

**Food and Drug Administration**  
**Center for Food Safety and Applied Nutrition (CFSAN)**  
**December 7-8, 2015**  
**Food Advisory Committee Meeting**  
**Charge and Questions**

**Topic: Addressing *Listeria monocytogenes* in Ready-To-Eat Foods**

## **I. Introduction**

See the document entitled “Background Document to Support the CFSAN Food Advisory Committee Meeting” for background on:

- The regulatory framework for ready-to-eat (RTE) foods, including:
  - FDA’s regulation entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food” (the CGMP and preventive controls rule; 21 CFR part 117) and the definition in that rule for RTE foods.
  - FDA’s “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” (the produce safety rule; 21 CFR part 112).
  - A 2008 draft Compliance Policy Guide (CPG) in which FDA considered allowing up to 100 colony-forming units (cfu) per gram for RTE foods that do not support the growth of *Listeria monocytogenes* (*L. monocytogenes*) because such foods were estimated to present a low risk of severe foodborne illness in the 2003 FDA/FSIS *Listeria* risk assessment, the 2004 FAO/WHO *Listeria* risk assessment, and the 2008 FDA re-tabulation.
  - A 2008 Draft Guidance for Industry on Control of *Listeria monocytogenes* in Refrigerated or Frozen RTE Foods.
- *L. monocytogenes*, including the historical basis for distinguishing RTE foods that support the growth of *L. monocytogenes* from those that do not.
- The science relating to FDA’s policies regarding *Listeria* in RTE foods, including:
  - A 1996 publication entitled “U.S. Position on *Listeria monocytogenes* in Foods.”

- A 2003 quantitative assessment of relative risk associated with consumption of 23 categories of RTE foods that had a history of contamination with *L. monocytogenes*, or that were implicated epidemiologically with an outbreak or a sporadic case of listeriosis. We refer to this risk assessment, which was issued by FDA and the Food Safety and Inspection Service (FSIS) in the U.S. Department of Agriculture (USDA), in consultation with the Centers for Disease Control and Prevention (CDC), as the 2003 FDA/FSIS *Listeria* risk assessment.
- A 2004 microbiological risk assessment of *L. monocytogenes* in RTE foods, conducted by the Food and Agriculture Organization (FAO) of the United Nations and the World Health Organization (WHO). We refer to this risk assessment as the 2004 FAO/WHO *Listeria* risk assessment.
- A 2008 FDA re-tabulation of the output data of the model used in the 2003 FDA/FSIS *Listeria* risk assessment. We refer to this as the 2008 FDA *Listeria* re-tabulation.
- A 2013 interagency quantitative, scientific assessment of the risk of listeriosis posed by consumption of RTE foods commonly prepared and sold in delicatessens in retail food stores, and the impact on risk by changes in practices in the deli setting.
- A 2015 FDA *Listeria* dose-response model that adjusts for variation in *L. monocytogenes* strain virulence and host susceptibility over 11 population subgroups with various comorbidities.
- Scientific developments since 2008, including:
  - Disease surveillance and epidemiological studies;
  - Outbreak investigations; and
  - Reports to FDA's Reportable Food Registry.

## **II. Determining Whether Food is Ready-to-Eat**

Our regulatory oversight relating to *L. monocytogenes* focuses on RTE foods. For some foods, there is little question as to whether the food is RTE, because the foods are generally consumed without cooking. Examples include many dairy products (e.g., milk, cheeses, ice cream), fruit (e.g. cantaloupe, apples), deli salads, fresh salsa, cookies, dry cereal, nuts and nut products, seed products, vegetables (such as broccoli florets, carrots, kale, and Brussels sprouts) that are commonly consumed raw (e.g., on salad) even though they also are commonly consumed after

cooking, and foods (such as dried milk products, spices, and seasonings) that are generally consumed in more than one way (i.e., with cooking or without cooking).

