



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



USDA/FDA Joint Public Meeting:

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

Tuesday, October 23 - Day 1 Housekeeping and Logistics

- This public meeting is webcast live and open to the press
 - Film crews and print media are present
- Building Amenities and Rules
- Public Comment

USDA/FDA Joint Public Meeting:

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

We welcome written public comments.

Please access the *Federal Register* Notice, on 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.

USDA/FDA Joint Public Meeting:

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

Welcome

Carmen Rottenberg

Acting Deputy Under Secretary
for Food Safety

USDA/FDA Joint Public Meeting:

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

Opening Remarks

Sonny Perdue, D.V.M

Secretary of Agriculture, USDA

USDA/FDA Joint Public Meeting:

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

Opening Remarks

Scott Gottlieb, M.D.

Commissioner, FDA



United States
Department of
Agriculture

Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



Introduction to Cell Culture Technology

David Goldman, M.D.
USDA Chief Medical Officer

Session 1

FDA

U.S. FOOD & DRUG
ADMINISTRATION

CENTER FOR FOOD SAFETY & APPLIED NUTRITION

Overview of Animal Cell Culture Technology for Food Production

**Joint Public Meeting on the Use of Cell Culture Technology
To Develop Products Derived From Livestock and Poultry**

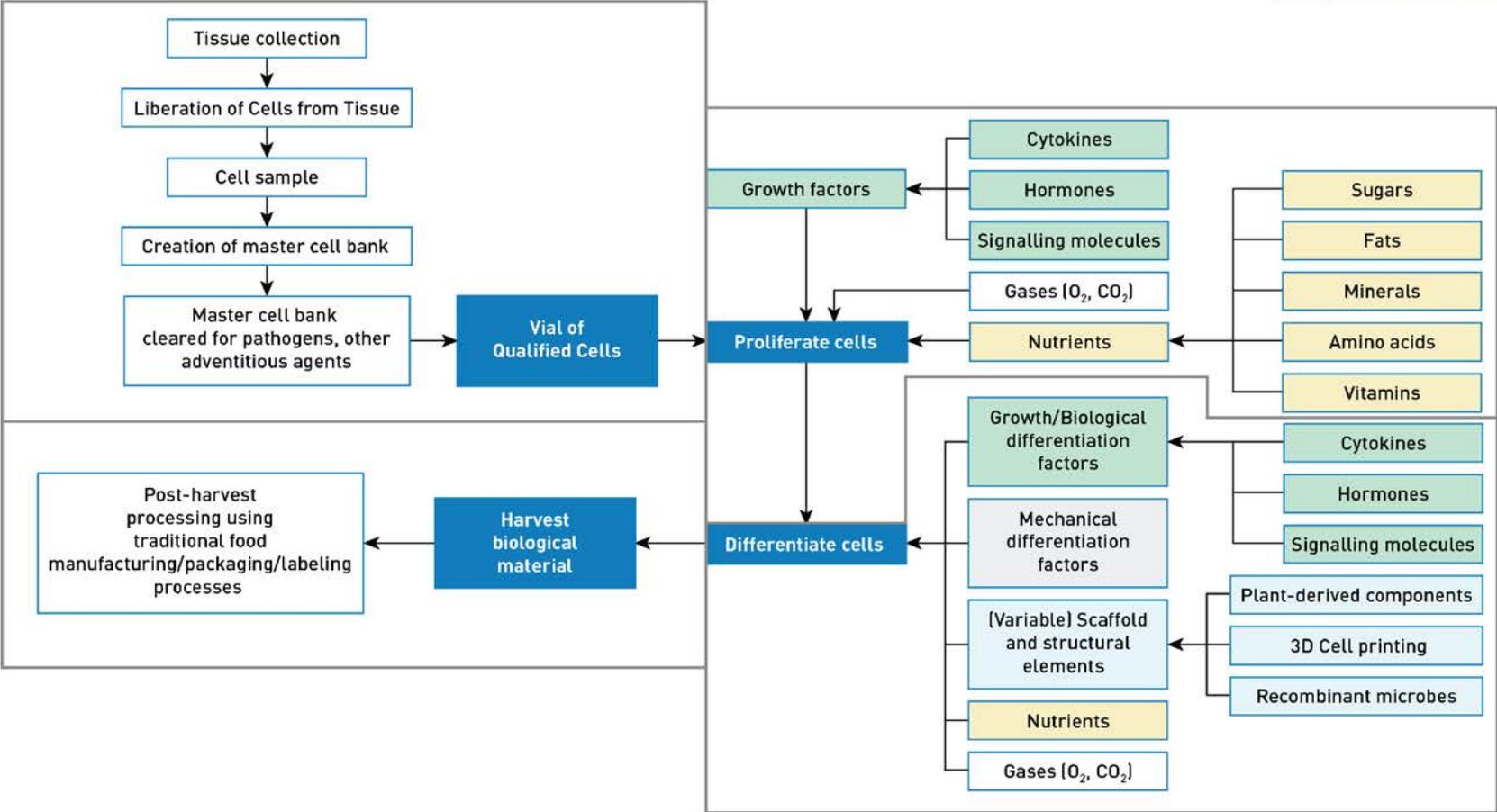
October 23, 2018

Leah Stitz, M.S., C.F.S.,

Public Affairs Specialist, Food and Cosmetic Information Center,
Center for Food Safety and Applied Nutrition (CFSAN), FDA

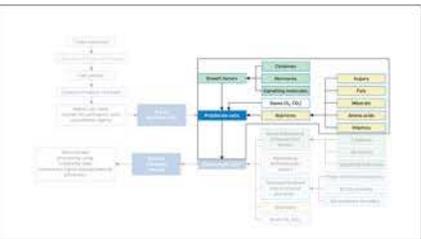
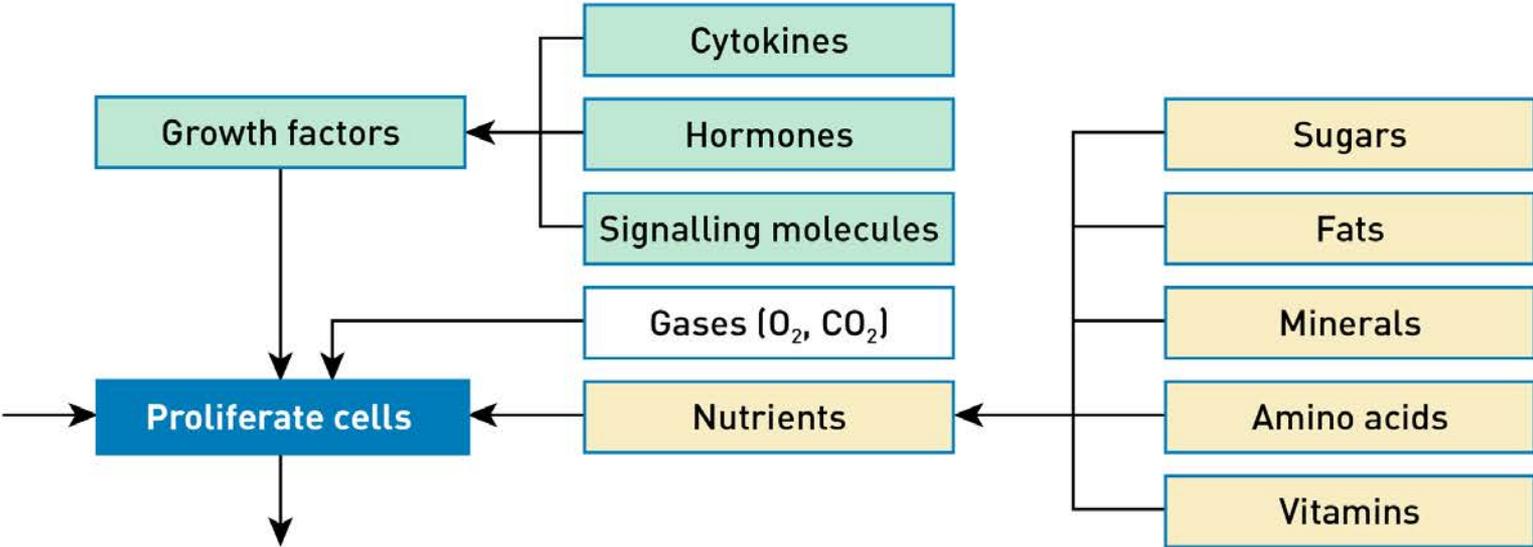
Animal cell culture food technology refers to the controlled growth of animal cells from livestock, poultry, fish, or other animals, their subsequent differentiation into various cell types, and their collection and processing into food.

