Ready-to Eat (RTE) Processed Products FSA Tool VS2

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:

HEAT TREATED, SHELF STABLE

NOT HEAT TREATED, SHELF STABLE

FULLY COOKED, NOT SHELF STABLE

SECONDARY INHIBITORS, NOT SHELF STABLE

The FSA Tool contains the following main sections:

- **Hazard Analysis and HACCP System (Questions RTE1 – RTE6)**
- **Lethality and Stabilization: Fully Cooked, Not Shelf Stable (RTE7 - RTE40)**
- **Lethality and Stabilization for Fermentation, Drying, and Salt-curing RTE Processing in the Heat Treated, Shelf Stable; Not Heat Treated, Shelf Stable; Secondary Inhibitors, Not Shelf Stable HACCP Processing Categories (Questions RTE41- RTE71)**
- **Non-meat Ingredients for RTE Products (Question RTE72 - RTE73)**
- ***Listeria* Rule (9 CFR 430) for RTE Products (Questions RTE74- RTE98)**

NOTE: 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 contribute to 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, *Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment (FSA) Methodology***
2. **FSIS Directive 5000.2, *Review of Establishment Data by Inspection Personnel.***
3. **FSIS Directive 10,240.4, *Verification Activities for the Listeria monocytogenes (Lm) Regulation and the Ready-to-Eat (RTE) Sampling Program***
4. **FSIS Compliance Guideline: *Controlling Listeria monocytogenes in Post-Lethality Exposed Ready-to-Eat Meat and Poultry Products;***

NOTE: For all questions in this FSA tool, please note that some FSA tool questions are not required questions and will only appear based on the answer responses provided. Also, it is not necessary to copy and paste information into a text box that you've provided in a previous text field question within the tool.

Hazard Analysis and HACCP System (Questions RTE1 – RTE6)

This section is designed to assess the establishment's HACCP system. The HACCP system includes the 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.

NOTE: If there are findings specific to lethality, stabilization and *Listeria* Rule, briefly reference and provide more details in their respective sections of this tool.

RTE1 **Has the establishment considered the relevant food safety hazards throughout the HACCP system?**

☐Yes

☐No

RTE2 **Describe the hazard(s) not properly considered or identified. Briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.**

Click here to enter text.

RTE3 **Has the establishment properly developed and implemented a written HACCP plan to address each food safety hazard determined to be "reasonably likely to occur"?**

***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE4 **Has there been a change that could affect the hazard analysis or HACCP plan during the previous 60 days?**

NOTE: Answer this question based on your review of selected of 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 questions RTE5

☐No

RTE5 **Briefly describe how the hazard analysis and/or HACCP plan was reassessed in response to the change. Briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.**

Click here to enter text.

RTE6 **HACCP Summary: If applicable, describe additional HACCP design or implementation of the establishment's HACCP system findings that are not described in the previous questions. Describe any vulnerability or noncompliance. Provide an assessment of how your findings impact the establishment's food safety system.**

Click here to enter text.

Lethality and Stabilization for RTE Products: Fully Cooked, Not Shelf Stable

This section is designed to assess the establishment's cooking and cooling of RTE products.

NOTE: The following questions should only be answered for RTE products in the fully cooked, not shelf stable HACCP category. This is the most common process used to produce RTE products.

RTE7 **Does the establishment achieve lethality of its RTE products in the fully cooked, not shelf stable HACCP category by cooking and stabilization by cooling or hot holding?**

☐Yes

☐No

Instruction: **Lethality Design: Cooking RTE Products**

RTE8 **Did the establishment identify all appropriate hazards as part of its hazard analysis at the cooking step?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE9 **Did the establishment identify a performance standard or target to be met by the HACCP system during cooking?**
***If the answer is no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If the answer is yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE10 **Does the establishment identify CCP critical limits, prerequisite program or other program limits for the cooking process?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE11 **Does the establishment maintain adequate scientific support for the design of its cooking CCP critical limit or prerequisite program or other program design?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE12 **Does the scientific support relate to the establishment's actual process, product, and hazard identified in the hazard analysis?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE13 **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?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE14 **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 cooking process?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

Instruction: **Cooking and Relative Humidity Questions**

The following question asks about a specific critical operational parameter in the cooking process, relative humidity.