For other foods, questions commonly arise about whether the food is RTE (e.g., frozen vegetables that consumers do not always cook even though the food bears cooking instructions, and food that appears to be cooked, even though the manufacturer has not processed the food with a “kill step” and labels the food with cooking instructions). Consumer research indicates that consumer cooking practices are not uniform and that many consumers do not follow some cooking instructions. A 2009 *E. coli* O157:H7 outbreak associated with prepackaged, refrigerated cookie dough demonstrates the potential for foods that bear cooking instructions to nonetheless be consumed without cooking. Frozen vegetables can be thawed and used without cooking in salads, whether in commercial salad bars or in the home. Recipes available to consumers describe the preparation of products such as salsa using frozen vegetables that are thawed but not cooked.

#### QUESTIONS:

1. Should frozen vegetables be considered to be RTE food even if they bear cooking instructions? If not, why not, and what mechanisms could be put in place to prevent illnesses such as those in the 2009 outbreak associated with a refrigerated cookie dough or to prevent illnesses from contaminated frozen foods that may be thawed and consumed without cooking? Are there some frozen vegetables that should not be considered RTE food? If so, what objective criteria would apply in determining which frozen vegetables should not be considered RTE food? Would such criteria be amenable to a decision-tree approach for the purpose of clearly distinguishing a frozen vegetable that is RTE from a frozen vegetable that is not RTE?
2. Should food that appears to be cooked be considered to be RTE food, even if the manufacturer has not processed the food with a “kill step” and labels the food with cooking instructions? Examples of such food include a vegetarian “hamburger” patty that is seared with grill marks; an egg roll with a browned wrapper; and frozen breaded foods (such as breaded seafood) that appear cooked but contain raw or partially cooked foods that require cooking. If not, why not and what mechanisms could be put in place to prevent illnesses from frozen foods that appear to be cooked?

### **III. Distinguishing RTE Foods on the Basis of Whether the Food Supports the Growth of *L. monocytogenes***

As discussed in the background document, the 2015 FDA *Listeria* dose-response model estimates that the number of annual cases of listeriosis from the consumption of low doses of *L. monocytogenes* could be higher than had been estimated in either the 2008 FDA re-tabulation or

the 2004 FAO/WHO *Listeria* risk assessment. Outbreaks of listeriosis, including fatalities in the most vulnerable subpopulations, have occurred with RTE foods (such as ice cream) that do not support the growth of *L. monocytogenes*, and quantitation of *L. monocytogenes* in samples of foods implicated in outbreaks support the conclusion of the 2015 FDA *Listeria* dose-response model that those subpopulations at greatest risk of developing listeriosis are also at a measurable risk of illness when consuming food contaminated with relatively low doses of *L. monocytogenes*, especially if highly virulent bacterial strains are involved. Evidence obtained by FDA during an ice cream outbreak investigation suggests that about 99% of one ice cream product sold to institutions (e.g., hospitals, schools, and nursing homes) during the final months of 2014 was contaminated with low levels of *L. monocytogenes* (92% of samples in the 10-20 CFU/g range). For all of these reasons, FDA now questions whether the 2008 draft CPG level of 100 cfu/g or more of *L. monocytogenes* in RTE foods that do not support growth provides an appropriate level of protection for the most vulnerable individuals in at-risk subpopulations, particularly when food is contaminated by highly virulent strains.

#### QUESTION:

3. Should FDA treat the presence of *L. monocytogenes* differently in RTE foods, depending on whether the food supports the growth of *L. monocytogenes*? If not, why not?

## **IV. Control of *Listeria monocytogenes* in Ready-To-Eat Foods**

The framework established in the CGMP and preventive controls rule directs a facility to evaluate whether *L. monocytogenes* is a hazard requiring a preventive control 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 *L. monocytogenes*. A facility that determines that *L. monocytogenes* is a hazard requiring a preventive control would then consider measures such as sanitation controls, an environmental monitoring program, and corrective action procedures in its food safety plan for that RTE food.