Overview of Animal Cell Culture Technology



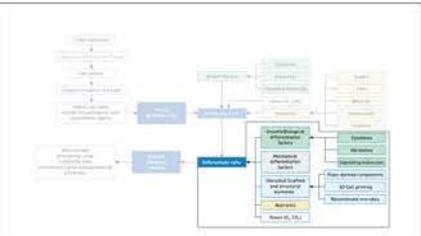
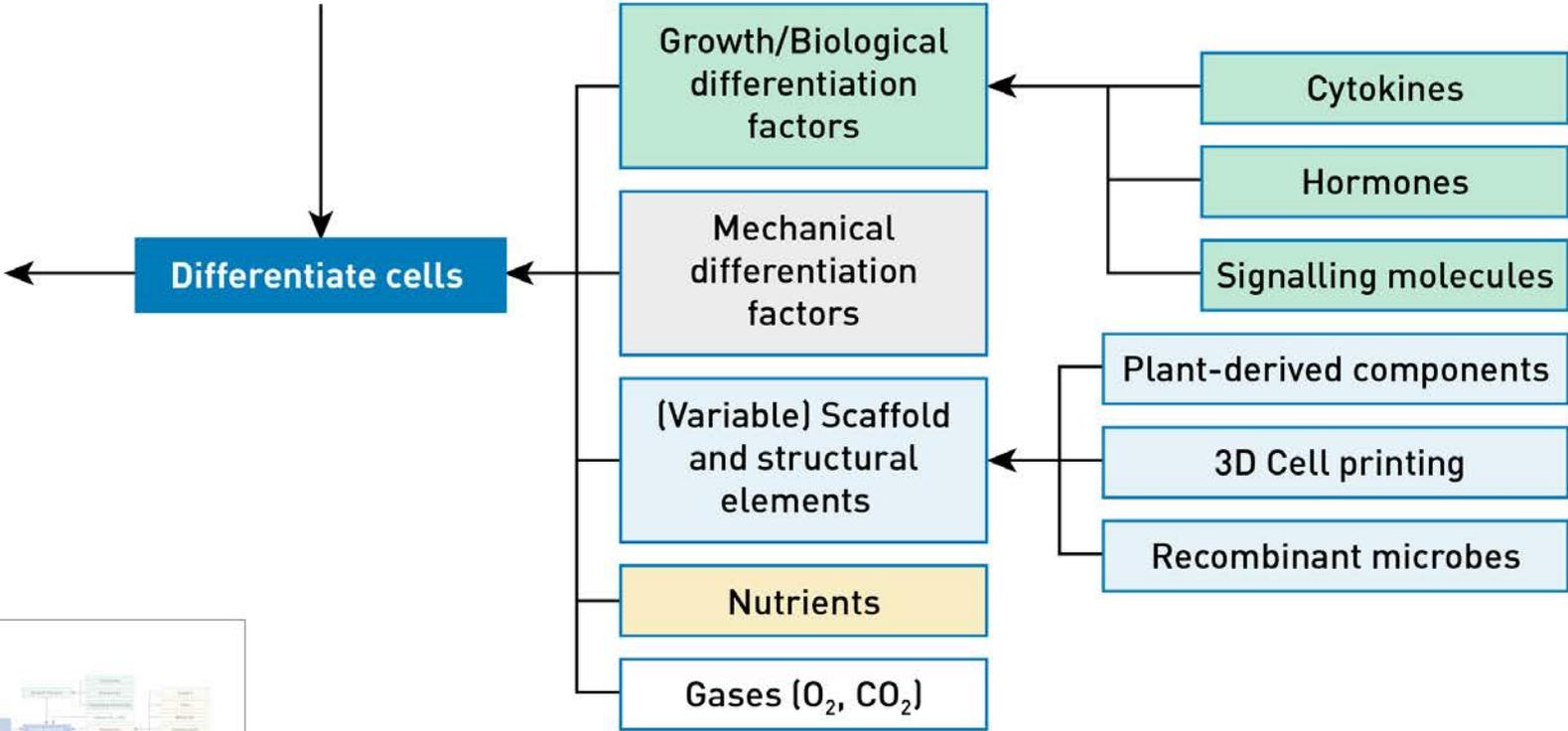
Overview of Animal Cell Culture Technology

Proliferation



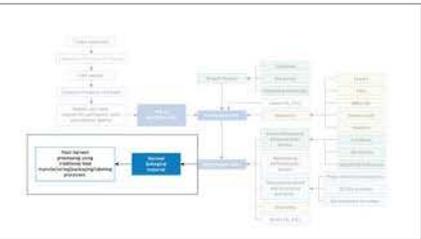
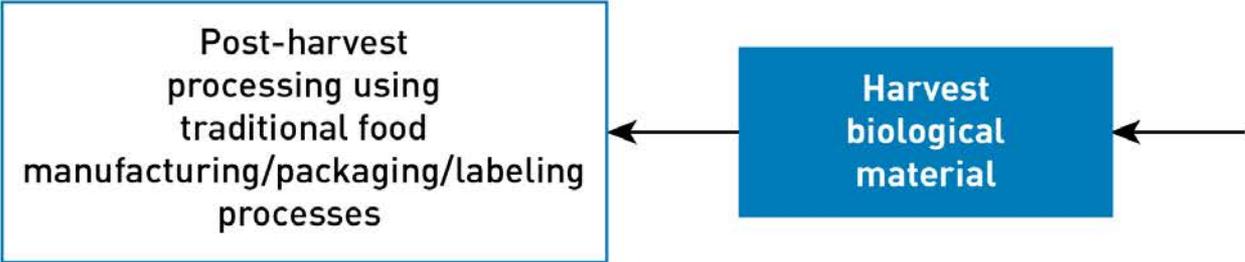
Overview of Animal Cell Culture Technology

Differentiation



Overview of Animal Cell Culture Technology

Harvest



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United States
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Agriculture

Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



Current USDA Regulatory Safety Frameworks for Foods and Products for Cell Culture Technology

Phil Bronstein, Ph.D.

