United States Department of Agriculture
Food Safety and Inspection Service

Ready-to-Eat (RTE) Processed Products FSA Tool VS3

This FSA tool is for establishments that produce **READY-TO-EAT (RTE) MEAT OR POULTRY PRODUCTS** that are considered to fall under the following HACCP processing categories:

FULLY COOKED, NOT SHELF STABLE
HEAT TREATED, SHELF STABLE
NOT HEAT TREATED, SHELF STABLE
SECONDARY INHIBITORS, NOT SHELF STABLE

The FSA tool contains the following main sections:

- HACCP (RTE1-RTE22)
- Lethality for RTE Products: Fully Cooked, Not Shelf Stable and Heat-Treated, Shelf Stable (RTE23)
- Stabilization for RTE Products: Fully Cooked, Not Shelf Stable and Secondary Inhibitors, Not Shelf Stable (RTE24)
- Lethality and Stabilization for RTE Products: Heat Treated, Shelf Stable; Not Heat Treated, Shelf Stable; and Secondary Inhibitors, Not Shelf Stable (RTE25- RTE26)
- Non-Meat Ingredients for RTE Products (RTE27)
- Non-Post-Lethality Exposed RTE Products (RTE28)
- *Listeria* Rule for RTE Products (RTE29 – RTE40)
- End-Product Testing (RTE41)
- Previous FSIS Positives (RTE42 – RTE43)
- RTE Tool Summary (RTE44)

In responding to questions in this tool, the EIAO is to focus on documenting any vulnerability and noncompliance, not making positive editorial findings.

A vulnerability is an identified weakness in the establishment's process that does not rise to the level of noncompliance but that could impact the establishment's ability to produce safe and wholesome meat or poultry products in accordance with FSIS statutory and regulatory requirements (i.e., the Acts and 9 CFR).

References:

1. FSIS Directive 5100.1, *Food Safety Assessment (FSA) Methodology;*
2. FSIS Directive 5000.2, *Review of Establishment Data by Inspection Personnel*;
3. FSIS Directive 7111.1, *Verification Procedures for Lethality and Stabilizatio*n;
4. FSIS Directive 10,240.4, *Listeria Rule Verification Activities*
5. FSIS Compliance Guideline: *Controlling Listeria monocytogenes in Post-Lethality Exposed Ready-to-Eat Meat and Poultry Products*;
6. FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A);
7. FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B);
8. FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments;
9. American Meat Institute Foundation. October 1997. Good Manufacturing Practices for Fermented Dry and Semi-Dry Sausage Products;
10. Blue Ribbon Task Force of the National Cattlemen's Beef Association. May 1996. Dry Fermented Sausage and E. coli O157:H7 (Research Report No. 11-316); and
11. FSIS Ready-to-Eat Fermented, Salt-Cured, and Dried Product Guideline.

For all questions in this FSA tool, please note that some FSA tool questions are not applicable questions for the processes being assessed and will only appear based on the answer responses provided. EIAOs are to copy and paste information into a text field if that answer was provided in a previous text field question within the tool, or another tool.

HACCP (RTE1-RTE22)

This section is designed to assess the establishment's HACCP system. The HACCP system includes hazard analysis, any supporting documentation, including prerequisite programs supporting decisions in the hazard analysis, and all HACCP records.

The EIAO is to document all relevant noncompliance and vulnerability findings for all HACCP processing categories covered in this tool.

RTE1 Select the categories assessed during the FSA (multiple categories may be selected).

- ☐ Fully Cooked, Not Shelf Stable
- ☐ Heat Treated, Shelf Stable
- ☐ Not Heat Treated, Shelf Stable
- ☐ Secondary Inhibitors, Not Shelf Stable

RTE2 Has the establishment considered the relevant food safety hazards throughout the HACCP system? Briefly describe any noncompliances and vulnerabilities (limit 4,000 characters).

- ☐ Yes
- ☐ No

RTE3 Does the HACCP system include a prerequisite program or supporting documentation (including normal consumer cooking practices) for any hazard that the establishment determines is "not reasonably likely to occur" (NRLTO) (9 CFR417.5(a)(1))? Briefly describe any vulnerability and any noncompliance that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 4,000 characters).

☐Yes

☐No

RTE4 Has the establishment properly developed and implemented a written HACCP plan to address each food safety hazard determined to be "reasonably likely to occur" (RLTO) (9 CFR 417.5(a)(2))? Describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 4,000 characters).

☐Yes

☐No

RTE5 Did a significant development occur in the last 60 days that affects the hazard analysis such as major process or product change, categorization change, or unforeseen hazard?

NOTE: Answer this question based on your review of the selected records (including any additional record review because of a food safety concern) as outlined in FSIS Directive 5100.1.

