United States Department of Agriculture
Food Safety and Inspection Service

Not Ready-to-Eat (NRTE) Processed Products FSA Tool VS3

This FSA tool is for establishments that produce **NOT READY-TO-EAT (NRTE) 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:

- HACCP (NRTE1-NRTE24)
- Design of the Heat Treatment, Fermentation, Salt-Curing or Drying for NRTE Processed Products (NRTE25 – NRTE27)
- End-Product Testing (NRTE28)
- Appearance of NRTE Products (NRTE29)
- NRTE Tool Summary (NRTE30)

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 Stabilization*;
4. FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B); and
5. American Meat Institute Foundation. October 1997. Good Manufacturing Practices for Fermented Dry and Semi-Dry Sausage Products.

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 (NRTE1-NRTE24)

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

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

NRTE2 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

NRTE3 Does the establishment utilize normal consumer-cooking practices to support hazard analysis decision-making?

☐Yes
☐No

NRTE4 Does the HACCP system include a prerequisite program or supporting documentation for any hazard that the establishment determines is "not reasonably likely to occur" (NRLTO) (9 CFR 417.5(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

NRTE5 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

NRTE6 Does the establishment apply a heat-treatment to the product and stabilize the product by cooling?

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

☐No

NRTE6a Did the establishment identify all appropriate hazards as part of its hazard analysis during the stabilization step(s)? Briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 2,000 characters).

☐Yes

☐No

NRTE6b 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 per 9 CFR 417.2(a)(1)? Briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 2,000 characters).

☐Yes

☐No

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

NRTE6c 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 NRTE5, 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? Briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 2,000 characters).

☐Yes

☐No

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

NRTE6d If the establishment does not fully cook the product to lethality, does its hazard analysis and scientific support address the cumulative growth of spore-formers (e.g., *C. perfringens*, *C. botulinum*) across the first heating and subsequent cooling step (limit 2,000 characters)?

☐Yes

☐No

☐No, establishment does not apply a partial heat-treatment

NRTE7 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

NRTE7a 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).

NRTE8 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

NRTE8a Does the supporting documentation show the antimicrobial treatments or additives 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

NRTE9 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

NRTE9a 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).

NRTE10 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

NRTE10a 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.

NRTE11 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, the support does not relate

☐No, the establishment does not have support

NRTE12 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

NRTE13 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

NRTE13a In the event of a worst-case scenario, when all antimicrobial interventions are not 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

NRTE14 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

NRTE15 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

NRTE16 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.

NRTE17 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), including chilling/cooling procedures if the establishment slaughters? Noncompliances and vulnerabilities are to be described in NRTE19.

☐Yes

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

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

NRTE18 Does the establishment maintain support for the selected monitoring and verification procedures and frequencies? Noncompliances and vulnerabilities are to be described in NRTE19.

☐Yes

☐No

NRTE19 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).

NRTE20 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

NRTE21 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

NRTE22 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

NRTE23 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).

NRTE24 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).

Design of the Heat Treatment, Fermentation, Salt-Curing or Drying for NRTE Processed Products (NRTE25 – NRTE27)

This section includes lethality processes that may not result in an RTE or fully cooked product. NOTE: An establishment may reclassify a RTE or fully cooked product as NRTE, as long as it is not defined by a standard of identity as a fully-cooked product (e.g., hot dogs per 9 CFR 319.180 and 319.181 or barbeque per 9 CFR 319.80 and 381.164).

NRTE25 Do you have any concerns with the NRTE determination made by the establishment being appropriate (e.g., because the product is required to be RTE by Standard of Identity) (limit 2,000 characters)?

☐Yes

☐No

NRTE26 If the establishment uses fermentation, salt-curing, or drying, provide your assessment of any vulnerability and describe any noncompliance with how *Staphylococcus aureus* (*S. aureus)* outgrowth is addressed during the process. Your assessment should consider whether the establishment maintains adequate support for all product variations, such as fermented sausages of differing diameters. Note: FSIS Directive 7111.1 indicates for shelf-stable products, FSIS recommends establishments limit the growth of *S. aureus* to ≤ 2.0-logs during the process, especially during the drying step and ensure no growth of *S. aureus* can occur during storage. For fermented products, 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) are used to control *S. aureus* outgrowth during the fermentation step (for more information see the American Meat Institute Foundation. October 1997, Good Manufacturing Practices for Fermented Dry and Semi-Dry Sausage Products) (limit 20,000 characters).

NRTE27 Briefly describe any vulnerability and any noncompliance findings not described previously regarding the establishment's heat treatment, fermentation, salt-curing, or drying design that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 20,000 characters).

End-Product Testing (NRTE28)

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 implemented 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.

NRTE28 Does the establishment conduct end-product testing for biological hazards? NOTE: End-product testing is not required.

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

☐No

NRTE28a Is this end-product testing conducted as part of its ongoing verification of any of the steps in its hazard analysis?

☐Yes

☐No

NRTE28b Is any end-product testing conducted for other purposes (e.g., customer specification)?

☐Yes

☐No

NRTE28c Do the establishment employees perform the sampling as described in the establishment's sampling protocol (aseptic technique, sample size and type, laboratory methods)? Noncompliances and vulnerabilities are to be described in NRTE28f.

☐Yes

☐No

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

NRTE28d Does the establishment maintain adequate support for the testing method (test portion, fit for intended use, validation, etc.)? Noncompliances and vulnerabilities are to be described in NRTE28f.

☐Yes

☐No

NRTE28e Has the establishment received any positive results in the previous 60 days? Noncompliances and vulnerabilities are to be described in NRTE28g.

☐Yes

☐No

NRTE28f Briefly describe the 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 decision in the hazard analysis (9 CFR 417.5(a)(1)) and assess the impact your findings have on food safety (limit 20,000 characters).

NRTE28g 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 products).

Appearance of NRTE Products (NRTE29)

NRTE29 Does the establishment produce any NRTE products that appear RTE?

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

☐No

NRTE29a Are the products accurately labeled: (1) to represent the product as one that is NRTE and requires cooking for safety, (2) with safe food handling instructions, and (3) with validated cooking instructions? Briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 2,000 characters).

☐Yes

☐No

NRTE29b Does the establishment maintain validation for the cooking instructions listed on the product label? Briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 2,000 characters).

☐Yes

☐No

NRTE29c Based on your knowledge and experience, provide your assessment of any vulnerability and describe any noncompliance findings regarding this establishment's NRTE process that have not been previously covered (limit 20,000 characters).

NRTE Tool Summary (NRTE30)

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.

NRTE30 Summarize 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 an FSA recommendation (limit 20,000 characters). Limit your response to three to five bullet points total.