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

Food Safety and Inspection Service

Who We Are



We are the public health agency in the USDA and is responsible for ensuring that meat, poultry, and processed egg products are safe, wholesome, and accurately labeled.

Our Authority

Through a series of Acts, Congress empowers FSIS to inspect all meat, poultry, and processed egg products in interstate commerce.

- Federal Meat Inspection Act (FMIA), 1906
- Agricultural Marketing Act (AMA), 1946
- Poultry Products Inspection Act (PPIA), 1957
- Humane Methods of Slaughter Act (HMSA), 1958
- Egg Products Inspection Act (EPIA), 1970

Food Safety and Inspection Service

What We Do

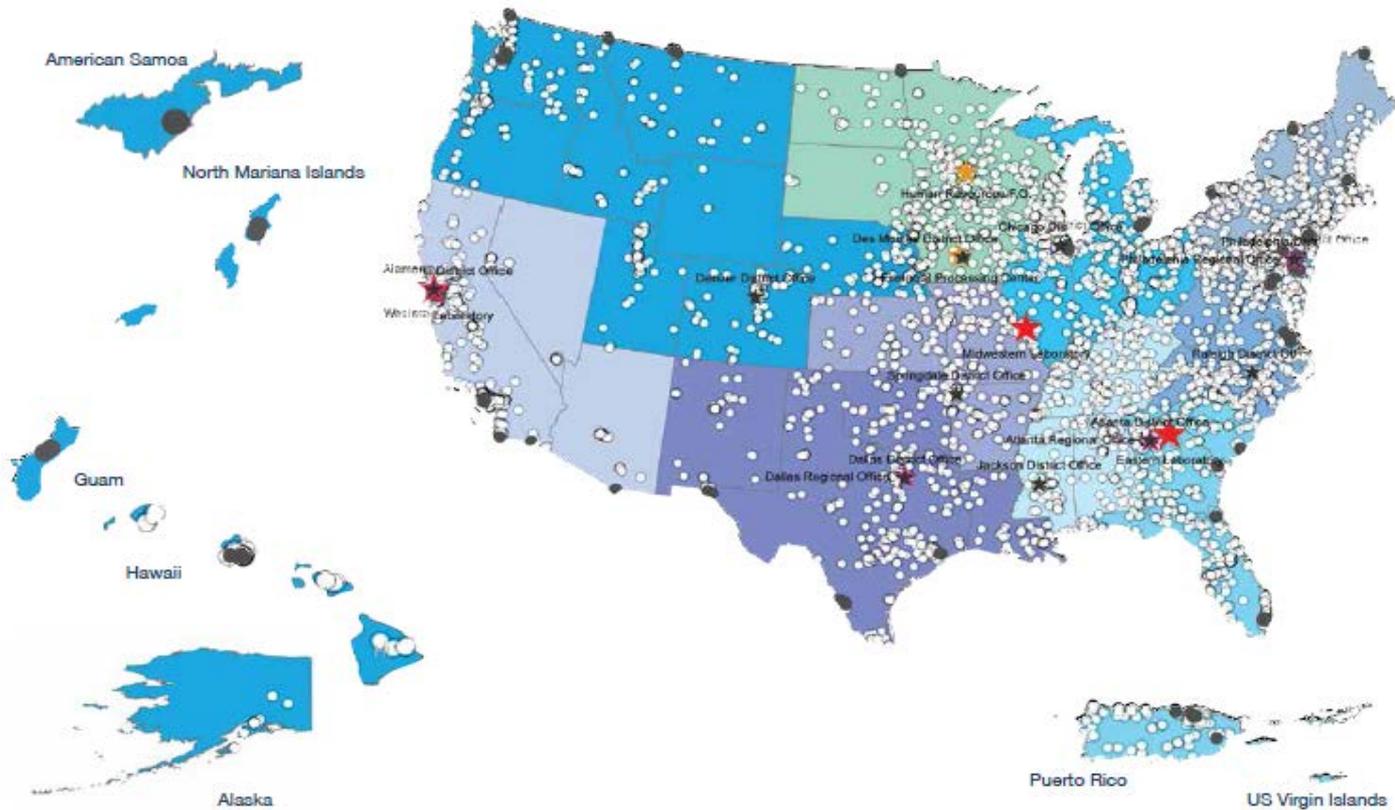
For meat, poultry, and egg products:

- Inspect domestic manufacturing
- Conduct laboratory analyses
- Carry out in commerce surveillance
- Conduct outbreak investigations and manage product recalls
- Determine equivalence of foreign food safety systems
- Re-inspect imported products

Food Safety and Inspection Service

By the Numbers

Where We Work



6,479 Establishments, 133 Import/Inspection houses, and 150,000 In-Commerce Facilities Nationwide

Food Safety and Inspection Service: **Investigation, Surveillance and Enforcement**



Investigation, Enforcement and Audit Employees:

Respond to...

- Foodborne illness outbreaks
- Natural disasters
- Intentional contamination events

Conduct...

- Surveillance
- Investigations
- Enforcement activities

Food Safety and Inspection Service

Inspection

- Continuous inspection of slaughter
 - 100% of livestock ante- and post-mortem
 - 100% of poultry post-mortem
- Inspection of meat and poultry processing every shift
- Continuous inspection of egg products processing
- 100% Reinspection of Imported Products

Antemortem Inspection



- Animal Health Inspection
- Humane Handling Inspection

[.6 | 10
Head of
eat Poultry]



Postmortem Inspection



100
Carcass y Carcass
Inspection

1 | 10
Food Safety
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- Slaughter HACCP
- Livestock Zero Tolerance Verification
- Poultry Zero Tolerance Verification
- Poultry Good Commercial Practices
- NPIS Zero Tolerance Food Safety Verification

Food Safety and Inspection Service

Inspection Force

- **Food Inspectors (~2,400) verify:**
 - Product handling, general sanitation
 - Antemortem and postmortem inspection
- **Consumer Safety Inspectors (~3,800) verify establishment programs:**
 - Sanitation Performance Standards
 - Sanitation Standard Operating Procedures
 - Hazard Analysis and Critical Control Point

- **Public Health Veterinarians (~750):**
 - Disposition of animals
 - Analyses of facilities and equipment
- **Enforcement Investigation and Analysis Officers (~130) conduct:**
 - Comprehensive food safety assessments
 - Other consumer protection activities

Food Safety and Inspection Service

Inspection In Depth



FSIS Inspection Employees:

- Coordinate inspection and enforcement activities
- Ensure the products that FSIS regulates are safe, wholesome, and properly labeled
- Perform in-depth evaluations and analyses of establishment HACCP systems and sanitation
- Gather data to inform our understanding of the risks in the food system

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



Food Safety and Inspection Service

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



Food Safety and Inspection Service

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



Food Safety and Inspection Service
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)

