Call to Action for Industry:
Using Food Safety Management Systems to Reduce *Listeria Monocytogenes*

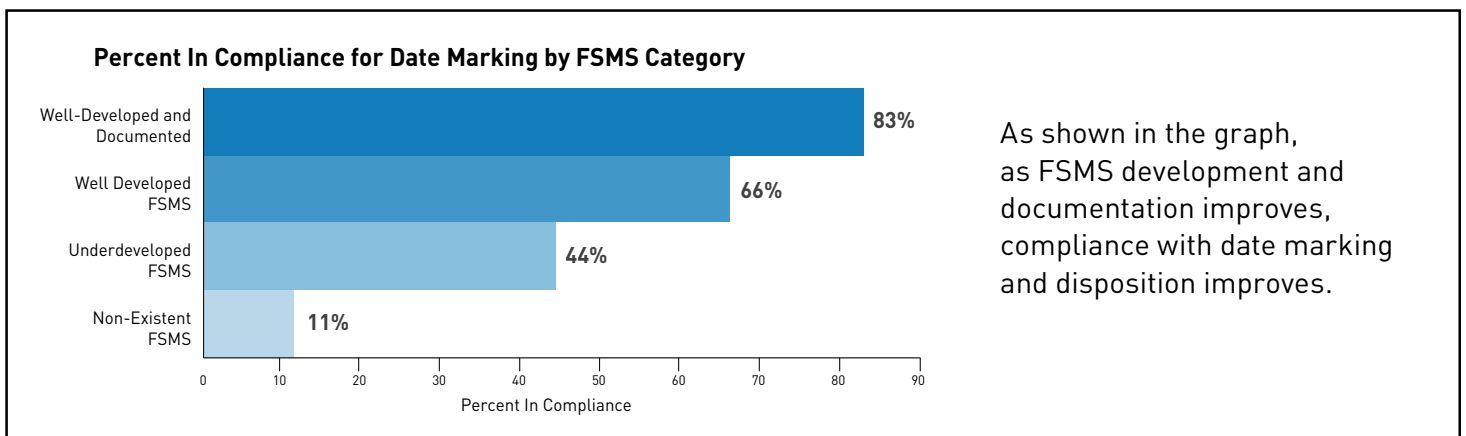FDA | **U.S. FOOD & DRUG** ADMINISTRATION
NATIONAL RETAIL FOOD TEAM

What did the 2015-2016 Deli data collection find out about foodborne illness risk factors and Food Safety Management Systems?

In the 2015-2016 Retail Food Store Deli data collection of the National Retail Risk Factor Study, the highest out-of-compliance foodborne illness risk factor was improper holding time/temperature. This risk factor was comprised of four data items outlined in the Retail Food Store Data Collection Form.

A key message from the Deli data collection was that Food Safety Management Systems (FSMS) were the strongest predictor of the compliance status of risk factors. A FSMS refers to a specific set of actions and/ or procedures to help achieve active managerial control. While FSMS vary across the retail and food service industry, the consistent components include the purposeful implementation of procedures, training, and monitoring. You can find more information on FSMS here.

For establishments with well-developed FSMS, the average number of data items out-of-compliance was reduced, resulting in a reduced occurrence of foodborne illness risk factors. These preliminary findings suggest that FSMS are a promising tool in reducing foodborne illness risk factors.

For the improper holding time/temperature risk factor, FSMS had the strongest impact on data item 8 which involves date marking and disposition, which is one of the primary controls in the FDA Food Code for the growth of *Listeria Monocytogenes* (Listeria), a pathogen of major concern in delis. The connection of FSMS to date marking compliance is shown in the following graph:

Percent In Compliance for Date Marking by FSMS Category

FSMS Category	Percent In Compliance
Well-Developed and Documented	83%
Well Developed FSMS	66%
Underdeveloped FSMS	44%
Non-Existent FSMS	11%

x-axis: Percent In Compliance (0, 10, 20, 30, 40, 50, 60, 70, 80, 90)

As shown in the graph, as FSMS development and documentation improves, compliance with date marking and disposition improves.