An effective regulatory approach to overseeing industry's control of *L. monocytogenes* in the food processing environment should encourage industry to establish robust *Listeria* control programs. By "robust," we mean that the control program would be designed to "seek and destroy" *Listeria* in food production environments, including food-contact surfaces and surrounding areas. However, FDA is concerned that our recommendation, in the 2008 draft Guidance for Industry (GFI), to determine whether an indicator organism (*Listeria* spp.) detected on a food-contact surface is actually the pathogen (i.e., *L. monocytogenes*) may have discouraged the development of robust *Listeria* control programs. FDA is considering changing its recommendation on when a firm should determine whether *Listeria* spp. that is found on a food-contact surface is the pathogen, *L. monocytogenes*.

For example, we are considering recommending that a firm react to a single positive finding of *Listeria* spp. on a food-contact surface with intensive cleaning and sanitizing to eliminate *Listeria* spp. from the area. If the firm obtains negative results at that previously positive site, as well as at additional surrounding sites, during subsequent consecutive production cycles, FDA's recommendation might be neutral on whether the firm should determine whether the *Listeria* spp. detected on the food-contact surface was *L. monocytogenes*. If, however, the firm finds *Listeria* spp. at that site or nearby sites within the next three production cycles, more intensive corrective actions would be appropriate, which could include determining whether the species is *L. monocytogenes*.

#### QUESTIONS:

4. Should we change our recommendation regarding when a firm should determine whether the *Listeria* spp. detected on a food-contact surface is *L. monocytogenes*? Do you agree with the approach we are considering regarding how a firm should react to a single positive finding of the indicator *Listeria* spp. on a food-contact surface? If not, why not? Do you have any recommendations for how the approach we are considering could be modified? Should such an approach include specific recommendations such as no more than X such instances within Y time-frame?
5. During inspection, FDA may collect large numbers of environmental samples to determine the sanitary status of a firm's production areas. What, if any, role could the number of samples FDA collects during a routine inspection have in a regulatory policy designed to encourage robust *Listeria* control programs? For example, should FDA take into account a robust program to control *Listeria* in the production environment by collecting fewer samples during inspection?
6. Do you have any recommendations for additional policies to encourage development of robust programs to control *Listeria* in the production environment for RTE foods?

## **V. Control of *Listeria monocytogenes* in Produce Packinghouses**

Recent investigations in outbreaks associated with contaminated produce have revealed multiple findings of *L. monocytogenes* in environmental samples collected from packinghouses. The recently announced produce safety rule does not establish requirements for environmental monitoring. However, FDA is strongly encouraging all food establishments that pack fresh produce to take appropriate measures to prevent *L. monocytogenes* that may be present in the environment from contaminating fresh produce. FDA is currently considering development of guidance documents specifically for the fresh produce packing and handling industry to encourage robust *Listeria* control programs in packinghouses, regardless of whether the packinghouse is a food facility that is subject to the requirements in 21 CFR part 117 for CGMPs and preventive controls, or is a farm that is subject to the new standards for produce safety in 21

CFR part 112. FDA also intends to continue outreach activities to ensure that produce packinghouses are fully aware of their responsibilities to prevent *L. monocytogenes* from becoming established in their production areas where it could contaminate produce that is packed and shipped from their establishments.

Although our regulatory focus is guidance and outreach for packinghouses to prevent contamination of fresh produce with *L. monocytogenes* during packing operations, we are interested in long-term scientific studies to address the potential for contamination of raw produce (e.g., lettuce, tomatoes, cucumbers, etc.) by *L. monocytogenes* while the produce is growing in a field. Prevalence data are not widely available for *L. monocytogenes* on such produce items. However, we believe that the wide-spread presence of *L. monocytogenes* in the outdoor environment, including in soil, makes it possible that produce could become contaminated with *L. monocytogenes* in the growing area. Although data regarding the level of such contamination are not widely available, our initial presumption is that the level of such contamination would be low.

