FAQs for the American Spice Trade Association (ASTA) on the Potential Risks Related to *Listeria monocytogenes* in Spices

March 2019

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Introduction:

The Food and Drug Administration (FDA) has primarily focused on *Salmonella* as the most likely biological hazard in spices based on the FDA risk profile for spices. As the Food Safety Modernization Act (FSMA) Preventive Controls for Human Food (PCHF) regulation has been implemented, FDA has identified an expanded range of biological hazards for which manufacturers should consider requiring a preventive control. Information published as a part of FSMA implementation has raised questions about whether spice companies should also be looking at *Listeria monocytogenes* (*Lm*) as a potential biological hazard requiring a preventive control. Although *Listeria monocytogenes* is not a pathogen that has historically been found in spices, FDA regulations and guidance for ready-to-eat (RTE) foods set forth requirements that could apply to spices.

Purpose:

The purposes of these Frequently Asked Questions (FAQs) are to help ASTA members understand the legal framework related to *Listeria* control and assist companies in determining if they need to consider *Listeria monocytogenes* as a biological hazard for spices as part of their hazard analysis.

Frequently Asked Questions

General Questions and FDA Regulations and Policies

1. **What is *Listeria monocytogenes?***
   Listeria monocytogenes (*Lm*) is an environmental pathogen that can contaminate foods and cause illness (listeriosis). Listeriosis is largely associated with RTE (dairy products, deli meats) foods that have intrinsic characteristics (such as pH and water activity) that support the growth of *Lm*.

2. **What are the FSMA requirements related to the control of *Listeria monocytogenes*?**
   The PCHF rule requires manufacturers to conduct a hazard analysis and implement controls for identified biological hazards that are significant enough to be considered "hazards requiring a preventive control" (HRPCs). *Listeria monocytogenes* is a biological hazard that needs to be considered as part of the hazard analysis to assess whether it is an HRPC.

   Additionally, the PCHF rule requires that the hazard analysis include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen. (See 21 CFR 117.130(c)(1)(ii).) *Listeria monocytogenes* is an environmental pathogen that needs to be considered as part of this evaluation. If contamination of RTE food with *Lm* is determined to be an HRPC, manufacturers will be expected to implement environmental monitoring if their spices are exposed to the environment and do not receive a subsequent lethality treatment. Additional information on environmental monitoring may be found in the ASTA Guidance on Environmental Monitoring Programs.

3. **What does the FDA draft guidance say about the control of *Listeria monocytogenes*?**

   FDA has issued draft guidance for industry on the control of *Listeria monocytogenes* in RTE foods. This guidance applies to all RTE foods that may be exposed to the environment prior to packaging if the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to *Listeria monocytogenes*) that would significantly minimize *Listeria monocytogenes*. The guidance can be found online: https://www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm535981.pdf

   This guidance document sets out recommendations related to personnel, plant design, equipment maintenance, raw materials, process controls, storage, transportation and environmental monitoring. The guidance provides recognition that intrinsic characteristics of food products, such as pH (<4.4), water activity (<0.92), or other listericidal properties may prevent the growth of *Listeria monocytogenes*. Nonetheless, since *Listeria*

monocytogenes contamination may be caused from personnel, tools/equipment, or other environmental factors that could introduce moisture, the recommendations set forth in this guidance apply broadly to all RTE foods – not only those foods in which *Listeria monocytogenes* is likely to occur or grow.

4. **Is *Listeria monocytogenes* a known hazard for spices?**
   Appendix 1 of the *FDA's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry* identifies potential hazards for specific food categories. Table 1P Spices and Herbs does not identify *Listeria monocytogenes* as a potential hazard for untreated raw herbs and spices, treated raw herbs and spices, or seasonings of any kind (dry, liquid, pastes, essential oils). Although this is just a draft document, it indicates FDA's current thinking on this issue. ASTA members are advised that additional justification may be needed in their hazard analysis, beyond simply citing Appendix 1. Additionally, where companies know or reasonably foresee *Lm* as a potential hazard based on their processing reality, regardless of whether or not *Lm* is listed as potential hazard in spice category on Appendix 1, companies will be obligated to control for it. Appendix 1 is available online at: https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM517402.pdf

   Scientific literature is another good source of information on this topic. The references section of this document includes several publications on the prevalence of *Lm* in spices and other low moisture foods.

