



Food Safety and Inspection Service
U.S. DEPARTMENT OF AGRICULTURE



FSIS Statutes and the EIAO

Where Does FSIS Get Its Authority?

Federal Meat Inspection Act
(FMIA)(21 U.S.C. 601 et seq.)

Poultry Products Inspection Act
(PPIA)(21 U.S.C. 451 et seq.)

Egg Products Inspection Act
(EPIA)(21 U.S.C. 1031 et seq.)

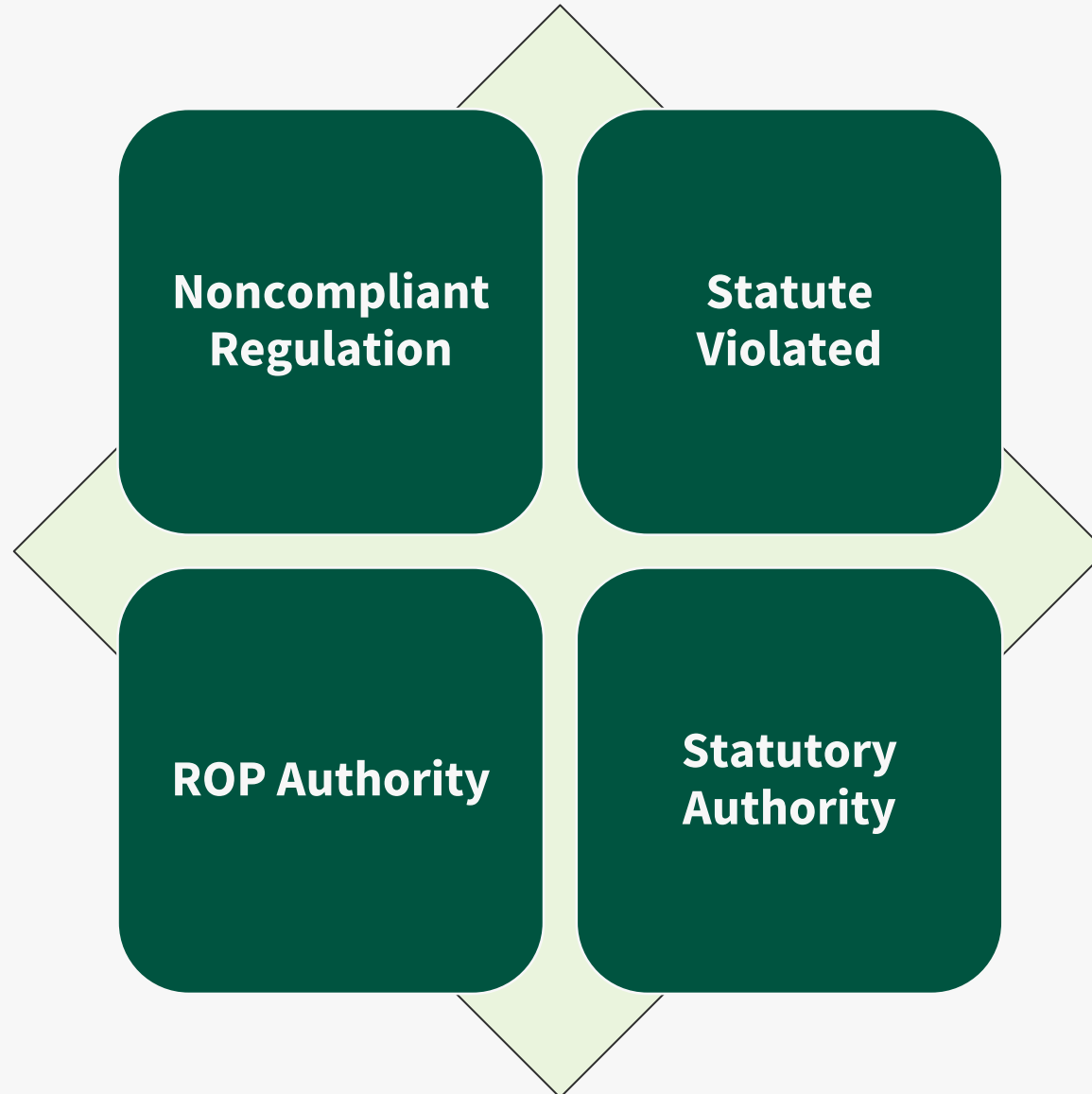
The Acts and Public Health– FSIS Mission

