

Food Safety Lessons Learned from the Lebanon Bologna Outbreak

What is the purpose of this Compliance Guideline?

This Compliance Guideline contains information regarding lessons learned from a Food Safety Inspection Service (FSIS) investigation of a Lebanon bologna product associated with a foodborne illness outbreak of *E. coli* O157:H7 in 2011. During the outbreak investigation, FSIS identified that inadequate validation of the Hazard Analysis Critical Control Point (HACCP) system design may have led to the production of adulterated product. Using the findings from the investigation, this guideline articulates how industry can meet FSIS expectations regarding the production of Lebanon bologna. It is important to note that this guideline represents FSIS's current thinking on this topic and should be considered usable as of the issuance date.

Who is this guidance designed for?

All Lebanon bologna processors.

How is this guidance being shared?

This guidance document is available on the FSIS web site for establishments to use. In addition, FSIS inspection program personnel were instructed to hold an awareness meeting in May 2012 (per Notice 36-12) with establishments that produce Lebanon bologna to share the lessons learned from the Lebanon bologna outbreak (including those covered in this document), and how the establishment can comply with regulatory requirements in 9 CFR 417.4(a)(1), 9 CFR 417.5(a)(1), and 9 CFR 417.5(a)(2).

Is this version of the guidance final?

Yes, this version of the guidance document, dated January 2013, is considered final and replaces the previous version of the document. No comments were received during the comment period; however, a change was made to the recommendations related to relative humidity on page 6 as a result of an askFSIS question received. Specifically, this version clarifies the circumstances under which relative humidity would not need to be monitored as part of the Hazard Analysis and Critical Control Point (HACCP) system. Guidelines will be continually updated to reflect the most current information available to FSIS and stakeholders, although comments will no longer be accepted through regulations.gov on this guidance document. In addition, this final version made changes to the recommended log reduction for *Listeria monocytogenes* to be consistent with other FSIS guidance documents.

Why was this guidance 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 had not properly validated their Lebanon bologna process. In particular, the establishment did not identify supporting documentation during the design of the HACCP system that closely matched the actual commercial process used. 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. However, in the supporting documentation identified by the establishment to represent a commercial process for Lebanon bologna, raw Lebanon bologna mix was compacted in smaller 27 millimeter diameter impermeable sealed glass tubes that were immersed in a well-controlled water bath.

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 supporting documentation. If the diameter of the establishment's product is larger than that of the product used in the supporting documentation, it is possible that the product core will take longer to reach the desired temperature and pH. Taking a longer time than 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 when an establishment designs its HACCP system during the initial validation period that it identify supporting documentation that is representative of the actual process so that the results can be repeatable. In the case of the establishment identified in the outbreak, additional supporting documentation should have been identified during initial validation demonstrating adequate reduction in pathogens would be achieved with a product of the same diameter and casing type as that used in the actual process.

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 validate their processes. There are two distinct elements to validation: 1) the scientific or technical support for the HACCP system design (design) and 2) the initial practical in-plant demonstration proving the HACCP system can perform as expected (execution). The key steps to achieving these two elements are summarized on the next page:

Element 1: Scientific or Technical Support (Design)

1. Identify supporting documentation (e.g., journal articles, challenge studies, or data gathered-in plant) that closely matches their process;
2. Identify supporting documentation that demonstrates the expected level of bacterial pathogen reduction (e.g., a 5- \log_{10} reduction of *Salmonella* spp. and *E. coli* O157:H7, and a 3- \log_{10} reduction of *Listeria monocytogenes*, although a 5- \log_{10} reduction or greater is desirable for providing an even greater safety margin for ensuring that *Lm* doesn't grow during cold storage to detectable levels); and
3. Identify the critical operational parameters from the supporting documentation relevant to their commercial process (i.e., fermentation temperature, relative humidity, come up time to low temperature heating step, hold time and temperature for low temperature heating step, equipment, pH and time to reach target pH, type and use of starter cultures, and product characteristics such as diameter, composition, and casing type).

Element 2: Initial In-Plant Demonstration (Execution)

4. Implement those same critical operational parameters in their production process (e.g. as a Critical Control Point (CCP), prerequisite program, or as part of the HACCP system);
5. Identify at least one product from each HACCP category to gather in-plant validation data; and
6. 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 all of the critical operational parameters from the supporting documentation relevant to their commercial production process. 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 its 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 supporting documentation 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 supporting documentation (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 supporting documentation. 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, decide that a limited number of other critical operational parameters will only be verified during the initial validation period (for example, 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 of a CCP or into a pre-requisite program can be met (for example the equipment, product composition provided it does not change or spatial configuration of a system). 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. Further information on validation can be found in the Draft FSIS Compliance Guideline HACCP Systems Validation found at:

(http://www.fsis.usda.gov/PDF/HACCP_Systems_Validation_Draft_Guidance_0412.pdf).

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 (RTE *Salmonella* Guidelines), found at http://www.fsis.usda.gov/PDF/Salmonella_Comp_Guide_091912.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 found in the RTE *Salmonella* Guidelines (referenced in the note above) and the *Listeria* Guidelines found at: http://www.fsis.usda.gov/PDF/Controlling_LM_RTE_guideline_0912.pdf.

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

Examples of critical operational parameters for the production of Lebanon Bologna include:

- Fermentation temperature
- Hold time and temperature for low temperature heating step
- Come up time to low temperature heating step
- Relative humidity
- Equipment
- Type and use of starter cultures
- pH and time to reach target pH
- 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 Good Manufacturing Practices (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 affect 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 most dried meat processes. A relatively high humidity is preferred to keep the product surface moist during the fermentation and intermediate heating steps, prior to 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.

NOTE: Humidity is inherently maintained and, therefore, does not need to be monitored as part of the HACCP system for products that use an impermeable casing. This is because impermeable casings will prevent or inhibit moisture loss so that the heat resistance of pathogens is not affected by the cooking process (e.g., sausages cooked in casings). In the case of the Lebanon bologna outbreak, the product used a permeable casing which allowed moisture loss to occur during the cooking process. In that case, relative humidity was not well-controlled and should have been because of the nature of the product. For more

information on processes in which humidity is inherently maintained and does not have to be added or monitored as part of the HACCP system, see the Appendix A Guidance on Relative Humidity and Time/Temperature for Cooking/Heating and Applicability to Production of Other Ready-to-Eat meat and Poultry Products found at: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/95-033F/Appendix_A_guidance_95-033F.pdf.

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 supporting documentation. 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, 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 supporting documentation, to ensure that fermentation is achieved, and the rate of pH drop is as expected. The starter culture should be formulated to ensure microbial dominance of fermentation strains 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 supporting documentation, 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 casings 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.