UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE

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AVAILABILITY OF FSIS READY-TO-EAT FERMENTED, SALT-CURED, AND DRIED PRODUCTS GUIDELINE

I. PURPOSE

This notice provides instructions for inspection program personnel (IPP) to notify establishments that a new FSIS Ready-to-Eat Fermented, Salt-Cured, and Dried Products Guideline is now available. This notice also provides instructions for IPP to notify establishments that FSIS will start verifying that establishments have adequate scientific support for producing these products starting 90 days after the weekly meeting. This notice also provides instructions for IPP to schedule a directed Hazard Analysis Verification (HAV) task for the Not Heat-Treated Shelf-Stable Hazard Analysis and Critical Control Point (HACCP) category or Heat-Treated Shelf-Stable HACCP category, following the instructions in FSIS Directive 5000.6, *Performance of the HAV Task,* 90 days after the issuance of this notice or after the establishment gathers its support, if it needs more than 90 days. This notice also provides instructions for Enforcement, Investigation, and Analysis Officers (EIAO) when performing Food Safety Assessments (FSA) and outreach in establishments producing fermented, salt-cured, and dried products.

II. BACKGROUND

A. On May 5, 2023, FSIS issued a RTE Fermented, Salt-cured, and Dried Products Guideline that was announced in the Federal Register (88 FR 29077). FSIS is seeking public comment on the guideline.

B. This guideline focuses on the safe production and supporting documentation for RTE shelf-stable products that are produced under the Not Heat-Treated Shelf-Stable HACCP category or Heat-Treated Shelf-Stable HACCP category. The guideline addresses the specific considerations related to supporting the lethality and shelf-stability of RTE shelf-stable fermented, salt-cured, and dried meat and poultry products.

1. RTE fermented meat and poultry products are products in which the raw meat or poultry are typically reduced in size, formulated with cure, starter culture, salt and seasoning mixture, stuffed in casings, fermented, sometimes heated with a low temperature heat step for food safety or smoked, and then dried. Example products covered in the guideline include salami, pepperoni, summer sausage, Lebanon bologna, soudjouk (sujuk or soujouk), and landjäger.

2. RTE salt-cured meat and poultry products are usually whole muscle products that are cured with salt and sodium nitrite or nitrate, then air dried, and sometimes smoked (if desired for certain flavor characteristics). Example products covered in the guideline include country cured ham, bresaola, and basturma.

3. RTE dried meat and poultry products can be comminuted, sliced whole muscle, or whole muscle products that may or may not be formulated with nitrite, may be smoked, are usually heated, and are air dried or oven dried. Example products covered in the guideline include droëwors and

biltong.

C. FSIS addressed fermentation and drying previously in *Food Safety Lessons Learned from the Lebanon Bologna Outbreak*. FSIS has removed the guideline from its website and incorporated information from the document into the RTE Fermented, Salt-Cured, and Dried Products Guideline. FSIS has also incorporated additional information related to drying to address the production of other fermented products, and salt-cured and dried products, as well as those products that rely on drying alone, such as biltong.

D. The RTE Fermented, Salt-cured, and Dried Products Guideline also includes lessons learned from two *Salmonella* outbreaks in 2021 associated with RTE fermented, dried, and salt-cured Italian-style meat products.

1. In the first outbreak, 40 *Salmonella* illnesses were linked to RTE antipasto Italian-style meats manufactured in an FSIS-regulated establishment. FSIS determined that the use of a reduced salt formulation combined with a lack of validated scientific support to achieve a 5.0-log reduction in *Salmonella* may have contributed to the outbreak.

2. In the second outbreak, 34 *Salmonella* illnesses were linked to RTE Italian-style salami sticks produced at another FSIS-regulated establishment. FSIS determined there was not sufficient evidence to support the fermentation and drying interventions to adequately control *Salmonella*.

3. In both outbreaks, FSIS assessments found that while processing controls, including meeting 'degree-hours' parameters (for *Staphylococcus aureus* control), following a minimum number of drying days (for *Trichinella* elimination), and achieving a final water activity level (for shelf-stability) were all met by the outbreak establishments, the controls were not validated to achieve a 5.0-log reduction in *Salmonella*.

