



Not Ready-To-Eat (NRTE) Processed Products FSA Tool vs2

This FSA tool is for establishments that produce NOT 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;
HEAT TREATED, NOT FULLY COOKED, NOT SHELF STABLE;
SECONDARY INHIBITORS, NOT SHELF STABLE

The FSA Tool contains the following main sections:

- Hazard Analysis and HACCP System (Questions NRTE1 – NRTE6)
- Design of the Heat Treatment, Fermentation, or Other Processes for NRTE Processed Products (NRTE7 - RTE41)
- NRTE Processed Products: Appearance (NRTE42 – NRTE44)

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*

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.

NRTE1 Has the establishment considered the relevant food safety hazards throughout the HACCP System?
 Yes



No

NRTE2 Briefly describe the hazard(s) not considered or identified. Briefly describe any vulnerability and cite any noncompliance. Assess the impact your findings have on the food safety system.

NRTE3 Has the establishment properly developed and implemented a written HACCP plan to address each food safety hazard determined to be “reasonably likely to occur”?

Yes

No

NRTE4 Has there been a change that could affect the hazard analysis or HACCP plan during the previous 60 days?

***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 text box blank.**

Yes - Click here to enter text.

No

NRTE5 Does the establishment accept returned product?

***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 text box blank.**

Yes - Click here to enter text.

No

NRTE6 If applicable, describe additional HACCP design findings not described in the previous questions and how you findings impact the establishment’s food safety system.

Click here to enter text.

Instruction: Design of the Heat Treatment, Fermentation, or Other Processes for NRTE Processed Products (NRTE7 - NRTE 41)

This section includes lethality processes that may not result in a RTE or fully cooked product.

NRTE7 Does the establishment process products that undergo further processing such as heat treatment, fermentation, drying, or salt curing that it classifies as NRTE?

Yes - If selected, answer the following questions

NRTE8, NRTE9, NRTE10, NRTE11, NRTE12, NRTE13, NRTE14, NRTE15, NRTE16, NRTE17, NRTE18, NRTE19, NRTE20, NRTE21, NRTE22, NRTE23, NRTE24, NRTE25, NRTE26, NRTE27, NRTE28, NRTE29, NRTE30, NRTE31, NRTE32, NRTE33, NRTE34, NRTE35, NRTE36, NRTE37, NRTE38, NRTE39, NRTE40, NRTE41

No

NRTE8 Do you have any concerns with the NRTE determination being appropriate?

***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 text box blank.**

Yes - Click here to enter text.

No

NRTE9 Does the establishment identify all appropriate hazards as part of its hazard analysis at the heat treatment, fermentation, or other 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 text box blank.**



Yes

No - Click here to enter text.

NRTE10 Does the establishment identify a performance standard or target to be met by the HACCP system by the heat treatment, fermentation, or other 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 text box blank.**

Yes

No - Click here to enter text.

NRTE11 Does the establishment maintain adequate scientific support for the design of its heat treatment, fermentation, or other 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 text box blank.**

Yes

No - Click here to enter text.

NRTE12 Does the scientific support relate to the establishment's actual process, product, and hazard identified in the hazard analysis?

***If the answer is no, briefly describe any vulnerability or noncompliance, and assess the impact your findings have on the food safety system. If the answer is yes, leave the free text box blank**

Yes

No - Click here to enter text.

NRTE13 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 text box blank.**

Yes

No - Click here to enter text.

NRTE14 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 heat treatment, fermentation, or other 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 text box blank.**

Yes

No - Click here to enter text.

NRTE15 Does the establishment use scientific support other than an FSIS guideline or regulation (e.g., journal article or challenge study)?

***If there is a concern with the establishment's support, provide a response in the free text box. Briefly describe any vulnerability or noncompliance, and assess the impact your findings have on the food safety system. If there is no concern, leave the free text box blank.**

Yes

No - Click here to enter text.

NRTE16 If the establishment's process does not achieve full lethality (e.g., a 5-log reduction of Salmonella), has it considered potential growth of microbiological hazards such as S. aureus, C. perfringens, C. botulinum, and B. cereus?

***If no, briefly describe any vulnerability or noncompliance, 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.

Product received full lethality

NRTE17 If the establishment uses fermentation as a lethality step, provide your assessment of any vulnerability and describe any noncompliance with how degree hours are incorporated into the CCP, prerequisite program, or other program.

[Click here to enter text.](#)

NRTE18 If the establishment produces a NRTE, shelf-stable product (e.g., country cured ham), provide your assessment of any vulnerability and describe any noncompliance with the parameters the establishment uses to ensure shelf stability of the product that are incorporated into the CCP, prerequisite program, or other program (e.g., water activity lower than 0.85 using salt concentration or drying, pH, combination of water activity and pH).

[Click here to enter text.](#)

NRTE19 Provide your assessment of any vulnerability and describe any noncompliance with in-plant validation data for the lethality step(s). Describe how your findings impact the establishment's food safety system.

[Click here to enter text.](#)

Lethality Monitoring, Verification, Corrective Action Design for NRTE Processed Products

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

NRTE20 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 heat treatment, fermentation, or other step(s).