Food Safety and Inspection Service: **Siluriformes Inspection**

Inspection Timeline

2008 & 2014

U.S. Farm Bill

Dec. 2015

Final rule for Siluriformes fish inspection published

2015-2016

Domestic, import, and international educational meetings

March 2016

18-month transitional period begins

Sep. 2017

Transitional period ends

March 2018

Vietnam, China, and Thailand meet documentation requirements

May 2018

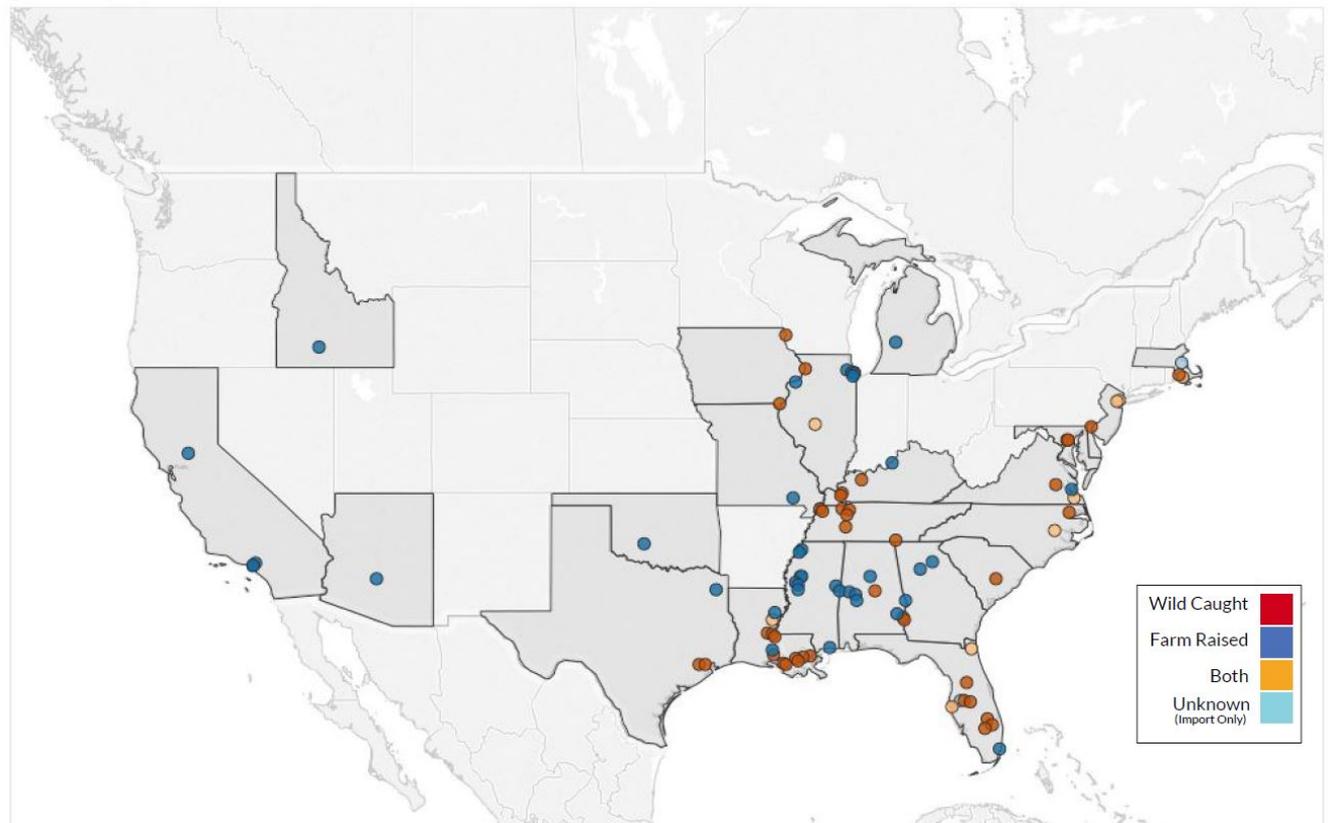
In-country equivalence audits begin

Sep. 2018

Proposed Rules on Equivalence published



Federally Inspected Siluriformes Establishments



Food Safety and Inspection Service: Imports and Equivalence



Countries

1

Import
Houses

F 1

.1

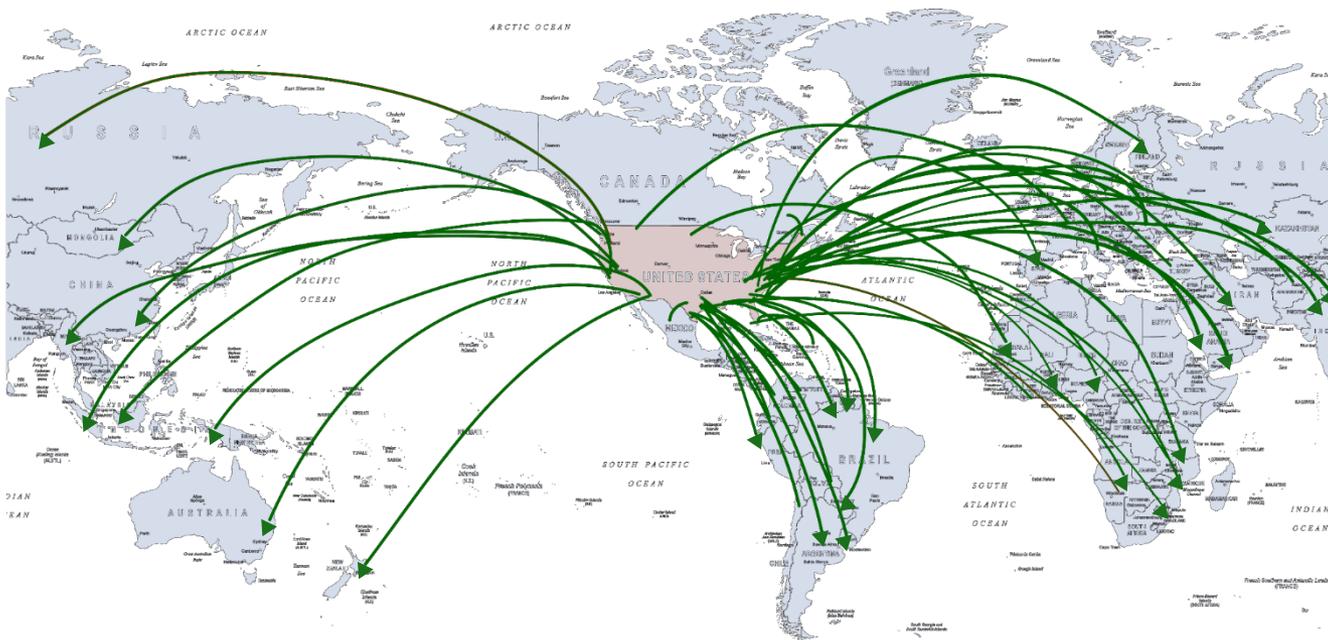
1 IO
Total Pounds

F 1

Food Safety and Inspection Service: **Equivalence**

- Document Review
- On-site Audits
- Port-of-Entry Re-inspection

Food Safety and Inspection Service: Export Certification



15 | 10
Pounds

Food Safety and Inspection Service Processing Inspection

6,
total
Establishments



,28
Processing Only
Establishments



Food Safety and Inspection Service

Processing Inspection: Complex Systems



- Canning
- Irradiation
- High Pressure Processing
- Fermenting
- Enzyme Assisted Processing
- Advanced Meat Recovery



Food Safety and Inspection Service

New Technology Review



Multidisciplinary Approach

Microbiologists, toxicologist, chemists, biologist, meat scientists, food technologists, laboratory scientists, pathologists, epidemiologists, economists, statisticians.