RTE15 **Does the establishment incorporate humidity into the cooking process?**
***If yes, leave the text box blank unless based on your assessment, you have findings. Briefly describe any vulnerability and any noncompliance with the establishment's support.**
***If no, describe if the establishment has support for why humidity is not a critical operational parameter and include your assessment of any vulnerability and describe any noncompliance**

☐Yes - Click here to enter text.

☐No - Click here to enter text.

RTE16 **Does the establishment's in-plant validation adequately support the cooking process?**
NOTE: Until further notice, EIAOs are to note any lack of data in the FSA but are not to use the lack of data as the only reason for noncompliance.
***If there are findings of any vulnerability or noncompliance, describe them in the free text and assess the impact your findings have on the food safety system. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

☐The establishment does not have in-plant validation

Instruction: **Lethality Monitoring, Verification, Corrective Action Design: Cooking RTE Product**

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

RTE17 **Does the establishment have monitoring and verification procedures and frequencies in its written program (i.e., HACCP plan, prerequisite program, or other program) for cooking.**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE18 **Does the establishment have support for its monitoring and verification procedures and frequencies in its written program (i.e., HACCP plan, prerequisite program, or other program) for cooking?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE19 **Does the establishment have corrective action procedures in its written program (i.e., HACCP plan, prerequisite program, or other program) for cooking?**

***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE20 **If applicable, describe additional findings regarding lethality monitoring, verification, and corrective action design for cooking RTE product that are not described in the previous questions and how your findings impact the establishment's food safety system. Briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.**
***This question is to be left blank if there are no additional findings.**
Click here to enter text.

Instruction: **Lethality Implementation: Cooking RTE Products**

RTE21 **Based on your review of records and observation of operations, do the establishment's records accurately reflect that the establishment is implementing the monitoring and verification procedures as designed for the cooking process step?**

NOTE: For deviations in the last 60 days, provide your assessment of whether all parts of 9 CFR 417.3 were addressed. Answer this question based on your review of selected of records (including any additional record review because of a food safety concern) as outlined in FSIS Directive 5100.1

***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE22 **As part of its ongoing verification of the cooking process, does the establishment conduct end product testing for biological hazards other than Listeria?**

***If yes, provide your assessment of whether the establishment took appropriate corrective actions in response to any positives during the previous 6 months. If no, leave the free text box blank.**

☐Yes - Click here to enter text.

☐No

RTE23 **Did the establishment identify all appropriate hazards as part of its hazard analysis during the cooling step?**

***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE24 **If the establishment fully cooks the product and then applies additional heating and cooling steps that do not achieve full lethality (e.g., an oil browning step or pasteurization treatment), does it identify all appropriate hazards as part of its hazard analysis at those steps?**

***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes or if the establishment does not apply additional steps, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

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

RTE25 **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?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes or if the establishment does not apply additional steps, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

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

RTE26 **Did the establishment identify a performance standard or target to be met by the HACCP system during cooling? Provide your assessment of any vulnerability and describe any noncompliance.**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE27 **Does the establishment identify CCP critical limits, prerequisite program or other program limits for the cooling process?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE28 **Does the establishment maintain adequate scientific support for the design of its cooling CCP critical limit or prerequisite program or other program design?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE29 **Does the scientific support relate to the establishment's actual process, product and hazard identified in the hazard analysis?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE30 **Does the establishment's scientific support demonstrate that the establishment's process meets the performance standards or targets it identified in the hazard analysis for each food safety hazard?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE31 **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 cooling process.
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE32 **If the establishment is using scientific support other than an FSIS guideline or regulation (e.g., journal article or challenge study), does establishment's study design adequately support the cooling process?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes or if the establishment is not using other support, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

☐The establishment is not using support other than FSIS guidelines or regulations.