[Click here to enter text.](#)

NRTE21 Provide your assessment of any vulnerability and describe any noncompliance with the establishment's support for its monitoring and verification procedures and frequencies in its written program (i.e., HACCP plan, prerequisite program, or other program) for the heat treatment, fermentation, or other step(s).

[Click here to enter text.](#)

NRTE22 Does the establishment have corrective action procedures in its written program (i.e., HACCP plan, prerequisite program, or other program) for the heat treatment, fermentation, or other 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 text box blank.**

Yes

No

Instructions: Lethality Implementation for NRTE Processed Products

NRTE23 Based on your review of records and observation of operations, provide your assessment of vulnerability and describe any noncompliance with the implementation of monitoring and verification procedures, and note if the records accurately reflect the process. For deviations in the last 60 days, provide your assessment of whether all parts of 9 CFR 417.3 were addressed.

[Click here to enter text.](#)

NRTE24 As part of its ongoing verification of the heat treatment, fermentation, or other 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.

Yes

No

NRTE25 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.

Yes - [Click here to enter text.](#)

No

Instruction: **NRTE Processed Products Stabilization Design**

NRTE26 Did the establishment identify all appropriate hazards as part of its hazard analysis during the stabilization 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 text box blank.

Yes

No - [Click here to enter text.](#)

NRTE27 If the establishment fully cooks the product and then applies additional heating and stabilization 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 the answer is no, briefly describe any vulnerability or noncompliance, and assess the impact your findings have on the food safety system. If the answer is yes, leave the free text box blank

Yes

No - [Click here to enter text.](#)

NRTE28 If the establishment fully cooks the product and then applies additional heating and stabilization steps that do not achieve full lethality as stated in question NRTE27, does the scientific support address the cumulative growth of spore-formers (e.g., *C. perfringens*, *C. botulinum*) across the first stabilization and subsequent heating and stabilization 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 leave the text box blank.

Yes

No - [Click here to enter text.](#)

No, establishment does not apply additional heating and stabilization steps that do not achieve full lethality

NRTE29 Did the establishment identify a performance standard or target to be met by the HACCP system during stabilization?

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 text box blank.

Yes

No - [Click here to enter text.](#)

NRTE30 Provide your assessment of any vulnerability and describe any noncompliance with the CCP critical limits, prerequisite program or other program limits for the stabilization process.

[Click here to enter text.](#)

NRTE31 Does the establishment maintain adequate scientific support for the design of its stabilization 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 text box blank.

Yes

No - [Click here to enter text.](#)

NRTE32 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 text box blank.**

Yes

No - [Click here to enter text.](#)

NRTE33 Provide your assessment of whether the establishment's scientific support demonstrates the establishment's process meets the performance standards or targets it identified in the hazard analysis for each food safety hazard.

[Click here to enter text.](#)

NRTE34 Provide your assessment of any vulnerability and describe any noncompliance with how the establishment incorporates the critical operational parameters in the scientific support into its CCP critical limits, prerequisite programs, and other program limits for the stabilization process.

[Click here to enter text.](#)

NRTE35 If the establishment is using scientific support other than an FSIS guideline or regulation (e.g., journal article or challenge study), provide your assessment of any concerns with the study design.

[Click here to enter text.](#)

NRTE36 Provide your assessment of any vulnerability and describe any noncompliance with in-plant validation data for the stabilization process.

[Click here to enter text.](#)

Instruction: [Stabilization Monitoring, Verification, Corrective Action Design for NRTE Processed Products](#)

NRTE37 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 stabilization?

***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 text box blank.**

Yes

No - [Click here to enter text.](#)

NRTE38 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 stabilization?

***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 text box blank.**

Yes

No - [Click here to enter text.](#)

NRTE39 Does the establishment have corrective action procedures in its written program (i.e., HACCP plan, prerequisite program, or other program) for stabilization?

***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 text**



box blank.

Yes

No - Click here to enter text.

NRTE40 If applicable, describe additional corrective action findings not described in the previous questions and how you findings impact the establishment's food safety system.

Click here to enter text.

Instruction: Stabilization Implementation

NRTE41 Based on your review of records and observation of operations, provide your assessment of any vulnerability and describe any noncompliance with the implementation of monitoring and verification procedures, and note if the records accurately reflect the process. For deviations in the last 60 days, provide your assessment of whether all parts of 9 CFR 417.3 were addressed.

Click here to enter text.

Instruction: NRTE Processed Products: Appearance (NRTE42 – 44)

NRTE42 Does the establishment produce any NRTE products that are appear RTE?

Yes - If selected, answer the following questions [NRTE43,NRTE44](#)

No

NRTE43 Are the products being labeled for further processing, and validated cooking instructions and labeled with safe food handling instructions.

***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 text box blank.**

Yes

No - Click here to enter text.

NRTE44 Does the establishment maintaining validation for the cooking instructions, data used to validate the adequacy of the cooking instructions, and differences between the support/validation for the cooking instructions and the cooking instructions listed on the product label.

***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 text box blank.**

Yes

No - Click here to enter text.

NRTE45 Based on your knowledge and experience, provide your assessment of any remaining vulnerability and describe any noncompliance you have concerning this establishment's NRTE process that have not been previously covered.

Click here to enter text.

NRTE Tool Summary:

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.

NRTE46 Summarize in up to three bullets of any vulnerability or noncompliance findings identified in the NRTE 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.](#)