What is *Listeria monocytogenes* and why is controlling it important?

Listeria is a pathogenic bacterium that causes **Listeriosis - a serious infection** that primarily affects...
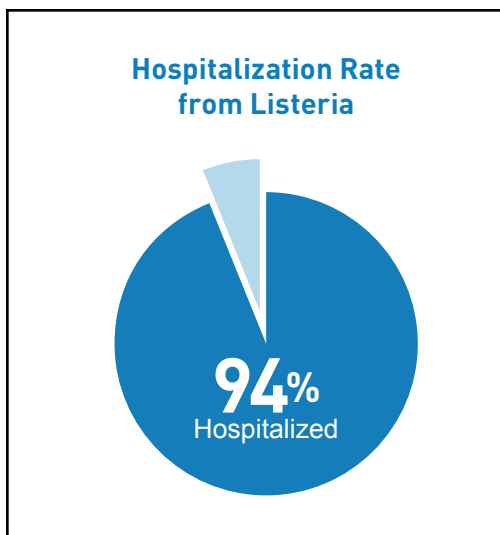
pregnant women and **newborns...**

adults aged 65 or older...

and **people with weakened immune systems.**

Hospitalization Rate from Listeria

94%
Hospitalized

Scallan, E., et .al. Foodborne Illness Acquired in the United States—Major Pathogens. *Emerging Infectious Diseases, 17 (1)*, 7-15.

CDC estimates Listeria is the 3rd leading cause of death from foodborne illness. An estimated 1,600 people get listeriosis each year, 1,500 are hospitalized, and about 260 die. People most at risk for infection include pregnant women and their newborns, adults aged 65 or older, and people with weakened immune systems. Listeria is ubiquitous in the environment and can be found in moist environments, soil and decaying vegetation.

Listeria is persistent in retail food environments and can grow in refrigeration temperatures below 1°C (33.8°F), which makes this organism a problem for the food industry. This makes date marking and disposition the primary prevention factor for Listeria in the retail environment. The Food Code specifies ready-to-eat, time/ temperature control for safety (TCS) food prepared in a food establishment and held longer than a 24 hour period shall be marked to indicate the date or day by which the food is to be consumed on the premises, sold, or discarded when held at a temperature of 5°C (41°F) or less for a maximum of 7 days.

What can the retail food industry do to improve FSMS and reduce Listeria?

FSMS are a promising practice to reduce foodborne illness risk factors. The National Retail Risk Factor Study categorized FSMS into four categories: non-existent, underdeveloped, well-developed, and well-developed and documented. Well-developed and documented systems have the greatest impact on compliance. These FSMS are complete, consistent, and primarily written. Maintaining documentation of the FSMS can be vital to its success.

Benefits of a Well-developed and Documented Food Safety Management System (FSMS)
Provide staff a tangible set of instructions to use for their training/guidance.
Maintain physical documents to discuss with your regulator when food safety issues arise. These are opportunities to improve your system and build a partnership with your regulatory authority in preventing foodborne illness.
Documenting activities provides a mechanism for verifying that the activities in the FSMS were properly completed.
In many cases, records can serve a dual purpose of ensuring quality and food safety.

From 2017 FDA Food Code, Annex 4 – Management of Food Safety Practices – Achieving Active Managerial Control of Foodborne Illness Risk Factors, HACCP Principle 7: Establish record-keeping and documentation procedures, p. 574.

Retail food establishments should take action to develop, implement, and strengthen their procedures, training, and monitoring within their establishment to create well-developed and documented FSMS. A resource for developing a well-developed and documented FSMS for date marking system can be found here: Date Marking and Disposition Fact Sheet.

A well-developed and documented FSMS should result in employees and management being able to complete the actions below.

