



United States
Department of
Agriculture



Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



Existing Regulations and the Food Safety and Inspection Service

February 22, 2019

Carmen M. Rottenberg
FSIS Administrator

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: **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

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

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: **Processing Inspection**

6,479
Total
Establishments



4,287
Processing-Only
Establishments



Food Safety and Inspection Service: **Processing Inspection: Complex Systems**



- Canning
- Irradiation
- High Pressure Processing
- Fermenting
- Enzyme-Based Processing
- Advance Meat Recovery



Food Safety and Inspection Service: **FSIS and FDA Collaboration**

- FSIS and FDA have a MOU regarding new food ingredients to be used in FSIS-regulated products.
- FDA determines the safety of new food ingredients.
- FSIS determines the suitability of the use of new food ingredients in regulated establishments by considering:
 - Effectiveness of ingredient or substance to have the appropriate intended use requested by the establishment.
 - Conditions of use in the establishment do not lead to adulterated product or mislead consumers.
 - Wholesomeness of product is not affected.

Food Safety and Inspection Service: **New Technology**

- ❑ Federal Register notice *FSIS Procedures for Notification of New Technology* (68 FR 6873)
 - New technology defined as: New, or new applications of, equipment, substances, methods, processes, or procedures affecting the slaughter of livestock and poultry or processing of meat, poultry, or egg products.
 - announced new procedures for submitting notifications of new technologies intended for use in official establishments and plants.
- ❑ FSIS Compliance Guidance: Procedures for New Technology Notifications and Protocols outlines procedures for submitting New Technology request

Food Safety and Inspection Service: New Technology: Overview of Submissions

Intended Use

- Describe the intended use

Method of Use

- Include method of use (e.g. spray cabinet, dip)
- Include operational parameters (e.g. concentration, temperature, pH, contact time, dwell time)

Regulations

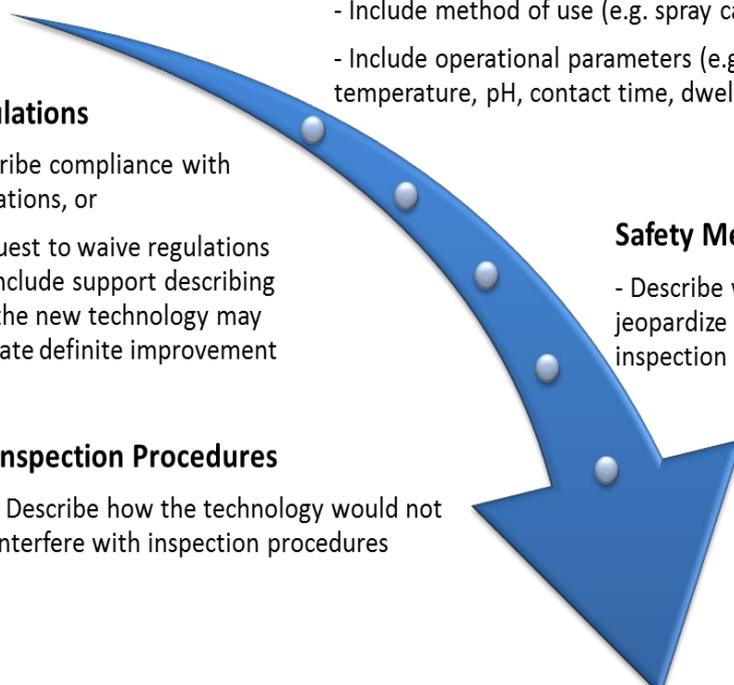
- Describe compliance with regulations, or
- Request to waive regulations and include support describing how the new technology may facilitate definite improvement

Safety Measures

- Describe why the technology will not jeopardize food safety and the safety of inspection personnel