FMIA Sec. 602.- It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged

Key Terms

- **Wholesome** - Conducive to or suggestive of good health and physical well-being
- **Adulterated** - In general, to render (something, in this case meat/poultry/eggs) poorer in quality by adding another substance, typically an inferior one or even filth/poison
- **Properly marked, labeled, and packaged** - That the product is marked/labeled with the true name/identity (it is what it is in the package) and that it is packaged so it is protected from adulteration from the surrounding environment

Statutory/Regulatory Thought Process



Citing the Codified Acts

Title 21 - Food and Drugs

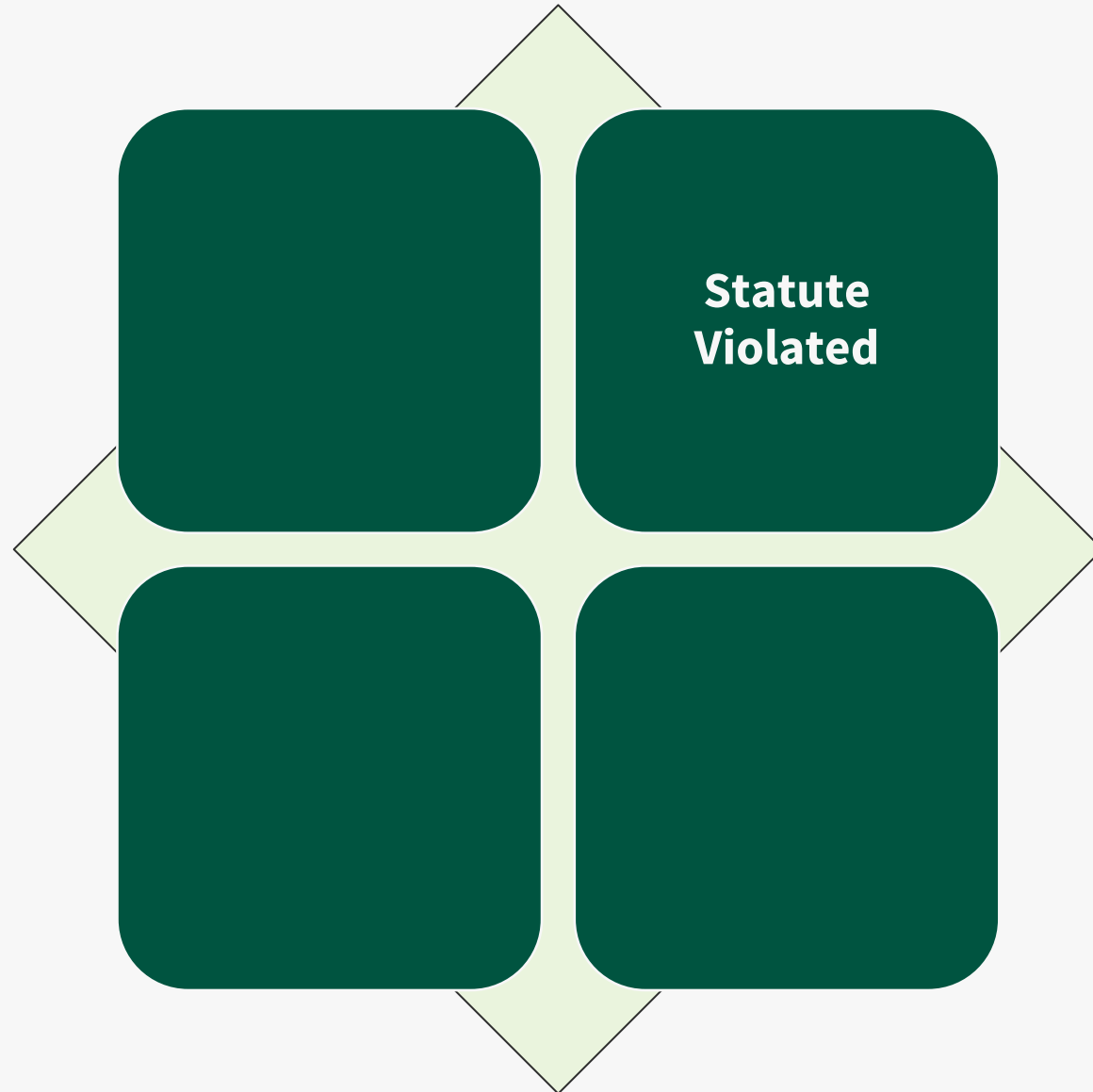
- FMIA begins with Section 601
- PPIA begins with Section 451