☐Yes – If selected, answer the following question(s)

☐No

RTE5a Briefly describe how the hazard analysis and/or HACCP plan was reassessed in response to the change. Briefly describe any vulnerability and noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 5,000 characters).

RTE6 Does the establishment apply antimicrobial treatments or additives that support decisions in the hazard analysis (e.g., CCPs, pre-requisite programs, or other programs)?

☐Yes – If selected, answer the following question(s)

☐No

RTE6a Does the supporting documentation show the antimicrobial treatments are safe and suitable (FSIS Directive 7120.1) (limit 4,000 characters)? Briefly describe any vulnerability and noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.

☐Yes

☐No

RTE7 Reprocessing: Does the establishment have reprocessing or reconditioning procedures in place and implemented (if observed) that prevent cross contamination of product?

☐Yes – If selected, answer the following question(s)

☐No

RTE7a Briefly describe the establishment's procedures for reprocessing or reconditioning. Include any vulnerability and any noncompliance with how the establishment's food safety system addressed reprocessing (limit 20,000 characters).

RTE8 Allergens: Does the establishment produce products that contain any of the "Big 9" allergens or other ingredients of public health concern? Big 9 allergens include: Wheat, Crustacean shellfish (e.g., crab, lobster, shrimp), Eggs, Fish, Peanuts, Milk, Tree nuts (e.g., almonds, pecans, walnuts), Soy, and Sesame.

☐ Yes – If selected, answer the following question(s)

☐ No

RTE8a Briefly describe any vulnerability and any noncompliance with how the establishment's food safety system addressed the identification, prevention and control, and declaration of allergens/ingredients. If applicable, address if the establishment has had a recall for undeclared allergens/ingredients in the past 6-months, and the corrective actions taken (limit 20,000 characters).

HACCP System Validation

This section is designed to assess the establishment's validation of its HACCP system.

RTE9 Does the establishment maintain adequate scientific or technical support that relates to the establishment's actual process, product, and hazard identified in the hazard analysis? (1st part of validation – design)? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes

☐No, support does not relate

☐No, establishment does not have support

RTE10 Does the establishment's scientific support demonstrate the process meets the performance standards or targets (i.e., pathogen reduction level) identified in the hazard analysis for each food safety system? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes

☐No, the support does not demonstrate that it meets the performance standards or targets

☐No, the establishment does not identify performance standards or targets

RTE11 Does the establishment use multiple interventions, including antimicrobial interventions, to meet the overall performance standard or target (i.e., multi-hurdle approach)?

☐Yes – If selected, answer the following question(s)

☐No

RTE11a In the event of a worst-case scenario when not all antimicrobial interventions are operational, does the establishment have support that the remaining antimicrobial interventions will adequately reduce the pathogen to an acceptable level?

☐Yes

☐No

☐Each antimicrobial intervention is required during production

RTE12 Does the establishment incorporate the critical operating parameters in the scientific support into its CCP critical limits, prerequisite programs, and other program limits? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes

☐No

RTE13 Does the establishment maintain in-plant validation data demonstrating the control measures, as written in the HACCP system, achieve the intended food safety outcome (2nd part of validation – execution)? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes

☐No

RTE14 Briefly describe any vulnerability or noncompliance finding with the establishment's HACCP system (i.e., HACCP plan, prerequisite program, or another program) validation that affect the establishment's ability to produce safe, wholesome, and unadulterated food not described above (limit 20,000 characters).

HACCP Monitoring, Verification, and Corrective Actions

This section is designed to assess the establishment's monitoring, verification, and corrective action procedures of those CCPs, prerequisite programs, or other programs.

RTE15 Does the establishment conduct the monitoring and verification (procedure and frequency) as written in its HACCP program (i.e., HACCP plan, prerequisite program, or another program)? Noncompliances and vulnerabilities are to be described in RTE17.

☐Yes

☐No, the establishment does not conduct monitoring and verification as written

☐No, the monitoring and verification are not written in its HACCP program

RTE16 Does the establishment maintain support for the selected monitoring and verification procedures and frequencies? Noncompliances and vulnerabilities are to be described in RTE17.

☐Yes

☐No

RTE17 Briefly describe any vulnerability and noncompliance finding with the establishment's monitoring and verification procedures and frequencies, including the support for its monitoring and verification procedures and frequencies in its program (i.e., HACCP plan, prerequisite program, or another program) (limit 20,000 characters).

RTE18 Does the establishment have corrective action procedures in its written program (i.e., HACCP plan, prerequisite program, or another program)? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes

☐No

RTE19 Has the establishment taken corrective actions as appropriate in response to deficiencies as required by 9 CFR 417.3 over the last 60 days?

