collect a sample at the establishment that provided the intervention (i.e., HPP) if the product will not be returned to the originating establishment. If the product returns to the originating establishment, a sample should be collected after the product returns.

Intervention Considerations

If treatment validation supports a minimum 5-log reduction for *Lm* in the package:

- Product is not considered Post-Lethality Exposed (PLE).
- Sample only under RTEPROD_RAND code.

If treatment is not identified for *Lm* and is applied to extend shelf life:

- Collect product before treatment.

Altered Practices

If establishment alters practices on sampling day and cannot support the change:

- Do not sample and reschedule if possible.
- Issue NR if no supporting documents.
- Some changes are supportable.

  Ex: Limiting lot size to facilitate holding product.
- For questions - ask your Frontline Supervisor or AskFSIS.

Altered Practices

Discuss altered practices at weekly meeting

- Inform establishment management that FSIS may:

  - In response to a Lm positive result, FSIS will perform a Public Health Risk Evaluation (PHRE), Food Safety Assessment (FSA), and Intensified Verification Testing (IVT) to review the sampling and testing methods used by the establishment. The establishment may be assuming a greater risk of allowing adulterated product into commerce. FSAs are performed by an Enforcement Investigation Analysis Officer (EIAO).

Lesson #3 - RTE Sampling Steps #4-6

RTE/SS Course

Step #4: Document the Sample in PHIS

- Enter sample collection data as per FSIS Directive 13,000.2
- Complete sample questionnaire in PHIS
- Submit both questionnaire & sample form electronically to the lab
- Print form, sign, and include in shipping container

Important Note: Remember to *sign the form*! If the lab receives the form unsigned and/or incomplete the sample will be discarded!

Step #5: Pack and Ship the Sample & Form

Identify sample and paperwork, and place into bag

Pack & Ship the Sample & Form

- Pack the sample Absorbent pad
- Gel pack
    - Cardboard separator
    - Ziplock bag containing the identified sample and paperwork
    - Extra small bar code stickers that were not used Foam plug

Pack & Ship the Sample & Form

Ship the Sample

Step #6: Respond to Results

- Access LIMS Direct
    - Received
    - Discarded
    - Results of analysis
- Alert on PHIS Homepage if sample result is POSITIVE

Provide sample result information to the establishment ASAP and document notification in an MOI as described in FSIS Directive 5,000.1, Verifying an Establishment's Food Safety System.

Step #6: Respond to Results

- If any FSIS RTE product sample tests positive for a pathogen, product in the sampled lot is ADULTERATED.
- Determine if the establishment sampled the same lot of product to be tested for *Lm*.
- If the establishment sampled, held product or maintained control pending its own results, and found it positive for *Lm* do not issue an NR.
- Verify the establishment's corrective actions.
- Issue an NR if the establishment fails to take appropriate corrective action.

Steps to Sampling-Positive Results

Issue an NR when FSIS finds the sample positive for *Lm* and the establishment did not find product positive or hold affected product.

- Use the appropriate HACCP Verification task (if the establishment's sampling program is included in its HACCP plan or other prerequisite program).
- Cite 417.4(a)
- If product is not held cite 417.5(c)
- Complete the HACCP Verification task

RTE Sampling- Establishment Testing

If an establishment test result for an RTE product sample or RTE food contact surface sample is **positive** for *Lm* and:

- Affected product was held Corrective
- Action was implemented
- Appropriate product disposition was made

- **Do not** issue an NR

RTE Sampling- Establishment Testing

If the establishment conducts environmental sampling and positive results are received:

- Verify appropriate actions are taken as outlined in the program.

- If there are repetitive positive results notify the District Office through supervisory channels.

Review Question

The name of the system that the IPP can check to get lab sample results is known as the LIMS system.

