



FOOD SAFETY & DEFENSE ALERTS

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TrendTrack™ Report

[Regulatory Affairs - FSMA - UD #72]

Snapshot

[FDA Issues Revised Draft Guidance for Control of Listeria monocytogenes in Ready-To-Eat Foods](#)

The U.S. Food and Drug Administration is releasing an updated [draft guidance, “Control of Listeria monocytogenes in Ready-To-Eat Foods,”](#) which supports ongoing efforts by industry and government agencies to reduce the risk of *Listeria monocytogenes* (*L. mono*) in ready-to-eat (RTE) foods.

The emphasis on prevention in this draft guidance is consistent with the [FDA Food Safety Modernization Act \(FSMA\)](#) and reflects the FDA’s current good manufacturing practice (CGMP) requirements, as well as new requirements for hazard analysis and risk-based preventive controls, including verification of preventive controls.

All food facilities that manufacture, process, pack, or hold RTE foods will benefit from clear guidance on measures to control *L. mono* in the food processing environment, regardless of whether the facility is subject to CGMPs, preventive controls, or both CGMPs and preventive controls.

Industry best practices and the “seek and destroy” approach used by the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) have been incorporated into the draft guidance.

Integrating these approaches along with the food safety requirements under FSMA, should lead to more effective efforts to control *L. mono* in RTE products. RTE facilities that produce foods that are regulated by both USDA/FSIS and FDA will also benefit from a uniform federal approach to reducing the risk of environmental contamination with *L. mono*.

End of Snapshot – Full Text Follows

FDA Issues Revised Draft Guidance for Control of Listeria monocytogenes in Ready-To-Eat Foods

[FDA][1/13/17 12:24]

Constituent Update

January 13, 2017

The U.S. Food and Drug Administration is releasing an updated [draft guidance, “Control of Listeria monocytogenes in Ready-To-Eat Foods,”](#) which supports ongoing efforts by industry and government agencies to reduce the risk of *Listeria monocytogenes* (*L. mono*) in ready-to-eat (RTE) foods. *L. mono*, a pathogen that can grow even in cold, refrigerated environments, is particularly harmful to the elderly, pregnant women and/or their pregnancy, and those who are immunocompromised.

The emphasis on prevention in this draft guidance is consistent with the [FDA Food Safety Modernization Act \(FSMA\)](#) and reflects the FDA’s current good manufacturing practice (CGMP) requirements, as well as new requirements for hazard analysis and risk-based preventive controls, including verification of preventive controls.

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Integrating these approaches along with the food safety requirements under FSMA, should lead to more effective efforts to control *L. mono* in RTE products. RTE facilities that produce foods that are regulated by both USDA/FSIS and FDA will also benefit from a uniform federal approach to reducing the risk of environmental contamination with *L. mono*.

The guidance includes recommendations for controls involving personnel, cleaning and maintenance of equipment, and sanitation, as well as for treatments that kill *L. mono* and formulations to prevent it from growing during storage of the food between production and consumption. The updated draft guidance does not change or alter what constitutes an RTE food.

The FDA is accepting public comments beginning on January 17, 2017. To electronically submit comments to the docket, visit www.regulations.gov and type **FDA-2008-D-0096** in the search box.

To submit comments to the docket by mail, use the following address. Be sure to include docket number **FDA-2008-D-0096** on each page of your written comments.

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Additional Information

- [Federal Register Notice](#)
- [Regulations.gov](#): please note that the public comment period opens on **January 17, 2017**
- [Draft Guidance for Industry: Control of Listeria monocytogenes in Ready-To-Eat Foods](#)

[More in Constituent Updates](#)

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