RTE33 **Does the establishment's in-plant validation data adequately support the cooling process?**
NOTE: Until further notice, EIAOs are to note any lack of data in the FSA but are not to use the lack of data as the only reason for noncompliance.
***If there are findings of any vulnerability or noncompliance, describe them in free text and assess the impact your findings have on the food safety system. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

☐The establishment does not have in-plant validation

RTE34 **If the establishment hot-holds the product, does it have controls and appropriate labeling to ensure that the temperature will be maintained throughout storage, distribution, and sale?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

☐The establishment does not hold product

RTE35 **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?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

☐The establishment does not hot-hold product

Instruction: **Stabilization Monitoring, Verification, Corrective Action Design: Cooling RTE Products**

RTE36 **Does the establishment have support for its monitoring and verification procedures and frequencies in its written program for cooling (i.e., HACCP plan, prerequisite program, or other program)?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE37 **Does the establishment have corrective action procedures in its written program (i.e., HACCP plan, prerequisite program, or other program) for cooling?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE38 **If applicable, describe additional findings regarding stabilization monitoring, verification, and corrective action design for cooking RTE product that are not described in the previous questions and how your findings impact the establishment's food safety system. Briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.**

*** This question is to be left blank if there are no additional findings.**

RTE39 **Based on your review of records and observation of operations, do the establishment's records accurately reflect that the establishment is implementing the monitoring and verification procedures as designed for product stabilization?**

NOTE: For deviations in the last 60 days, provide your assessment of whether all parts of 9 CFR 417.3 were addressed. Answer this question based on your review of selected of records (including any additional record review because of a food safety concern) as outlined in FSIS Directive 5100.1.

***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE40 **Cooking and Cooling Summary: Provide a summary of your findings regarding the establishment's cooking and cooling process RTE product. Briefly describe how your findings impact the establishment's food safety system. Briefly describe any vulnerability or noncompliance, and assess the impact your findings have on the food safety system.**

Click here to enter text.

Instruction: Lethality and Stabilization for RTE Products: Heat Treated, Shelf Stable; Not Heat Treated, Shelf Stable & Secondary Inhibitors, Not Shelf Stable (Questions RTE 42- RTE75)

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

RTE41 **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 questions
RTE42,RTE43,RTE44,RTE45,RTE46,RTE47,RTE48,RTE49,RTE50,RTE51,RTE52,RTE53,RTE54, RTE55,RTE56,RTE57,RTE58, RTE59,RTE60,RTE61,RTE62,RTE63,RTE64,RTE65,RTE67,RTE67, RTE68,RTE69,RTE70,RTE71

☐No

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

RTE42 **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)?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE43 **Did the establishment identify a performance standard or target to be met by the HACCP system by the lethality step(s)?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE44 **Does the establishment identify CCP critical limits, prerequisite program or other program limits for the lethality step(s)?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE45 **If the establishment uses fermentation as a lethality step, does the establishment incorporate degree hours into the CCP, prerequisite program, or other program?**
***Briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.**

☐Yes - Click here to enter text.

☐No - Click here to enter text.

☐Establishment does not use fermentation as a lethality step

RTE46 **Does the establishment maintain adequate scientific support for the design of its lethality CCP(s) critical limit or prerequisite program or other program design?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE47 **Does the scientific support relate to the establishment's actual process, product and hazard identified in the hazard analysis?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE48 **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?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE49 **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

RTE50 **If the establishment is using scientific support other than an FSIS guideline or regulation (e.g., journal article or challenge study), is the study design adequate?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

☐The establishment does not use support other than FSIS guidelines or regulations

RTE51 **Does the establishment's in-plant validation data adequately support the establishment's lethality step(s)?**
NOTE: Until further notice, EIAOs are to note any lack of data in the FSA but are not to use the lack of data as the only reason for noncompliance.
***If there are findings of any vulnerability or noncompliance, describe them in the free text and assess the impact your findings have on the food safety system.**

☐Yes

☐No - Click here to enter text.

