U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Key Questions for 2026 *Listeria monocytogenes* Public Meeting and Docket

Reducing L. monocytogenes in Foods During Manufacturing and Processing

1. In 2017, FDA published a draft guidance titled "Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Guidance for Industry" which describes many established practices that can significantly minimize or prevent the contamination of ready-to-eat (RTE) food with *L. monocytogenes*.
    a. With the recommended measures from the 2017 draft guidance as a baseline, what additional voluntary and scalable practices would be effective to help manufacturers and processors of RTE foods further minimize or prevent the contamination of RTE food with *L. monocytogenes*?
    b. What logistical, scientific, or technical barriers exist for the adoption of practices that can significantly minimize or prevent the contamination of RTE food with *L. monocytogenes*? How can these barriers be overcome?
    c. What specific barriers prevent smaller or newer operations from accessing information on *L. monocytogenes* control or from implementing best practices? How can these barriers be addressed?

2. For effective *L. monocytogenes* control, manufacturers, processors, and other actors in the supply chain need to understand *L. monocytogenes* and how to minimize or prevent its introduction to, or growth in, RTE food. Common sources of information and advice on the control of *L. monocytogenes* include state extension programs, commercial food safety consultants, membership in industry trade associations, and attendance at food safety conferences and workshops. Beyond these sources, are there additional approaches to ensuring manufacturers and processors have access to and can utilize information on measures to minimize or prevent the contamination of RTE food with *L. monocytogenes*?

3. RTE foods that support the growth of *L. monocytogenes* present the greatest risk for listeriosis. However, several recent listeriosis outbreaks in the U.S. have been associated with ice cream, an RTE food in which *L. monocytogenes* will not grow during storage since the food is held and consumed in the frozen state. Investigational data from some of these outbreaks found extensive *L. monocytogenes* contamination at low levels throughout most of the implicated ice cream (for example, 99.4% of samples tested were contaminated in one outbreak), indicating contamination during the manufacturing process.
    a. How can FDA and its partners promote greater understanding among manufacturers and processors of RTE foods that do not support the growth of *L. monocytogenes about* survival and growth of this pathogen in the manufacturing and processing environment and the risk of subsequent transfer to foods?
    b. Are there additional control measures that manufacturers and processors of RTE

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foods that do not support the growth of *L. monocytogenes* should implement to prevent contamination of their food from the environment?

c. How can FDA and other stakeholders help manufacturers and processors of RTE foods that do not support the growth of *L. monocytogenes* to take appropriate steps to prevent contamination of their food from the environment?

Reducing L. monocytogenes in RTE Foods at Retail Food Establishments

4. The Interagency Risk Assessment: *L. monocytogenes* in Retail Delicatessens (Sept 2013) simulated the retail deli environment and evaluated how various sanitary and food handling practices may influence the risk of listeriosis in the U.S. associated with consuming ready-to-eat foods that are sliced, prepared, or packaged in retail grocery delis.
    a. What other operations in retail food establishments should FDA evaluate to determine how various sanitary and food handling practices may influence the risk of listeriosis in the U.S.?
    b. How can industry, regulators, academics, and consumer groups work together to drive adoption of safer retail practices to further reduce the incidence of listeriosis?

Reducing the Risk of L. monocytogenes During Consumer Storage and Use, and Improving the Awareness of L. monocytogenes Among Vulnerable Populations

5. While firms have a responsibility to provide product free of contamination, the growth of *L. monocytogenes* in ready-to-eat (RTE) foods during consumer storage and use has been consistently identified by risk assessments as a significant risk factor for listeriosis.
    a. FDA hosts several webpages (e.g., Listeria (Listeriosis) | FDA, What You Need to Know About Preventing Listeria Infections | FDA, and others) which provide information about the risk of listeriosis to various groups of consumers, including those in vulnerable populations.
        i. Are there specific vulnerable populations or consumer groups which are not covered by existing FDA materials on *L. monocytogenes*?
        ii. Are there specific key topic areas which are not covered by existing FDA materials directed towards consumers on *L. monocytogenes*?
    b. In what ways could food safety messaging to consumers about safe food handling practices and the risk of listeriosis be improved? How could FDA increase the reach and effectiveness of these food safety messages?
    c. How can industry, regulators, academics, and consumer groups work together to advance adoption of food safety practices in the home which would further reduce the incidence of listeriosis?

Overarching Topics

6. Several dose-response models for *L. monocytogenes* have been developed from epidemiological data and baseline food survey data with various assumptions, including by FDA (Pouillot *et al.*, 2015; in *Risk Analysis*, v35, n1), the Joint FAO/WHO Expert

Meetings on Microbiological Risk Assessment (FAO/WHO Microbiological Risk Assessment Series, No. 48), and the European Food Safety Authority (*EFSA Journal*, 16(1), 5134). These studies substantiate unique aspects of *L. monocytogenes* regarding host susceptibility and orders-of-magnitude difference in the probability of illness for a given ingested dose of the pathogen, in comparison to other invasive foodborne pathogens such as *Salmonella* spp. and STEC O157.

   a. Are there additional adjustments, beyond those which have already been considered (such as host susceptibility, pathogen characteristics, and food matrix), which should be considered when evaluating the dose-response relationship for *L. monocytogenes* to assist in risk management?
   b. What additional insights can be gained from *L. monocytogenes* dose-response models derived from outbreak data? For example, FDA published another dose-response study (Pouillot *et al*., 2016; in *Emerging Infectious Diseases*, v22, n12), which was based on data from an outbreak of listeriosis linked to milkshakes made from ice cream contaminated with low-levels of *L. monocytogenes* at high prevalence.
   c. In what way can dose-response modeling help further inform risk management decisions (e.g., sampling strategies)?

7. In the public meeting, FDA provided an overview of four areas the Agency has identified for to help reduce listeriosis in the U.S.: reducing *L. monocytogenes* in foods during manufacturing/processing, reducing *L. monocytogenes* in RTE foods at retail food establishments, reducing the risk of *L. monocytogenes* during consumer storage and use, and improving the awareness of *L. monocytogenes* among vulnerable populations.
   a. Beyond these four areas, what other areas should FDA consider?
   b. On what research questions should FDA direct its research resources?
   c. How should FDA address changes in U.S. demographics and dietary patterns, such as an aging population and shifts towards less-processed foods?