*If yes, note whether all applicable parts of 9 CFR 417.3 were met. If no, note why the establishment did not take appropriate corrective actions (limit 4,000 characters).

☐Yes

☐No

☐N/A, the establishment has not had any deficiencies over the last 60 days.

RTE20 Do the records include the actual times, temperatures, or other quantifiable values, and include the product code(s), product name or identity, or slaughter production lot? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes

☐No

RTE21 Based on your review of records and observation of operations, briefly describe any vulnerability and noncompliance findings not described in previous questions with the implementation of monitoring and verification procedures that affect the establishment's ability to produce safe, wholesome, and unadulterated products. Note if the records accurately reflect the process (limit 20,000 characters).

RTE22 HACCP Summary: Describe any HACCP design findings not described in the previous questions and how your findings impact the establishment's food safety system (limit 20,000 characters).

Lethality for RTE Products: Fully Cooked, Not Shelf Stable and Heat-Treated, Shelf Stable (RTE23)

This section is designed to further assess the establishment's cooking of RTE products. The following questions should only be answered for RTE products in the Fully Cooked, Not Shelf Stable (this is the most common process used to produce RTE products) or Heat- Treated, Shelf Stable HACCP categories.

RTE23 Does the establishment achieve lethality of its RTE products in the Fully Cooked, Not Shelf Stable HACCP category or Heat-Treated Shelf, Stable HACCP by cooking?

☐Yes – If selected, answer the following question(s)

☐No, the establishment receives fully cooked RTE ingredients and assembles

☐No, the establishment does not produce products in these categories

RTE23a Does the establishment incorporate humidity into the cooking process according to its scientific support? Briefly describe any vulnerability or noncompliance (limit 2,000 characters).

☐Yes

☐No

RTE23b If the establishment does not incorporate humidity into the cooking process, does the establishment have support for why relative humidity is not a critical operational parameter? Briefly describe any vulnerability or noncompliance (limit 2,000 characters).

☐Yes

☐No

RTE23c Have there been trends in monitoring related to the cooking processes that would indicate repetitive deviations or have there been any other findings such as consumer complaints related to undercooking that could affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 20,000 characters)?

RTE23d Cooking Summary: Briefly describe any additional vulnerabilities or noncompliance findings regarding the establishment's cooking process for RTE product that are not described previously and assess the impact your findings have on the food safety system (limit 20,000 characters).

Stabilization for RTE Products: Fully Cooked, Not Shelf Stable and Secondary Inhibitors, Not Shelf Stable (RTE24)

This section is designed to further assess the establishment's stabilization of RTE products. The following questions should only be answered for RTE products in the Fully Cooked, Not Shelf Stable (this is the most common process used to produce RTE products) or Secondary Inhibitors, Not Shelf Stable HACCP categories.

RTE24 Does the establishment achieve stabilization of its RTE products in the Fully Cooked, Not Shelf Stable HACCP or Secondary Inhibitors, Not Shelf Stable category by cooling or hot-holding?

☐Yes – If selected, answer the following question(s)

☐No, the establishment does not produce products in this category

RTE24a If the establishment fully cooks the product and then applies additional heating and cooling steps that do not achieve full lethality, does the scientific support address the cumulative growth of spore-formers (e.g., *C. perfringens*, *C. botulinum*) across the first cooling and subsequent heating and cooling steps? Describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. Briefly describe any vulnerability or noncompliance (limit 2,000 characters).

☐Yes

☐No

☐The establishment does not apply additional heating and cooling steps that do not achieve full lethality

RTE24b If the establishment hot-holds the product, does the establishment adequately address hot-holding in the hazard analysis, supporting documentation, CCPs or prerequisite programs, and validation (including controls to ensure that the temperature will be maintained throughout storage, distribution, and sale)?

☐Yes

☐No

☐The establishment does not hot-hold product

RTE24c Stabilization Summary: Briefly describe any additional vulnerabilities or noncompliance findings regarding the establishment's cooling process for RTE product that are not described previously and assess the impact your findings have on the food safety system (limit 20,000 characters).

Lethality and Stabilization for RTE Products: Heat Treated, Shelf Stable; Not Heat Treated, Shelf Stable; and Secondary Inhibitors, Not Shelf Stable (RTE25- RTE26)

Questions in this section should only be answered for RTE products in the heat treated, shelf stable; not heat treated, shelf stable; and secondary inhibitors, not shelf stable HACCP plans. These products are less commonly produced than cooked RTE products.

Lethality Design: Fermentation, Drying, and Salt-Curing RTE Products

Questions in this section are specific to fermentation, drying, and salt-curing.

