

FSMA Update and the New Era of Smarter Food Safety

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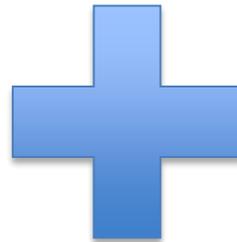
Presented to the 3-A SSI Education Event, Minneapolis, MN

May 18, 2022

OFS supports today's theme:

Design to Clean: Creating a Hygiene focused Culture

**FDA FOOD SAFETY
MODERNIZATION ACT**





FSMA enables FDA to better protect public health in multiple ways

- Focus on *preventing* food safety problems rather than relying primarily on reacting to problems after they occur
- Provided FDA with new enforcement authorities
- New tools to hold imported foods to the same standards as domestic foods
- Directed FDA to build an integrated national food safety system in partnership with state and local authorities

FSMA: Rules Finalized

- Accredited Third-Party Certification
- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (PCHF)
- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (PCAF)
- Foreign Supplier Verification Programs (FSVP)
- Laboratory Accreditation
- Mitigation Strategies to Protect Food Against Intentional Adulteration (IA)
- Sanitary Transportation of Human and Animal Food
- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (PSR)

FSMA: Rules Proposed

- Agricultural Water
 - Would replace the pre-harvest microbial quality criteria and testing requirements in the Produce Safety Rule with requirements for systems-based pre-harvest agricultural water assessments
- Food Traceability
 - Would establish additional traceability recordkeeping requirements for persons who manufacture, process, pack, or hold foods the Agency has designated for inclusion on the Food Traceability List

Hygienic design is a foundational GMP

- The requirements that food contact surfaces be designed, manufactured, installed, and maintained in a manner to prevent cross contamination with pathogens existed as CGMPs before FSMA
- An underlying principle of FSMA is that hazards be controlled, and this can't be done without meeting these CGMP requirements
- The PSR brought some of these CGMP requirements into the rule because the CGMPs in part 117 do not apply to farms
- The PSR established, for the first time, science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption

Hygienic design and the PSR rule

- 112.123(a) You must **use equipment and tools that are of adequate design, construction and workmanship** to enable them to be adequately cleaned and properly maintained
- 112.123(d)(1) You must **inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces** of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.
- 112.123(d)(2) You must **maintain and clean all non-food-contact surfaces** of equipment and tools subject to this subpart used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce.

Hygienic design and field equipment

- Several recent produce-related outbreaks have involved poor hygienic design on equipment
- Equipment surfaces/materials are often chosen to reduce damage to produce, but may not be microbiologically cleanable
- Produce, such as lettuce, is right from the field – hygienic design therefore extends to equipment used in the field
- Pathogens have been isolated from equipment used to harvest lettuce

Hygienic design and CGMPs in the PCHF rule

- 117.40(a)(1) All plant equipment and utensils used in manufacturing, processing, packing, or holding food **must be so designed and of such material and workmanship as to be adequately cleanable**, and must be adequately maintained to protect against allergen cross-contact and contamination
- 117.40(a)(3) Equipment must be **installed so as to facilitate the cleaning** and maintenance of the equipment and of adjacent spaces.
- 117.40(c) Equipment that is in areas where food is manufactured, processed, packed, or held and that does not come into contact with food **must be so constructed that it can be kept in a clean and sanitary condition.**



Top cites from Limited Scope PCHF inspections

(Inspectional timeframe 10/01/2019 to 05/12/2022)

1. Pest control
2. Manufacturing, processing, packing, holding – controls
3. Equipment and utensils – design and maintenance
4. Personnel
5. Sanitary operations – plant maintenance
6. Plant construction and design
7. Sanitation of food contact surfaces – frequency
8. Sanitary facilities and control
9. Sanitary operations – plant sanitation
10. Training of employees and records

Top cites from Full Scope PCHF inspections

(Inspectional timeframe 10/01/2019 to 05/12/2022)

1. Hazard analysis – identification of hazard
2. Food safety plan
3. Sanitation controls, verification procedures (EMP)
4. Preventive controls, identification
5. Pest control
6. Process controls, monitoring procedures
7. Sanitation controls, monitoring procedures
8. Personnel
9. Sanitary operations – plant maintenance
10. Allergen controls, monitoring procedures

The PCHF rule and RTE foods

- Whenever an 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 the pathogen, the hazard evaluation must include an evaluation of environmental pathogens (117.130(c)(1)(ii))
- When contamination with environmental pathogens is a hazard that requires a preventive control, the appropriate type of control is a sanitation control

Controlling *L. monocytogenes* in RTE foods



- Recommendations for the hygienic design and construction of facilities and equipment
- Recommendations for establishing an environmental monitoring program

Contains Nonbinding Recommendations

Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Guidance for Industry Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 180 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2007-D-0494 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1700.