- True
- False

Lesson #4-RTE Sampling Corrective Actions

RTE/SS Course

Verifying Corrective Actions

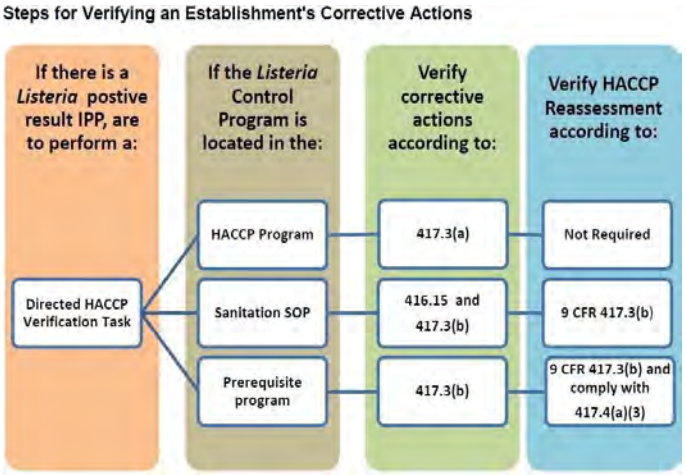
- If any RTE product tests positive for a pathogen of public health concern, product is ADULTERATED.
- If an RTE product contact surface tests positive for *Lm*, the product passing over the surface is adulterated unless a validated 5-log reduction in *Lm* was applied to it.
- 417.3(a) if pathogen addressed in HACCP plan.
- 416.15 & 417.3(b) if pathogen is addressed in SSOP (unforeseen hazard).
- 417.3(b) & 417.4(a)(3) if pathogen addressed in pre-requisite program (unforeseen hazard).

Verifying Corrective Actions

- Verify disposition of affected product
    - Can the establishment support that contamination would be limited to that product lot or individual production lines?
    - Was product destroyed?
    - Was product reworked with a validated process to achieve adequate lethality for *Lm* and *Salmonella*?

Steps to Sampling: Corrective Action Verification

This chart shows the steps and regulations for verifying the establishment's corrective actions in response to a positive lab sample result.



Off-Site Disposition of Product

- Adulterated product can be shipped under appropriate controls to another federally inspected facility, renderer, or landfill operation for disposition.
- Verify the establishment:
    1. Maintained records identifying establishment, renderer, or landfill operation that received positive product.
    2. Maintained control of product destined to landfill operation or renderer while it was in transit (e.g., through company seals).

Off-Site Disposition of Product

- Verify the Establishment:
  - Maintained control of product 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 and accompanied by FSIS Form 7350-1).
  - Maintained records showing that positive product received the proper disposition, including documentation showing proper disposal of the product from the establishment, renderer, or landfill operation where disposition occurred.

Off-Site Disposition of Product

- HACCP Verification task cannot be completed until the producing establishment has:
    - Documentation from the establishment, renderer, or landfill that shows proper disposal/disposition.
    - Performed the pre-shipment review including the corrective actions.
- Issue an NR if noncompliance is found while verifying the establishment's off-site product disposition corrective actions
    - *Lm* addressed in the HACCP, cite 417.3(a)
    - *Lm* addressed in the SSOP, cite 416.15 and 417.3(b)
    - *Lm* addressed in a pre-requisite program, cite 417.3(b)

Intensified Verification Testing (IVT) Sampling Program

- The District Office is to schedule a Public Health Risk Evaluation (PHRE) to determine if an EIAO is to conduct an FSA with intensified verification testing (IVT) sampling:
    - Within 30 days of RTEPROD positive
    - IVTCONT = Food Contact Surfaces (includes brine which contacts product) samples
    - IVTPROD = Product samples
    - IVTENV = Environmental samples (includes brine which does **not** contact product)

Routine *Lm* Sampling Program (R*Lm*)

- IPP are to be aware that EIAOs also collect R*Lm* samples. R*Lm* - routine sampling conducted by person (EIAO) trained in Intensified Verification Testing.
    - Product (**R*LM*PRODC**)
    - Food Contact Surface (**R*LM*CONT**)
        - Includes brine which contacts product
    - Environmental samples (**R*LM*ENVC**)
    - Brine samples (non-food contact) (**R*LM*ENVR**)

R*Lm* or IVT Positive Sample Results

- IPP should follow EIAO recommendations:
    - Issue NR using appropriate HACCP task citing 417.4(a) & 301.2 or 381.1 for *Lm* positive in product or on a food contact surface from the R*Lm* sampling program.
    - Issue NR under SPS Verification task citing 416.4(b) when there are issues with the design or execution of the establishment's environmental sampling.