RTE25 Does the establishment achieve lethality by processes other than cooking alone (e.g., heat treated, shelf stable; not heat treated, shelf stable; and secondary inhibitors, not shelf stable)?

☐Yes – If selected, answer the following question(s)

☐No

RTE25a Did the establishment identify all appropriate hazards as part of its hazard analysis at the lethality step(s) (e.g., fermentation, drying, or salt-curing)?

☐Yes

☐No

RTE25b Did the establishment identify a performance standard or target to be met by the HACCP system by the lethality step(s)? For example, did the establishment identify a target of a 5-log reduction in *Salmonella* or an alternative lethality such as Option #5 from The Blue Ribbon Task Force in which the raw batter of sausage is tested in conjunction with the application of a process that achieves at least a 2-log reduction in the hazard of concern. NOTE: FSIS does not consider test and hold (also sometimes described as Option #3 from the Blue Ribbon Task Force document) as acceptable support because it relies on finished product testing alone and does not support a specific log reduction in levels of target pathogens.

☐Yes

☐No

RTE25c Does the establishment identify CCP critical limits, prerequisite program or other program limits for the lethality step(s)? Note: For multi-hurdle lethality products, establishments may use multiple CCPs or a combination of one or more CCPs and prerequisite programs to support that a combination of lethality steps achieves the targeted reduction in *Salmonella.*

☐Yes

☐No

RTE25d If the establishment uses fermentation as a lethality step, does the establishment incorporate degree-hours (the amount of time in hours above 60°F it takes at a specific temperature to reduce the pH to 5.3 or below) into the CCP, prerequisite program, or other program to address *Staphylococcus aureus* outgrowth? For more information see American Meat Institute Foundation. October 1997. Good Manufacturing Practices for Fermented Dry and Semi-Dry Sausage Products. Briefly describe any vulnerability or noncompliance (limit 2,000 characters).

☐Yes

☐No

☐The establishment does not use fermentation as a lethality step

RTE25e Does the establishment maintain adequate scientific support (e.g., journal articles or challenge studies) that the design of its lethality CCP(s) critical limit or prerequisite program or other program design (1st part – design) achieves 5-log reduction in *Salmonella* or an alternative lethality?

NOTE: Meeting degree-hours or meeting Trichinae recommendations has not been validated to achieve any specific reduction in *Salmonella.* Establishments often conduct challenge studies for fermented, salt-cured, and dried products to support the unique combination of critical operational parameters because other types of accepted support such as published processing guidelines or validated pathogen modeling programs are not available and journal articles often do not match an establishment's unique combination of critical operational parameters.

☐Yes

☐No

RTE25f Does the scientific support relate to the establishment's actual process, product and hazard identified in the hazard analysis? If not, does the establishment have justifications or additional support for why differences in critical operational parameters are not significant?
Examples of critical operational parameters used during fermentation, salt-curing, and drying include: Product formulation (i.e., salt concentration, use of nitrite/nitrate, etc.), antimicrobial application, fermentation temperature, target pH, time to reach target pH, and smoke, type and use of starter cultures, curing time, curing temperature, salt coverage of exposed muscle tissue, drying room temperature, drying time (*i.e.*, days or weeks), and product characteristics.

☐Yes

☐No

RTE25g Does the establishment's scientific support demonstrate the process meets the performance standards or targets identified in the hazard analysis for each food safety hazard?

☐Yes

☐No

RTE25h Does the establishment incorporate the critical operational parameters in the scientific support into its CCP critical limits, prerequisite programs, and other program limits for the lethality steps?

☐Yes

☐No

RTE25i Briefly describe the lethality steps and antimicrobial interventions used to achieve a 5-log reduction. Provide your assessment of any vulnerability or noncompliance findings not described above that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 20,000 characters)

Stabilization and Shelf-Stability Design: Shelf-Stable Products

This section is designed for establishments that produce fermented, dried, and salt-cured products that typically stabilize their products (i.e., prevent spore-forming bacteria from growing to significant levels) and achieve shelf-stability by reducing the pH and/or water activity.

RTE26 Does the establishment produce a shelf-stable product (e.g., heat treated, shelf stable or not heat treated, shelf stable)?

- ☐ Yes – If selected, answer the following question(s)
- ☐ No

RTE26a Does the establishment demonstrate through its HACCP plan, prerequisite program, or other program and its scientific support that the process precludes the growth of spore-formers (e.g., in fermented products a starter culture, dextrose, and nitrite are often used in combination to prevent outgrowth of spore-formers)?

