Resource 3

QUESTIONS AND ANSWERS
Table of Contents

SAMPLE COLLECTION 2

SAMPLE RESULTS 4

FOLLOW-UP OR INTENSIFIED SAMPLING 10

INSPECTION ACTIVITIES 13

HACCP/SANITATION SOP/PREREQUISITE PROGRAMS 18

VALIDATION/VERIFICATION 20

READY-TO-EAT VERSUS NOT-READY-TO-EAT 21

READY-TO-EAT POST-LETHALITY EXPOSED PRODUCTS 23

POST-LETHALITYTREATMENT 24

ANTIMICROBIAL AGENT OR PROCESS 27

ALTERNATIVES 33

PRODUCTION VOLUME 39

LABELING 40

GENERAL 41

NOTE:
The section headings in the Table of Contents can be linked to the section in the text by clicking on the key words in blue.

For this second update, a new section, “Ready-to-Eat Post-Lethality Exposed Products”, now follows the section “Ready-to-Eat Versus Not-Ready-to-Eat.” The new questions and answers are: 13, 18, 29, 30, 76, 77, 78, 89, 90, 92, 93, 94, 102, 121, 122, and 123. The answer to 124 is revised. For the new questions and answers, only the question is in color print.

SAMPLE COLLECTION

1. **Question:** If a sample is collected on a Friday but not picked up by Federal Express on that day, and if the next scheduled pick up is Monday, can the sample be kept in the cooler or freezer until Monday and then shipped?

   Answer: Inspection program personnel should try to avoid holding samples over the weekend whenever possible because the establishment would most likely be holding the sampled lot. If Federal Express cannot pick up the sample on the day of collection, inspection program personnel can refrigerate or freeze the sample until it can be picked up. However, inspection program personnel should not hold samples for more than three days (i.e., Friday to Monday) prior to shipping.

2. **Question:** The interim final rule requires that an establishment define the size of the sampling site. How does one go about defining a standard size when the equipment to be sampled will vary widely and will likely require differing sample sizes to be most effective?

   Answer: In determining the sample size for a food contact surface (FCS), the establishment must take into account that the FCS on any individual piece of equipment will vary. For this reason, the establishment's written program must provide clear directions on how samples will be taken depending on the available size of the FCS. For example, for equipment with FCS less than 1 square foot (12 in. X12 in.), the entire surface should be sampled. For FCS larger than 1 square foot, a contiguous area of at least that size should be sampled.

3. **Question:** Would USDA test the same RTE sites as the plant?

   Answer: Yes. FSIS may test the same food contact surface sites as the plant does.

4. **Question:** In a small plant there is no line. What is a line?

   Answer: A line refers the flow of product during production. This includes whatever equipment is contacting RTE product.

5. **Question:** When should a plant take an environmental swab for *L. monocytogenes*? Are food contact surfaces to be tested pre-operationally and during operations?

   Answer: There is no regulatory requirement regarding when to test food

contact surfaces. The Compliance Guidelines recommend sampling at least 3 hours after the start of operations as being the most effective at detecting *L. monocytogenes* or indicator organisms. Pre-operational testing of equipment, including food contact surfaces is part of the Sanitation SOP.

6. **Question:** Can an ATP test be used on RTE equipment?

   Answer: ATP testing can be used in the sanitation program for verifying the effectiveness of cleaning and sanitizing during pre-op. However, to verify the effectiveness of controls for *L. monocytogenes*, testing for *L. monocytogenes* or its indicators is used.

7. **Question:** Can a plant produce a smaller volume of product on the day they are to test for *L. monocytogenes*?

   Answer: This is up to the plant. The plant must document that testing a smaller volume of production will ensure that effective control of *L. monocytogenes* or indicator organisms is maintained.

8. **Question:** With different pieces of equipment, how many sites are required to be sampled?

   Answer: The number of sites sampled depends on the type of equipment, processing operation, and plant layout. Sampling sites are not limited to food contact surfaces but **may** include non-food contact environmental samples (e.g., gloves, switches, floors, ceilings, drains, etc.) The regulatory requirement is for testing FCS, but other environmental surfaces may be sampled too.

9. **Question**: If an establishment is just starting sampling, how often should it sample to build up a history?

   Answer: The number of samples and the frequency of sampling will depend on the daily production volume, product or process risk. It might be better to start out at a higher level and then decrease if need be.

10. **Question**: If a food contact surface is sampled during operation, should that equipment be cleaned and sanitized (if possible) to break the lot connection and reduce the amount of product affected? What is the FSIS perspective and recommendation?

    Answer: Food contact surfaces should be sampled using aseptic techniques so that contamination is not introduced. The food contact surfaces swabbed for sampling should be rinsed or wiped after sample collection if there are non-GRAS components of the sampling medium.

This does not mean that the lot will be defined by amount of product produced before the sampling and cleaning of the sampled surface. A lot is considered as product that is produced from cleanup to cleanup unless the establishment has its own definition of a lot. If the establishment performs a complete cleaning and sanitizing at anytime during the shift, the lot size could be reduced.

11. **Question:** What will FSIS target for testing if two different products are in the same category?

Answer: If 2 or 3 products are under the same Alternative, FSIS will target the higher risk product or process. For example, for an establishment that produces deli meat, hotdog, and pate, FSIS will collect samples for deli meats first, hotdog next and pate last. Likewise, if an establishment chooses to have a hotdog product in Alternative 2, and another type of hot dog product in Alternative 3, FSIS will sample the hotdog product in Alternative 3 first before the hotdog product in Alternative 2.

12. **Question:** Why does FSIS require a 1 pound sample for jerky when other labs only require 4oz?

Answer: The amount of product requested depends on the type and number of tests that are performed. The Agency tests for more than one pathogen in a sample and/or samples for biosecurity issues. For example, one pound is requested for monitoring samples and two pounds for HACCP verification samples.

13. **Question:** Should the ICMSF sampling plan in the Compliance Guidelines table be used for regular sampling or only for hold and test sampling?

Answer: For routine sampling, the establishment can use whatever sampling plan it justifies as appropriate to demonstrate that the product is safe. For hold and test sampling for *L. monocytogenes*, a statistically-based sampling plan should be used. The ICMSF table provides examples of statistically-based sampling plans that are commonly used for demonstrating lot acceptance.

SAMPLE RESULTS

14. **Question:** If an establishment delivered product from a sampled lot to a customer but retrieved all of it before the report of the FSIS sample result, will the product be deemed to have been shipped?

Answer: Yes, once an establishment completes its pre-shipment record review, the product is considered “eligible for shipment or “shipped.” Upon report of a positive result, establishments are expected to prevent product

from entering commerce in accordance with sections 9 CFR 417.3(a)(4) or (b)(3)of the regulations and to process it in a manner that will make it no longer adulterated. Product adulterated with a pathogen that is not processed in such a manner will be condemned. Inspection program personnel are not to take any regulatory control actions unless the establishment fails to control product as specified in 9 CFR 417.3(a)(4) or (b)(3).

15. **Question:** If a product or food contact surface sample tests positive for a pathogen, what is the status of product(s) produced on days subsequent to the day the sample was collected?

Answer: In general, FSIS does not consider product that is produced on days subsequent to the day of sampling and that is coded differently from the sampled lot to be represented by the sample. Under most circumstances, the product is not subject to retention, detention, or voluntary recall. A positive sample does call into question the adequacy of an establishment's process for producing safe product. For deli and hotdog products in Alternative 3, the establishment must verify the effectiveness of the corrective actions by conducting follow-up testing. Upon report of a positive sample, inspection program personnel will perform the appropriate HACCP 02 procedure on the product's HACCP plan, and an 01B01 and an 01C01 procedure on the establishment's Sanitation SOPs covering the time period from when the sample was collected to the present. If, in performing these procedures, inspection program personnel find that the establishment shipped adulterated product other than the sampled lot, this additional product will be subject to detention, voluntary recall, or seizure. For example, if inspection program personnel find that the establishment failed to meet the critical limit at the cooking CCP and took no corrective action on subsequent lots, all product affected by this failure is subject to retention, detention, voluntary recall, or seizure.

16. **Question:** The Compliance Guidance indicates that for *Listeria* spp. testing the methodology should employ enrichment, and that screening should be conducted using immunoassay, nucleic acid assay or equivalent *Listeria* spp. specific technology. Does this mean that cultural methods such as enrichment, followed by plating on MOX, followed by additional cultural identification steps that stop short of species identification would not be acceptable?

Answer: As indicated in the guidelines, any methodology used by a regulatory body or validated by a recognized body is acceptable. Other methods that have been validated or recognized in peer-reviewed articles would be acceptable.

17. **Question:** Can an establishment test in-house for *L. monocytogenes*?

Answer: Yes. Testing for *L. monocytogenes* can be used to verify the effectiveness of the controls used. The method should be AOAC approved or equivalent to FSIS testing procedures. The FSIS methods can be found in the Microbiology Laboratory Guidebook - http://www.fsis.usda.gov/OPHS/microlab/mlgbook.htm.

18. **Question:** Is the use of company wide data (e.g., Sentinel Site Program) to support its food contact surface (FCS) testing frequencies acceptable, even though individual plant conditions vary?

Answer: A company can use company wide data in determining their frequency of FCS testing as long as the products have the same process, Alternative, and treatment, and the frequency of testing is documented in their sanitation program. In addition, the sanitation program must comply with the requirements in 9 CFR 430.4 (b).

19. **Question:** Does a sample test result that is positive for *Listeria* spp. or *Listeria*-like organisms indicate that the product is adulterated?

Answer: No. However, FSIS considers a finding of *Listeria* spp. or *Listeria* – like organisms on product or a food contact surface to be an indication of the potential presence of the pathogen, and that the process may not be appropriately controlled. The establishment should take corrective actions as specified in its control program. This may include taking new or additional verification samples of product and of the food contact surface.