Review Question

_____is a verification activity for RTE products.

- Recall
- Enforcement
- Sampling
- Documentation

Review Question

When an establishment has a sanitation program that includes sampling RTE product as part of the HACCP plan, you do not have to collect RTE samples.

- True
- False

Review Question

When an establishment has a sanitation program that includes sampling RTE *product contact surfaces* as part of the SSOP program, and they receive a positive for *L. monocytogenes*, what actions would we require them to do? (check all that apply)

- Implement corrective actions as per 9 CFR 417.3 & 416.15
- Make appropriate disposition of the affected product
- Notify the IIC
- Hold the affected product

Review Question

Establishment management must be notified of a pending sample collection:

- Enough in advance to allow the establishment to hold the product, but not soon enough to allow it to alter the process
- Because of the Freedom of Information Act (FOIA)
- When you receive the analysis result
- After pre-shipment review has been completed

Review Question

When should a RTE sample be sent to the lab for an *L. monocytogenes* directed sample?

- The first day pickup for shipment is available after the samples is collected
- They day before the "use by" date
- Just prior to packaging
- As soon as the lot is assembled

Lesson #5- RTE Sampling

Key Points & Review Questions

RTE/SS Course

Key Points of the RTE Sampling Module

- **Understand that the FSIS Sampling Program verifies that establishment food safety systems are effective and performance standards/regulations are being met.**
- **Know the pathogens of concern in RTE products that FSIS samples for.**
- **Understand the terms: environmental samples, food contact surface samples, final package, Short weight/slack filled, sampled lot.**
- **Understand the product sample difference between RTEPROD_RAND and RTEPROD_RISK.**

Key Points of the RTE Sampling Module continued

- **Understand the Sample Timeframe Window and why it is important not to wait until the end of the window to collect the sample.**
- **Know why and when the IPP needs to notify establishment management of a sample collection.**
- **Know how to use the LIMS-Direct System to check on sample receipt by the lab and for sample results.**
- **Understand the procedures of how the IPP verify corrective actions for a positive sample result.**

Review Question

_____is a verification activity for RTE products.

- Sampling
- Enforcement
- Documentation
- Recall

Review Question

RTE sliced ham is analyzed for (check all that apply)

- *Salmonella*
- *Staphylococcus enterotoxin*
- *L. monocytogenes*
- *E. coli* O157:H7

Review Question

When an establishment has a sanitation program that includes sampling RTE product as part of the HACCP plan, you do not have to collect RTE samples.

- True
- False

Review Question

When an establishment has a sanitation program that includes sampling RTE *product contact surfaces* as part of the SSOP program, and they receive a positive for *L. monocytogenes*, what actions would we require them to do? (check all that apply)

- Notify the IIC
- Hold all the affected product
- Make the appropriate disposition of the affected product
- Implement corrective actions as per 9 CFR 417.3 & 416.15

Review Question

Establishment management must be notified of a pending sample collection:

- Enough in advance to allow the establishment to hold the product, but not soon enough to allow it to alter the process
- Because of the Freedom of Information Act (FOIA)
- After pre-shipment review has been completed
- When you receive the analysis result

Review Question

If a sample is too large for the shipping container, you should:

- Select a different product produced under the same HACCP plan
- Contact the FSIS lab for a larger shipping container
- Contact the District Office
- Have the establishment use a different package to enclose the product