- ☐ Yes
- ☐ No

RTE26b FSIS recommends that establishments that prevent the outgrowth of spore-formers by achieving certain pH and/or water activity prior to cooling still cool the product in a timely manner (i.e., continuously) to ensure growth of post-processing contaminants such as *Staphylococcus aureus* and *Listeria monocytogenes* is limited.

If the establishment stabilizes its products by pH and/or water activity, does it cool the product in a timely manner (i.e., continuously)?

- ☐ Yes
- ☐ No
- ☐ N/A

RTE26c If the establishment produces a shelf-stable product, does the establishment incorporate the critical operational parameters from its scientific support (e.g., water activity lower than 0.85, pH, combination of water activity and pH) into the CCP, prerequisite program, or other program?

- ☐ Yes
- ☐ No
- ☐ The product is not shelf stable

RTE26d Briefly describe any vulnerability and any noncompliance findings regarding the establishment's stabilization design that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 20,000 characters).

Non-Meat Ingredients for RTE Products (RTE27)

RTE27 Does the establishment add non-meat ingredients (e.g., sauces, spices, glazes, etc.) to any RTE products after the final lethality step?

☐Yes – If selected, answer the following question(s)

☐No

RTE27a Provide your assessment of any vulnerability and describe any noncompliance with the support in the hazard analysis specifically related to the non-meat ingredients added after the final lethality step. Briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 20,000 characters).

Non-Post-Lethality Exposed RTE Products (RTE28)

This section is designed to assess how establishments address non-post-lethality exposed products.

RTE28 Does the establishment produce non-post-lethality exposed products (e.g., cook-in-bag product; *sous vide* is a type of cook-in-bag)?

☐Yes – If selected, answer the following question(s)

☐No

RTE28a Does the establishment include the cook-in-bag or other lethality step achieved in the package in the flow chart and hazard analysis according to 9 CFR 417.2(a)(2)? Briefly describe any vulnerability or noncompliance (limit 2,000 characters).

☐Yes

☐No

RTE28b If the establishment applies High Pressure Processing (HPP) to treat the products as non-post-lethality exposed, does the establishment have scientific support demonstrating that the treatment achieves at least a 5-log reduction in *Listeria monocytogenes*?

If yes, consider whether the scientific support relates to the establishment's actual process and product. Note that establishments may evaluate factors such as pH, water activity, composition, and preservatives to determine if these are critical factors for a specific food. Briefly describe any vulnerability or noncompliance (limit 2,000 characters).

☐Yes

☐No

RTE28c Does the establishment ensure that the cooking bag is completely sealed (impermeable) so that moisture is contained within the bag or contaminants do not enter the bag? Cooking bags may be compromised during steps, such as molding or shaping. The establishment should have a process to verify the package integrity, and if leakers are observed, reprocess, or recook the product. Briefly describe any vulnerability or noncompliance (limit 2,000 characters).

☐Yes

☐No

Listeria Rule for RTE Products (RTE29 – RTE40)

This section is designed to assess how establishments address post-lethality exposed (PLE) products.

NOTE: This section only applies to RTE products per 9 CFR 430.4.

Listeria Control Alternatives

- Alternative 1 (Alt. 1): The establishment uses a post-lethality treatment (PLT) to reduce or eliminate *Lm* in the product and an antimicrobial agent or process (AMAP) to limit or suppress growth of *Lm* in the product.
- Alternative 2, Choice 1 (Alt. 2a): The establishment uses a PLT to reduce or eliminate *Lm* in the product.
- Alternative 2, Choice 2 (Alt. 2b): The establishment uses an AMAP to limit or suppress growth of *Lm* in the product.
- Alternative 3 (Alt. 3): The establishment relies on sanitation alone to control *Lm* in the processing environment and on the product. There are separate requirements for deli meat and hotdogs under this alternative.

RTE29 Does the establishment produce post-lethality exposed RTE products?

☐Yes – If selected, answer the following question(s)

☐No

RTE29a Which alternative does the establishment use to produce post-lethality exposed RTE products? Select all that apply.

☐Alternative 1 (use of a PLT and an AMAP)

☐Alternative 2 choice 1 (use of only a PLT)

☐Alternative 2 choice 2 (use of only an AMAP)

☐Alternative 3 (sanitation alone, does not use PLT or AMAP)

RTE29b Does the establishment minimize cross-contamination and maintain separation of raw and RTE product?

Include in your assessment traffic patterns, controlling movement of equipment, maintaining physical separation (if applicable), and restricting use of garments or utensils to specific areas.

☐Yes

☐No

RTE29c Are conditions that may contribute to product and FCS contamination corrected as soon as possible?

☐Yes

☐No

RTE29d Briefly describe any vulnerability and noncompliance findings regarding establishment or facility conditions that could lead to *Lm* cross-contamination that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. Note: Your assessment may include conditions (e.g., condensation, holes in wall, air flow, rusty or pitted equipment) (limit 20,000 characters).