Inspection Procedures

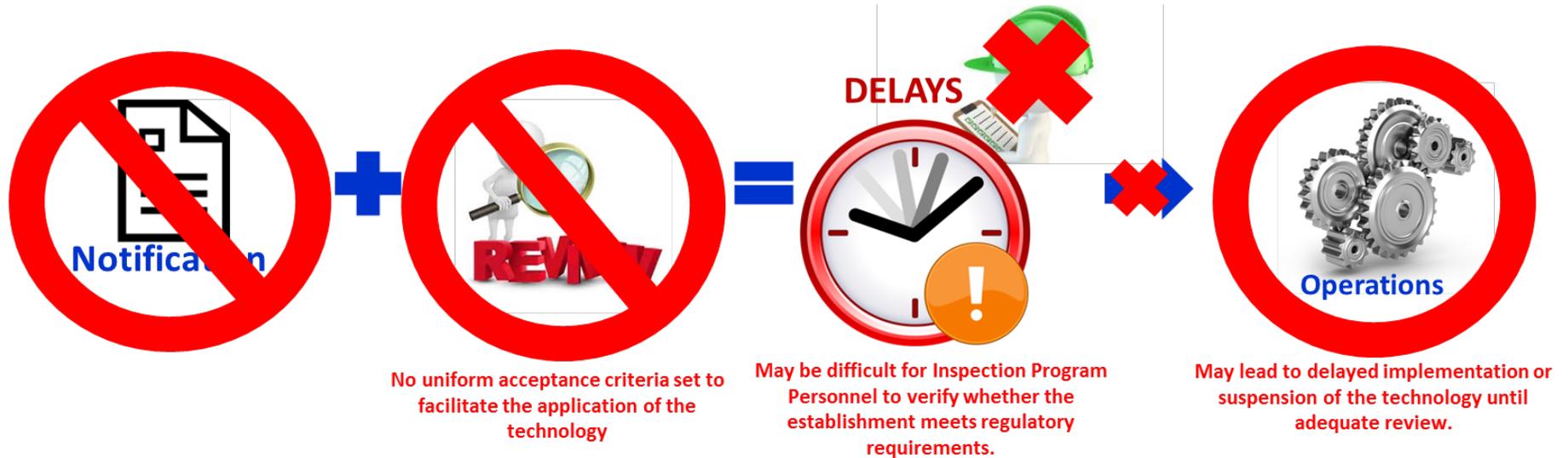
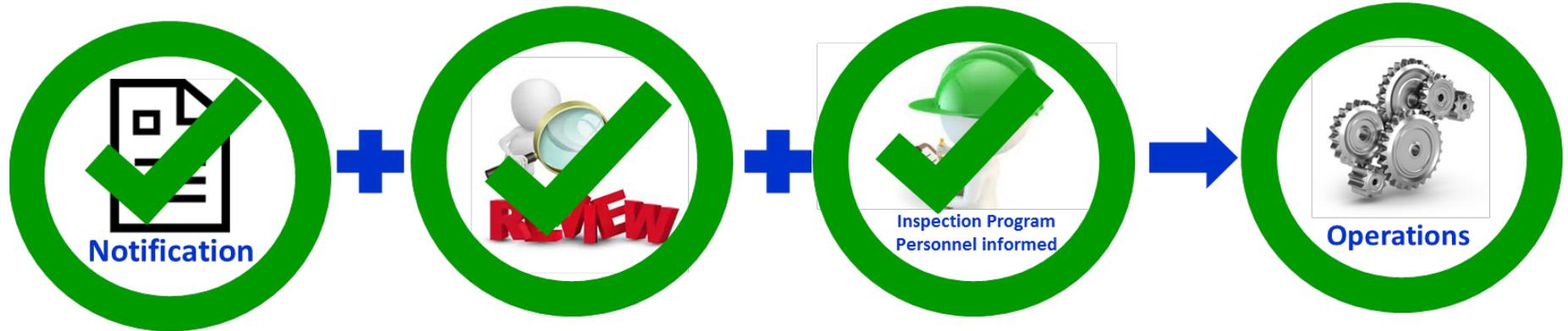
- Describe how the technology would not interfere with inspection procedures



United States Department of Agriculture
Food Safety and Inspection Service
Risk, Innovations, and Management Staff
Patriots Plaza III, Mail Stop 3782
1400 Independence Ave., SW
Washington, DC 20250
Fax: 301-245-4703
<http://askfsis.custhelp.com>

Food Safety and Inspection Service:

New Technology: Why is submitting to FSIS important?



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: **Review Outcomes**

Letter of No Objection

FSIS does not object to the use of the technology.

Letter of Permission

The letter granting permission to conduct in-plant trials at official establishments.

Waiver Letter

Letter waiving provisions of the regulations to conduct in-plant trials.

Withdrawal

A submission is withdrawn at the request of the Submitter.

Temporary Suspension

A submission is put on a temporary hold permitting the submitter time to gather additional scientific support (e.g. time to conduct experiments in a lab or test facility).

Food Safety and Inspection Service:

USDA's Labeling Requirements

- USDA has established requirements for the content and design of labels [9 CFR Part 317 (meat), 9 CFR 381 Subpart N and Y (poultry)]
- Requirements are based on the statutory mandate to assure that labels are truthful, accurate, and not misleading, and that products are not misbranded
- Required labeling features in regulations are linked to misbranding provisions of Acts
- FSIS label pre-approval required per 21 USC 607(d) [meat] and 21 USC 457(c) [poultry]; FDA does not pre-approve labels

Food Safety and Inspection Service:

Prior Label Approval

- Certain types of labeling require submission for evaluation by LPDS (9 CFR 412.1)
 - labels for temporary approval
 - labels for products produced under religious exemption
 - labels for products for export with labeling deviations
 - labels with special statements and claims

- FSIS requires the submission of such labels because they are more likely to present significant policy issues that have health or economic significance

Food Safety and Inspection Service: **Preparing for the Future**

- FSIS is prepared for future inspection and enforcement:
 - Science-based approaches
 - Evaluating and adapting to new technologies
- Prepared and well-positioned to regulate animal cell tissue harvesting, production, and labeling
- Protect the food supply regardless of the method of production

Food Safety and Inspection Service: **Appendix: FDA/FSIS MOU**

❑ [MOU Number 225-00-2000](#)

- This is a collaborative FSIS-FDA memorandum of understanding (MOU) regarding food ingredients intended for use in FSIS-regulated products, i.e., in the production of meat, poultry, and egg products at FSIS-regulated establishments.
- For GRAS and FCN submissions
 - The Federal Food, Drug, and Cosmetic Act provides FDA with the authority to determine the safety, wholesomeness, and accurate labeling of food
 - FSIS determines the suitability of the use of food ingredients used in the production of meat, poultry, and egg products in accordance with applicable FSIS laws, regulations, and policies.

Food Safety and Inspection Service: **Appendix: Web Resources**

- ❑ FSIS Compliance Guideline Procedures for New Technology Notifications and Protocols
<https://www.fsis.usda.gov/wps/wcm/connect/c64d8f3b-56aa-49c9-91f3-daf0caaba6bd/New-Technology-Protocols-042015.pdf?MOD=AJPERES>
- ❑ FSIS Directive 7120.1. :This directive provides an up-to-date list of substances that may be used in the production of meat, poultry, and egg products.
- ❑ FSIS regulation 9 CFR 424.21(c) provides a list of food ingredients that are approved for use in the production of meat, poultry and egg products
- ❑ FDA's Ingredients, Packaging & Labeling Webpage
<https://www.fda.gov/Food/IngredientsPackagingLabeling/default.htm>