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

# FSIS NOTICE	36-12	5/25/12

FSIS VERIFICATION OF LEBANON BOLOGNA PROCESSES

I. PURPOSE

In March 2011, there was a recall of a Lebanon bologna product associated with a foodborne illness outbreak of *Escherichi coli* (*E. coli*) O157:H7. The FSIS investigation following the outbreak revealed that the establishment's actual process did not closely match the supporting documentation with respect to, among other factors, diameter and casing type. This notice instructs inspection program personnel (IPP) to hold an awareness meeting with the establishment to share information regarding lessons learned from the Lebanon bologna outbreak and how the establishment can comply with regulatory requirements in 9 CFR 417.4(a)(1), 417.5(a)(1), and 417.5(a)(2). IPP are to document this meeting in a Memorandum of Interview (MOI). This notice also provides instructions to Enforcement, Investigation, and Analysis Officers (EIAOs) to use when conducting routine or for-cause Food Safety Assessments (FSAs) at establishments that produce Lebanon bologna. The purpose of providing this information is so that lessons learned from the investigation can be applied at other establishments to ensure these issues do not occur again.

II. BACKGROUND

A. What is Lebanon bologna, and how is it traditionally produced?

1. Lebanon bologna is a coarse ground, fermented, semi-dry sausage product.

2. The traditional production process for Lebanon bologna relies on a multiple hurdle approach to produce a safe product. Thus, no single procedure, process, or step renders the product safe. Rather, a combination of steps such as fermentation and low temperature heating is necessary. The multiple hurdle approach is necessary to achieve at least a 5-log reduction in *Salmonella* spp. and *E. coli* O157:H7 and sufficient lethality for *Listeria monocytogenes* (*Lm*), as recommended in the *Salmonella* Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products (http://www.fsis.usda.gov/PDF/Salmonella_Comp_Guide_042211.pdf).

B. What are some measures establishments can take to manufacture Lebanon bologna

safely?

1. An FSIS investigation into the processing of the Lebanon bologna product that was recalled in March 2011 revealed that the critical operational parameters (i.e., those parameters of an intervention that must be met in order for the intervention to operate as intended) used in the commercial process did not closely match the actual process. For example, key parameters were derived from experiments performed in narrow diameter impermeable glass tubing, but the commercial process relied on wider diameter permeable casings that allowed moisture exchange with the environment. The difference between the critical operational parameters used in the commercial process and the critical operational parameters used in the support documents could have allowed *E. coli* O157:H7 to survive in the product.

2. Therefore, in order to manufacture Lebanon bologna safely, it is particularly important that establishments:

   i. Identify supporting documentation that closely matches their process (e.g., journal articles, challenge studies, or data gathered-in plant);

   ii. Identify supporting documentation that demonstrates the expected level of bacterial pathogen reduction (e.g., 5 log reduction of *Salmonella* spp. and *E. coli* O157:H7, and adequate reduction of *Lm*);

   iii. Identify the critical operational parameters from the supporting documentation relevant to their commercial process;

   iv. Implement those same critical operational parameters in their production process (e.g. as a CCP, prerequisite program, or as part of the HACCP system);

   v. Gather data demonstrating the effectiveness of the implementation of the critical operational parameters.

III. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES

A. Awareness/Weekly Meeting

1. IPP at establishments that produce Lebanon bologna are to meet with establishment management at the next weekly meeting following the issuance of this notice.

2. IPP are to discuss the information in this notice with establishment management including the information in Attachment 1. IPP are to refer establishments to www.fsis.usda.gov/PDF/Compliance_Guideline_Lebanon_Bologna.pdf for more information.

3. IPP are to inform the establishment that as part of the Hazard Analysis Verification Procedure in PHIS, they will be verifying, among other things, that the establishment's HACCP system complies with the regulatory requirements in 9 CFR 417.4(a)(1), 417.5(a)(1), and 417.5(a)(2). In addition, they are to inform the

establishment that EIAOs, during their next routine or for-cause FSA, will also be verifying the establishment's compliance with these regulatory requirements, including whether the establishment's supporting documentation closely matches its process, and whether it has identified and implemented all of the critical operational parameters in the supporting documentation in its actual process.

4. IPP are to document this meeting in a Memorandum of Interview (MOI) according to FSIS PHIS Directive 5000.1, Verifying an Establishment's Food Safety System.

5. In the documentation, among the regular weekly topics, IPP are to:

   i. Briefly explain the purpose of this notice, and

   ii. State how the establishment management responded.