☐The establishment does not have in-plant validation data

RTE52 **Does the establishment have monitoring and verification procedures and frequencies in its written program (i.e., HACCP plan, prerequisite program, or other program) for the lethality step(s)?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE53 **Does the establishment have support for its monitoring and verification procedures and frequencies in its written program (i.e., HACCP plan, prerequisite program, or other program) for the lethality step (s)?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE54 **Does the establishment have corrective action procedures in its written program (i.e., HACCP plan, prerequisite program, or other program) for the lethality step(s)?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE55 **If applicable, describe additional findings regarding lethality monitoring, verification, and corrective action for fermentation, Drying, and Salt-curing RTE Products that are not described in the previous questions. Briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.**
*** This question is to be left blank if there are no additional findings.**
Click here to enter text.

Instruction: **Lethality Implementation: Fermentation, Drying, and Salt-Curing RTE Products**

RTE56 **Based on your review of records and observation of operations, do the establishment's records accurately reflect that the establishment is implementing the monitoring and verification procedures as designed for the lethality process step?**
NOTE: For deviations in the last 60 days, provide your assessment of whether all parts of 9 CFR 417.3 were addressed. NOTE: Answer this question based on your review of selected of records (including any additional record review because of a food safety concern) as outlined in FSIS Directive 5100.1.
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE57 **As part of its ongoing verification of the lethality step(s), does the establishment conduct end product testing for biological hazards other than Listeria?**
***If yes, provide your assessment of whether the establishment took appropriate corrective actions in response to any positives during the previous 6 months. If no, leave the free text box blank.**

☐Yes - Click here to enter text.

☐No

RTE58 **Does the establishment conduct end product testing for biological hazards other than Listeria for other purposes (e.g., customer specification)?**
***If yes, provide your assessment of whether the establishment took appropriate corrective actions in response to any positives during the previous 6 months. If no, leave the text box blank.**

☐Yes - Click here to enter text.

☐No

Instruction: **Stabilization Design: Fermentation, Drying, or Salt-Curing RTE 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) by reducing the pH and/or water activity.

RTE59 **Did the establishment identify all appropriate hazards as part of its hazard analysis at the stabilization step(s) (e.g., fermentation, drying, or salt-curing)?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE60 **Does the establishment demonstrate through its HACCP plan, prerequisite program, or other program and its scientific support that the pH and/or water activity precludes the growth of spore-formers?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE61 **FSIS recommends that establishments that implement a heat-treatment but stabilize its products by pH and/or water activity still cool the product in a timely manner to ensure growth of post-processing**

contaminants such as *Staphylococcus aureus* and *Listeria monocytogenes* is limited.
If applicable, does the establishment still cool the product in a timely manner?
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE62 **If the establishment produces a shelf-stable product, does the establishment incorporate into the CCP, prerequisite program, or other program and its support for those parameters (e.g., water activity lower than 0.85 using salt concentration or drying, pH, combination of water activity and pH)?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

☐The product is not shelf stable

RTE63 **Does the establishment's in-plant validation data adequately support the stabilization step(s)?**
NOTE: Until further notice, EIAOs are to note any lack of data in the FSA but are not to use the lack of data as the only reason for noncompliance.
***If there are findings of any vulnerability or noncompliance, describe them in the free text and assess the impact your findings have on the food safety system. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

☐The establishment does not have in-plant validation

Instruction: **Stabilization Monitoring, Verification, Corrective Action Design: Fermentation, Drying, and Salt-curing RTE Products**

RTE64 **Does the establishment have monitoring and verification procedures and frequencies and in its written program (i.e., HACCP plan, prerequisite program, or other program) for the stabilization step(s) including those related to achieving shelf-stability?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE65 **Does the establishment have support for its monitoring and verification procedures and frequencies in its written program (i.e., HACCP plan, prerequisite program, or other program) for the stabilization step(s) including those related to achieving shelf-stability?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE66 **Does the establishment have corrective action procedures in its written program (i.e., HACCP plan, prerequisite program, or other program) for the stabilization step(s) including those related to achieving shelf-stability?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE67 **If applicable, describe additional findings regarding stabilization monitoring, verification, and corrective action for Fermentation, Drying, and Salt-curing RTE Products that are not described in the previous questions. Briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.**
*** This question is to be left blank if there are no additional findings.**
Click here to enter text.