Listeria Rule: Sampling and Testing

This section is designed to assess whether the establishment's sampling and testing programs that are part of the establishment's HACCP system (e.g., as ongoing verification for a CCP or prerequisite program), are designed appropriately and performed under validated conditions, and that the establishment reacts appropriately to sampling results.

As instructed in FSIS Directive 5100.1, the EIAO is to:

- Directly observe the establishment collecting samples according to its supporting documentation if the establishment conducts sampling during the course of the FSA;
- Review establishment sampling results from the previous 6 months in establishments;
- Document all relevant noncompliance and vulnerability findings for all HACCP processing categories covered in this tool; and
- Review the Foodborne Pathogen Test Kits Validated by Independent Organizations database to determine whether the method used by the establishment is fit for purpose and performed under validated conditions.

RTE30 Sampled Lot Definition: Considering rework, returned product, carry-over, commingling, and cross-contamination during processing, does the establishment have a supportable basis for its sampled lot definition (microbiological independence)?

☐Yes

☐No

RTE31 Describe the establishment's sample lot definitions, the support and rationale for lot independence, and any flaws in the process that would question the establishment's microbiological independence determination (limit 20,000 characters).

Listeria Rule: Non-Food Contact Surface (NFCS) and Product Sampling and Testing Design

RTE32 Does the establishment perform *Listeria* sampling and testing on NFCS and/or product?

☐Yes (proceed to next question)

☐No

RTE33 Does the establishment maintain adequate support for NFCS and/or product sampling procedures (written instructions, appropriate collection device, validation, etc.)?

☐Yes

☐No

RTE34 Based on your observation of the sampling procedures, does the establishment collect samples according to the validated sampling methods? Briefly describe any vulnerability or noncompliance (limit 2,000 characters).

NOTE: Consider weaknesses in the implemented sampling program, which may hinder the establishment's ability to ensure that effective control of *Lm* or indicator organisms is maintained.

☐Yes

☐No

☐NFCS and/or product sampling were not observed during the FSA

RTE35 Does the establishment maintain adequate support for NFCS and/or product testing methods (fit for intended use, validation, etc.).

☐Yes

☐No

RTE36 Does the establishment analyze the NFCS and/or product samples in a laboratory on site?

☐Yes – If selected, answer the following question(s)

☐No, the establishment uses a third- party laboratory

RTE36a Based on your observation of the testing procedure performed on site, does the establishment perform testing following validated testing methods? Briefly describe any vulnerability or noncompliance (limit 2,000 characters). NOTE: Consider weaknesses in the implemented testing procedures, which may hinder the establishment's ability to ensure that effective control of *Lm* or indicator organisms is maintained.

☐Yes

☐No

☐N/A, the testing procedures were not observed during the FSA

RTE37 Has the establishment had any *Listeria* positive tests of non-food contact surfaces or product samples? If yes, assess whether the establishment conducted follow-up testing in response to positive test results. Include whether the positive results are *Listeria* species or *Listeria monocytogenes* and briefly describe any vulnerability or noncompliance (limit 2,000 characters).

☐Yes

☐No

Listeria Rule: Food Contact Surface (FCS) Testing

This section applies to establishments that produce product under any *Listeria* control alternative.

NOTE: FCS testing is required for establishments under Alt. 3 and Alt. 2b. FCS testing is not required for establishments producing RTE products under Alt. 2a and 1, however answer this section if the establishment conducts FCS optionally.

RTE38 Does this establishment conduct food contact surface (FCS) testing?

NOTE: FCS testing is required for alternatives 3 and 2b. It is optional for alternatives 2a and 1.

☐Yes as REQUIRED by the *Listeria* rule for Alt. 3 and Alt. 2b; or OPTIONALLY under Alt. 1 and Alt. 2a – If selected, answer the following question(s)

☐No, there is noncompliance with the *Listeria* Rule for Alt. 3 and Alt. 2b

☐No, the establishment does not produce products under Alt. 1 and Alt. 2a

☐No, the establishment does not produce any Post-Lethality Exposed (PLE) Products

Listeria Rule: FCS Sampling and Testing Design

RTE38a Is FCS testing designed to verify sanitation in the post-lethality environment?

☐Yes

☐No

RTE38b Does the FCS testing design include hold and test procedures following a positive FCS testing?

☐Yes

☐No

RTE38c Provide your assessment of any vulnerability and describe any noncompliance with hold-and-test procedures being implemented as written (limit 20,000 characters).

RTE38d Does the FCS sampling and testing design include the frequency of FCS testing, identification of the location of sites for sampling, and the size of sites to be sampled?