5. **If *Listeria monocytogenes* is not a potential hazard for spices according to Appendix 1, why are our customers asking us to test for it?**
   Customers may be seeking information about *Lm* because of the risk factors in the product that they are producing. For example, if a customer is producing a refrigerated dairy-based dip/spread that would support the growth of *Listeria*, they may wish to obtain information on the potential risk of the presence of this pathogen from their ingredient supplier. Customers also may be seeking information about *Lm* because they do not have sufficient knowledge about whether *Lm* is an HRPC for spices. Additionally, since all companies that produce RTE foods that are exposed to the environment without a subsequent kill step are required to have an environmental monitoring program in place, customers may expect their suppliers to be performing environmental monitoring for *Listeria*. Companies may be trying to limit their exposure to Listeria. They do not want to add additional potential sources of contamination and are having all of their raw material suppliers test for *Listeria*.

6. **How do we know if we make RTE food?**
   FDA defines Ready-to-Eat foods in 21 CFR 117.3 as: "any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards." FDA is in the process of drafting a guidance document addressing which foods are RTE. Additionally, ASTA has published an FAQ on Ready-to-Eat Foods that is available at: https://www.astaspice.org/government-relations-advocacy/complying-with-u-s-policy-regulations/asta-ready-to-eat-faqs/

7. **How do we know if our food is exposed to the environment without a subsequent kill step?**
   FDA's environmental monitoring requirements apply whenever a RTE food is exposed to the environment prior

to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen. An example of a product exposed to the environment would be a dry blending operation producing seasoning mixes for soups or salads.

Hazard Analysis

8. **What is the process to conduct a hazard analysis for *Listeria monocytogenes*?**
   There are several templates available for download on the internet and many companies have an existing internal template or process available to use. In general, it is recommended that a cross-functional team be convened to conduct the hazard analysis. This allows the team to work together, walk the plant floor, and discuss the likelihood and severity of any potential occurrence of *Listeria monocytogenes* to inform the hazard analysis.

   There are several ways to conduct a hazard analysis. Generally, a robust hazard analysis takes the following three key factors into consideration:
   1. Products, their formulation, and their contribution of risk to the food production system
   2. Operational practices – for *Listeria monocytogenes* this should include any practices that introduce moisture
   3. Personnel practices that could be contributing factors

   An example of a common hazard analysis format is:

      i. Hazard identification of known or reasonably foreseeable biological, chemical, and physical hazards;
      ii. Evaluation of identified hazards to assess the severity of illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls (this often is evaluated with quantitative risk assessment scores and a Risk Assessment table); and
      iii. Determination of whether the identified hazards are significant enough to be considered HRPCs

9. **What factors should a hazard analysis for *Listeria monocytogenes* take into account?**
   FDA's draft guidance on control of *Listeria monocytogenes* in RTE foods is a great primer for understanding the risk of *Listeria monocytogenes*. The hazard analysis should include an evaluation of the effect of the following on the safety of the food you produce:
   - The formulation of the food;
   - The condition, function, and design of the facility and equipment;
   - Raw materials and other ingredients;
   - Transportation practices;
   - Manufacturing/processing procedures;
   - Packaging activities and labeling activities;

- Storage and distribution;
- Intended or reasonably foreseeable use;
- Sanitation, including employee hygiene; and
- Any other relevant factors, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins).

Environmental Monitoring

10. What considerations should spice companies look at with respect to including *Listeria* as part of their environmental monitoring program?

Current Good Manufacturing Practices apply to all companies that process spices, seasonings, herbs, and extracts. Sanitation controls should be in place based on the type of cleaning done, either wet or dry. Wet environments tend to promote the survival and proliferation of *Listeria monocytogenes*. These environments warrant an environmental monitoring program. In dry goods manufacturing, the overall risk of *Listeria monocytogenes* is typically low. However, any addition of water, including that used for washing and sanitizing can be sources of and contribute to the growth of *Listeria monocytogenes* and could warrant inclusion of *Listeria* in an environmental monitoring program. If there are bays where some equipment is washed away from the production floor, this may be an area which deserves additional consideration.

Each company should consider through their hazard analyses whether their sanitation programs are adequate to control their identified hazards. Performing environmental monitoring to verify that sanitation practices are adequate will go a long way towards food safety, prevention of microbiological contamination, and promotion of adequate mitigation of the identified microbiological risks. Environmental monitoring can be a two-fold process to:

1. Discover by "Seek and Destroy" techniques any pathogen harborage in your facility
2. Verify how well sanitation is carried out in all types of non-product contact and product contact cleaning

Companies should consider the following questions when assessing the implications of establishing an environmental monitoring program for *Listeria*:

- How strong is your sanitation program?
- What resources will be needed to carry out an environmental monitoring program?
- What actions will be taken should there be a need for corrective actions toward the presence of any pathogen in your environment?
- How can you ensure that you have personnel resources that are properly trained and have experience to analyze, trend, and lead corrective actions from the data gathered in the environmental monitoring program?