20. **Question:** If a RTE product tested by FSIS is found positive for a pathogen, is the HACCP plan automatically inadequate, and should the inspector immediately take a withholding action?

Answer: According to 417.6(e), the HACCP plan may be found inadequate. In determining whether the HACCP plan is inadequate, the Agency will take into account all available information and consider the entire situation before making a determination of HACCP plan inadequacy. The cause and significance of a positive result varies from case to case depending on the circumstances of processing involved, and the pathogen found. FSIS will consider whether some or all products produced under the same or a substantially similar HACCP plan are affected, whether there have been other incidents of product contamination with the pathogen, and whether incidents of product contamination have been persistent or recurring. Establishments are required to take corrective and preventive actions in accordance with 9 CFR 417.3.

Product that tests positive for *Listeria monocytogenes* or other pathogens is considered adulterated and must be condemned or reworked according to the establishment's HACCP plan or corrective and preventive action arrived at under 9 CFR 417.3(b) for unforeseen hazards or deviation not covered by a corrective action in the HACCP plan. When considering a withholding action, inspection program personnel will follow the procedures in FSIS Directive 5000.1, Chapter IV, Rules of Practice Part III, and 9 CFR Part 500. If the IIC determines, on the basis of available information, that the establishment is continuing to produce and ship product that may be adulterated, the IIC should withhold the marks of inspection and inform the DO.

21. **Question:** If a food contact surface tests positive for *L. monocytogenes*, will the plant have the opportunity to test the product involved?

Answer: If a food contact surface tests positive for *L. monocytogenes* USDA would consider the affected product adulterated and would retain or request a voluntary recall. Testing of affected product is not an option. The plant could rework the product with a process that is destructive of *L. monocytogenes*.

22. **Question:** What if plant gets a positive environmental sample in a floor drain?

Answer: An environmental sample positive for *L. monocytogenes* or indicator organisms should initiate intensified cleaning and sanitizing. Keeping up with plant sanitation is one way to control *L. monocytogene*s contamination. Testing of non-contact surfaces should be included in the Sanitation SOP, HACCP plan, or prerequisite program. Required hold and test procedures apply only to food contact surface and product testing.

23. **Question:** Is the establishment required to hold lots when it or FSIS tests RTE food contact surfaces?

Answer: Establishments producing products under Alternative 2, using antimicrobial agents or processes, or Alternative 3 are required to identify the conditions under which they will implement hold and test procedures. For hot dogs and deli meats in Alternative 3, if an establishment obtains a positive test of a food contact surface during follow-up testing, the establishment must hold and test product lots that may have become contaminated. When FSIS takes samples for testing, establishments decide if they want to hold products.

24. **Question:** What is meant by "the post-lethality processing environment," and how will sampling and testing of this environment come into play following a positive test result for *L. monocytogenes* or *Listeria* spp. on a

product contact surface?

Answer: The post-lethality processing environment encompasses all areas an exposed product goes through from the end of the lethality step to the time it is packaged. Should a post-lethality processing environment contact surface test positive, the agency would expect that the establishment would investigate the potential source of the positive finding and where that source is located, then take corrective actions to eliminate the source and verify the effectiveness of the corrective actions. In certain situations, the source of *Listeria* may be the specific equipment that tested positive, such as a slicer. In other situations, such as a positive on a conveyor belt, the source may be a different location than the area tested.

25. **Question:** The use of the term "indicator organism" throughout the both the *Listeria* rule and compliance guidelines seems to be in conflict with the definition of "indicator organism" as defined by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). The rule links the "indicator organism" to *L. monocytogenes*; in this case, is the term "index organism" more appropriate?

Answer: FSIS Directive 10,240.4 and related publications will use the appropriate terminology as defined by the NACMCF. However, FSIS does believe that the term "indicator organism" is appropriate because a condition or state of sanitary control is being addressed. The presence of Indicator organisms is indicative of failure of process controls.

26. **Question:** If an establishment that produces hotdog or deli products under Alternative 3 tests for indicator organisms and has a second positive result for *Listeria* spp. or *Listeria* -like organisms does this mean that the establishment's control and testing programs that are incorporated into their HACCP plan, Sanitation SOPs, or prerequisite programs are automatically inadequate?

Answer: No. FSIS will take into consideration how the establishment responds to the positives, the type of intensified testing the establishment conducts, and the conditions that may have led to the second positive. In some cases, the second positive may have occurred from lack of proper execution of control programs, and in other cases may indicate a design problem. In this case, establishments that choose Alternatives 1 and 2 or Alternative 3 for non-deli and non-hotdog products must take corrective actions as specified in their sanitation and testing programs contained in their HACCP plan, Sanitation SOP or prerequisite programs. In addition, establishments must follow their hold-and- test program.

Establishments that choose Alternative 3 for deli and hotdog products are

to hold product and test for *L. monocytogenes,* take the corrective actions specified in their sanitation and testing programs, and test food contact surfaces until the food contact surface testing indicates that problems have been corrected. The lots of product produced after the second (follow-up) food contact surface positive test must be held until the problems that caused the positive test results have been corrected. (See 'Hold and Test Scenario' in the Compliance Guidelines.)

27. **Question:** Can establishments use product that tested positive for a pathogen as "rework?" Are there special restrictions?

Answer: The regulations do not prohibit the use of product that tested positive for a pathogen as "rework." An establishment is expected to address the use of such product in its HACCP plan. The plan should address any hazards presented by the practice, such as the potential hazard of increased tolerance of bacteria that survived a "kill" step. If such product is reworked routinely, then critical limits and CCPs need to account for any additional potential hazards. If contaminated product is reworked only occasionally, the plan may only need to address the procedures, critical limits, and CCPs to be met when lots containing rework are processed. When product that tested positive is identified after it has left an establishment, it may be returned to the originating establishment where it can be further processed. The product should be clearly identified as adulterated with *L. monocytogenes*. However, the frequent detection of *L. monocytogenes* in the product or processing environment suggests a continuing lack of control for sanitation and may require reassessment of the HACCP plan, Sanitation SOP, or prerequisite program.

28. **Question:** Can an establishment refer to FSIS testing results instead of conducting required tests?

Answer: No. FSIS does not routinely take product or environmental samples. Product sampling is not conducted at a level to ensure the product is free of *L. monocytogenes* or other foodborne pathogens. Intensified verification sampling for *L. monocytogenes* is conducted in response to a problem at, or originating from, the establishment.

29. **Question:** Can an establishment use the results of FSIS verification sampling instead of taking their own product sample if an FSIS sample is taken at the time the company is scheduled to take their HACCP verification sample?

Answer: Yes, if FSIS verification sampling occurs within the same time frame as that defined in the establishment's HACCP plan, then the establishment may use the results from the FSIS sample. For example, if

an establishment samples their product once a quarter as part of the verification activities in their HACCP plan and FSIS takes a sample in that same quarter, then the company can use the FSIS results as part of the verification for their HACCP plan. An establishment may not use FSIS verification sampling to support other decisions in their hazard analysis.

30. **Question:** Is a thermometer considered a food contact surface?

Answer: Yes, a thermometer is considered a food contact surface because it touches the food when it is used. However, it is food contact surface that must be sampled per the *Listeria* rule when it is used to take the temperature of the food at the time that it is post-lethality exposed, (e.g., taking the temperature of the food when it is out of the cooking bag).

FOLLOW-UP OR INTENSIFIED SAMPLING

31. **Question:** During follow-up verification sampling that may be scheduled from headquarters, must the samples be collected on consecutive production days?

Answer: The sample request forms should come with a note that instructs the inspection program employee to collect the samples within 60 days, if possible. Samples do not have to be collected on consecutive production days. The purpose of the follow-up sampling is to verify the effectiveness of the establishment's corrective and preventive measures. It is not necessary to sample consecutive lots to verify the effectiveness of these measures.

32. **Question:** For Alternative 1, FSIS suggests that when food contact surfaces are tested, and there are 2 consecutive positives, there should be intensified testing. What are Agency expectations regarding the nature of this intensified testing?

Answer: Intensified testing includes increasing the frequency of sampling and number of samples collected. The areas tested should be expanded to those adjacent to the FCS that tested positive. FSIS suggests that for Alternative 1, establishments initiate intensified testing when there are 2 consecutive positives. FSIS expects that whenever a FCS tests positive for *Listeria* spp., *Listeria*-like organisms, or *L*. *monocytogenes*, that the establishment would take immediate steps to determine the source of the positive test result, take corrective action, and verify the effectiveness of the corrective action in eliminating the source of the contamination.

33. **Question:** For Alternative 2, with only a post-lethality treatment, if the

retest of the food contact surface is positive, corrective action is repeated until samples are negative – there is no requirement for intensified testing as for Alternative 1, which involves use of both a post-lethality treatment and an antimicrobial agent or process. This would appear to be a less stringent approach than for Alternative 1. Are these examples written as the Agency intended?

Answer: The *Listeria* final rule does not require intensified testing for either Alternative 1 or 2. The compliance guidelines, on the other hand, recommend intensified cleaning and sanitation. For Alternative 1, the compliance guidelines recommend intensified testing if there are two consecutive positives. FSIS did not intend to have unlimited testing in the case of Alternative 2 products/processes. FSIS anticipates that, absent an establishment demonstrating a science-based alternative, intensified testing likely will be conducted after 2 consecutive FCS positives for Alternative 1, 2 consecutive positives for Alternative 2 and Alternative 3 – non-deli/hot dog, and after one positive for Alternative 3 deli/hot dog.

34. **Question:** How many samples, which locations, and how frequently should samples be taken as follow-up to show that corrective actions have been effective?

Answer: This depends on the specific process, the plant, and the location of the positive site that is being "corrected." Sampling frequency is expected to be higher for deli meats and hot dogs in Alternative 3 than for other products.

35. **Question:** Is a testing frequency of one time a year acceptable?