#### QUESTIONS:

7. Are there studies that could be conducted to distinguish between contamination of produce that might occur in a packinghouse and contamination of produce that might occur in the growing area?
8. What design parameters should be applied in studies to obtain prevalence data for raw produce as a result of contamination in the growing area? For example, should it focus on produce items that are more likely to be contaminated during growing and practices used during growing? What sampling plans would be appropriate?

## **VI. Priorities for Sampling**

FDA's long-standing approach to sampling foods for the presence of *L. monocytogenes* has been that RTE foods that support the growth of *L. monocytogenes* are a higher priority for sampling than RTE foods that do not support growth of *L. monocytogenes*, which, in turn, are a higher priority for sampling than foods that are not RTE. Even though scientific modeling and outbreaks support a conclusion that those subpopulations at greatest risk of developing listeriosis are also at a measurable risk of illness when consuming food contaminated with relatively low doses of *L. monocytogenes*, especially if highly virulent bacterial strains are involved, we have not considered changing this approach to sampling foods.

#### QUESTION:

9. Do you agree with continuing this approach to sampling foods for the presence of *L. monocytogenes*? If not, how would you change this approach?

## **VII. Recommendations on Dietary Restrictions for the Most Vulnerable Populations**

FDA provides advice and recommendations to consumers on safe food preparation practices, including recommendations to seniors and to pregnant women on foods to avoid to reduce the risk of foodborne illness from consumption of food contaminated with bacterial pathogens. We summarize our current advice and recommendations to consumers in the Appendix to this document.

### **QUESTIONS:**

10. What, if any, changes should FDA make to its current dietary recommendations?
11. Is there a need for specific fact sheets targeting special populations (e.g., dietitians, geriatric practitioners, elder care facilities)?

## **VIII. Other Issues**

This section provides an opportunity for the FAC to address any additional issues that would help FDA in addressing the presence of *L. monocytogenes* in RTE foods.

### **QUESTION:**

12. Do you have any recommendations for additional approaches to achieve the goal of reducing the prevalence of *L. monocytogenes* in RTE foods?

## **Appendix. Dietary Recommendations for the Most Vulnerable Subpopulations**

### **A. *Foods Seniors are Advised Not to Eat***

To reduce risks of illness from bacteria in food (including *L. monocytogenes* and other foodborne pathogens), seniors (and others who face special risks of illness) are advised not to eat:

- Raw fin fish and shellfish, including oysters, clams, mussels, and scallops.
- Hot dogs and luncheon meats, unless they are reheated until steaming hot.
- Raw or unpasteurized milk or soft cheeses (such as Feta, Brie, Camembert, blue-veined, and Mexican-style cheese) unless they are labeled "made with pasteurized milk."
- Unpasteurized refrigerated pâtés or meat spreads. Canned or shelf-stable pâtés and meat spreads may be eaten.

- Refrigerated smoked seafood unless it is contained in a cooked dish, such as a casserole.
- Refrigerated smoked seafood, such as salmon, trout, whitefish, cod, tuna, or mackerel, is often labeled as "nova-style," "lox," "kippered," "smoked," or "jerky." These products are found in the refrigerator section or sold at deli counters of grocery stores and delicatessens. Canned or shelf-stable smoked seafood may be eaten.
- Raw or lightly cooked eggs or products containing raw eggs such as salad dressings, cookie or cake batter, sauces, and beverages such as egg nog. (Such foods made from commercially pasteurized eggs are safe to eat).
- Raw meat or poultry.
- Raw sprouts (alfalfa, clover, and radish).
- Unpasteurized or untreated fruit or vegetable juice. (These juices must bear a warning statement on the label).