Statute citation example

- **21 U.S.C. 601(m)(1)**
- **21 U.S.C. 454(a)(1)**

Regulation citation example

- **9 CFR 416.1**



Statute Violated = Adulterated Product

When is product adulterated?

- Defined in FMIA Section 601 and PPIA Section 453
- *Key principle for food safety issues, as it provides the basis for many of the food safety related enforcement actions*

Adulteration Definition – 1

- **Section 601 (m):**
 - “The term “adulterated” shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:”
- **Section 601(m)(1):**
 - If it bears or contains any poisonous or deleterious substance which may render it injurious to health;...

Adulteration Definition – 2

- **Section 601 (m)(2)(A):**
 - If it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance (...) which may, in the judgment of the Secretary, make such article unfit for human food;
- **Section 601(m)(2)(B):**
 - If it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 346a of the FFDCA.

Adulteration Definition – 3

Section 601 (m)(2)(C):

- **(C)** *If it bears or contains any food additive which is unsafe...*
- **Food Additives:**
 - **Direct**- preservatives, carcass washes
 - **Indirect**- equipment sanitizers

UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC		
FSIS DIRECTIVE	7120.1 Rev. 59	8/7/24
SAFE AND SUITABLE INGREDIENTS USED IN THE PRODUCTION OF MEAT, POULTRY, AND EGG PRODUCTS		
I. PURPOSE		
<p>This directive provides inspection program personnel (IPP) with the latest updates to the list of substances that may be used in the production of meat, poultry, and egg products. As a reminder, this directive no longer provides the complete listing of approved substances, On-Line Reprocessing (OLR) and Off-Line Reprocessing (OFLR) Antimicrobial Intervention Systems. Instead, it only provides a list of the latest changes. The complete listing of OLR and OFLR Antimicrobial Intervention Systems is available at the link above. FSIS is also providing a link to the complete list of safe and suitable ingredients and the list in 9 CFR 424.21(c) of additional acceptable food ingredients. This Directive and its associated documents do not supersede regulations, including standards of identity (9 CFR 319 and 9 CFR 381 subpart P). Establishments are to ensure that their use of the listed substances is compliant with all regulatory requirements.</p>		
II. CANCELLATION		
FSIS Directive 7120.1, Revision 58 <i>Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products</i> , 6/21/23		

Adulteration Definition - 4

Section 601 (m)(3):

- *If it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food.*



FMIA Adulterated Product

Section 601 (m)(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.*





21 U.S.C. 608

The Secretary shall cause to be made, by experts in **sanitation** or by other competent inspectors, such inspection of all slaughtering, meat canning, salting, packing, rendering, or similar establishments in which amenable species are slaughtered and the meat and meat food products thereof are prepared for commerce as may be necessary to inform himself concerning the **sanitary conditions** of the same, and to **prescribe the rules and regulations of sanitation** under which such establishments shall be maintained; and where the **sanitary conditions of any such establishment are such that the meat or meat food products are rendered adulterated, he shall refuse to allow said meat or meat food products to be labeled, marked, stamped or tagged as "inspected and passed."**

Webster's Definitions

- **Sanitation** - "...development and application of sanitary measures for the sake of cleanliness, protecting health, etc."
- **Sanitary** - "... of or pertaining to health or the conditions affecting health, especially with reference to cleanliness, precautions against disease, etc."