Answer: Each plant must decide and explain in their sanitation program why their frequency of testing food contact surfaces is sufficient to ensure effective control of control *L. monocytogenes*. A minimum testing frequency of twice a year is recommended in the Compliance Guidelines for products produced according to Alternative 1. Historical data that includes testing is one means to support the frequency of testing.

36. **Question:** An establishment produces hotdog and deli products using Alternative 3 and has 3 production lines in the post-lethality processing area. The establishment receives a positive result for *L. monocytogenes* or indicator organism on line 1 food contact surface. Does the establishment need to sample food contact surfaces only from line 1 or from all the 3 lines for the follow-up testing?

Answer: The follow-up testing is verification that the corrective actions taken by the establishment are effective. If the establishment can support that line 1 is using equipment, personnel and processing area that is

separate and independent of the other lines (i.e., not used by other lines) and has supporting documentation that there is no history of cross-contamination among the three lines, then corrective actions should be conducted on line 1 and follow-up testing should be conducted on the food contact surfaces of line 1. If there are positives on FCS during this follow-up testing, the product produced on this line would be subject to test and hold.

If the establishment could not support its claim that line 1 is independent of the other 2 lines and does not have supporting documentation that there is no history of cross-contamination among the 3 lines, the establishment needs to take corrective actions on the entire processing area and test food contact surface samples from the 3 lines for the follow-up test.

37. **Question:** An establishment that produces deli and hotdog products in Alternative 3 checks product contact surfaces for *Listeria* species on Monday for the first time. The test comes back positive on Thursday. How would this affect the product produced on Monday, Tuesday, Wednesday, and Thursday?

Answer: It would not affect product produced on Monday through Thursday. However, on Thursday, the establishment must initiate corrective actions, intensified cleaning and sanitizing, and verify the effectiveness of the corrective actions by follow-up testing of the food contact surfaces. Attachment 6, Hold-and-Test Scenario Flowchart, in the Compliance Guidelines describes the process.

If the establishment tests for *L. monocytogenes* and test is positive, product that comes into direct contact with a FCS that tests positive for *L. monocytogenes* is considered adulterated and must be recalled if it was not held. That product must be destroyed or reworked with a process that is destructive of *L. monocytogenes*. The establishment must have supporting documentation explaining why products produced on Tuesday, Wednesday and Thursday would not be contaminated with *L. monocytogenes*, or else test product lots on these days for *L. monocytogenes*. On Thursday, the establishment must take corrective actions, conduct intensified cleaning and sanitizing, and test food contact surfaces for *L. monocytogenes* or indicator organisms to verify the effectiveness of the corrective actions.

38. **Question:** How can a plant manufacturer comply with hold and test procedures and still meet customer needs?

Answer: The establishment needs to plan for at least 72 hours to obtain an initial test result. This is only in cases where hold and test is required.

39. **Question:** What if product is classified in Alternative 2 and a food contact surface is positive when testing?

Answer: For products in Alternative 2 using antimicrobial agents or processes, and in Alternative 3, non-deli or hotdog products, if a food contact surface tests positive for *Listeria* spp. or *Listeria*-like organisms, the establishment must take corrective actions, verify that the corrective actions are effective by follow-up testing of food contact surfaces, and follow its hold and test procedures, if applicable. When a food contact surface tests positive for *L. monocytogenes*, affected product is considered adulterated. Products that have been shipped need to be recalled. The establishment must determine disposition of the product, whether to be reworked or destroyed.

40. **Question:** If I am required to hold and test my products, since the test takes 3 days, but my shelf-life of product is 1-2 days, how does the Agency expect I could hold my product pending results?

Answer: An establishment is not required to hold products pending results of the food contact surface testing, unless the product is a deli or hotdog product produced under Alternative 3 and the establishment has collected a follow-up FCS test that is positive for *Listeria* spp. or *L. monocytogenes*. In this case, the prudent establishment would suspend production after cleaning and testing of the lot following the second positive to verify that the problem has been corrected.

INSPECTION ACTIVITIES

41. **Question:** For Alternative 1, FSIS is not requiring establishments to have a testing program for food contact surfaces (FCS); however, the Agency recommends such testing at least twice a year. What actions would the Agency anticipate taking (e.g., enhanced verification testing) if a plant does not incorporate this testing in its program?

Answer: The recommended testing of FCS under Alternative 1 is for periodic verification that the post-lethality treatment is not challenged with a level of *L. monocytogenes* that the post-lethality treatment was not designed to eliminate or reduce. If inspection program personnel have questions about the establishment's response, they should contact their frontline supervisor or the TSC.

42. **Question:** When sampling plans are required for food contact surfaces (FCS), there is a requirement for an "explanation of why the testing

frequency is sufficient." What are the criteria surrounding this required "explanation?" Who decides whether the establishment's "explanation" is adequate?

Answer: The Agency expects that the establishment be able to articulate its thought process regarding why it selected a particular frequency. Evidence, such as scientific articles or prior history, could be used, as well as practical considerations such as laboratory capacity, timing and cost/benefit analysis. Should there be an issue involving the "adequacy" of the explanation, inspection program personnel generally are directed to contact their front line supervisor or the TSC with specific questions. In addition, if warranted, in-plant inspection personnel can also use the expertise, skills, and knowledge of the Enforcement Investigation Analysis Officer (EIAO) in determining whether the establishment's control system is in compliance with the regulatory requirements.

43. **Question:** Are there situations in which inspection program personnel may submit an inspector-generated sample?

Answer: Yes, there may be situations in which inspection program personnel may feel that it is necessary to request permission to collect an inspector-generated sample. For example, an establishment produces a deli meat product under Alternative 2. Inspection program personnel observe that the establishment has modified the production process for this product, and it no longer uses an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*. The product is now covered by Alternative 3, but the establishment has not modified its sanitation and testing program according to 430.4(b)(3)(iii) to reflect this change. In this situation, after consulting with their frontline supervisor to obtain permission to collect the sample, inspection program personnel are to obtain form FSIS 10,210-3, "Requested Sample Form," through channels from the Office of Public Health and Science prior to collecting a "for cause" sample. Remember, inspection program personnel must consult with their frontline supervisors before taking any inspector-generated samples.

44. **Question:** If inspection program personnel have not received a sample request form in a number of months, should they take inspector-generated samples?

Answer: No. Inspector-generated samples should not be submitted solely because the inspector has not received a generated sample request in the past few months. In its sampling programs, FSIS is concentrating its resources on those establishments that have chosen Alternative 3. Consequently, there will likely be times when certain products and facilities following Alternative 1 or Alternative 2 will be sampled less

frequently than they have been in the past.

45. **Question:** If an establishment is using sliced deli meats or hot dogs as ingredients of a multi-component product such as a frozen meal, dinner, entree, or open-faced hot sandwich, are the finished products or in-process deli-meats or hot dogs subject to the verification testing program?

Answer: The finished product is subject to verification testing.

46. **Question:** What is the importance of food contact surface testing for products that receive a post- lethality treatment that has been validated to destroy any *L. monocytogenes* that might be present?

Answer: The FSIS public health focus is on products that have a greater likelihood of becoming contaminated after the lethality step and on products that support the growth of *L. monocytogenes*. Since products that receive a post-lethality treatment that has been validated to be effective under the operational conditions in the establishment are unlikely to become further contaminated, the establishments that produce these products need not frequently test food contact surfaces or the environment where these products are produced. However, as noted in a previous response, testing of food contact surfaces serves to ensure that the effectiveness of the post-lethality treatment is not reduced by an excessive level of *L. monocytogenes*.

47. **Question:** How is the adequacy of testing frequency determined since there are no black and white guidelines and there can be some inconsistencies between FSIS personnel?

Answer: The establishment is responsible for providing documentation, explaining why the frequency of testing is sufficient to ensure that effective control of *L. monocytogenes* or indicator organisms is maintained. The Compliance Guidelines provide suggested minimum frequencies for testing food contact surfaces for the 3 Alternatives. The establishment can start with those frequencies and adjust later as necessary.

48. **Question:** What are the criteria regarding the need for corrective action for Alternatives 1, 2, and 3?

Answer: Guidelines for specific criteria for corrective action are described in the FSIS Compliance Guidelines to Control *Listeria monocytogenes* in Post-Lethality Exposed Ready-To-Eat Meat and Poultry Products. Corrective actions are to be followed by targeted testing to verify that the corrective actions were effective.

49. **Question:** Paragraph 430.4(b)(3)(ii)(C) of the interim final rule allows for the release of product (i.e., deli meat and hotdog) placed on hold using a "sampling method and frequency that will provide a level of statistical confidence that assures that each lot is not adulterated." What is meant by a "level of statistical confidence"? Is this based on the cases of sampling plans classified by the International Commission on Microbiological Specifications for Foods (ICMSF)?

Answer: FSIS recognizes the limitations of any sampling and testing plan to ensure product safety with 100% confidence. FSIS recognizes that the lower the likelihood of contamination (e.g., <1%) the higher the number of samples required to obtain a high degree (e.g., 95%) of confidence that the pathogen is absent from the sampled lot. Furthermore, FSIS recognizes that statistical sampling is not relevant to environmental sampling and testing, and that repeated sampling and testing of the environment is the best method to determine whether corrective actions (e.g., enhanced cleaning and sanitation) have been effective in eliminating potential harborage of any contamination. Although the agency will not dictate any particular sampling plan with regard to lot release following a *Listeria* spp. positive FCS finding, historically, FSIS has recognized the use of ICMSF sampling plans for release of product. Under an ICMSF sampling plan, the number of samples would be dictated by the "case." Case 13 (n (number of samples)=15, c (number of samples that can be positive) =0) applies if conditions reduce the hazard (e.g., the product will be cooked or contain an agent that would kill *L. monocytogenes*); Case 14 (n=30, c=0) applies if the conditions cause no change in the hazard (e.g., the product is frozen or shelf stable); and Case 15 (n=60, c=0) applies if conditions may increase the hazard (e.g., the product is refrigerated and supports growth of *L. monocytogenes*).
The Compliance Guidelines provide a table for these sampling plans. The establishment could also contact a trade association, processing authority, or statistician for a testing frequency that ensures effective control of *L. monocytogenes* or indicator organisms.