6. If IPP have any questions or concerns about how the establishment responds to what was discussed at the weekly meeting, they are to raise those concerns or questions through supervisory channels. Based on the concerns raised by IPP through supervisory channels, District Offices (DO) may determine that an EIAO needs to conduct a for-cause food safety assessment (FSA) per Section V of this notice.

7. IPP are to keep the MOI electronically in PHIS and are to provide a copy to establishment management.

IV. EIAO RESPONSIBILITIES

A. EIAOs that perform a for-cause FSA in an establishment that produces Lebanon bologna, as determined by the DO per Section V, are to review the information in Attachment 1 of this notice which contains information about common critical operational parameters identified during traditional Lebanon bologna processing. EIAOs that perform a routine FSA in an establishment that produces Lebanon bologna are also to review the information in Attachment 1. EIAOs can use this information to help identify critical operational parameters in the establishment's supporting documentation and to determine whether the establishment is implementing these parameters.

B. EIAOs are to gather the necessary information regarding the critical operational parameters by reviewing establishment records and observing the establishment's operations.

C. EIAOs are to analyze the information they have gathered to determine whether the establishment has identified the critical operational parameters from their scientific supporting documentation relevant to their commercial production process. If the establishment has not identified the critical operational parameters from its scientific supporting documentation or does not have scientific supporting documentation, the EIAO is to follow the instructions in part IV.D below. If the establishment has identified the critical operating parameters from their scientific supporting documentation, then the EIAO is to consider the following:

1. If the establishment has incorporated one or more critical operational parameters as part of a CCP, the EIAO is to review the support for the CCP. If the EIAO finds that the CCP records do not demonstrate the critical operational parameters in the scientific supporting documentation are being implemented in accordance with 9 CFR 417.5(a)(2), EIAOs are to recommend to supervisory personnel that the in-plant inspection team issue an NR. When recommending the issuance of an NR, the EIAO is to follow the instructions in chapters 3, 13, and 15 in FSIS Directive 5100.1, EIAO Food Safety Assessment Methodology.

NOTE: In some circumstances, an establishment may be able to support using critical operational parameters that are different from those in the support documents (e.g., higher concentrations of antimicrobials or higher thermal processing temperatures). In these cases, EIAOs are to consider whether the establishment has justification supporting that the levels chosen are at least as effective as those in the support documents.

2. If the establishment has incorporated one or more critical operational parameters as part of a pre-requisite program, the EIAO is to review the support for the pre-requisite program. If the EIAO finds that the pre-requisite program records do not demonstrate that the critical operational parameters are being implemented as described in the supporting documentation, and the establishment does not have another justification or rationale, the EIAO is to recommend to supervisory personnel that the in-plant inspection team issue an NR. They are to issue the NR when the program is not effectively preventing the relevant hazard from being reasonably likely to occur in accordance with 9 CFR 417.5(a)(1). When recommending the issuance of an NR, the EIAO is to follow the instructions in chapters 3, 13, and 15 in FSIS Directive 5100.1, EIAO Food Safety Assessment Methodology.

3. If the establishment has implemented one or more critical operational parameters as part of the design of their system, the EIAO is to observe the establishment's system to determine whether the critical parameters have been properly incorporated. Establishments may have identified a limited number of critical operational parameters (e.g., product diameter or casing type) that were only verified during the initial set-up or validation period but that were not identified as CCPs or included in a pre-requisite program because the parameters do not change over time. As such, establishments may not have records of the implementation of the critical operational parameters at this time. If EIAOs are able to observe the implementation of the critical operational parameters from the scientific support, but records of their implementation do not exist from the initial validation, EIAOs are not to recommend that IPP issue a noncompliance or use the lack of records as a basis for other enforcement actions at this time. However the EIAO is to document the information as part of the FSA report and is to discuss the lack of records with the establishment and recommend that such parameters be included in a CCP, pre-requisite program, or decision-making document.

D. If the establishment has not identified the critical operational parameters from its scientific support, does not have scientific supporting documentation, or has not included the parameters as part of a CCP, prerequisite program, or other part of its system, the EIAO is to recommend to supervisory personnel that IPP issue an NR per 9 CFR 417.4(a)(1). EIAOs are to recommend the issuance of a Notice of Intended Enforcement (NOIE) if, taken together with other relevant findings, an establishment's scientific or

technical support is inadequate, and the establishment's HACCP system is inadequate for any of the reasons provided in 9 CFR 417.6, taking the action under 9 CFR 500.4(a).