☐Yes

☐No

RTE38e Are all possible FCS sampling sites identified?

☐Yes

☐No

RTE38f Is the FCS testing design sufficient 1) to ensure effective control of *Listeria*-like, *Listeria* spp., or *Listeria monocytogenes*, and 2) to detect low numbers of *Lm* or indicator organisms, if present? Briefly describe any vulnerability or noncompliance (limit 2,000 characters).

NOTE: Assess the laboratory analysis method and sample collection method.

☐Yes

☐No

RTE38g Does the establishment maintain adequate support for the FCS sampling procedures (written instructions, appropriate collection device, validation, etc.)?

☐Yes

☐No

RTE38h Based on your observation of the sampling procedure, does the establishment collect samples according to the validated sampling methods? Briefly describe any vulnerability or noncompliance (limit 2,000 characters).

NOTE: Consider weaknesses in the implemented sampling program, which may hinder the establishment's ability to ensure that effective control of *Lm* or indicator organisms is maintained.

☐Yes

☐No

☐ N/A, the sampling was not observed during the FSA

RTE38i Does the establishment maintain adequate support for the FCS testing method (fit for intended use, validation, etc.). Briefly describe any vulnerability or noncompliance (limit 2,000 characters).

☐Yes

☐No

RTE38j Has the establishment had any initial FCS positive tests in the past 6 months? If yes, assess whether the establishment conducted follow-up testing on FCS sites. Briefly describe any vulnerability or noncompliance (limit 2,000 characters).

☐Yes

☐No

RTE38k Briefly describe any vulnerability and any noncompliance findings regarding the establishment's sampling and testing design that are not described in the previous questions that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 20,000 characters).

RTE38l If the establishment applies High Pressure Processing (HPP) to the product to address *Lm* positive product or product that passed over a *Lm* positive FCS, does the establishment have supporting documentation demonstrating that the treatment achieves at least a 5-log reduction in *Listeria monocytogenes*? If yes, consider whether the scientific support relates to the establishment's actual process and product. Note that establishments may evaluate factors such as pH, water activity, composition, and preservatives to determine if these are critical factors for a specific food). Briefly describe any vulnerability or noncompliance (limit 2,000 characters).

☐Yes

☐No

Listeria Rule: Post Lethality Treatment (PLT) Design

This section applies to establishments that produce product under any *Listeria* control alternative.

NOTE: PLT is required for establishments under Alt. 1 and Alt. 2a. PLT is not required for establishments producing RTE products under Alt. 2b and 3, however answer this section if the establishment applies PLT optionally.

RTE39 Does this establishment utilize or apply a post-lethality treatment (PLT)?

☐Yes, as required by the *Listeria* rule under Alt. 1 or Alt. 2a or optionally for other Alternatives – If selected, answer the following question(s)

☐No, the establishment produces products under *Listeria* Rule for Alt. 1 or Alt. 2a but they do not have a PLT.

☐No, the establishment does not produce products under Alt. 1 and Alt. 2a

☐N/A, the establishment does not produce any Post-Lethality Exposed (PLE) Products

RTE39a Does the establishment's validation (scientific support and in-plant validation) adequately support the PLT is sufficient to control the level of contamination (e.g., achieves at least a 1-log reduction of *Lm*) PLT? Briefly describe any vulnerability or noncompliance (limit 2,000 characters).

NOTE: Specifically consider whether critical operational parameters, equipment and procedures, product, or product formulation are being implemented the same or similar to the scientific support. If the establishment implements different parameters than the scientific support, consider whether they demonstrated that changes are effective.

☐Yes

☐No

Listeria Rule: Antimicrobial Agent or Process (AMAP) Design

This section applies to establishments that produce product under any *Listeria* control alternative.

NOTE: AMAP is required for establishments under Alt. 1 and Alt. 2b. AMAP is not required for establishments producing RTE products under Alt. 2a and 3, however answer this section if the establishment applies AMAP optionally.

RTE40 (Single Choice) Does this establishment utilize or apply an Antimicrobial Agent or Process (AMAP)?

- ☐ Yes, as required by the *Listeria* rule under Alt. 1 or Alt. 2b or optionally under other alternatives – If selected, answer the following question(s)
- ☐ No, establishment produces products under the *Listeria* Rule for Alt. 1 or Alt. 2b but they do not have a AMAP
- ☐ No, the establishment does not produce products under Alt. 1 and Alt 2b
- ☐ N/A, the establishment does not produce any post-lethality exposed (PLE) products

RTE40a If the establishment is using one or more antimicrobial agents, are they safe and suitable for use as described in FSIS Directive 7120.1?