RTE68 **Based on your review of records and observation of operations, do the establishment's records accurately reflect that the establishment is implementing the monitoring and verification procedures as designed for product stabilization?**
NOTE: For deviations in the last 60 days, provide your assessment of whether all parts of 9 CFR 417.3 were addressed.
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE69 **As part of its ongoing verification of the stabilization step(s), including those related to achieving shelf-stability, does the establishment conduct end product testing for biological hazards other than Listeria?**
***If yes, provide your assessment of whether the establishment took appropriate corrective actions in response to any positives during the previous 6 months. If no, leave the free text box blank.**

☐Yes - Click here to enter text.

☐No

RTE70 **Does the establishment conduct end product testing for other purposes (e.g., customer specification)?**
***If yes, provide your assessment of whether the establishment took appropriate corrective actions in response to any positives during the previous 6 months. Briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If there are no findings of vulnerability or noncompliance, leave the free text box blank.**

☐Yes - Click here to enter text.

☐No

RTE71 **Provide a summary of your findings regarding the establishment's fermentation, drying or salt-curing process for RTE products that have not been previously covered. Briefly describe how your findings impact the establishment's food safety system. Briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.**
***If there are no additional findings, this question can be left blank.**

Click here to enter text.

Instruction: **Non-meat Ingredients for RTE Products (Questions RTE72& RTE73)**

RTE72 **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 questions RTE73

☐No

RTE73 **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.**
***This question is to be left blank if there are no vulnerability or noncompliance findings.**
Click here to enter text.

Instruction: ***Listeria*** **Rule for RTE Products (Questions RTE74- RTE98)**

This section is designed to assess how establishment's addresses 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.**

***References:**
FSIS Directive 10,240.4*, Verification Activities for the Listeria monocytogenes (Lm) Regulation and the Ready-to-Eat (RTE) Sampling Program*

FSIS Compliance Guideline: *Controlling Listeria monocytogenes in Post-Lethality Exposed Ready-to-eat Meat and Poultry Products*;

RTE74 **Does the establishment produce post-lethality exposed RTE products?**

☐Yes - If selected, answer the following questions RTE75,RTE76,RTE77,RTE78,RTE81,RTE82

☐No

RTE75 **Which alternative does the establishment use to produce post-lethality exposed RTE products?**

☐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)

RTE76 **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.**

***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE77 **Are conditions that may contribute to product and FCS contamination corrected as soon as possible? *If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE78 **If applicable, describe any additional findings regarding establishment or facility conditions that could lead to Lm cross-contamination that were not previously addressed. Note: Your assessment may include conditions (e.g., condensation, holes in wall, air flow, rusty or pitted equipment). Briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.**

***This question is to be left blank if there no additional findings of vulnerability or noncompliance.**

Click here to enter text.

Instruction: **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 review establishment sampling results from the previous 6 months in RTE establishments and document all relevant noncompliance and vulnerability findings for all HACCP processing categories covered in this tool.

RTE79 **Has the establishment had any Listeria positive tests other than FCS sites?**
NOTE: If yes, assess whether the establishment conducted follow-up testing in response to positive test results.
***Briefly describe any vulnerability or noncompliance, and assess the impact your findings have on the food safety system in the free text box. If there are no vulnerabilities or noncompliance, leave the free text box blank.**

☐Yes - Click here to enter text.

☐No - Click here to enter text.