Companies may determine that they should include *Listeria* in their environmental monitoring program if an initial review of the environment shows that it is conducive to the presence and growth of *Listeria monocytogenes*. Before adding *Listeria monocytogenes* to your program, we encourage you to ensure that you

have appropriate corrective action resources and mechanisms to respond to any presumptive pathogen occurrences.

Additional resources on environmental monitoring can be found in the resource and reference section of this document.

11. What do we do if we detect *Listeria*?

If *Listeria* is detected, you will need to take corrective actions. You will need to take steps to ensure that the cause of the contamination is identified and corrected, as well as to minimize the potential for foods to become contaminated with *Lm*.

The corrective actions you take will depend on factors that include:

- Your environmental monitoring strategy for the food;
- Whether *Listeria* is detected on a food contact surface (FCS) (i.e., zone 1) or non-FCS;
- Whether the result was an isolated positive or there have been multiple positives; and
- The proximity of a contaminated non-FCS to FCSs.

The types of appropriate corrective actions will vary significantly depending on these facts. Which corrective actions you take depends upon your specific situation. Potential actions could include conducting intensified cleaning and sanitizing, conducting intensified sampling and testing, conducting a root cause analysis, and implementing "hold and test" procedures. FDA's *Listeria* draft guidance is an excellent resource to assess corrective actions to take if you detect *Listeria* through environmental monitoring.

References and Resources

12. Where can I find background information on *Listeria monocytogenes* to understand what it is?

There are several resources available on the internet and academic textbooks. The CDC has at link to *Listeria monocytogenes* that provides significant background information that is helpful for purposes of conducting a hazard analysis: https://www.cdc.gov/*Listeria monocytogenes*/index.html

13. Where can I find information about recalls of spices due to *Listeria monocytogenes*?

You can stay abreast of new recalls by subscribing to Recall Alerts at: https://www.fda.gov/Safety/Recalls/
You can review past recalls in FDA's enforcement reports, which are available at:
https://www.fda.gov/safety/recalls/enforcementreports/default.htm

14. Where can we locate the FDA guidance for *Listeria monocytogenes*?

The FDA draft guidance for *Listeria monocytogenes* in RTE foods is available at:
https://www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm535981.pdf

15. Are there any scientific references to *Listeria monocytogenes* in spices and other low-moisture foods?

The following studies evaluated *Listeria monocytogenes* in spices or other low-moisture foods:

- J.L. Banach, I. Stratakou, H.J. van der Fels-Klerx, H.M.W.D. Besten, M.H. Zwietering. European alerting and monitoring data as inputs for the risk assessment of microbiological and chemical hazards in spices and herbs. Food Control, 69 (2016), pp. 237-249
- Blessington, T., E.J. Mitcham, and L.J. Harris. 2012. Survival of Salmonella enterica, Escherichia coli O157:H7, and *Listeria monocytogenes* monocytogenes on inoculated walnut kernels during storage. J. Food Protect. 75:245-254.
- Kimber, M. A., H. Kaur, L. Wang, M.D. Danyluk, and L.J. Harris. 2012. Survival of Salmonella, Escherichia coli O157:H7, and *Listeria monocytogenes* on inoculated almonds and pistachios stored at –19, 4, and 24°C. J. Food Protect. 75:1394–1403

16. Where can we locate the PCHF final rules?

The rule is codified at 21 CFR Part 117. It is available online at: https://tinyurl.com/ybydlxpq. There are numerous supporting documents, including FDA's draft guidance and preamble, available online at: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm

17. Where can I find more information about environmental monitoring?

You can find more information at the following references:

- ASTA Guidance on Environmental Monitoring
- https://www.eurofinsus.com/food-testing/resources/?keyword=environmental
- http://foodsafety.neogen.com/pdf/whitepapers/tag-theachesongroup/tag_sanitationenvironmentalmonitoring_0414.pdf
- ASTA webinar on How to Develop a FSMA Ready Environmental Monitoring Program https://www.astaspice.org/education/meetings-workshops-webinars/past-asta-seminars-for-download/how-to-develop-a-fsma-ready-environmental-monitoring-program/