50. **Question:** Based on the Compliance Guidelines, it appears that under Alternative 3, hold and test procedures must be conducted for hot dogs and deli meats after a second positive test on a FCS (following an initial positive and corrective action), whereas for other products under this Alternative, hold and test must occur after 3 consecutive positive food contact surface tests. Is this correct?

Answer: The *Listeria* interim final rule requires hold and test procedures be conducted after a positive follow-up test on a FCS for deli meat and hotdog products under Alternative 3. The Compliance Guidelines recommends procedures on how the establishment can comply to this requirement. However, for all other products, there is no magic number;

rather, the establishment is free to select at what point hold and test will be initiated, provided it can be justified.

51. **Question:** If an establishment employs hold and test procedures, how would FSIS define the "lot" to be held?

Answer: FSIS Directive 10,240.4 refers to the sampled lot as "all product represented by the sample (i.e., the sampled lot)". The establishment, not the Agency, defines a production lot, and it is usually from clean up to clean up.

52. **Question:** If a positive result came from a product that was in a common cooler, would the whole cooler be considered a common lot?

Answer: No, but the establishment should check other products that may have been close to affected product for cross contamination. The establishment's Sanitation SOP or prerequisite program should address product traffic control to prevent cross contamination between raw and cooked product. Raw and cooked products should be covered and separated in the cooler.

53. **Question:** What *Listeria* test data must be shared with FSIS personnel?

Answer: A description of the *Listeria* Control Program and associated data from monitoring and follow-up sampling are required to show that the program is effective. This includes environmental tests conducted pre-operationally or during operation. These are verification tests for the effectiveness of the sanitation program. FSIS believes that any decision-making data relative to the production of meat and poultry products is required to be made available to FSIS, particularly if the decision-making documentation affects the safety of the product. *Listeria* Control Program data must be available for 2 years.

54. **Question:** When will the Agency take samples?

Answer: FSIS will collect product samples for pathogen testing after the pre-shipment review. The CSIs will inform the establishment before collecting samples.
If the establishment has a history of food contact surface positives for *Listeria*-spp. or *Listeria*-like organisms or the District Office determines that an assessment indicates the need for environmental testing, FSIS would conduct intensified verification testing on food contact and non-food contact surfaces in addition to further product sampling. FSIS will collect food contact surface and environmental samples during processing. The Agency will not notify the establishment for this sampling. EIAO's may be

asked to do the sampling.

55. **Question:** If a plant is three hours into operation and USDA comes to take a RTE sample this could produce a large amount of product to hold.

Answer: The establishment is not required to hold product when FSIS takes samples for product or environmental testing. However, if the sample tests positive for *L. monocytogenes*, the establishment must recall the affected product. The amount of product held, or possibly subject to recall, is the entire lot of product from which the sample was selected. A lot is usually defined as that produced from cleanup to cleanup.

56. **Question:** Will USDA EIAOs reassess a plant's HACCP plan for *Listeria* like they did for *E. coli* O157:H7?

Answer: They may, this is still under consideration.

HACCP/SANITATION SOP/PREREQUISITE PROGRAMS

57. **Question:** In the rule, FSIS states that if an establishment has implemented a post-lethality treatment, it must be included in the HACCP plan. If the establishment has data to demonstrate that *L. monocytogenes* is not a hazard reasonably likely to occur, must the post-lethality treatment be considered a CCP? Could an establishment include the treatment in a prerequisite program accessible to FSIS via the hazard analysis?

Answer: It is conceivable that if the establishment can support its determination that *L. monocytogenes* is not reasonably likely to occur, without any reference to the post-lethality treatment, then the establishment would not be required to include such step as a CCP in its HACCP plan. However, FSIS would be interested in the establishment's justification for having the post-lethality treatment if it is unnecessary for *Listeria* control.

58. **Question:** What manner of monitoring (when, where and how temperatures are taken) of the post lethality treatment will the Agency find acceptable?

Answer: FSIS will not dictate the monitoring and verification procedures for post-lethality treatments. That is the responsibility of the individual establishment.

59. **Question:** Although the rule allows flexibility where control measures are placed in the food safety system (especially with respect to antimicrobial agents/processes), the rule requires that establishments have documentation that supports the decision in its hazard analysis that *L.*

monocytogenes is not a hazard that is reasonably likely to occur if it elects to incorporate the control measures in its sanitation SOPs or prerequisite program, rather than in its HACCP plan. What are the evaluation criteria inspection personnel will use in determining whether the documentation is sufficient?

Answer: Inspection program personnel determine whether the establishment has documented its decision making in the hazard analysis as to why the *Listeria* control program was placed in a prerequisite program. In addition, inspection program personnel verify that the HACCP plan, hazard analysis, sanitation SOP, and prerequisite programs meet regulatory requirements. If certain questions arise that are beyond their expertise, inspection program personnel generally are directed to contact their front line supervisor or the TSC. In addition, if warranted, in-plant inspection personnel can also use the expertise, skills, and knowledge of the EIAO in determining whether the establishment's control system is in compliance with the regulatory requirements.

60. **Question:** When measures for addressing *L. monocytogenes* are included in a prerequisite program other than a Sanitation SOP, the establishment must ensure that the program is effective and "does not cause the hazard analysis or the HACCP plan to be inadequate." Likewise, in the compliance guidelines, FSIS indicates that the establishment must verify that the antimicrobial program is effective, and "that it does not cause the hazard analysis or the HACCP plan to be inadequate." What does the Agency mean by this?

Answer: An effective prerequisite program will reduce the likelihood of occurrence of a hazard. Based on such a program, an establishment could deem a hazard not reasonably likely to occur in its hazard analysis and need not adopt a CCP for the hazard. However, if the prerequisite program is not effective (or is not being followed), it means the hazard may become reasonably likely to occur. In such a case, the HACCP plan would be inadequate, since it does not include a CCP for the hazard. Accordingly, FSIS expects that establishments will routinely assess the effectiveness of the prerequisite programs and make any necessary adjustments to ensure that *L*. *monocytogenes* does not become a hazard reasonably likely to occur.

61. **Question:** What information is needed in the Sanitation SOPs to explain how food contact surfaces are kept sanitary and free of *L. monocytogenes*?

Answer: FSIS expects the same degree of detail for that currently included in the establishment's Sanitation SOP, provided that the specific

sanitation requirements of the regulation are addressed either in the Sanitation SOP or other specific program regarding *Listeria* control.

62. **Question:** How do USDA laws apply to inspected retail exempt product?

Answer: USDA laws apply to retail if the product is adulterated.

63. **Question:** Can partially cooked and fully cooked product be produced in the same room?

Answer: Yes. However, the HACCP plan, Sanitation SOP and prerequisite programs should include the procedures used to prevent cross contamination of the fully cooked product.

VALIDATION/VERIFICATION

64. **Question:** Are there specific requirements (e.g., log-reductions) for validating the efficacy of post-lethality treatments, antimicrobial agents, and antimicrobial processes?

Answer: FSIS has chosen not to establish specific requirements, allowing the establishments to select the appropriate levels based on their operations and the product's expected shelf life and use. However, FSIS would anticipate that the establishment will have documentation to support its actions and conclusions. On post-lethality treatments, FSIS expects the establishment's HACCP documentation would demonstrate that the post-lethality treatment will be adequate to reduce a level of contamination that has a potential to occur before packaging to undetectable levels. For antimicrobial agents and processes, the agency expects that there will not be a significant increase in numbers of organisms during the product's shelf life to a level resulting in a public health risk.

65. **Question:** In Table 1 "Summary of final rule requirements by establishment group," group #2 (68 FR 34229), do items 5 and 6 (validation and verification) apply when freezing is used as the antimicrobial process? (i.e., Is validation of freezing effectiveness required and must an establishment demonstrate effectiveness of freezing in controlling *L. monocytogenes* on an ongoing basis?)

Answer: On validation, pursuant to 9 C.F.R. §§ 417.2 & 417.5 of the HACCP regulations, an establishment must have its decision-making documents as to whether a food safety hazard is likely to occur. Since freezing is a well-recognized bacteriostatic process, an establishment would not need extensive scientific support. The Compliance Guidelines were modified to state this and to include a chart to be used as the source of scientific justification. As to verification, many establishments include

freezing as a CCP for stabilization (cooling of product). The continuing verification for this CCP could be used to verify the effectiveness of the bacteriostatic process. If freezing is not a CCP in a HACCP plan, FSIS would expect some verification activities to demonstrate that the product is indeed being frozen below the level which the scientific validation documents establishes as having the bacteriostatic effect.

66. **Question:** What records would the agency require for products with formulations that are inherently anti-listerial but that may not be formulated specifically for that purpose but rather to achieve the desired product characteristics (e.g., BBQ and pickled meats, precooked bacon, beef snack sticks)? Would the establishment be required to make changes to the HACCP plan to account for the anti-listerial benefit of the formulation/process?

Answer: As to the records that would be required to substantiate the anti-listerial properties of a product formulation, FSIS would expect that the establishment would have scientific support for the conclusion that the nature of the product, as manufactured by the establishment, has such an effect, e.g., citations to published data. As to inclusion in the HACCP plan, that would only be required for a post-lethality treatment (see below). If the post-lethality listericidal effect is based solely on the product characteristics, the agency would expect that the process of achieving the characteristics would be incorporated in the HACCP plan.

67. **Question:** Can you give an example of information that validates the use of diacetate in a RTE product?

Answer: Information that validates the use of diacetates in product can be found in scientific journals such as the Journal of Food Protection and Meat Science. Summaries of some studies on diacetates and their references are included in the Compliance Guidelines.

68. **Question:** Can establishments use the studies cited in the Compliance Guidelines for verification as they do for the Compliance Guidelines in Appendices A and B in the final rule for certain meat and poultry products?