For the full text of FDA’s advice to seniors regarding food safety, see “To Your Health! Food Safety for Seniors” at

<http://www.fda.gov/Food/FoodborneIllnessContaminants/PeopleAtRisk/ucm182679.htm>

**B. Specific Advice to Pregnant Women Regarding *Listeria monocytogenes*\***

To reduce risks of illness from bacteria in food (including *L. monocytogenes* and other foodborne pathogens), pregnant women are advised not to eat:

- Improperly reheated hot dogs, luncheon meats, cold cuts, fermented or dry sausage, and other deli-style meat and poultry.
- Unpasteurized (raw) milk and soft cheeses made with unpasteurized (raw) milk.
- Smoked seafood and salads made in the store such as ham salad, chicken salad, or seafood salads.
- Raw vegetables.

**C. General Advice to Pregnant Women Regarding Foodborne Pathogens\***

Type of Food	Higher Risk	Lower Risk
Meat and Poultry	<ul style="list-style-type: none"> <li>• Raw or undercooked meat or poultry</li> </ul>	<ul style="list-style-type: none"> <li>• Meat or poultry cooked to a safe minimum internal temperature</li> </ul>

Type of Food	Higher Risk	Lower Risk
Seafood	<ul style="list-style-type: none"> <li>• Any raw or undercooked fish, or shellfish, or food containing raw or undercooked seafood e.g., sashimi, found in some sushi or ceviche.</li> <li>• Refrigerated smoked fish</li> <li>• Partially cooked seafood, such as shrimp and crab</li> </ul>	<ul style="list-style-type: none"> <li>• Previously cooked seafood heated to 165 °F</li> <li>• Canned fish and seafood</li> <li>• Seafood cooked to 145 °F</li> </ul>
Milk	<ul style="list-style-type: none"> <li>• Unpasteurized (raw) milk</li> </ul>	<ul style="list-style-type: none"> <li>• Pasteurized milk</li> </ul>
Eggs	<p>Foods that contain raw/undercooked eggs, such as:</p> <ul style="list-style-type: none"> <li>• Homemade Caesar salad dressings</li> <li>• Homemade raw cookie dough</li> <li>• Homemade eggnog</li> </ul>	<ul style="list-style-type: none"> <li>• At home: Use pasteurized eggs/egg products when preparing recipes that call for raw or undercooked eggs</li> <li>• When eating out: Ask if pasteurized eggs were used</li> </ul>
Sprouts	<ul style="list-style-type: none"> <li>• Raw sprouts (alfalfa, bean, or any other sprout)</li> </ul>	<ul style="list-style-type: none"> <li>• Cooked sprouts</li> </ul>
Vegetables	<ul style="list-style-type: none"> <li>• Unwashed fresh vegetables, including lettuce/salads</li> </ul>	<ul style="list-style-type: none"> <li>• Washed fresh vegetables, including salads</li> <li>• Cooked vegetables</li> </ul>
Cheese	<p>Soft cheeses made from unpasteurized (raw) milk, such as:</p> <ul style="list-style-type: none"> <li>• Feta</li> <li>• Brie</li> <li>• Camembert</li> <li>• Blue-veined</li> <li>• Queso fresco</li> </ul>	<ul style="list-style-type: none"> <li>• Hard cheeses</li> <li>• Process cheeses</li> <li>• Cream cheese</li> <li>• Mozzarella</li> <li>• Soft cheeses that are clearly labeled “made from pasteurized milk”</li> </ul>

Type of Food	Higher Risk	Lower Risk
Hot Dogs and Deli Meats	<ul style="list-style-type: none"> <li>• Hot dogs, deli meats, and luncheon meats that have not been reheated</li> </ul>	<ul style="list-style-type: none"> <li>• Hot dogs, luncheon meats, and deli meats reheated to steaming hot or 165 °F</li> </ul>
Pâtés	<ul style="list-style-type: none"> <li>• Unpasteurized, refrigerated pâtés or meat spreads</li> </ul>	<ul style="list-style-type: none"> <li>• Canned or shelf-stable pâtés or meat spreads</li> </ul>

\* Full text of FDA’s Food Safety for Pregnant Women brochure can be seen at <http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/UCM312787.pdf>.