U.S. Department of Health and Human Services
Food and Drug Administration

What about NRTE foods?

- The requirements for hygienic design of equipment found in the CGMPs apply to all food
- Firms making NRTE food are not required to include an evaluation of environmental pathogens in their hazard evaluation, but...
- All equipment and utensils used in manufacturing, processing, packing, or holding food must be designed and maintained to protect against allergen cross-contact and contamination

Recent guidance on enforcement policy

- Extension of Enforcement Policy for Supply-Chain Program Requirements Applicable to Co-Manufacturers of Human Food and Animal Food
- Enforcement Policy for Certain Entities and Requirements Under the Mitigation Strategies to Protect Food Against Intentional Adulteration Regulation
- Enforcement Policy for Supplier Approval and Verification Requirements in Part 117, Part 507, and the FSVP Regulation

**Current Good Manufacturing Practice and Preventive Controls, Foreign Supplier Verification Programs, Intentional Adulteration, and Produce Safety Regulations:
Enforcement Policy Regarding Certain Provisions**

Guidance for Industry

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2021-D-0563, listed in the notice of availability published in the *Federal Register*.

For questions regarding this document, you may contact the FSMA Technical Assistance Network online at <https://www.fda.gov/food/guidanceregulation/fsma/ucm459719.htm>, by mail at Food and Drug Administration; 5001 Campus Drive; Wiley Building, HFS-009; Attn: FSMA Outreach; College Park, MD, 20740, or by phone at 1-888-SAFEFOOD (1-888-723-3366).

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine

Recent guidance on enforcement policy

- None of these enforcement policy decisions reduce the importance of or requirements for hygienic design and maintaining food contact surfaces in a such a manner that they do not contribute to contamination by pathogens

Foods Program Guidance Under Development



Hazard Analysis and Risk-Based Preventive Controls for Human Food; Appendix 1: Potential Hazards for Foods and Processes; Draft Guidance for Industry	FSMA
Hazard Analysis and Risk-Based Preventive Controls for Human Food; Chapter 11: Food Allergen Controls; Draft Guidance for Industry	FSMA
Hazard Analysis and Risk-Based Preventive Controls for Human Food; Chapter 16: Validation of Process Controls; Draft Guidance for Industry	FSMA
Hazard Analysis and Risk-Based Preventive Controls for Human Food; Chapter 17: Classifying Food as Ready-To-Eat or Not Ready-to-Eat; Draft Guidance for Industry	FSMA
Hazard Analysis and Risk-Based Preventive Controls for Human Food; Chapter 18: Acidified Foods; Draft Guidance for Industry	FSMA
Questions and Answers Regarding the Accredited Third-Party Certification Program: Draft Guidance for Industry	FSMA
Refusal of Inspection by a Foreign Food Establishment or Foreign Government; Guidance for Industry	FSMA
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals; Guidance for Industry	FSMA
Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations: Guidance for Industry	FSMA

[Foods Program Guidance Under Development](#)

OFS PREVENTION STRATEGIES

HOW DO WE BEND THE CURVE ON FOODBORNE PATHOGEN OUTBREAKS?

Why develop Prevention Strategies?

- More foodborne illness outbreaks detected due to enhanced disease attribution capabilities
- Structured process to transition from outbreak response to prevention
 - identifying gaps in understanding
 - identifying activities to resolve gaps
- Opportunity to bring stakeholder clarity to prevention activities
- Specific opportunities to make progress on Healthy People 2030

What is a Prevention Strategy (what's in it?)