E. If the EIAO finds noncompliance and plans to use the noncompliance as support for an NOIE, she or he is to only reference the noncompliance in the report and is not to recommend that the inspection team issue an NR. However, it may be necessary for the inspection team to take an appropriate regulatory control action. EIAOs are to explain in the FSA the need for a regulatory control action.

V. DISTRICT OFFICE RESPONSIBILITIES

A. Based on the concerns raised by IPP through supervisory channels, the DO may determine that an EIAO needs to conduct a for-cause food safety assessment to assess factors such as what the verification results reveal about food safety, and whether the design of the food safety system is adequate.

B. The DO may issue an NOIE, in accordance with 9 CFR 500.4(a), in situations where FSIS personnel have found that the food safety system is inadequate for any of the reasons provided in 9 CFR 417.6.

VI. DATA ANALYSIS

On a quarterly basis, the Office of Policy and Program Development (OPPD) will review data from FSAs generated during the prior quarter to determine whether new policy or guidance is needed for establishments producing Lebanon bologna.

Refer questions regarding this notice to the Risk, Innovations, and Management Division through askFSIS at http://askfsis.custhelp.com or by telephone at 1-800-233-3935 (press 2 and 3).

Acting Assistant Administrator
Office of Policy and Program Development

Attachment 1

Information on Lessons Learned from the Lebanon Bologna Outbreak

Why was this Notice developed?

In March 2011, there was a recall of a Lebanon bologna product that was associated with a foodborne illness outbreak of *E. coli* O157:H7. An FSIS investigation into the processing of the product revealed that the establishment relied on supporting documentation, a published study, which did not match the actual commercial process used. In the support, to represent a commercial process for Lebanon bologna, raw Lebanon bologna mix was compacted in 27 millimeter diameter impermeable sealed glass tubes that were immersed in a well-controlled water bath. However, in the actual process at the establishment, raw Lebanon bologna mix was compacted in 52 to 119 mm diameter permeable casings that were placed in a large smokehouse fitted with a single source of heat and humidity that was not well-controlled.

The difference in the diameter and type of casing material likely led to a lower reduction in foodborne pathogens of concern in the actual process than what was demonstrated in the support. One reason is because if the diameter of the establishment's product is larger than that of the product used in the support, it is possible that the product core will take longer to reach the desired temperature and pH. Taking a longer time then expected to reach the desired temperature and pH may lead to a lower level of pathogen reduction. Critical operational parameters, such as the product diameter and type of casing material, can also affect the amount of moisture exchange between the product and the environment and can play a role in the effectiveness of the fermentation. For these reasons, it is important that the support used by the establishment is representative of the establishment's actual process, so that the results can be repeatable.

What are some measures establishments can take to manufacture Lebanon bologna safely?

In order to manufacture Lebanon bologna safely, it is particularly important that establishments:

i. Identify supporting documentation that closely matches their process (e.g., journal articles, challenge studies, or data gathered-in plant);

ii. Identify supporting documentation that demonstrates the expected level of bacterial pathogen reduction (e.g., 5 log reduction of *Salmonella* spp. and *E. coli* O157:H7, and adequate reduction of *Lm*);

iii. Identify the critical operational parameters from the supporting documentation relevant to their commercial process;

iv. Implement those same critical operational parameters in their production process (e.g. as a CCP, prerequisite program, or as part of the HACCP system);

v. Gather data demonstrating the effectiveness of the implementation of the critical operational parameters.

Establishments should identify supporting documentation that closely matches their process and should identify, implement, and monitor all of the critical operational parameters from the supporting documentation relevant to their commercial production process or provide justification for their decision not to do so. Critical operational parameters are the specific conditions that an intervention or process must operate under in order for it to be effective. Such critical operational parameters include pH, time, temperature, relative humidity, equipment settings or calibration, and spatial configuration. If the critical operational parameters used in an establishment's process do not closely match those in the supporting documentation, adequate lethality may not be achieved and the establishment may not be able to support the decisions in their hazard analysis on an ongoing basis as required in 417.5(a)(1).

> **NOTE:** FSIS recommends that the supporting documentation address the "worst case" scenario because of variability in the actual process for the critical operational parameters identified. For example, the support should be based on the highest expected pathogen load, shortest amount of time it takes the actual product to achieve the target temperature for the low temperature heat step, the longest amount of time it takes the actual product to reach the target pH, or the lowest relative humidity achieved. Such "worst case" scenarios can be determined by reviewing monitoring and pre-requisite records the establishment currently collects associated with the critical operational parameters identified in the supporting documentation.