Procedures

- Describe the critical limits for holding foods requiring refrigeration at proper temperature that apply to their food establishment.

- List the steps / tasks (how and when) that food employees perform to ensure that the identified critical limits for holding foods requiring refrigeration at proper temperature are achieved.

- Identify specific employees who have been assigned the responsibility to correctly perform procedures for holding foods requiring refrigeration at proper temperature.

- Institute, implement, and maintain a Standard Operating Procedure (SOP) that describes:
  - The date marking and disposition system used by the establishment, to include which products need date marking and disposition.
  - The employee(s) responsible for each task.
  - The employee(s) responsible for monitoring of temperatures and discard dates of date marked product.
  - How and how often employees are to be trained on date marking.

Training

- Ensure that the date marking and disposition system used by the food establishment is included in the food employee training program.

- Confirm that the critical limits for holding foods requiring refrigeration at proper temperature are included in the establishment's food employee training program.

- Describe the methods/process (how and when) for providing training to front line employees on the critical limits and procedures for holding food requiring refrigeration at proper temperature.

- Identify specific employees who are assigned the responsibility to train front line food employees on holding food requiring refrigeration at proper temperature.

- Provide written materials (PowerPoint presentations; videos; handouts; course books or policy manuals; reminder cards; wall charts; posters; etc.) that are used to support their food safety training for holding food requiring refrigeration at proper temperature within their establishment.

Monitoring

- Confirm that the critical limits for holding foods requiring refrigeration at proper temperature are included in the establishment's monitoring program.

- Describe the methods / process (how and when) for monitoring procedures for holding foods requiring refrigeration at proper temperature to confirm that employees are following the establishment's procedures.

- Identify specific employees who are assigned the responsibility to monitor procedures for holding foods requiring refrigeration at proper temperature. In addition, management is able to describe the corrective actions food employees will take when food is not maintained at proper refrigeration temperatures.

- Produce written forms / records / logs / checklists / calibration records / etc., used to document the findings from monitoring procedure for holding foods requiring refrigeration at proper temperature within the establishment.

- Describe the process (how and when) for monitoring of RTE-TCS foods that must be discarded as per the date marking and disposition system used by the food establishment.

Resources

The FDA Food Code is the primary resource for compliance and enforcement of food safety provisions, and guidance for the reduction of Listeria in retail food establishments. Below is a list of links to specific pages in the Food Code and its Annexes to assist regulatory authorities in this effort to control Listeria at retail and foster FSMS. The annexes are provided specifically to assist the regulatory authority to apply the provisions of the Food Code uniformly and effectively. These resources can provide tremendous assistance to those charged with applying Food Code provisions.

- Annex 3 – Public Health Reasons/Administrative Guidelines
- Annex 4 – Management of Food Safety Practices - Achieving Active Managerial Control of Foodborne Illness Risk Factors
- Annex 4 – Management of Food Safety Practices – Why are Records Important?
- Annex 7 – Model Forms, Guides, and other Aides

Below is a list of other federal resources available that can be used to assist in the development of FSMS in retail food establishments. We encourage establishments to utilize and share these and other available resources to make progress towards the prevention of foodborne illness risk factors.

- Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments
- FDA Job Aid: Time and Temperature Control for Safety Food
- FDA Bad Bug Book
- FDA Materials on Sanitation Concerns with Commercial Deli Slicers
- FDA Advice for Retailers on Listeria
- CDC Advice on Listeria
- FDA Retail Food Protection Industry Educational Material on Date Marking
- Foodborne Illness Video Testimonials (Listeriosis)
- FDA Retail Food Protection Industry Educational Material (scroll to date marking section)
- USDA-FSIS Guidance for Controlling Listeria monocytogenes (Listeria) in Retail Delicatessens
- CDC - 4 Takeaways for Retail Delis

Questions?

For more information visit our website at: http://www.fda.gov/retailfoodriskfactorstudy