



United States
Department of
Agriculture



U.S. FOOD & DRUG
ADMINISTRATION

USDA/FDA Joint Public Meeting

The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry





Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



**Introduction to Strategies to
Address Potential Hazards and
Appropriate Regulatory
Oversight Frameworks**

Phil Bronstein, Ph.D.

*Executive Associate of Regulatory Operations,
Office of Field Operations, FSIS, USDA*

Food Safety and Inspection Service

Inspection In Depth: Sanitation Performance Standards

Verify Sanitation Performance Standards (SPS)

Focus on conditions that may result in adulteration of product:

- Establishment grounds & facilities
 - potable water
 - acceptable sewage system
- Sanitary operations
 - demonstrate the safety of a chemical usage
- Establishments must provide:
 - sufficient light
 - receptacles identified for inedible



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Inspection In Depth: Sanitation SOPs

Written procedures must:

- Contain procedures performed **daily**, before and during operation.
- Identify procedures to verify sanitation of **food contact surfaces, equipment, and utensils**.
- Specify the procedure **frequency**
- Identify personnel responsible for the implementation of the procedures
- Be signed and dated



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Inspection In Depth: Sanitation SOPs

Verify that establishments:

- Conduct pre-operation procedures in the Sanitation SOPs
- Conduct procedures in the **frequencies** specified.
- Monitor the **daily** implementation of the procedures
- Take appropriate **corrective action** when the sanitation SOPs have failed



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Inspection In Depth: HACCP

**Comply with Hazard Analysis &
Critical Control Point (HACCP)
requirements (9 CFR 417)**

- Hazard Analysis, Plan, and records must be written and available to inspection personnel
- HACCP System must be validated



Designing the HACCP System – 9 CFR 417

The seven principles of HACCP, which encompass a systematic approach to the identification, prevention, and control of food safety hazards include:

- 1. Conduct a Hazard Analysis**
- 2. Determine Critical Control Points**
- 3. Establish Critical Limits**
- 4. Establish Monitoring Procedures**
- 5. Establish Corrective Actions**
- 6. Establish Recordkeeping and Documentation Procedures**
- 7. Establish Verification Procedures**

90-Day Validation of HACCP System

Collect 90 days of production data to demonstrate the effective execution of the HACCP plan and ability to meet critical control points. Records include:

- HACCP documents
- Decision-making documents for the CCPs
- Critical operational parameter logs
- Initial equipment set up or calibration documents
- Sampling results for the product and process of interest

Element 1:
Scientific or
Technical
Support
(Design)

Element 2: Initial
in-plant Validation
Data
(Execution)

Strategies to Address Potential Hazards and Appropriate Regulatory Oversight Frameworks

Foods Under FDA's Jurisdiction

Jenny Scott, *M.S.*

Senior Advisor, Office of Food Safety, CFSAN, FDA

A Key Component of the FDA Regulatory Framework

- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR part 117)

Current Good Manufacturing Practice Requirements

- Appropriate quality control operations must be employed to ensure that food is suitable for human consumption.
- Raw materials and other ingredients must be clean and suitable for processing into food.
- All food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.
- Individuals engaged in manufacturing, processing, packing, or holding food must receive training in the principles of food hygiene and food safety.

Hazard Analysis and Risk-Based Preventive Controls

- Conduct a hazard analysis for known or reasonably foreseeable biological, chemical and physical hazards
- Implement preventive controls for those hazards identified as requiring them
 - Process controls, food allergen controls, sanitation controls, any other needed controls, and a recall plan
- Monitor and verify the preventive controls, take correction actions when needed
- Conduct supplier verification when preventive controls are applied to raw materials/ingredients before receipt
- Document actions in records available for FDA review

FDA's Framework Is Flexible

- Regulatory framework provides flexibility to address a broad array of food facilities and manufacturing processes.
- FDA's inspection system is also designed to be adaptable to inspect the broad array of manufacturing, processing, packing and holding facilities under FDA jurisdiction.





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Session 3: Open Public Comment on Addressing Potential Hazards and Providing Appropriate Regulatory Oversight

- Is there an effective and efficient application of pre-market programs to ensure the safety of foods produced by animal cell culture?
- What preventive controls and other tools are best suited to managing potential hazards at each stage of production? What type and frequency of inspection will be appropriate for various stages of the manufacture of these products, given the potential hazards and assessed risks at different stages?

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Session 3: Open Public Comment on Addressing Potential Hazards and Providing Appropriate Regulatory Oversight

- Would inspection type, frequency, or other oversight activities beyond those associated with existing food products be appropriate?
- What type and frequency of inspection will be appropriate for products that combine cell cultured food products and other ingredients? Would inspection type, frequency, or other oversight activities beyond those associated with existing food products be appropriate?

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BREAK

Public meeting will
resume at 2:30 p.m. ET

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Session 4: Formal Public Comment

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Closing Remarks

Carmen Rottenberg

**Acting Deputy Under Secretary
for Food Safety**

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We welcome written public comments.

Please access the *Federal Register* Notice, on [regulations.gov](https://www.regulations.gov), to add your comment to the public record.

Docket Number: FSIS-2018-0036

<https://www.regulations.gov/docket?D=FSIS-2018-0036>

If you wish to mail your comments, send to: Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250-3700.

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Thank you!

**The meeting will
resume tomorrow
at 8:30 a.m. ET**