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Compliance Policy Guide

Guidance for FDA Staff

Sec. 555.320

Listeria monocytogenes

DRAFT GUIDANCE

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For questions regarding this draft document, contact the Center for Food Safety and Applied Nutrition (CFSAN) at 301-436-1400.

**U.S. Department of Health and Human Services
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Center for Food Safety and Applied Nutrition
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Guidance for FDA Staff**

Sec. 555.320 *Listeria monocytogenes*

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

I. INTRODUCTION:

The purpose of this Compliance Policy Guide is to provide guidance to FDA Staff on FDA's enforcement policy for *Listeria monocytogenes* (*L. monocytogenes*) in foods.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND:

L. monocytogenes is a pathogenic bacterium that is widespread in the environment and may be introduced into a food processing facility. *L. monocytogenes* can contaminate foods and cause a mild illness (called listerial gastroenteritis) or a severe, sometimes life-threatening, illness (called invasive listeriosis). Foods that have been implicated in outbreaks of invasive listeriosis have been foods that are ready-to-eat (RTE).

RTE foods can be contaminated if ingredients in the foods are contaminated with *L. monocytogenes* and are not treated to destroy viable cells of this pathogen, or if *L. monocytogenes* is allowed to contaminate the RTE food because of improper sanitary conditions or practices. Most RTE foods do not contain detectable numbers of *L. monocytogenes*. For many RTE foods, contamination with *L. monocytogenes* can be avoided – e.g., through the application of current good manufacturing practice requirements that establish controls on ingredients, listericidal processes, segregation of foods that have been cooked from those that have not, and sanitation. Sanitation controls include effective environmental monitoring programs designed to identify and eliminate *L. monocytogenes* in and on surfaces and areas in the plant.

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In 2003, FDA and the Food Safety and Inspection Service of the United States Department of Agriculture, in consultation with the Centers for Disease Control and Prevention of the United States Department of Health and Human Services, released a quantitative assessment (the Risk Assessment) of relative risk associated with consumption of certain 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. The Risk Assessment estimated that the risk of listeriosis would vary widely among these food categories.

According to the Risk Assessment, foods estimated to pose the highest risk of being associated with listeriosis are RTE foods that support the growth of *L. monocytogenes*. Examples of RTE foods that support the growth of *L. monocytogenes* include:

- Milk;
- High fat and other dairy products (*e.g.*, butter and cream);
- Soft unripened cheeses (greater than 50 percent moisture) (*e.g.*, cottage cheese and ricotta cheese);
- Cooked crustaceans (*e.g.*, shrimp and crab);
- Smoked seafood (*e.g.*, smoked finfish and mollusks);
- Raw seafood that will be consumed as sushi or sashimi;
- Many vegetables (such as broccoli, cabbage, and salad greens);
- Non-acidic fruit (such as melon, watermelon, and papaya); and
- Some deli-type salads and sandwiches (particularly those containing seafood and those prepared at retail establishments without acidification and/or the addition of antimicrobial substances).

In contrast, the foods estimated to pose the lowest risk of being associated with listeriosis are foods that, because of intrinsic factors, extrinsic factors, and/or processing factors do not support the growth of *L. monocytogenes*. Intrinsic factors include chemical and physical factors that are normally within the structure of the food, *e.g.*, pH and water activity. Extrinsic factors are those that refer to the environment surrounding the food, *e.g.*, storage temperature. Processing factors include substances added to adjust the pH of food (*e.g.*, acids) and substances that, alone or in combination with other substances, have antimicrobial properties (*e.g.*, sorbates and benzoates). It is well established that *L. monocytogenes* does not grow when:

- The pH of the food is less than or equal to 4.4;
- The water activity of the food is less than or equal to 0.92; or
- The food is frozen.

Foods may naturally have a pH or water activity that prevents growth of *L. monocytogenes* or processing factors may be deliberately used to achieve those characteristics (*e.g.*, by adding acid to deli-type salads to bring the pH to less than or equal to 4.4). At pH values above 4.4, processing factors generally are used in combination to prevent the growth of *L. monocytogenes* (*e.g.*, sorbates or benzoates may be used in combination with organic acids such as acetic acid, lactic acid, and citric acid in foods such as deli-type salads). The effectiveness of a particular listeristatic control measure in preventing growth in a particular RTE food generally is determined case-by-case, for example, using the results of growth studies specific to the food matrix.

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Examples of RTE foods that generally are considered to not support the growth of *L. monocytogenes* include:

- Fish that are preserved by techniques such as drying, pickling, and marinating;
- Ice cream and other frozen dairy products;
- Processed cheese (e.g., cheese foods, spreads, slices);
- Cultured milk products (e.g., yogurt, sour cream, buttermilk);
- Hard cheeses (less than 39 percent moisture) (e.g., cheddar, colby, and parmesan);
- Some deli-type salads, particularly those processed to a pH less than 4.4 and those containing antimicrobial substances such as sorbic acid/sorbates or benzoic acid/benzoates under conditions of use documented to be effective in preventing the growth of *L. monocytogenes*;
- Some vegetables (such as carrots); and
- Crackers, dry breakfast cereals, and other dry foods.

Fruits, vegetables, and cheeses (e.g., soft and semi-soft cheeses) not listed in this CPG may include some products that support growth as well as other products that do not support growth.