- Affirmative, deliberate approach undertaken by the FDA to limit or prevent the reoccurrence of a root cause that led to an outbreak or adverse incident
- Strategy may incorporate recommendations for research, policy development, publications/communications, industry influence, industry training, compliance activities, regulator training, rule-making, and guidance development
- Goal: Prevention strategy for every outbreak - prioritize execution

Current OFS Prevention Strategies



Prevention Strategy example: *L. monocytogenes* in Imported Specialty Mushrooms

Phase 1 – Communications and Stakeholder Engagement

- Translations of the Produce Safety Rule and guidance
- Outreach on cultural differences in mushroom consumption
- Engagement with competent authorities in the Republic of Korea, China, Japan, Taiwan, and Canada

Phase 2 – Targeted Research and Regulatory Activities

- Targeted sampling of enoki mushrooms
 - FDA sampling at port of entry
 - State sampling via LFFM
- Research to better understand *L. monocytogenes* and enokis

Phase 3 – Long-term Targeted Extension for the Mushroom Industry

- Facilitate the availability of training for enoki mushroom producers





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New Era of Smarter Food Safety

FDA's New Era of Smarter Food Safety



- The New Era of Smarter Food Safety represents a new approach to food safety, leveraging technology and other tools to create a safer and more digital, traceable food system.
- Smarter food safety is about more than just technology. It's also about simpler, more effective, and modern approaches and processes. It's about leadership, creativity, and culture.
- It builds on work that FDA has done to implement the Food Safety Modernization Act (FSMA), which established science and risk-based protections.

Tech-enabled Traceability



Smarter Tools and Approaches for Prevention and Outbreak Response



New Business Models and Retail Modernization



Food Safety Culture



What is....
Food Safety Culture?

Food safety culture (a few definitions)



The aggregation of the prevailing, relatively constant, learned, shared attitudes, values and beliefs contributing to the hygiene behaviors used within a particular food handling environment

Griffith, Livesey, and Clayton (2010)

Shared values, beliefs and norms that affect mindset and behavior toward food safety in, across, and throughout an organization.

GFSI Technical Working Group

Our Goals for Food Safety Culture



Promote food safety culture throughout the food system



Further promote food safety culture throughout the agency



Develop and promote smarter food safety consumer education campaign





Research on food safety culture

Identify the challenges, barriers, and opportunities to influence attitudes and modify behaviors related to food safety culture



Internal food safety culture

Assess FDA's internal food safety culture and identify ways to strengthen it



Industry food safety culture

- Encourage and support a culture of food safety in the establishments we regulate
- Support approaches to adequately assess food safety culture in establishments

Webinar Series

Promote and discuss best practices, gaps, opportunities in improving food safety culture

Please join co-hosts Frank Yiannas and Michael Taylor as they kick off a webinar series

Key Concepts in Addressing Food Safety Culture as a Science-Not a Slogan

Thursday, November 4, 2021
10:30 AM - 12:00 PM ET



Co-sponsored by the FDA and the Alliance to Stop Foodborne Illness



Frank Yiannas
FDA Deputy Commissioner for Food Policy and Response



Michael Taylor
Former FDA Deputy Commissioner for Foods & Veterinary Medicine



Donald Prater
FDA Associate Commissioner for Imported Food Safety



Conrad Chaijiers
FDA Director of the Office of Analytics & Outreach at CFSAN



Roberta Wagner
VP of Regulatory & Technical Affairs, Consumer Brands Assn.



Gillian Kelleher
VP of Food Safety & Quality Assurance for Wegmans

REGISTER HERE

Food Safety Culture in the New Era of Smarter Food Safety
A quarterly webinar series
co-sponsored by FDA and The Alliance to Stop Foodborne Illness



Making Leaders Risk Aware and Push to Reduce Risk

February 16, 2022
12:30 - 1:15 PM ET

GUEST SPEAKERS



Nancy Wilson
Director of Quality Assurance, Risk Management and Safety at Wawa



Dr. Randy Huffman
Chief Food Safety and Sustainability Officer at Maple Leaf Foods

Ask your questions during the Q&A

REGISTER FOR FREE HERE



Consumer education

Identify new messaging, tools, and strategies to promote food safety culture among consumers

New Era of Smarter Food Safety



- Dramatic improvements in reducing the burden of foodborne illness cannot be made without doing more to influence the beliefs, attitudes, and, most importantly, the behaviors of people and the actions of organizations.
- Collectively, FDA and all stakeholders should strive to ensure that we are doing everything possible to quickly incorporate the lessons learned from contamination events into prevention efforts, and to complete our work as expeditiously as possible.

In closing

- Hygienic design is a foundational GMP that underlies FSMA requirements
- Hygienic design and sanitation deficiencies are among the most frequently cited during PCHF inspections
- Some segments of the food industry are farther along in implementing hygienic design than others
- We must do more to influence the beliefs, attitudes, and behaviors of people and the actions of organizations.
- We should work quickly incorporate the lessons learned from contamination events into prevention efforts



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