In some circumstances, establishments may be able to support using critical operational parameters that are different from those in the support documents (e.g., higher concentrations of antimicrobials or higher thermal processing temperatures). In these cases, establishments should provide justification supporting that the levels chosen are at least as effective as those in the support documents. This justification is needed because different levels of a critical operational parameter may not always be equally effective. For example, higher processing temperatures may result in the surface of the product drying out before adequate lethality is achieved. In addition to ensuring that the levels chosen are at least equally as effective, establishments should ensure the levels are also safe and suitable (http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/7120.1.pdf).

Once all of the relevant critical operational parameters from the supporting documentation have been identified, establishments should implement and monitor those parameters in their system. During the initial set-up of their system, establishments may decide that one or more critical parameters from their scientific supporting documentation are either monitored as a CCP in response to a hazard that the establishment has identified as reasonably likely to occur or that are verified on an ongoing basis as part of a pre-requisite program in response to a hazard that the establishment has identified as not reasonably likely to occur because of the execution of that pre-requisite program. Establishments are required to support the development of critical limits for CCPs, per 9 CFR 417.5(a)(2) used to control hazards identified as reasonably likely to occur and are required to support the development of pre-requisite programs used to prevent hazards identified as not reasonably likely to occur per 9 CFR 417.5(a)(1).

Establishments may also, however, identify a limited number of other critical operational parameters that are only verified during the initial validation period (e.g., product diameter or casing type). Establishments are required to validate the design and execution of their

HACCP system per 9 CFR 417.4(a)(1), which would include ensuring that critical operational parameters that are not incorporated into a critical limit for a CCP or into a pre-requisite program can be met. Examples may include equipment configuration (e.g., number and pressure of spray nozzles) or product composition (e.g., salt content), provided it does not change. These parameters should be included in a decision-making document but do not necessarily need to be monitored on an ongoing basis, provided they do not change over time.

> **NOTE:** For information that can be used to control *Salmonella* and *E. coli* O157:H7 in Lebanon bologna and other semi-dry fermented sausage products, establishments can refer to the FSIS *Salmonella* Compliance Guidelines for Small and Very Small Establishments that Produce Ready-to-Eat (RTE) Meat and Poultry Products, found at http://www.fsis.usda.gov/PDF/Salmonella_Comp_Guide_042211.pdf.

Finally, in addition to ensuring the critical operational parameters used in an establishment's process closely match those in the supporting documentation; establishments should also make efforts to ensure that sanitary conditions are maintained in their post-lethality processing environment. This will help ensure that RTE products are not contaminated after the lethality step. Steps should also be taken to ensure the safety of ingredients that are added to the product, to ensure that contaminated ingredients are not added after the lethality treatment. Further information on sanitation in RTE establishments and ensuring the safety of ingredients can be fund in the RTE *Salmonella* Guidelines (referenced in the note above) and the *Listeria* Guidelines found at: http://www.fsis.usda.gov/oppde/rdad/FRPubs/97-013F/LM_Rule_Compliance_Guidelines_May_2006.pdf.

What are the critical operational parameters for the production of Lebanon Bologna?

- Fermentation temperature
- Hold time and temperature for low temperature heating step
- Come up time to low temperature heating step
- Relative humidity
- Equipment
- pH and time to reach target pH
- Type and use of starter cultures
- Product characteristics (e.g., diameter, composition, and casing type)

These parameters may also apply to other fermented, semi-dry processes.

In addition to using the critical operational parameters identified in the supporting documentation, it is important for establishments to use source materials prepared under GMPs designed to minimize contamination and the presence and growth of pathogens of public health concern. If pathogen levels are high on source materials, the process may not be sufficient to achieve full lethality, and some pathogens could survive in the product.

Specific considerations for several critical operational parameters as related to Lebanon

bologna processes are outlined below:

1. Fermentation temperature/heating come up time (CUT)/ hold time and temperature for low temperature heat step – The temperature that the product is heated to and the amount of time the product is held at this temperature are critical to ensuring that adequate lethality is achieved. The establishment should have an understanding of factors that could impact the temperature of the product (e.g., cold spots or variation in temperature of the oven during different seasons). In addition to the hold time and temperature, the time it takes the product to reach the target temperature for the low temperature heat step (also known as the come up time or CUT) may be important. A number of factors, such as product diameter and relative humidity, affect heat transfer and the amount of time it takes the product to reach the target temperature. It is important for the establishment to understand how the actual temperature of the product, the CUT, and the amount of time the product is held at the target temperature compare to the supporting documentation. If the CUT in the establishment's process is shorter than the time it takes in the study, for example, then the establishment's process may result in a lower level of pathogen reduction.