NOTE: For fermented products, the 'degree-hours' concept is typically used to ensure that growth of *Staphylococcus aureus* is limited during fermentation when the temperature is over 60°F (15.6°C) (the critical temperature at which staphylococcal growth begins). Good Manufacturing Practices for Fermented Dry and Semi-dry Sausage Products describes the degree-hours concept in detail.

4. Lessons learned from these two outbreaks are also included in FSIS' Outbreak Investigation After Action Review.

III. IPP RESPONSIBILITIES

A. If an establishment produces a fermented, salt-cured, or dried product, IPP are to share and make establishment management aware of this new guidance document at the next weekly meeting.

B. If IPP have questions about whether a product is considered fermented, salt-cured, or dried, IPP are to review the RTE Product Group Flowchart available in IPP Help, *FSIS RTE Sampling*.

C. IPP are to be aware that these documents are guidance, not requirements. IPP are to make compliance determinations based on the regulatory requirements.

D. IPP are to inform establishment management that:

1. The RTE Fermented, Salt-cured, and Dried Products Guideline is available on the FSIS website at FSIS Ready-to-Eat Fermented, Salt-Cured, and Dried Products Guideline.

2. The new guideline provides information on HACCP requirements in 9 CFR 417 associated with safe production of RTE shelf-stable, fermented, salt-cured, and dried products that rely on multi-hurdle approaches to achieve lethality and shelf-stability.

3. The guidance is focused on the needs of small and very small meat and poultry official establishments, although large establishments can also benefit from the information in the guidelines.

4. IPP will start verifying that establishments have scientific support for their HACCP systems for these products starting about 90 days from this weekly meeting.

5. IPP are to find out if the establishment needs more than 90 days to gather new support (*e.g.*, it is conducting a challenge study).

6. IPP are to document this discussion in a Memorandum of Interview (MOI) following the instructions in FSIS Directive 5010.1, *Food Safety Related Topics for Discussion During Weekly Meetings with Establishment Management*.

E. After 90 days of the issuance of the notice, if the establishment has adequate scientific support, IPP are to schedule a directed HAV task for the Not Heat-Treated Shelf-Stable HACCP category or Heat-Treated Shelf-Stable HACCP category. However, if the establishment needs additional time to gather scientific support, IPP are to wait until the support has been gathered before performing the HAV task. IPP are to follow the instructions in FSIS Directive 5000.6 when performing the HAV task. Additional instructions are also provided below to specifically address fermentation, salt-curing, and drying.

1. For lethality (typically achieved over multiple steps, such as fermentation/acidification, salt-curing, and drying), IPP are to verify that the establishment has included the pathogen reduction targets in the processing steps of its HACCP plan or supporting documentation. IPP are to be aware that:

   a. The lethality treatment for RTE shelf-stable meat and poultry products should achieve at least a 5.0-log reduction of *Salmonella* and Shiga toxin-producing *Escherichia coli* (STEC), (for products containing beef), as recommended in the FSIS Ready-to-Eat Fermented, Salt-Cured, and Dried Products Guideline and FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A). The lethality treatment of RTE shelf-stable meat and poultry products should also achieve at least a 3.0-log reduction in *Listeria monocytogenes (Lm)*, although a 5.0-log reduction or greater is desirable as recommended in the RTE Fermented, Salt-cured, and Dried Products Guideline.

   b. Establishments may have scientific support that demonstrates a 5.0-log reduction in *Salmonella* only and does not include STEC or Lm.

   c. Establishments may have scientific support that demonstrates a 5.0-log reduction in STEC only and does not include *Salmonella* or *Lm*.

   d. Establishments may have scientific support that demonstrates reductions in *Lm* only and does not include *Salmonella* or STEC. In this case, FSIS recommends the support should demonstrate at least a 5.0-log reduction in *Lm* in order to support at least a 5.0-log reduction in *Salmonella* and STEC (in beef) is achieved.

   e. Establishments that are unable to demonstrate a 5.0-log reduction in *Salmonella*, STEC (in products containing beef), or *Lm* have the option of applying an alternative lethality (*i.e.,* a lethality target or log reduction that is different from FSIS recommendations but achieves an equivalent probability that no viable *Salmonella* organisms or other pathogens of concern remain in the finished product). An example of an alternative lethality is “Option #5” from The Blue Ribbon Task Force, in which the raw batter of sausage is tested in conjunction with the application of a process that achieves at least a 2.0-log reduction in the hazard of concern.

f. FSIS does not consider test and hold (also sometimes described as "Option #3" from The Blue Ribbon Task Force document) as acceptable support because it relies on finished product testing alone and does not support a specific log reduction in levels of target pathogens.