21 U.S.C. 608 – HACCP, SSOP, SPS

Provides FSIS the ability to ensure product is handled and held in a sanitary manner

- Legal basis upon which the SPS, SSOP, and HACCP regulations are based



Rulemaking Authority

- 608 – “...and to prescribe the rules and regulations of sanitation under which such establishments shall be maintained....”
- 621 – “...and said Secretary shall, from time to time, make such rules and regulations as are necessary for the efficient execution of the provisions of this chapter.”

HACCP Bridge



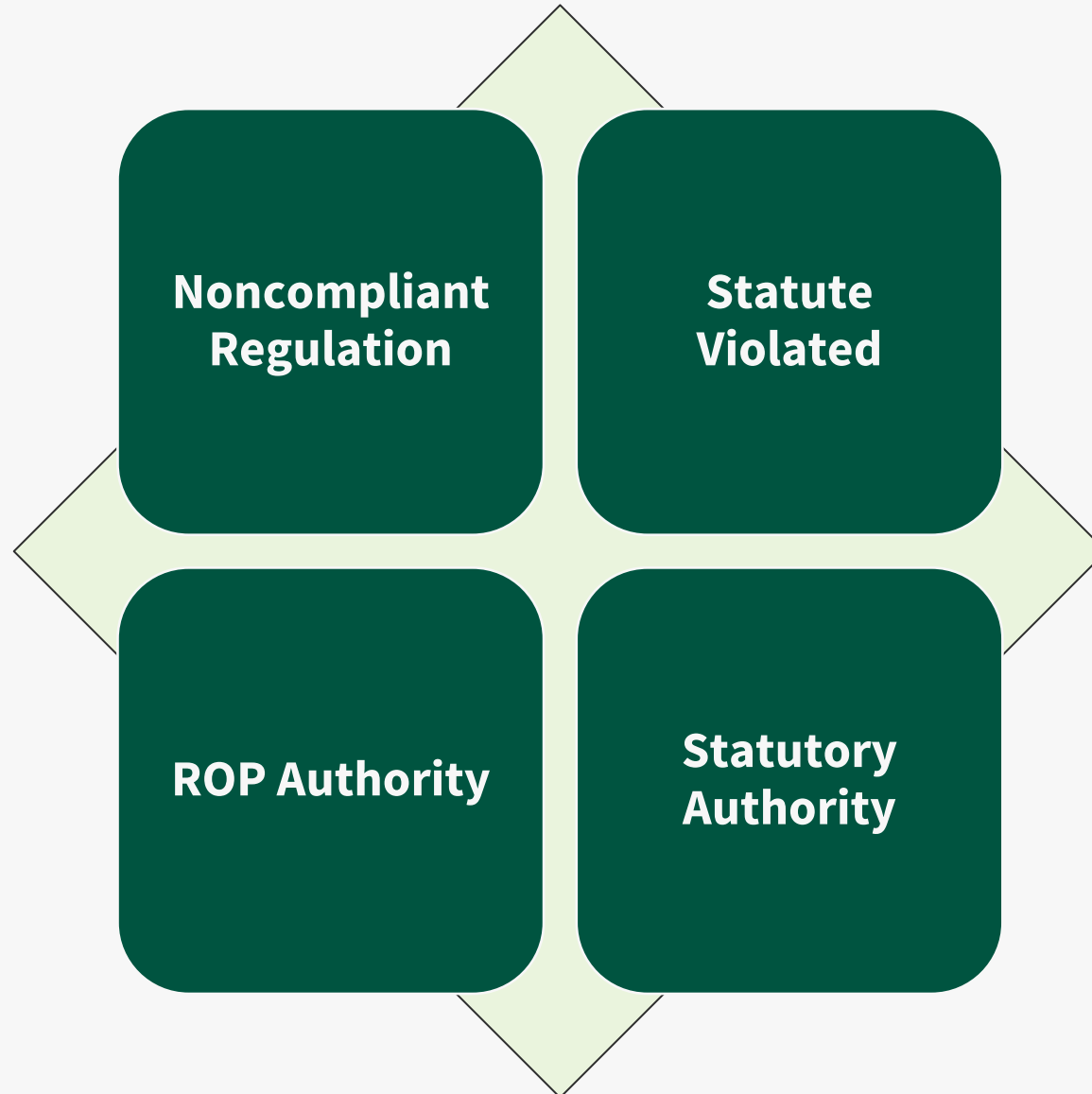
9 CFR 417.2(e)