2. Equipment – Differences in equipment (e.g., smokehouses and ovens) used in the processing of Lebanon bologna can influence the effectiveness of the process and, in particular, the speed of fermentation or acidification and heating. For this reason, the establishment should gain an understanding of the humidity profile as well as the pH and temperature profile of the product throughout the process. In addition, seasonality of atmospheric conditions, cold-spot determination, or heating consistency should be understood and used to inform monitoring and verification procedures and the frequencies at which those procedures are monitored and verified.

3. Relative humidity – Relative humidity is an important parameter in all dried meat processes. A relatively high humidity is preferred to keep the product surface moist during the fermentation and intermediate heating steps, prior to subsequent drying. Controlling humidity prevents premature and uneven drying at the surface and also shortens the time it takes for the product core to reach the desired temperature. For these reasons, it is important that the lower end of the relative humidity range in the establishment's process is at least as high as the lower end of the relative humidity range used in the supporting documentation and is applied at the appropriate process steps.

4. pH and time to reach target pH – Semi-dry sausage products like Lebanon bologna are usually fermented to a pH of between 4.4 - 4.6. The establishment should be fermenting its product to the pH that is recommended in the support. In addition to the pH level itself, the time it takes the product to reach the desired pH is also important. If a product takes too long to reach the desired pH, the acid resistance and pathogenicity of *E. coli* O157:H7 and *Salmonella* may increase. In addition, these conditions may favor *Staphylococcus aureus* growth and enterotoxin production. Therefore, it is also important that the establishment monitor the time it takes the product to reach pH of 5.3. The American Meat Institute has determined that a process documented to reduce product pH to 5.3 within a defined number of hours at a defined temperatures (known as the degree-hours) is

capable of controlling growth of *Staphylococcus aureus* (for more information on the degree-hour concept see the American Meat Institute's Good Manufacturing Practices for Fermented Dry and Semi-dry Sausage Products: http://www.meathaccp.wisc.edu/assets/Heat_Treated_Shelf_Stable/AMIF_degreehours.pdf). For these reasons, it is critically important that establishments monitor the pH of the product during fermentation as well as the time it takes the product to reach the desired pH. They need to ensure that the time it takes the product to reach the desired pH is consistent with the supporting documentation and is within an acceptable number of degree-hours.

NOTE: According to the Food Standards and Labeling Policy Book, a Lebanon bologna product that has a Moisture Protein Ratio (MPR) of 3.1:1 or less and a pH of 5.0 or less does not require refrigeration. However, meeting these criteria does not necessarily mean that the product has received sufficient log reduction for pathogens of public health concern (e.g., *E. coli* O157:H7, *Salmonella,* and *Listeria monocytogenes*).

5. Starter culture - The starter culture used in the product should be similar in composition to that used in the support, to ensure that fermentation is achieved and the rate of pH drop is as expected. The starter culture should be formulated to ensure that microbial fermentation strains dominate over any potential pathogens and to inhibit potential *Staphylococcus aureus* growth during fermentation. In addition, the starter culture used for fermentation can affect whether bacteriocins (toxins produced by bacteria that inhibit the growth of other similar bacteria) are produced, and the type of bacteriocins produced, which can affect the level of reduction for bacterial pathogens.

6. Product Characteristics –

    a. Casing diameter - Product casing size and shape are critical operational parameters in fermented, semi-dry processes because they affect heat transfer. For Lebanon bologna and other similar products, it is important that the diameter of the product used in the establishment's process is the same or smaller than that of the product used in the supporting documentation. If the diameter of the establishment's product is larger than that of the product used in the support, it is possible that the product core will take longer to reach the desired temperature and pH and a lower level of pathogen reduction would be achieved.

    b. Product formulation – Product formulation plays a role in the fermentation process and in the heat transfer during the intermediate heating step. Product formulation also may affect microbial resistance to acid or heat. The establishment should have an understanding of the critical operational parameters associated with the product formulation (e.g., % salt, moisture level, nitrite or any other preservatives, and % fat) and should ensure that the material used in the supporting documentation is similar to their product with respect to those critical operational parameters.

    c. Casing – The casing influences moisture exchange. Products with impermeable, semi-permeable, or permeable casing exchange moisture with the environment differently and can, therefore, influence the rate of

product acidification, the penetration of heat into the interior of the product, and the maximum internal temperature reached by the product. Therefore, the establishment should ensure that the type of casing used in its process is the same as that used in the supporting documentation.