Answer: Yes, provided the product, processing procedures, and ingredients are equivalent to those in the studies. For example, if the pH and concentration of antimicrobial in the study were both considered critical, then the product must have that pH and contain the antimicrobial in the concentration used in the study.

READY-TO-EAT VERSUS NOT-READY-TO-EAT

69. **Question:** The interim final rule only applies to ready-to-eat (RTE) products. Will the provisions in the old Directive 10.240.3 (Attachment 2) still apply in distinguishing between RTE and not-ready-to-eat (NRTE) product? How will the agency classify products containing both raw and cooked ingredients?

Answer: The table that shows what constitutes a RTE product will be carried forward in the new directive (Resource1). Under the directive, products containing both raw and cooked ingredients (e.g., a frozen entrée containing blanched vegetables and fully cooked meat) will not be considered RTE if: (1) the product label prominently indicates the need to cook the products for safety, and (2) there are validated cooking instructions.

70. **Question:** Does the agency intend to require all products considered NRTE to bear safe handling instructions in addition to validated cooking instructions (for example, a partially cooked frozen dinner)?

Answer: A safe handling statement would be required if the meat or poultry component is NRTE. If the non-meat component requires cooking for safety, the safe handling instructions are not required but are encouraged.

71. **Question:** Are frozen foods to be cooked by the consumer considered to be RTE?

Answer: A frozen product to be cooked may be either RTE or NRTE. FSIS distinguishes between RTE and NRTE foods in Attachment 2 to the new directive.

72. **Question:** Does partially cooked product have to comply with *L. monocytogenes* control measures?

Answer: Partially cooked or not fully cooked products are not RTE products and are not covered by the rule. An example is a not fully cooked ham.

73. **Question:** Would Country Cured Hams have to comply with *L. monocytogenes* control measures?

Answer: If the country cured ham was produced and labeled as RTE, it would have to comply with the regulation.

74. **Question:** Is a frozen RTE sausage patty applicable to the Alternatives?

Answer: Yes, if it is post-lethality exposed.

75. **Question:** Why does 319.180 not cover bratwurst?

Answer: 9 CFR 319.180 covers RTE cooked sausages such as hotdogs, franks, wieners which have 40 percent added fat and water limitation based on finished product. Sausages such as bratwurst, covered under 319.140, have no fat limit but have a 10 percent water restriction based on the finished product. Cooked sausages covered under 319.140, have not been linked to listeriosis cases and outbreaks and may be consumed without reheating.

READY-TO-EAT POST-LETHALITY EXPOSED PRODUCTS

76. **Question:** Are those post-lethality exposed RTE products that were listed as non-targeted products with regards to sampling in Directive 10,240.3, such as lard, margarine, popped pork skins, dried soup bases, and pickled pig's feet covered by the *Listeria* rule?

Answer: Yes, if these products are post-lethality exposed RTE products, they are covered by the *Listeria* rule. Directive 10,240.3 was replaced by Directive 10,240.4.

77. **Question:** Can a post-lethality exposed RTE product that was sliced and packaged and subsequently subjected to high hydrostatic pressure processing (HPP) be considered not post-lethality exposed and not covered by the *Listeria* rule?

Answer: Post-lethality treatment of a RTE meat or poultry product with HPP may exempt the finished product from the *Listeria* rule if the lethality achieved by the HPP process is equivalent to that required for other RTE products. The HPP process would be equivalent to a cook-in-bag process if all pathogens were eliminated, the performance standard for product cooling is met, or documented to be not applicable, and the product was not exposed after the HPP. The HACCP plan would need to cover the entire food safety process, and explicitly state that it covers the combined lethality pre-exposure and post-exposure, if applicable, such that the lethality is demonstrated to be intended to address *Salmonella* and *Escherichia coli* O157:H7 if it is a beef product. The pressure and time at that pressure would have to be clearly stated in the validation for each formulation. Validation based solely on calculated or assumed extrapolated lethality or an assumed but unconfirmed integrated lethality would be insufficient. Finished ready-to-eat product found to contain any bacterial pathogens of concern or their toxins or toxic metabolites will be considered adulterated.

78. **Question:** An establishment produces a product that is post-lethality exposed. After it is packaged, it is sent to another establishment for post-lethality treatment. Is the establishment that produced the product required to have a CCP?

Answer: It depends on the establishment's hazard analysis and HACCP plan. If the originating establishment identifies a food safety hazard post-lethality, and knowingly sends the product to another official establishment to be treated with a post-lethality treatment, and it labels the product "for further processing", then the treatment must be handled by the originating establishment as a CCP. In this particular instance the originating establishment is making the determination that it will control the hazard by "further processing" with a post-lethality treatment in the receiving establishment thereby meeting the requirements for Alternative 2.

If the originating plant is producing the product and putting it into commerce without a finished product qualification of "for further processing" as part of the identity and control of the product, then the originating plant activity is separate from that of the receiving plant and no CCP is needed. In this particular instance the establishment is making the determination that they will control the sanitary conditions in their post-lethality environment by meeting Alternative 3 and the use of a sanitation program.

POST–LETHALITY TREATMENT

79. **Question:** The June 6, 2003 Interim Rule defines a post lethality treatment as "a lethality treatment that is applied or is **effective** after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure." The lethality treatment for dried meat snacks results in a low water activity [<0.85] which is still **effective** after the product is packaged and not only suppresses *L. monocytogenes* growth but can cause *L. monocytogenes* death. How does FSIS view <0.85 water activity as a post lethality treatment?

Answer: Since products with water activity less than 0.85 will not support the growth of *L. monocytogenes* and can sometimes even cause *L. monocytogenes* death, FSIS will consider water activity of <0.85 at the time the product is packed to be a post-lethality treatment if there is a listericidal effect in the specific product and the establishment has documentation that the intended effect occurs prior to distribution of the product into commerce. The level of pathogen reduction necessary to result in a safe, unadulterated product, based on the expected highest level of post-lethality contamination, also would need to be included as

part of the support documentation. FSIS is identifying criteria that it will tentatively use to assess risk-based verification activity. Generally, if establishments achieve lethality of *L. monocytogenes* such that greater than 2 $\log_{10}$ reduction occurs, FSIS would view this process as more protective than one providing less lethality.

80. **Question:** As noted above, many dried meat products not only do not support the growth of *L. monocytogenes* but *L. monocytogenes* present on the product will die. If challenge studies are conducted to prove the death of some identified amount of *L. monocytogenes*, will FSIS consider the products to fall under Alternative I?

Answer: When challenge or inoculation studies show death of *L. monocytogenes* during shelf life and are incorporated into the establishment's HACCP plan, those products likely will fall under Alternative 1.

81. **Question:** FDA has established in the Food Code a definition for foods that are not "potentially hazardous". In the May 1999 "*Listeria* Guidelines for Industry" [text included in footnote][*] FSIS quoted the FDA Food Code guidelines for industry to use when assessing the hazards of *Listeria*. If meat/poultry products meet one or more of the definition criteria, the product is not a potentially hazardous food. How will FSIS use these criteria to determine the appropriate Alternative?

Answer: Merely because a product is not "potentially hazardous" under the Food Code will not be definitive in terms of the appropriate classification. The Food Code definition could include products meeting the processing requirements of Alternatives 1 and 2. The establishment

[*] Currently available information indicates that establishments should view a RTE meat or poultry product as a food that supports the growth of *Listeria monocytogenes* unless the 1999 Food Code (DHHS, U. S. Public Health Service, FDA) excludes the product from its definition of a "Potentially hazardous food" (excerpts) because (1) the product has an a_w value of 0.85 or less; (2) the product's pH is 4.6 or below when measured at 24°C (75°F); (3) a food, in an unopened hermetically sealed container, that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution; (4) laboratory evidence demonstrates that the rapid and progressive growth of infectious or toxigenic microorganisms or the growth of *C. botulinum* can not occur, and that may contain a preservative, other barrier to the growth of microorganisms, or a combination of barriers that inhibit the growth of microorganisms; or (5) the product does not support the growth of microorganisms…"

should determine whether a process has a listericidal effect, and whether the growth is suppressed to determine the classification within the appropriate Alternatives outlined in the regulation.

82. **Question:** Would the use of infrared (IR) technology on meat and poultry products be considered a post-lethality treatment? If the IR is applied immediately before the slicer, is this close enough to the final product packaging to qualify as a post-lethality treatment?

Answer: Under special circumstances, infrared technology, such as the use of an infrared oven, is an accepted post-lethality treatment, provided environmental conditions after the infrared process are rigorously controlled to prevent exposure of the product to contamination by *L. monocytogenes* and the effectiveness of the environmental controls is verified on an on-going basis. The post-lethality treatment needs to be included in the establishment's HACCP plan and validated to reduce or eliminate *L. monocytogenes* to the stated level. The establishment must validate that contamination with *L. monocytogenes* does not occur after application of the post-lethality treatment and before packaging. In essence, such operations would need to demonstrate that the application of the infrared treatment on the pre-packaged product is equivalent in preventing pathogen contamination to an operation that applies the infrared treatment on post-packaged product. The operation from post-lethality treatment through packaging would be comparable to aseptic packaging. Generally, the features of a properly functioning infrared treatment on a pre-packaged product involve specialized environmental controls (including positive pressure in the room to force room air out and filtered air in; extremely strict limitations on access to the room). Also, if the product temperature remained at or above the lethality temperature after the infrared oven and before and during packaging, it could be considered a hot-filled product, and therefore, would not be considered a post-lethality exposed product.

An activity such as slicing is recognized as a high risk source of *L. monocytogenes* contamination in a post-lethality environment. However, if the establishment incorporates special control measures that mimic, to the maximum extent possible, a sterile processing environment (essentially an aseptic operation), such an activity can be considered as part of the post-lethality treatment. The validation, however, would be expected to be quite complicated and need to be supported by a substantial demonstration of on-going effectiveness of the operation.