417.2(e)- (aka ‘the bridge’)- Pursuant to **21 U.S.C. 456, 463, 608**, and **621**, the failure of an establishment to develop and implement a HACCP plan that complies with this section, or to operate in accordance with the requirements of this part, may render the products produced under those conditions adulterated

9 CFR 417.2(e) and & 9 CFR 417.16 (a-e)

- **417.6 (a-e)** – A HACCP plan may be found to be inadequate if:
 - ...
 - a) HACCP plan in action does not meet requirements of 9 CFR part 417
 - b) Establishment not performing tasks in HACCP plan
 - c) Establishment fails to take corrective actions required by 9 CFR 417.3
 - d) HACCP records not being maintained
 - e) Adulterated product produced or shipped

Statutory/Regulatory Summary



Statutory/Regulatory Example 1

A finished product storage warehouse, where meat product is stored, has significant amounts of rodent feces in several locations on the floor, but none was observed on the product.



Example 1

What regulations are noncompliant?

9 CFR 416.2(a)-establishment must have a pest management program to prevent insanitary conditions), and **9 CFR 416.2(b)(3)**-establishment must be constructed and maintained to prevent entrance of vermin

What ROP gives us authority to take enforcement?

9 CFR 500.3(a)(4)-Suspension without prior notification because sanitary conditions are such that products would be rendered adulterated.

Example 1 Continued

What enforcement action is appropriate?

Suspension Without Prior Notification

What statute gives us that authority?

21 U.S.C. 608

What statutory adulteration provision applies?

21 U.S.C. 601(m)(4)- product produced, held, or packaged under insanitary conditions is adulterated.

Statutory/Regulatory Example 2

An establishment fails to follow its preoperational SSOPs and IPP document numerous associated noncompliances on preop inspection over a period of weeks in which food contact surfaces were found in an insanitary condition.



Example 2

What statutory adulteration provision applies?

21 U.S.C. 601(m)(4)-product produced, held, or packaged under insanitary conditions is adulterated

What regulations are noncompliant?

9 CFR 416.13(a)- preoperational procedures not implemented or not effective

9 CFR 416.14- failure to routinely evaluate the effectiveness of the SSOPs

Example 2 Continued

What enforcement action is appropriate?

NOIE

What ROP gives us authority to take enforcement?

9 CFR 500.4(b)- Suspension with Prior Notification (NOIE)

Statutory/Regulatory Example 2 Continued

What statute gives us that authority?

21 U.S.C. 608

If sanitary conditions are such that product may be rendered adulterated FSIS may refuse to allow the marks of inspection be applied

Statutes Workshop



HACCP Recordkeeping Workshop

During an FSA, an EIAO observes a livestock slaughter establishment has a CCP for a hot water rinse to control pathogens but has no supporting documentation for the critical limit

What would be the statutory / regulatory thought process for a possible enforcement action if the safety of the product is in question?

Recordkeeping Workshop Results

417.5(a)(2) – no support for the CL

417.4(a)(1) – establishment did not validate the CCP

417.6 (a) – this situation may represent an inadequate system because there is no support for the CL

NOIE 500.4(a)- The HACCP system is inadequate due to multiple or recurring noncompliances (or NOS 500.3 if adulterated product shipped.)

21 USC 601(m)(4) adulteration due to insanitary conditions. Prepared packed or held under conditions in which it MAY have become contaminated or otherwise rendered

21 USC 608 – FSIS may refuse to provide inspection because of insanitary conditions

Statutes for EIAO's

fsis.usda.gov