III. POLICY:

FDA will review the available evidence on a case-by-case basis to determine if a food is a RTE food that supports growth or a RTE food that does not support growth.

A. Ready-to-Eat Food

“Ready-to-eat food” (RTE food) means a food that is customarily consumed without cooking by the consumer, or that reasonably appears to be suitable for consumption without cooking by the consumer.

A food may be considered to be suitable for consumption without cooking by the consumer, and thus a RTE food, even though cooking instructions are provided on the label. For examples, fresh and frozen crabmeat and individually quick frozen (IQF) peas and corn may be RTE foods. Some consumers eat such products without cooking, because they appear to be ready-to-eat.

B. Ready-to-Eat Foods that Support Growth of *L. monocytogenes*

Generally, we intend to consider that a RTE food will support the growth of *L. monocytogenes* if it does not meet the characteristics of a RTE food that does not support growth, as indicated in section III.C.

FDA may regard a RTE food that supports growth of *L. monocytogenes* to be adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act; the FD&C Act) (21 U.S.C. 342(a)(1)) when *L. monocytogenes* is present in the food based on the detection method indicated in section IV.A.

C. Ready-to-Eat Foods that Do Not Support Growth of *L. monocytogenes*

A RTE food does not support the growth of *L. monocytogenes* if the food:

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- Has a pH that is less than or equal to 4.4; or
- Is customarily held and consumed in a frozen state; or
- Has a water activity that is less than 0.92; or
- Is processed using an effective listeristatic control measure (e.g., an antimicrobial substance or a combination of factors such as pH, water activity, and antimicrobial substances).

FDA may regard a RTE food that does not support the growth of *L. monocytogenes* to be adulterated within the meaning of section 402(a)(1) of the Act (21 U.S.C. 342(a)(1)) when *L. monocytogenes* is present at or above 100 colony forming units per gram of food (cfu/g).

IV. REGULATORY ACTION GUIDANCE:

A. Ready-to-Eat Foods that Support Growth of *L. monocytogenes*

The following represents criteria for recommending legal action to CFSAN/Office of Compliance/Division of Enforcement (HFS-605):

- *L. monocytogenes* is detected in one or more subsamples of a RTE food that supports the growth of *L. monocytogenes*.

Use Bacteriological Analytical Manual Online, Chapter 10 – “*Listeria monocytogenes*,” “Detection and Enumeration of *Listeria monocytogenes* in Foods” as the method for detecting and confirming presence of *L. monocytogenes* (available at <http://www.cfsan.fda.gov/~ebam/bam-10.html>).

B. Ready-to-Eat Foods that Do Not Support Growth of *L. monocytogenes*

Consult with CFSAN/Office of Compliance/Division of Enforcement (HFS-605) before recommending legal action for RTE foods that do not support the growth of *L. monocytogenes*. Use ISO 11290-2:1998(E) “Microbiology of food and animal feeding stuffs - Horizontal method for the detection and enumeration of *Listeria monocytogenes* - Part 2: Enumeration method” as the method for enumerating *L. monocytogenes*. (ISO 11290-2:1998/Amd. 1:2004(E) “Microbiology of food and animal feeding stuffs - Horizontal method for the detection and enumeration of *Listeria monocytogenes* - Part 2: Enumeration method AMENDMENT 1: Modification of the enumeration medium” amends ISO 11290-2:1998(E). The amendment uses ALOA agar instead of PALCAM agar. If ALOA agar is not commercially available in the United States, use PALCAM according to ISO 11290-2:1998(E)). ISO methods are available from the International Organization for Standardization at <http://www.iso.org/iso/en/ISOOnline.frontpage>.

Use rapid biochemical test kits according to the Bacteriological Analytical Manual Online, Chapter 10 – “Detection and Enumeration of *Listeria monocytogenes* in Foods” Section E-11 (available at <http://www.cfsan.fda.gov/~ebam/bam-10.html>), instead of ISO 11290-2:1998(E) Section 9.5, for confirmation of *L. monocytogenes* isolates.

C. Foods that are Not RTE Foods

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Consult with CFSAN/Office of Compliance/Division of Enforcement (HFS-605) when *L. monocytogenes* is present in a food that is not a RTE food.

D. Other Considerations

The criteria in this guidance do not establish an acceptable level of *L. monocytogenes* in food. FDA may choose to take legal action against adulterated food that does not meet the criteria for recommending legal action to CFSAN.

Further, the criteria in this guidance do not excuse violations of the requirement in section 402(a)(4) of the Act (21 U.S.C. 342(a)(4)) that food may not be prepared, packed, or held under insanitary conditions or the requirements in FDA's good manufacturing practices regulation (21 CFR part 110). As set out in 21 CFR 110.80, food manufacturers must take “[a]ll reasonable precautions ... to ensure that production procedures do not contribute contamination from any source.”

V. SPECIMEN CHARGES:

A. Domestic Seizure

The article of food was adulterated when introduced into and while in interstate commerce and is adulterated while held for sale after shipment in interstate commerce within the meaning of the Act, 21 U.S.C. 342(a)(1), in that it bears and contains a poisonous or deleterious substance, namely *Listeria monocytogenes*, which may render it injurious to health.

B. Import Detention

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears to be adulterated within the meaning of section 402(a)(1) of the FD&C Act in that it bears and contains a poisonous or deleterious substance, *Listeria monocytogenes*, which may render it injurious to health.

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