83. **Question:** What is the definition or what is meant by lower level with regards to growth limiting factors, and is this limited to a 2 log reduction?

Answer: The term lower level refers to a level of reduction or inhibition that is less than the baseline or reference level. For example, in the table titled "Expected Levels of Control for Post-lethality Treatments and Antimicrobial Agents or Processes" in the Compliance Guidelines (p. 21), for post-lethality treatment, less than 2 $\log_{10}$ is a lower level of reduction of *L. monocytogenes* than the reference higher level of 2 $\log_{10}$.

ANTIMICROBIAL AGENT OR PROCESS

84. **Question:** The June 6, 2003 Interim Rule defines an antimicrobial agent as "A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *L. monocytogenes*, or that has the effect of suppressing or limiting growth of *L. monocytogenes* in the product throughout the shelf life of the product." Does FSIS require a specific concentration of inhibitor to qualify as an antimicrobial agent?

Answer: There is no "required" percentage. It is up to the establishment to determine which inhibitors to use and at what amount to maintain quality while enhancing safety. However, the establishment must validate that the antimicrobial agent has an inhibitory effect on the growth of *L. monocytogenes* and maintains that effect throughout the shelf life of the product. Generally, inhibiting growth of *L. monocytogenes* to not more than 2 $\log_{10}$ of growth throughout the product shelf life likely would be considered acceptable.

85. **Question:** Starter cultures or vinegar, used in product manufacturing or directly in formulations, will result in products with a pH <4.6 [creating a product that is not "potentially hazardous" per the FDA Food Code]. How does FSIS view the use of a starter cultures and vinegar as antimicrobial agents?

Answer: FSIS will consider starter cultures or vinegar as antimicrobial agents if the addition of the starter culture or vinegar results in a finished product with a pH of <4.6, and the establishment documents that this pH level in the specific product suppresses/limits growth.

86. **Question:** Could cure (156 ppm added nitrite) be considered an antimicrobial agent?

Answer: Sodium nitrite as an antimicrobial agent is primarily used to inhibit *Clostridium botulinum* growth and toxin production in cured meats.

A study has shown an inhibitory effect of nitrite, salt, and vacuum packaging on *L. monocytogenes* growth in fish. The establishment would have to provide documentation on the inhibitory effect of nitrite on *L. monocytogenes* in meat and poultry and indicate what other factors, such as salt concentration, are critical for the inhibitory effect.

87. **Question:** The June 6, 2003 Interim Rule defines an antimicrobial process as "suppressing or limiting the growth of a microorganism, such as *L. monocytogenes*, in the product throughout the shelf life of the product." Many dried meat products undergo processes, such as fermentation and/or drying, that create inherent product characteristics [pH<4.6, water activity<0.85] that do not allow growth of *L. monocytogenes* during shelf life. Will FSIS view the use of fermentation and drying processes as antimicrobial processes?

Answer: Fermentation and drying will be considered antimicrobial processes if they result in finished product with pH or water activity that suppresses or limits the growth of *L. monocytogenes*. If this "process" is also listericidal during the shelf life of the product, it could also serve as a post-lethality treatment.

88. **Question:** On page 71 of the Guidelines (eighth bullet), FSIS states that "antimicrobials used in the formulation must have an effective anti-listerial activity throughout the commercial shelf life of the product." What is meant by this statement? The preamble to the interim final rule states that the effect of freezing could only continue throughout the shelf life of the product if the product were maintained continuously in the frozen state. Would a frozen product that is thawed under refrigeration just prior to use thus be excluded from the definition of an antimicrobial process?

Answer: The requirement that an antimicrobial process or product formulated with an antimicrobial agent suppress or limit growth throughout the commercial life means that the anti-listerial activity must be validated to be effective throughout the shelf life of the product or before use. These validation records must be available to FSIS. The requirement that a product remain frozen throughout its shelf life is intended to exclude situations where a product is distributed frozen and then thawed and sold as a refrigerated product. If the product is thawed as part of the preparation process, the product will be deemed to have been frozen throughout its shelf life.

89. **Question:** When conducting a shelf life study of an antimicrobial agent or process, what are the important factors to be considered to show that the antimicrobial agent or process is effective in suppressing the growth of *L. monocytogenes*?

Answer: Some of the factors to be considered in the shelf life study of a product with an added antimicrobial agent to determine that the agent is effective in suppressing growth of *L. monocytogenes* are:

1. Suppression of *L. monocytogenes* growth in product during shelf life – growth should be lower in the product with added antimicrobial than growth in the untreated control. Although the Compliance Guidelines set a maximum of less than 2 log growth of *L. monocytogenes* during the shelf life of product with added antimicrobials for the purposes of the challenge study, it is best to target a lower amount of growth than this.
2. The rate of growth of *L. monocytogenes* in product – *L. monocytogenes* growth rate in product with added antimicrobial should be slower than the growth rate in product without added antimicrobial.
3. Temperature for holding product during the shelf life study – Most studies use the temperature that the product is normally held during storage as the temperature during shelf life studies e.g., refrigerated temperature of 38-40 ° F. Shelf life studies can also use or include a temperature of 45 ° F to hold product since this reflects consumer handling. The NACMCF report on "Considerations for Establishing Safety-Based Consume-By Date Labels for Refrigerated Ready-to-Eat Foods" on August 27, 2004 (www.fsis.usda.gov/ophs/nacmcf/2004/NACMCF_Safety-based_Date_Labels_082704.pdf) recommended that it is more realistic to use a higher temperature for shelf-life studies because foods can encounter a range of temperatures below and above 45 ° F, with higher temperature more likely in grocery store cases and during consumer handling, and therefore they more accurately reflect reality. A product with an added antimicrobial agent showing *L. monocytogenes* growth of 2 logs at 38-40 ° F storage temperature may not be viewed by FSIS as protective of public health as another product showing the same growth when stored at a higher temperature. Establishments planning to conduct shelf life studies can use the guidance for other factors important in designing a shelf life study in the full NACMCF report cited above.

90. **Question:** Can an antimicrobial agent be used both as a post-lethality treatment and an antimicrobial agent and qualify the product produced under this process for Alternative 1?

Answer: The *Listeria* rule states that a post-lethality treatment may be an antimicrobial agent that reduces or eliminates microorganisms on the product and an antimicrobial agent or process that suppresses or limits growth. In a specific situation where one antimicrobial agent or treatment is to be considered as both a post-lethality treatment and the antimicrobial agent in order to qualify for Alternative 1, the challenge study can be used to validate whether the intervention can be used both as a post-lethality

treatment that reduces *L. monocytogenes* by at least 1 log and an antimicrobial agent that suppresses *L. monocytogenes* growth throughout the product's shelf life. The results of the challenge study should show that the antimicrobial agent reduces the *L. monocytogenes* inoculum by at least 1.0 log and be able to suppress the growth of the *L. monocytogenes* inoculum remaining after the post-lethality reduction, during the product's shelf life to result in not more than 2.0 logs growth. For example, if 4 logs of *L. monocytogenes* was shown to be inoculated in the product with added antimicrobial, and it was shown that there was a 1.5 log reduction after 1 day of storage, then the basis (i.e. starting point) for outgrowth suppression part of the study would be [4 log-1.5 log] = 2.5 log .The study has to show that *L. monocytogenes* growth is less than 2 logs and the growth rate of *L. monocytogenes* in the product with added antimicrobial is slower than that for the product without added antimicrobial. Therefore, in order to demonstrate outgrowth suppression for this validation example, the final level of inoculated *L. monocytogenes* at end of shelf life should be 2.5 log + <2 log = <4.5 log (less than 4.5 log).

For purposes of the shelf life challenge study, a growth of less than 2 logs is suggested by the compliance guidelines. However, in reality, *L. monocytogenes* if present, is present at a very low level, and there should be no growth during shelf life in the presence of antimicrobials. If *L. monocytogenes* is found in the product, the product is adulterated.

91. **Question:** The Compliance Guidelines mention the possibility that an antimicrobial process could serve as both a post-lethality treatment and a growth inhibitor. Formulated products that are shelf stable, such as country cured ham and pepperoni, are mentioned as examples. Does the Agency have any examples for non-shelf stable products? Are there circumstances under which freezing could serve both as a post-lethality treatment and antimicrobial process, which would allow product to fall under Alternative 1?

Answer: At this time, the Agency does not have a particular product in mind. The question is whether the processing/formulation of the product is such that it continues to inhibit and reduce/eliminate organisms. If an establishment can demonstrate such an effect through freezing (either through scientific articles or laboratory studies), the establishment could deem freezing as a post-lethality treatment. However, FSIS is identifying criteria that it will tentatively use to assess risk-based verification activity. Generally, if establishments achieve suppression of *L. monocytogenes* such that growth is not more than 2-logs during shelf life, FSIS will likely consider this to qualify as a growth inhibitor. Likewise, if the post-lethality treatment achieves 1 log or higher reduction, FSIS will likely consider this to qualify as a post-lethality treatment for Alternative 1 or 2.

92. **Question:** Can an antimicrobial agent that acts as a post-lethality treatment and is applied to the surface of the product still serve as a post-lethality treatment if the product is sliced in the establishment after the antimicrobial agent has been applied?

Answer: No. The antimicrobial agent that acts as a post-lethality treatment on the product's surface protects the product from contamination. However, when the product is sliced in the establishment, the sliced surfaces are exposed to additional contamination and since these surfaces are not treated with the antimicrobial agent, there is a possibility of *L. monocytogenes* contamination.

93. **Question:** Can an antimicrobial agent applied to the surface of the product still serve as an antimicrobial agent if the product is sliced after the antimicrobial agent has been applied?

Answer: No. The antimicrobial agent applied to the product's surface protects the product from contamination. When the product is sliced in the establishment, the sliced surfaces are exposed to additional contamination. Since these are not treated with the antimicrobial agent, there is a possibility of *L. monocytogenes* contamination unless the establishment documents that the antimicrobial agent inhibits or suppresses the growth of *L. monocytogenes* throughout the product including the untreated surfaces after the slicing operation.