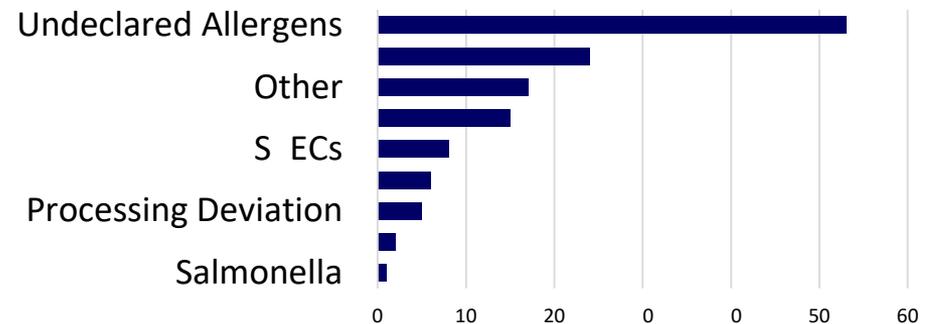
Evaluate to determine:

1. Affects product safety;
2. Violates FSIS regulations;
3. Interferes with inspection procedures;
4. Jeopardizes the safety of inspection program personnel; or
5. Is deemed **suitable** for use in meat, poultry or egg products

Food Safety and Inspection Service: Recall Process

A recall is a firm's voluntary removal of product from commerce when there is reason to believe those products are adulterated or misbranded under the provisions of the FMIA, PPIA or EPIA.

Recall Details



Current FDA Regulatory Safety Frameworks for Foods and Products of Cell Culture Technology

October 23, 2018

Bill Jones, FDA

FOOD AND FOOD SAFETY

What is Food?

Federal Food, Drug, and Cosmetic Act (FFDCA)
Sec. 201(f) defines the term “Food” to mean

- 1) Articles used for food or drink for man or other animals
- 2) Chewing gum
- 3) Articles used for components of any such article

Food must be safe and not adulterated

FFDCA Sec. 402 (a) considers a food is adulterated (1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health. But in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health

Food must be safe and not adulterated

FFDCA Sec. 402 considers a food is adulterated

(2)(C) if it bears or contains (i) any food additive that is unsafe within the meaning of section 409

(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health

FDA Food Safety Modernization Act

- Focus on prevention and risk-based safety standards
- New enforcement authorities
- Important new tools to hold imported foods to the same standards as domestic foods

Hazard Analysis and Risk-Based Controls

- A key component of FSMA amends FFDCA with Sec. 418 “Hazard Analysis and Risk-Based Preventive Controls”
- Implementing regulation - 21 CFR part 117
“Current Good Manufacturing Practice, Hazard Analysis, and Risk Based Preventive Controls for Human Food.”
 - Updates cGMP
 - Requires food safety plan for facilities that manufacture, process, pack or hold human food (unless an exemption applies)

Required Food Safety Plan

- Hazard analysis
 - Known or reasonably foreseeable
 - Biological, chemical, physical hazards
- Preventive controls
 - Process, allergen, sanitation, other as needed
- Oversight and management of controls
 - Monitoring, correction, corrective action, verification
- Supply chain program
 - If needed based on hazard analysis
- Recall plan

When Evaluating A New Production Process for a Food

- Hazards identified by the food safety plan?
- Appropriate and adequate controls?
- Are all ingredient uses safe and lawful?

Jeremiah Fasano, FDA

FOOD INGREDIENTS

What Is A Food Ingredient?

Any substance the intended use of which

results or may reasonably be expected to result

in its becoming a component

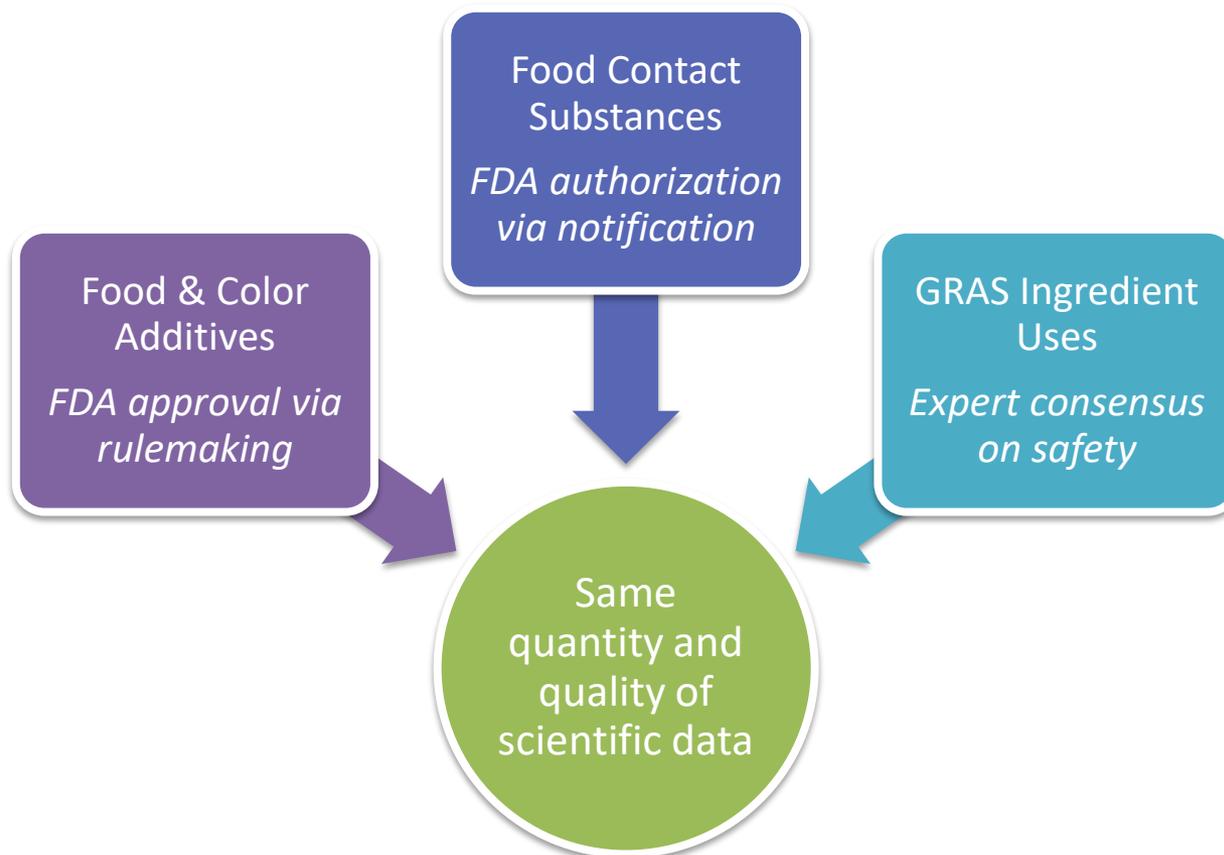
or otherwise affecting the characteristic of any food