RTE80 **Provide your assessment of any vulnerability and describe any noncompliance with hold-and-test procedures being implemented as written. If there are no findings, leave the free text box blank.**

Click here to enter text.

Instruction: **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.**

RTE81 **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 questions RTE82,RTE83,RTE84,RTE85,RTE86,RTE87,RTE88

☐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

Instruction: **Listeria Rule: Testing Design (Questions RTE82 - RTE98)**

RTE82 **Is FCS testing designed to verify sanitation in the post-lethality environment?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE83 **Does the FCS testing design include hold and test procedures following a positive FCS testing?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank**

☐Yes

☐No - Click here to enter text.

RTE84 **Does the FCS testing design include the frequency of FCS testing, identification of the location of sites for sampling, and the size of sites to be sampled?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE85 **Are all possible FCS sampling sites identified?**
***If no, identify all FCS sites not identified by the establishment. Also, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE86 **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?**
NOTE: Assess the laboratory analysis method and sample collection method.
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE87 **Based on your observation of the sampling procedure, does the establishment collect samples according to the design of the FCS testing?**
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.
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text blank.**

☐Yes

☐No - Click here to enter text.

RTE88 **Has the establishment had any initial FCS positive tests in the past 6 months?**
NOTE: If yes, assess whether the establishment conducted of follow-up testing on FCS sites.
*** Briefly describe any vulnerability or noncompliance, and assess the impact your findings have on the food safety system in the free text box. If there are no vulnerabilities or noncompliance, leave the free text box blank.**

☐Yes - Click here to enter text.

☐No - Click here to enter text.

Instruction: **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 apply PLT optionally.

RTE89 **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 questions RTE90,RTE91,RTE92

☐No, there is noncompliance with the Listeria Rule for Alt. 1 or Alt. 2a/

☐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

RTE90 **Does the establishment's validation and documentation adequately support the PLT?**
NOTE: Specifically consider whether critical operational parameters, equipment and procedures, product, or product formulation are being implemented the same or similar to the validation study. If the establishment implements different parameters than the scientific support, consider whether they demonstrated that changes are effective.
***If yes, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If no, leave the free text box blank**

☐Yes - Click here to enter text.

☐No

RTE91 **Did the establishment initially gather in-plant validation data for the PLT?**
***If yes, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If no, leave the free text box blank.**

☐Yes - Click here to enter text.

☐No

RTE92 **Does the establishment's data show that the reduction of Lm by the PLT is sufficient to control the level of contamination?**
NOTE: If the PLT is a pre-packaging PLT, consider if the validated control measures in place prevent recontamination after treatment and before re-packaging.
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank**

☐Yes

☐No - Click here to enter text.

Instruction: 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 apply AMAP optionally.

RTE93 **(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 questions RTE94,RTE95,RTE96,RTE97,RTE98
☐No, there is noncompliance with the Listeria Rule for Alt. 1 or Alt. 2b

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

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

RTE94 **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 - Click here to enter text.

RTE95 **Does the establishment's validation and documentation adequately support the AMAP?**
NOTE: Specifically consider whether critical operational parameters, equipment and procedures, product, or product formulation are being implemented the same or similar to the validation study. If the establishment implements different parameters than the scientific support, consider whether they demonstrated that changes are effective.

***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE96 **Did the establishment initially gather in-plant data to demonstrate the adequacy of the AMAP to inhibit Lm growth (e.g., no more than 2-logs growth of Lm)?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE97 **Does the establishment's data show that the reduction of Lm by the AMAP is sufficient to control Lm growth in product for usual production, rework, and product with excess contamination?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

RTE98 **Did the validation study include a shelf life study to determine the growth of Lm during storage?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

Instruction: **RTE Tool Summary:**

This question is designed to focus on the <u>most significant</u> 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.

RTE99 **Summarize in up to three bullets of 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 a FSA recommendation. Describe the impact the findings have on the establishment's food safety system.**

Click here to enter text.