94. **Question:** Can an establishment apply an antimicrobial agent or process to the surface of the slicing equipment to prevent contamination by *L. monocytogenes* in addition to its use as an antimicrobial agent or post-lethality treatment?

Answer: The establishment needs supporting documentation that the antimicrobial agent or process applied to the cutting blades and prongs prevents *L. monocytogenes* growth and contamination from the slicer through the packaging step and that the effectiveness of the agent is not diminished during and after the slicing operation through the expected product shelf life. Compelling data demonstrating the effectiveness of the treatments and sanitation throughout the operation, clean-up to clean-up, is also needed.

95. **Question:** Can a RTE product with a water activity of 4.8% be acceptable for an Alternative?

Answer: Water activity is not expressed as a percent. Water activity can range from 0.2 for milk powder to 0.98 or greater for meat and poultry. A product with a water activity of 0.85 is usually considered shelf stable and

would not support the growth of *L. monocytogenes*. pH also is not expressed as percent and ranges from 1 to 14. A pH of 4.8 alone would not inhibit the growth of *L. monocytogenes* and would not qualify as an antimicrobial agent.

96. **Question:** Are there any other antimicrobial agents besides sodium lactate/diacetate that can be used?

Answer: These are the two antimicrobial agents that research studies have shown to be effective in suppressing *L. monocytogenes* growth when added to the formulation of RTE meat and poultry products. Other approved antimicrobials for RTE products are acidified sodium chlorite, nisin, and ozone.

97. **Question:** Is modified atmosphere packaging (M.A.P.) an antimicrobial process?

Answer: M.A.P can be used as an antimicrobial agent if documentation can support that it suppresses growth of *L. monocytogenes* and other pathogens and their toxins or toxic metabolites, throughout its refrigerated shelf life.

98. **Question:** Can acid or liquid smoke be used as an anti-microbial agent/process?

Answer: Acid and liquid smoke may be considered antimicrobial agents if the establishment provides documentation in its HACCP plan, Sanitation SOP or other prerequisite program that the acid or liquid smoke suppresses or limits growth of *L. monocytogenes* throughout the shelf life of the product.

99. **Question:** If a product is shipped frozen and it is maintained frozen and has a low pH, does the antimicrobial process need to render the product shelf stable, as it is indicated in the Compliance Guidelines? On page 6 of the Compliance Guidelines it states, “An example of an antimicrobial process that controls the growth of LM in the post-lethality environment is a lethality process that renders a RTE product shelf stable.”

Answer: The Compliance Guidelines provided two examples of antimicrobial processes that control the growth of *L. monocytogenes* in the post-lethality environment. One is a lethality process that renders the RTE product shelf stable. That means the product doesn’t need to be refrigerated and will not support growth of *L. monocytogenes* and other pathogens during storage at ambient temperature.
The other antimicrobial process is freezing. *L. monocytogenes* will not grow in a frozen product as long as it is maintained in the frozen state, but

could resume growth after it is thawed. A frozen product is not considered shelf stable.

100. **Question:** Freezing - If a product is frozen in a package and then thawed does it need to be labeled as previously frozen?

Answer: Products that are frozen and thawed need to be labeled previously frozen and cannot qualify for Alternative 2 with antimicrobial process. Only product that is frozen and sold frozen (not thawed in the process) to the consumer is considered as having an antimicrobial treatment.

101. **Question:** Does an establishment need to provide additional validation information over what is in the Compliance Guidelines with regards to freezing, pH and water activity?

Answer: The establishment needs to validate the process in relation to *L. monocytogenes*, except when these values are below the limit of *L. monocytogenes* growth: pH below 4.39, water activity below 0.92 and temperature below -0.4°C as stated in the Compliance Guidelines. However, the establishment must have the supporting documentation and must conduct monitoring and verification activities.

102. **Question:** Which government Agency should I ask for approval on the use of an antimicrobial agent applied to inedible meat casings?

Answer: The addition of antimicrobial agents to casings for the effect of reducing or controlling microbial growth would be an ingredients approval issue. In most cases, such a request would involve a petition for food additive approval or a GRAS Notification, both of which are submitted to FDA. In some cases, depending on the nature of the substance(s), FSIS may be able to conduct an “Acceptability Determination.” These scenarios are described in the Memorandum of Understanding (MOU) between FSIS and FDA on the approval of ingredients used in meat and poultry products and are available at: http://www.fsis.usda.gov/OPPDE/larc/ingredients/mou.htm. In all cases, FSIS evaluates the suitability of the proposed antimicrobial, while FDA simultaneously determines the safety of the substance(s). Some listed/approved uses are in FSIS Directive 7120.1. Inquiries can be directed to the Labeling and Consumer Protection Staff.

ALTERNATIVES

103. **Question:** Will definitions for Low Risk products be applicable?

Answer: "Risk” categories as used in the previous directive have been

deleted. After October 6th, establishments must choose Alternatives 1, 2 or 3 for RTE post-lethality exposed products.

104. **Question:** Alternative 1 and 2 look the same to me, please explain.

Answer: Alternative 1 uses two control methods: 1) a post-lethality treatment that eliminates or reduces *L. monocytogenes*; and 2) an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes* throughout the shelf life of the product.

Alternative 2 uses only one of the control methods mentioned above. A product in Alternative 1 has potentially the lowest risk of *L. monocytogenes* contamination because it uses 2 control methods, followed by a product in Alternative 2, which has a potentially higher risk. A product in alternative 3 potentially has the highest risk because it does not use any of these control methods and *L. monocytogenes* if present can grow.

105. **Question:** Does a ham product cooked in an impermeable bag have to comply with one of the three RTE Alternatives?

Answer: If the ham is not removed from the impermeable bag after cooking nor repackaged before shipping, then it is not post-lethality exposed and not subject to the *Listeria* rule. If it is removed from the cooking bag and repackaged, then it is subject to the rule because it was post-lethality exposed.

106. **Question:** Would further processing of a RTE ham (slicing) have to comply with *L. monocytogenes* control measures?

Answer: Yes, this would be applicable to the RTE Alternatives. The entire process is considered, whether it involves formulation to packaging or just slicing and packaging.

107. **Question:** Is a ham a lower risk if unsliced? Is it a different risk factor?

Answer RTE fully cooked ham that is removed from the cooking bag and repackaged, whether sliced or unsliced is post-lethality exposed.

108. **Question** Can a UV light be used as an intervention on RTE product?

Answer: If the establishment can validate that the process eliminates, reduces or suppresses *L. monocytogenes*, it can be used as a control method.

109. **Question:** What is the FSIS sampling frequency for Alternative 2?

Answer: No frequencies have been established by USDA.

110. **Question:** If a product is made under Alternative 2 or 3, and there is a positive *L. monocytogenes* sample, how many more samples would be required by USDA?

Answer: The Agency does not require a set number of samples. Rather the establishment must test at a frequency that provides a level of statistical confidence ensuring the lots tested are not adulterated with *L. monocytogenes*. The Agency would consider the number of follow-up samples, if any, based on the establishment's corrective actions and verification of their effectiveness.

111. **Question:** Can an establishment fall under more than one Alternative?

Answer: FSIS recognizes that establishments may be producing products under different Alternative control programs. These various products may best be covered in individual HACCP plans, though an establishment is free to adopt whatever program can best enable compliance. However, the establishment could have products in all Alternatives.

112. **Question:** If a plant wants to change Alternatives, can they?

Answer: Yes, if the establishment changes the production process to meet the requirements for the particular Alternative. For example, if an establishment employs only sanitation procedures to control *L. monocytogenes* (Alternative 3) but later uses an antimicrobial agent or process, it could then meet the requirements for Alternative 2. Establishments are encouraged to use antimicrobial agents or post-lethality treatments if possible in order to reduce the risk of *L. monocytogenes*.

113. **Question**: Can there be two Alternatives within a single HACCP plan?

Answer: Once again, the decision can be made by the establishment. Products are grouped in a single HACCP plan when the hazards, CCPs, and critical limits are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and observed in practice. Thus, a single HACCP plan could cover hot dogs formulated with and without antimicrobial agents (Alternative 2 and Alternative 3), provided that the HACCP plan clearly distinguishes any critical differences.

114. **Question:** Some establishments produce multiple types of products on the same line. Will the agency require that the control program, including sampling and test and hold procedures, be the same for all products produced on the line under Alternatives 2 and 3 even though product characteristics differ?

Answer: The Alternatives presented in the interim final rule are based on the relative risk posed by various products depending on their characteristics and ordinary preparation practices. If an establishment uses the same FCS on the same production day (clean-up to clean-up) for products falling within two Alternatives, FSIS would likely view that the products would be treated as if they were in the higher risk category with respect to environmental sampling. However, with respect to hold and test procedures, the number of samples tested would be related to product risk (see question # 40).

115. **Question:** On the topic of FSIS verification, the Rule states that different options will bring different levels of scrutiny. What about situations in which a plant's production is mixed, i.e. the plant produces cured products with lactate and diacetate but also produces non-cured products without this anti-microbial agent and would rely solely on sanitation practices for the non-cured product? Assuming that the plant's tonnage is evenly split between the two, how does FSIS structure its scrutiny and verification?

Answer: FSIS scrutiny and verification are based primarily on the risk categories of the products. As discussed above, if an establishment produces products using two (or three) Alternative control programs, the agency's focus will be on product manufactured under Alternative 3, then 2, then 1.

116. **Question:** Would frozen RTE products (entrees, chicken nuggets, turkey franks) fall under Alternative 2? What about other products that are processed in a manner that suppresses growth?

Answer: Freezing would be considered as suppressing the growth of *L. monocytogenes* provided the product is frozen after processing and maintained in a frozen state throughout the product shelf life (e.g. not slacked – thawed or softened – prior to retail sale). If the product was slacked prior to retail, the establishment could not consider the product as meeting the requirements of Alternative 2 and most likely would have to handle the product according to Alternative 3. Product pH (antimicrobial agent) or drying (antimicrobial process) are other methods of commonly used to suppress or prevent the growth of *L. monocytogenes* in products such as salami and jerky, respectively.