- ☐ Yes
- ☐ No

RTE40b Does the establishment's validation (scientific support and in-plant validation) adequately support the AMAP inhibits *Lm* growth (e.g., no more than 2-logs growth of *Lm*) over the shelf-life? Briefly describe any vulnerability or noncompliance (limit 2,000 characters).

NOTE: Specifically consider whether critical operational parameters, equipment and procedures, product, or product formulation are being implemented the same or similar to the scientific support. If the establishment implements different parameters than the scientific support, consider whether they supported that those changes are effective.

- ☐ Yes
- ☐ No

RTE40c Does the establishment's validation include a shelf-life study to determine the growth of *Lm* during storage?

- ☐ Yes
- ☐ No

RTE40d Briefly describe any vulnerability and any noncompliance findings regarding the establishment's AMAP design that are not described in the previous questions that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 20,000 characters).

End-Product Testing (RTE41)

This section is designed to assess whether the establishment's sampling and testing programs that are part of the establishment's HACCP system (e.g., as ongoing verification for a CCP or prerequisite program), are designed appropriately and performed under validated conditions, and that the establishment reacts appropriately to sampling results.

As instructed in FSIS Directive 5100.1, the EIAO is to:

- Directly observe the establishment collecting samples according to its supporting documentation if the establishment conducts sampling during the course of the FSA;
- Review establishment sampling results from the previous 60 days in establishments;
- Document all relevant noncompliance and vulnerability findings for all HACCP processing categories covered in this tool; and
- Review the Foodborne Pathogen Test Kits Validated by Independent Organizations database to determine whether the method used by the establishment is fit for purpose and performed under validated conditions.

RTE41 Does the establishment conduct end-product testing for biological hazards?

☐Yes – If selected, answer the following question(s)

☐No

RTE41a Is this end-product testing conducted as part of its ongoing verification of the lethality step(s) and stabilization step(s), including those related to achieving shelf-stability?

☐Yes

☐No

RTE41b Is any end-product testing conducted for other purposes (e.g., customer specification)?

☐Yes

☐No

RTE41c Does the establishment maintain adequate support for the testing method (test portion, fit for intended use, validation, etc.)?

☐Yes

☐No

RTE41d Do the establishment employees perform the sampling as described in the establishment's sampling protocol (aseptic technique, sample size and type, laboratory methods)?

☐Yes

☐No

RTE41e Did the establishment receive any positive results from end-product testing in the previous 60 days, and/or during the period of time around the initial risk based for- cause trigger for the FSA?

☐Yes

☐No

RTE41f Briefly describe the biological hazard analyzed, sampling methodology, testing methodology, and your observation of the sampling collection. Briefly describe any vulnerability or noncompliance (if the sampling and testing is used to support decisions in the hazard analysis (9 CFR 417.5(a)(1)) and assess the impact your findings have on food safety (limit 20,000 characters).

RTE41g Summarize how the establishment addresses positives, identifies trends and how the sample results are used for decision making within the HACCP system. Briefly describe any vulnerabilities and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 20,000 characters). Note: Specify if the sampling results are within the 60 days or the additional time period.

Previous FSIS Positives (RTE42 – RTE43)

RTE42 During review of the "Public Health Risk Evaluation for Establishment" report (*Lm*) and the "Further characterization of Positive Samples for an Establishment," was a history of harborage at this establishment identified by the FSIS samples?

☐Yes – If selected, answer the following question(s)

☐No, there is no history of harborage at this establishment.

RTE42a Has the establishment identified and eliminated the source of harborage? Please respond even if the establishment reclassified their product as not post-lethality exposed. Briefly describe any vulnerability or noncompliance (limit 2,000 characters).

☐Yes

☐No

RTE43 Based on the products the establishment produces and a review of the laboratory sampling results obtained from the PHRE report, is the in-plant team receiving the appropriate sampling tasks through PHIS according to the establishment's products and production volume?

NOTE: If the EIAO identifies that the appropriate sampling tasks are not being assigned to the in-plant team, they are to contact the FLS.

☐Yes

☐No

RTE Tool Summary (RTE44)

This question is designed to focus on the most significant noncompliance or vulnerability findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. Summarize the findings that bear most directly on the FSA recommendation with respect to what action, if any, is necessary with respect to the establishment's HACCP system. The answer to this question is to be used to construct the Executive Summary.

RTE44 Summarize any vulnerability or noncompliance findings identified in the RTE Processed Products tool that have an impact on the establishment's ability to produce safe, wholesome, unadulterated product and are critical to determine an FSA recommendation. Describe the impact the findings have on the establishment's food safety system (limit 20,000 characters). Limit your response to three to five bullet points total.