including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food

Reasonable Certainty of No Harm



Practical Implementation



All ingredients must be lawful for their intended use

Assessing the Effects of Significant Manufacturing Process Changes

Process considered only insofar as it affects properties or safety of food



Important to understand potential impacts on properties relevant for safety



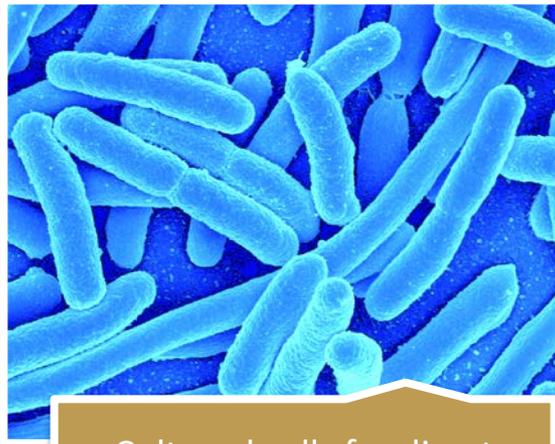
Information needed to establish safety may change if process changes

Guidance issued in 2014: 79 FR 36533

Examples from Past Experience



Substances produced by cultured cells



Cultured cells for direct consumption

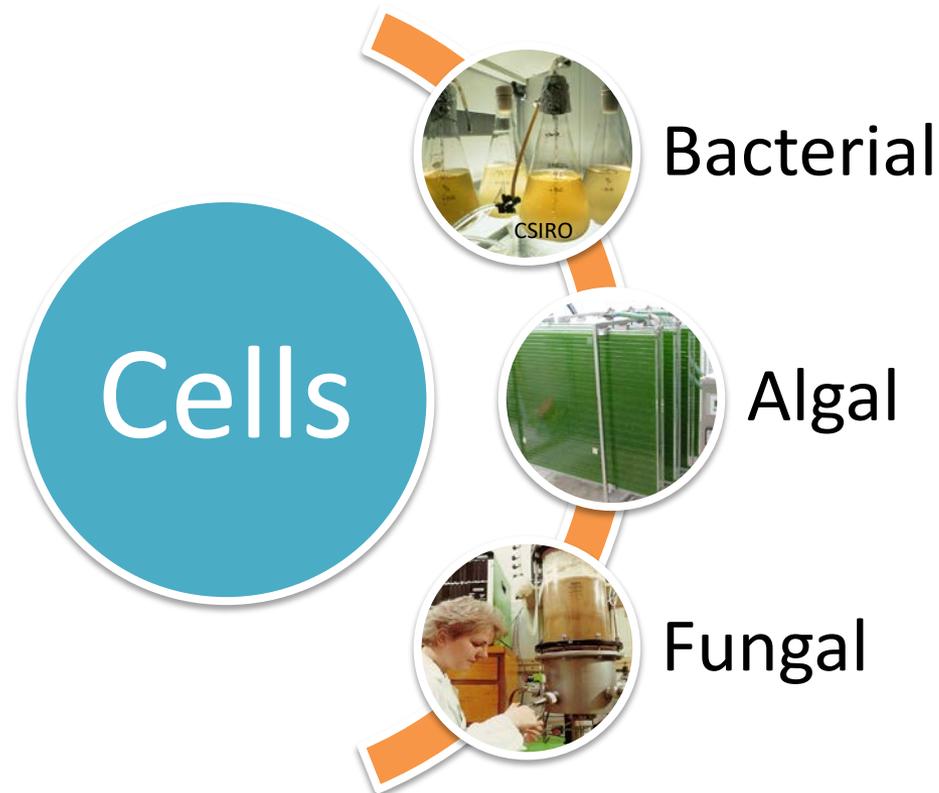


New plant varieties produced by modern biotechnology

Substances Produced by Cultured Cells



Cultured Cells Evaluated as Direct Food Ingredients



New Plant Varieties Produced Using Modern Biotechnology

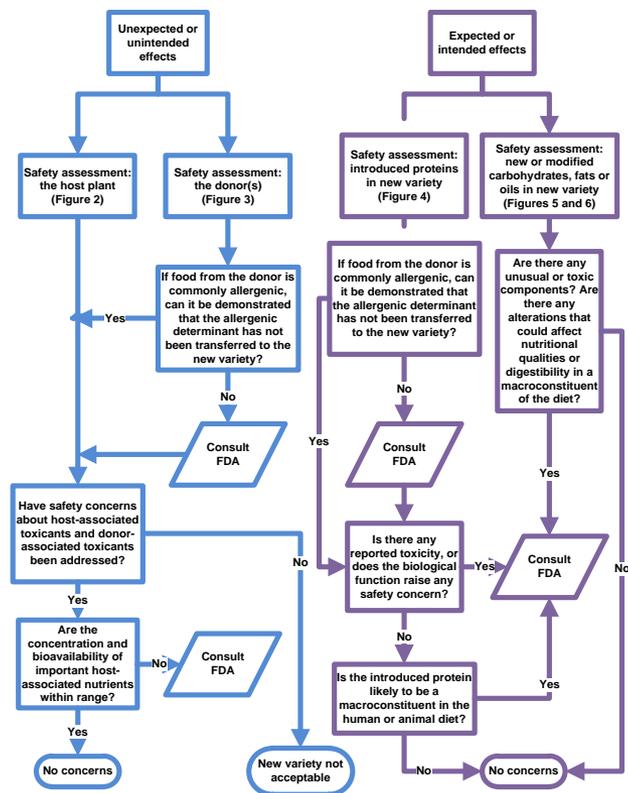


Figure 1. Safety Assessment of New Varieties: Summary

Observations from Past Experience

- Biological production systems are complex
- Questions about consistency and control of outcomes often arise during the safety evaluation
- These questions can be successfully addressed during the safety evaluation process prior to market entry

When Evaluating a New Food Ingredient Production Process

Properties of substance

Relationship to process

Introduced constituents

Relevance for safety

Doug Stearn, FDA

FDA TOOLS AND CAPABILITIES

Regulatory Tools

- Prevention
- Inspection and compliance
- Advisory Actions
- Enforcement

Responsibilities and Authorities

- >88,000 FDA-registered domestic food facilities (plus >200,000 foreign food facilities)
- FSMA established a new approach to ensuring a safe food supply
 - Risk-Based Surveillance Modeling
 - High Risk / Non-High Risk Inspection Frequency
 - Product Sampling
 - Impact of Preventive Controls for Human Food (PCHF) Rule

Responsibilities and Authorities

- Inspections only one mechanism for ensuring food safety. Other tools:
 - foreign supplier verification programs
 - systems recognition/regulatory cooperation with other trusted international partners
 - third party auditing programs
 - border surveillance and screening
- Mandatory reporting; FDA authority to require food recalls

Key Areas of Preventive Controls

- Preventive Controls
 - Sanitation Control Program
 - Avoiding cross contamination, equipment cleaning and sanitation, environmental monitoring program
 - Allergen Control Program
 - Cleaning and sanitizing equipment, cross contact, labeling controls
 - Process Controls
 - Cooking, pH, formulation, refrigeration
 - Supply-Chain Program
 - Supplier approval, receipt of incoming ingredients and raw materials, verification activities
- Food Safety Plan
- Modernized GMPs