117. **Question:** Alternative 2 includes products that receive a post-lethality treatment or an antimicrobial agent or process. Does this category include other products that do not support the growth of *L. monocytogenes*?

Answer: Alternative 2 includes all products that receive a post-lethality treatment or use an antimicrobial agent or process to prevent or limit the growth of *L*. *monocytogenes* throughout the shelf life of the product. If the product does not support the growth of *L. monocytogenes*, it in all likelihood has received an antimicrobial process (e.g., drying or freezing) or contains an antimicrobial agent (e.g., lactate or diacetate).

118. **Question:** If hotdogs are exposed to ozone just before packaging, which category or Alternative would this fall into, 1 or 2?

Answer: In order for ozone to be considered an Alternative 1 process, the ozone would have to act immediately in eliminating or reducing the level of *L. monocytogenes* then continue to function as an antimicrobial agent in suppressing or limiting any growth of *L. monocytogenes* in the final or packaged product during its refrigerated shelf life. The establishment would have to provide documentation that ozone is an antimicrobial agent for *L. monocytogenes,* and validate that it is a post-lethality treatment.

For use in an Alternative 2 process, the ozone treatment could act either as an antimicrobial agent or post-lethality treatment. The establishment would have to provide the necessary documentation and validation.

119. **Question:** If an establishment does not have a hot dog or deli product, should it handle a positive for *Listeria* test as a regular corrective action?

Answer: RTE products other than deli and hotdogs that are post-lethality exposed are covered by the rule. The establishment should determine what alternative its products fall into. A positive *Listeria* test will involve more than corrective actions.

120. **Question:** If an establishment's product is in Alternative 3 and is not a deli product, what does the establishment do to verify that the process is effective, and how will FSIS verify?

Answer: The establishment needs to have a sanitation program to control *L. monocytogenes* that includes verification that the sanitation program is effective by testing of food contact surfaces and a hold and test program. FSIS will verify if sanitation program is effective by sampling products or food contact surface and other environmental surfaces.

121. **Question:** Will the use of a combination of radiant heating on a product before packaging and hot water pasteurization on the packaged product

qualify the product for Alternative 1?

Answer: No, because Alternative 1 requires the use of a post-lethality treatment that reduces *L. monocytogenes* and an antimicrobial agent that suppresses the growth of *L. monocytogenes* throughout the product's shelf life. The use of a combination of radiant heating on a product before packaging and hot water pasteurization on the packaged product can qualify the product for Alternative 2, using a post-lethality treatment. In this example, the hot water pasteurization serves as the condition that precludes the environmental exposure after the pre-packaging radiant heat treatment.

A combination of two post-lethality treatments or any two treatments can qualify a product for Alternative 1 as long as one of the treatments results in at least a 1.0 log reduction of *L. monocytogenes* and the other treatment results in suppressing the growth of *L. monocytogenes* throughout the product's shelf life.

122. **Question:** If a company has a product in Alternative 2, with an antimicrobial agent, and the company tests product for *L. monocytogenes* after the product's expiration date and finds the product positive for *L. monocytogenes,* what should be the company's action and should FSIS be informed relative to consideration for asking for a voluntary recall?

Answer: If the product that tested positive for *L. monocytogenes* is still in the retail stores after the shelf life has expired, the establishment must notify FSIS and would be expected to voluntarily recall the product. The recall will prevent consumers from purchasing and consuming the product and prevent the possibility of foodborne illness. Ordinarily, product with an expiration date for safety such as "Use by date' or "Consume by date" will not be purchased or consumed by an informed or prudent consumer. However, there are consumers who do not read these labels and can purchase and consume these products. Therefore, a recall of these products is the best way to protect public health.

The establishment should reassess the validation study used in support of the antimicrobial agent and find out if it has evidence that the product did not have detectable *L. monocytogenes* prior to expiration of the product's shelf-life. The establishment has to determine if it needs to repeat or conduct another study to support the effectiveness of the antimicrobial agent. In addition, during the shelf life study, which is designed to evaluate the effectiveness of the antimicrobial agent, the study should use at least two temperatures for storage of the product, one at the regular refrigerated temperature of storage for the product, and one at a higher temperature, such as at 45 ° F, to reflect consumer handling temperature. To validate the premise that the antimicrobial agent suppresses the pathogen during

the shelf-life of the product, an establishment should test the product at time intervals, including after the shelf life of the product has expired to show the product's performance. In determining the "use by date" to be put on the label, establishments should include additional days before the expiration date as a safety margin before growth of *L. monocytogenes* commences.

An establishment that includes a "use by date for safety" or "consume by date for safety" should adopt measures that will prevent purchase of expired products. One measure is to place these label features in a prominent and conspicuous location on the label so consumers can easily see the statement. Secondly, it should instruct the retail or grocery establishments to take products off the shelf once the expiration date is attained to prevent consumers from purchasing expired products.

123. **Question:** An establishment formulates product with an ingredient that suppresses growth throughout the shelf-life of the product. This product meets the criteria for Alternative 2. The product is then shipped to another establishment where it is sliced. After slicing and packaging, does the product still qualify for Alternative 2?

Answer: Not necessarily. The establishment slicing the product would need to obtain documentation from the original establishment showing that it received a treatment that suppresses *L. monocytogenes* growth throughout the product shelf life and that it was placed in Alternative 2. Suppressing *L. monocytogenes* growth throughout the shelf life can be guaranteed as long as the product is stored in its intact package at the refrigerated temperature designated. The guarantee of *L. monocytogenes* growth suppression holds until the package is opened and sliced for immediate consumption by consumers. However, if the product is opened and sliced at another establishment and then re-packaged for further sale, there is no guarantee that the suppression during the shelf life of the repackaged product could still hold. During opening of the package and slicing, the product can get contaminated at a rate that the original antimicrobial treatment may not be able to suppress.
Without some form of well controlled sharing of documentation, the second plant has to separately validate the control program in order to qualify for Alternative 2. Documentation is needed on what is transpiring between the two plants and how the product is labeled and controlled.

PRODUCTION VOLUME

124. **Question:** FSIS expects establishments to provide production volume and other information on a form that will be electronically available. What are the Agency's expectations as to when this form must be submitted?

Answer: FSIS Form 10,240-1 is currently available at www.fsis.usda.gov/Forms/index.asp. FSIS developed an electronic form and made slight changes in the form. The electronic form can be filled and submitted on line. FSIS will issue a Notice when the modified electronic form is available. The form is to be submitted annually and whenever there is a significant change in the alternative category or volume of production.

125. **Question:** Will FSIS change the verification sampling due to plant size or volume of product produced, and if so when?

Answer: As stated in the Compliance Guidelines, under Production Volume, and in the NOTE under Chapter 3, A. in FSIS Directive 10,240.4, product volume information will be used to develop the new RTE risk-based sampling program. As soon as FSIS collects sufficient production volume information, it will develop sampling frequencies for verification based on volume of production.

LABELING

126. **Question:** Both the preamble to the rule and the compliance Guidelines provide examples of validated claims that would be permitted on product labeling. In all cases, the labeling claim is for "X added to prevent the growth of *L. monocytogenes*." Would claims such as "X added to enhance product quality and safety," be permissible?

Answer: The agency will consider any claim that identifies the substance being used, the benefits of the substance, and why it has been used. The claim must be specific, however, to *Listeria* control, and it should be limited to safety and not quality attributes. However, FSIS is identifying criteria that it will tentatively use to assess risk-based verification activity. Generally, if establishments achieve suppression of *L. monocytogenes*, but there is 2-$\log_{10}$ or more growth of *L. monocytogenes* during shelf life, FSIS may not consider this to qualify as a growth inhibitor for a claim.

127. **Question:** What are the regulations that cover nutrition labeling and ready-to-serve, ready-to -cook products?

Answer: 9CFR 317.312 and 381.412 are the references. Nutrition labeling is not changed or affected by the Listeria rule, but it can help in determining whether the product is RTE or not. Workshop 1 of the five *Listeria* workshops (http://www.fsis.usda.gov/oa/haccp/lmworkshop.htm) contains additional information regarding labeling and determining if the product is RTE.

GENERAL

128. **Question:** How does the agency plan to ensure uniform interpretation of company records, agency policy, and implementation of enforcement actions by FSIS inspection personnel?

Answer: As a result of training and supervision, FSIS attempts to achieve uniform interpretation of regulatory requirements. However, because of the scientific basis of the interim final rule, the Directive likely will specify that should the in-plant inspector have any questions regarding an establishment's *Listeria* control program, inspection program personnel are to go through supervisory channels with specific questions. In addition, if warranted, in-plant inspection personnel can also use the expertise, skills, and knowledge of the EIAO in determining whether the establishment's control system is in compliance with the regulatory requirements.

129. **Question:** Must Export products meet these RTE requirements?

Answer: All RTE products must meet USDA requirements.

130. **Question:** Is retail exempt product or custom exempt product subject to the *Listeria* interim final rule?

Answer: They are not applicable but the USDA inspector must be informed that product is exempt before the product is formulated. There would be no inspection at retail.

131. **Question:** Will these RTE results be released under the Freedom of Information Act?

Answer: Results from FSIS sampling can be released under the Freedom of Information act.

132. **Question:** Is there a way to accept *L. monocytogenes* information from a blind or unidentified source to report plant data to the Agency?

Answer: Yes. We have established partnerships where we are able to do this as long as it complies with OMB requirements and the data is shared with Agency personnel.

133. **Question:** How will the Agency evaluate the impact of the rule?

Answer: The data collected will be one measure. FSIS will work with CDC and state epidemiologists to track prevalence. FSIS will also look at overall compliance with the rule and movement through alternatives. We

will focus on higher risk plants.