2. IPP are to review the scientific and technical support to verify it supports the lethality treatment and achieves the target pathogen reduction that the establishment has included in the processing steps of its HACCP plan or supporting documentation (*e.g.*, a 5.0-log reduction of *Salmonella* only or a 5.0-log reduction of *Lm* only).

3. IPP are to be aware that meeting 'degree-hours' parameters (for *Staphylococcus aureus* control), following a minimum number of drying days (for *Trichinella* elimination), and achieving a final water activity level (for shelf-stability) have not been validated to achieve a 5.0-log reduction in *Salmonella*.

4. IPP are to be aware that if an establishment produces different diameter products but only has a study performed with one diameter, it must determine the impact of differences from the study to the actual process (*e.g.*, drying time) to make sure the process is still effective in achieving the target 5.0-log reduction.

F. If while reviewing the scientific or technical support, or the establishment's plan, IPP have a concern about a technical aspect of the document, or if there are concerns with an establishment's scientific support for the hazard analysis or the in-plant validation data, IPP are to contact their supervisor prior to making a compliance determination. If needed, the supervisor is to ask the District Office to assign an EIAO to review the program or scientific support.

G. After 90 days of the issuance of the notice, if the establishment has not gathered adequate scientific support or has not communicated to FSIS as to how they will gather their support, IPP are to contact their supervisor prior to making a compliance determination. If needed, the supervisor is to ask the District Office to assign an EIAO to review the program or scientific support. The District Office may determine additional enforcement or administrative actions may be warranted as described in FSIS Directive 5000.1, Chapter VI, Rules of Practice.

IV. EIAO RESPONSIBILITIES

A. EIAOs are to review and familiarize themselves with the information in the FSIS Ready-to-Eat Fermented, Salt-Cured, and Dried Products Guideline. The information represents the most current scientific research and critical operational parameters related to fermentation, salt-curing, and drying.

B. If an EIAO performs a Public Health Risk Evaluation at an establishment producing RTE shelf-stable fermented, salt-cured, and dried meat and poultry products, they are to review the MOIs to see if the establishment communicated a plan for gathering additional support to IPP. If the establishment needs time to gather scientific support, EIAOs are to wait until the support has been gathered before performing the FSA, if recommended per FSIS Directive 5100.4, *Public Health Risk Evaluation Methodology*.

C. During an FSA, as instructed in FSIS Directive 5100.1, *Food Safety Assessment Methodology*, Chapter V, Section VI, EIAOs are to evaluate whether the establishment has adequate scientific support for the design of its HACCP system (*e.g.*, critical control point, prerequisite program, or other program design) on file, and whether in-plant validation data demonstrate that the establishment can implement its system as designed for these products.

NOTE: Considerations for different types of scientific support that may be used to support the lethality or shelf-stability of fermented, salt-cured, or dried meat and poultry products is discussed in Appendix 4 of the RTE Fermented, Salt-Cured, and Dried Products Guideline.

D. When performing outreach activities, EIAOs are to make establishment management aware of the

RTE Fermented, Salt-cured, and Dried Products Guideline. EIAOs are to provide technical assistance as part of the compliance assistance resources they provide, according to the instructions in FSIS Directive 5100.1. Outreach materials related to the RTE Fermented, Salt-cured, and Dried Products Guideline can be found in IPP Help, *FSIS RTE Sampling*, and shared with establishments.

V. QUESTIONS

Refer questions regarding this notice to your supervisor or as needed to the Office of Policy and Program Development (OPPD) through askFSIS, or by telephone at 1-800-233-3935. When submitting a question, complete the web form and select HACCP Deviation & Validation as the Inquiry Type.

NOTE: Refer to FSIS Directive 5620.1, *Using askFSIS*, for additional information on submitting questions.

Assistant Administrator
Office of Policy and Program Development