The Shift to Systems-Based Oversight

- Benefits and Limits of Inspection and Testing
- The Movement Toward Quality Systems
- FDA Experience
 - Medical Products Regulation and FSMA
 - Special Concerns Related to Product Innovation
 - Constructing Systems-Based Inspections and Oversight

Laboratories

- FDA operates 13 field laboratories in U.S. and P.R., eight of which are Human and Animal Food Laboratories.
- All field labs are ISO 17025 accredited
- Examples of testing and analysis include:
 - detection of food borne pathogens
 - veterinary drug residues
 - pesticides
 - nutritional composition
 - environmental contaminants

Import Safety

- Food from abroad must be as safe as domestic
- Importers responsible for ensuring that their foreign suppliers have adequate preventive controls in place
- FDA does some foreign inspections
- FDA can also consider third party certification that foreign food facilities meet U.S. requirements
 - Can require mandatory certification for high-risk foods
 - Voluntary qualified importer program--expedited review
 - Can deny entry if FDA access for inspection is denied

Regulatory Tools

- ✓ Prevention
- ✓ Inspection and compliance
 - Advisory Actions
 - Enforcement



USDA/FDA Joint Public Meeting:

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

BREAK

Public meeting will
resume at 10:20 a.m. ET



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USDA/FDA Joint Public Meeting

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





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Session 2

Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



Overview of Potential Hazards Associated with Traditional Meat and Poultry Products

*Emilio Esteban, D.V.M., M.B.A.,
M.P.V.M., Ph.D.*

*Chief Scientist, Office of Public Health Science,
FSIS, USDA*

Food Safety and Inspection Service:

Key points to regarding hazards

- Continuous on-site inspection
- Science-led decision making
 - Three labs with one system that produces results in real-time for field decisions
- Flexible to add new targets and new commodities (micro, chem, physical)
- Full transparency from expectations, to enforcement to data sharing
- Ongoing monitoring programs and outbreak/emergency response

Food Safety and Inspection Service: Foodborne Illness Prevention



Perform food safety inspection at more than 6,000 establishments nationwide



Maximize domestic and international compliance with food safety policies



Public education and outreach to increase safe food-handling practices



Collaborate with internal and external stakeholders

How FSIS prevents foodborne illness

Food Safety and Inspection Service: Office of Public Health Science



FSIS evaluates
approximately
100,000
Food samples
every year.

- Three laboratories:
 - Athens, Georgia – EL
 - St. Louis, Missouri – MWL
 - Albany, California – WL
- Assist in investigating national and international outbreaks
- Monitor current and emerging foodborne threats
- Advise leadership on matters of science to improve policies and program



Food Safety and Inspection Service: **FSIS Laboratories**



- **FSIS Office of Public Health and Science (OPHS) has three field service labs that collect isolates from routine monitoring and follow-up testing:**
 - ★ **Athens, Georgia – EL**
 - ★ **St. Louis, Missouri – MWL**
 - ★ **Albany, California – WL**
- **FSIS also has a laboratory division (Microbiology Characterization Branch, MCB) that performs isolate characterization and is involved in characterizing strains linked to outbreak investigations**

Food Safety and Inspection Service: Hazards and How FSIS Addresses Them

- Microbiological
- Chemical
- Physical
- Emerging Issues
- Allergens
- Identity



Food Safety and Inspection Service: Science-Based Decisions: Data

- Sampling Data
 - 80,000 microbiological samples each year
- FSIS Inspection Data
 - Daily information about all slaughter and processing facilities

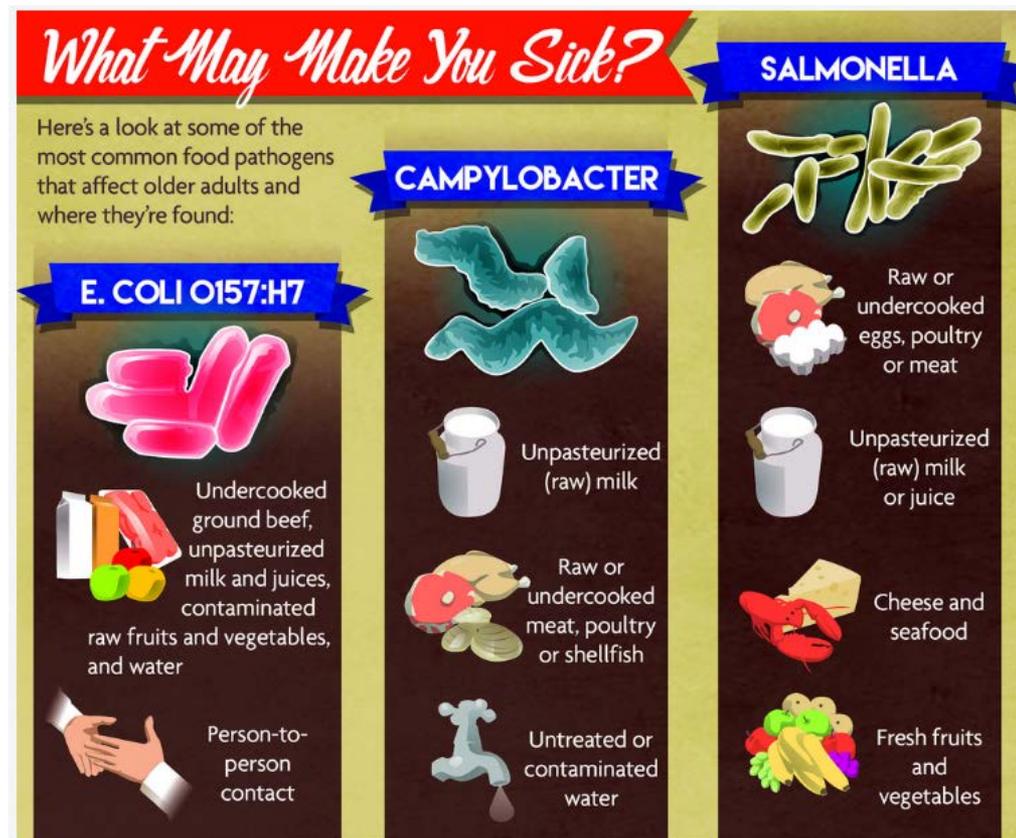


- Identification followed by characterization
 - Serotype
 - Antimicrobial Resistance
 - Whole Genome Sequencing

Food Safety and Inspection Service:

FY 2017 Microbiological Sampling

- >143,000 microbiological tests in 2017
- Raw and cooked beef, pork, poultry, egg, and Siluriformes fish
- 4 key bacterial foodborne pathogens:
 - *E. coli*
 - O157:H7 and non-O157
 - *Campylobacter*
 - *Salmonella*
 - *Listeria monocytogenes*



Food Safety and Inspection Service:

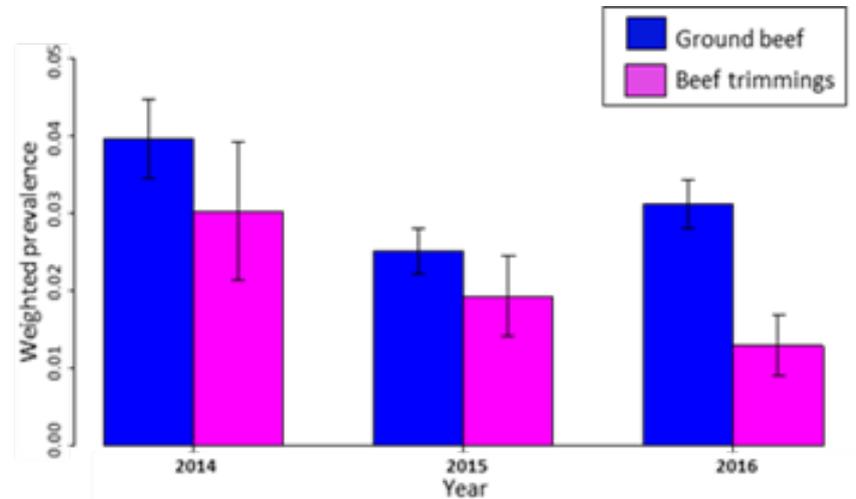
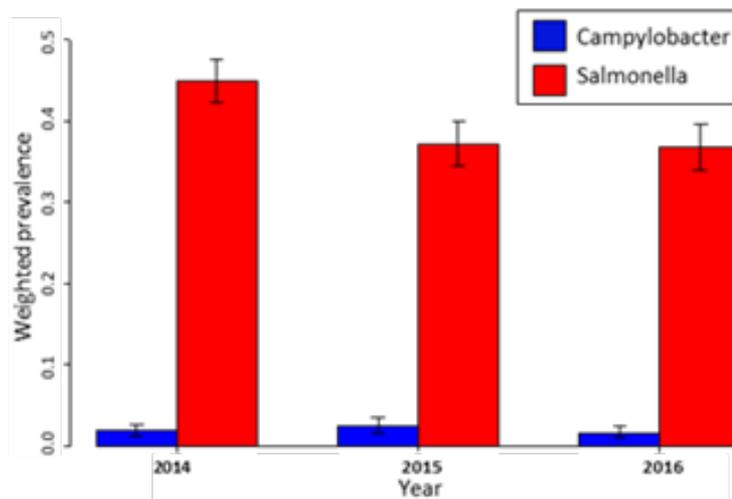
Listeria monocytogenes in Ready-to-Eat Products

- Environmental bacteria can contaminate food after lethality treatments
 - Deli meat is a key concern
- FSIS sampling and every-shift inspection presence in RTE production fight against *Listeria monocytogenes*



Food Safety and Inspection Service: Microbiological Test Results Identify Trends

- Early identification of changing prevalence
- Downward trend recently observed in comminuted chicken (left) and raw ground beef and beef trim (Salmonella results, right)



Food Safety and Inspection Service:

Veterinary Drugs

- FDA approves drugs and sets tolerances, withdrawal times
- FSIS methods test for residues of over 90 drugs in muscle, kidney, and liver; violations reported publicly on website and to FDA if investigation warranted
 - Antibiotics including antibacterial, antifungal, anti-helminthic
 - Synthetic hormones
 - Beta-agonists
 - Anti-inflammatory and tranquilizer drugs

Food Safety and Inspection Service: Pesticides

- EPA registers pesticides and sets tolerances (legal limits), FSIS tests for residues and reports violations
- FSIS methods can detect 108 pesticides and metabolites including DDT, chlorpyrifos
- Review and update method as needed

The screenshot shows the EPA website page for "Regulation of Pesticide Residues on Food". The page features a blue header with the EPA logo and navigation links for "Environmental Topics", "Laws & Regulations", and "About EPA". A search bar is located in the top right corner. Below the header, the main title "Regulation of Pesticide Residues on Food" is displayed in a large, bold font. A sub-header explains that tolerances are the maximum amount of a pesticide allowed to remain in or on a food. The page is organized into four main sections: "About Tolerances" with a green highlighter icon, "Finding Tolerances" with a hand-drawn diagram of a path, "Setting and Revoking Tolerances" with an image of fresh produce, and "Tolerance Tools" with an image of a computer mouse and keyboard. A "Related Information" sidebar on the right lists links for "Pesticide registration", "Dietary risk assessment", and "Find more pesticide information".

Food Safety and Inspection Service: Pathology

-
- Identify and remove sick animals
 - Food safety conditions
 - Central Nervous System (antemortem)
 - Septicemia/Toxemia
 - Non-food safety conditions
 - Arthritis
 - Pneumonia
 - Process deviations resulting in foreign material in product



Food Safety and Inspection Service: Wholesomeness and other testing

- Speciation
- Water content
- Food Chemistry
 - Protein
 - Sodium
 - Fat
- Allergens



Food Safety and Inspection Service: Special Focus

- Cell culture methods commonly incorporate antibiotics and cell growth modulators
- Potential contaminants in cell culture such as *Mycoplasma* spp.
- Undifferentiated cell lines resemble cancer and could cause disease in immune suppressed people



Food Safety and Inspection Service: Our Partnerships Make Us Stronger



To ensure the safety along
the farm-to table continuum,
FSIS collaborates with:

- Federal agencies
- States
- Tribal authorities
- Stakeholders



The public health community is more powerful
when it speaks with a single voice and shares
resources in service of a common mission.

Overview of Potential Cell Culture Technology Hazards Including Summary of Hazards Discussed at the FDA Science Board Meeting

Jeremiah Fasano, *Ph.D.*

*Consumer Safety Officer, Division of Biotechnology and
GRAS Notice Review, Office of Food Additive Safety,
CFSAN, FDA*

Issues to Consider

- Adventitious agents in source materials and in culture
- Added substances: Culture media and structural materials
- Properties of cultured cells

Adventitious Agents in Source Materials

- Could adventitious agents be plausibly introduced into culture from seed cells or culture materials that might pose risks to human health from a finished food product? If so, what are they, and what tools would be most effective at managing these risks?

Adventitious Agents in Culture

- What does previous cell culture experience tell us about the potential for contamination during the culture process, scaling effects, and likelihood of risks to human health from a finished food product?

Added Substances in Culture Media

- What kinds of substances used in cell culture media would be present in meaningful amounts in the finished food product, and are ordinary food ingredient evaluation procedures sufficient to ensure safety?

Added Structural Materials

- What kinds of structural materials might be used to culture tissues, e.g. scaffolding, and are there any that could not be addressed by ordinary food ingredient safety assessment?

Cellular Properties: Safety

- How likely is it that cultured animal cells could produce harmful substances as a result of errors in the culture process?

Cellular Properties: Nutrition

- What are the characteristic nutritional properties of foods produced by traditional techniques from animals such as cattle, swine, poultry, and fish; and what departures from these characteristics would be expected in food products of animal cell culture technology derived from their respective sources? Are these departures material with regard to nutritional or non-nutritional considerations?





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USDA/FDA Joint Public Meeting

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Session 2: Open Public Comment on Potential Hazards

- What hazards are the same between traditional meat and poultry products and products of cell culture technology, and which hazards are different?
- What are the most significant sources of potential hazards?
- Are there hazards that have not been raised, or are there aspects of the hazards that have not been discussed?

USDA/FDA Joint Public Meeting:

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

LUNCH

Public meeting will
resume at 1:05 p.m. ET