



## FSIS Statutes and the EIAO

1

### Where does FSIS get our 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.)

2

2

## 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.**

3

3

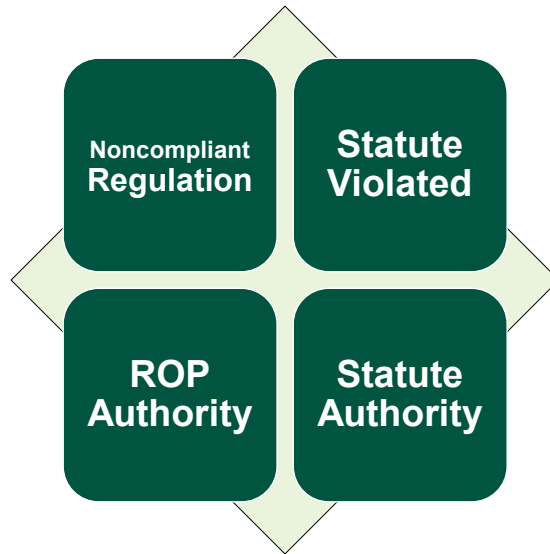
## Key Terms

- **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.

4

4

## Statutory / Regulatory Thought Process



5

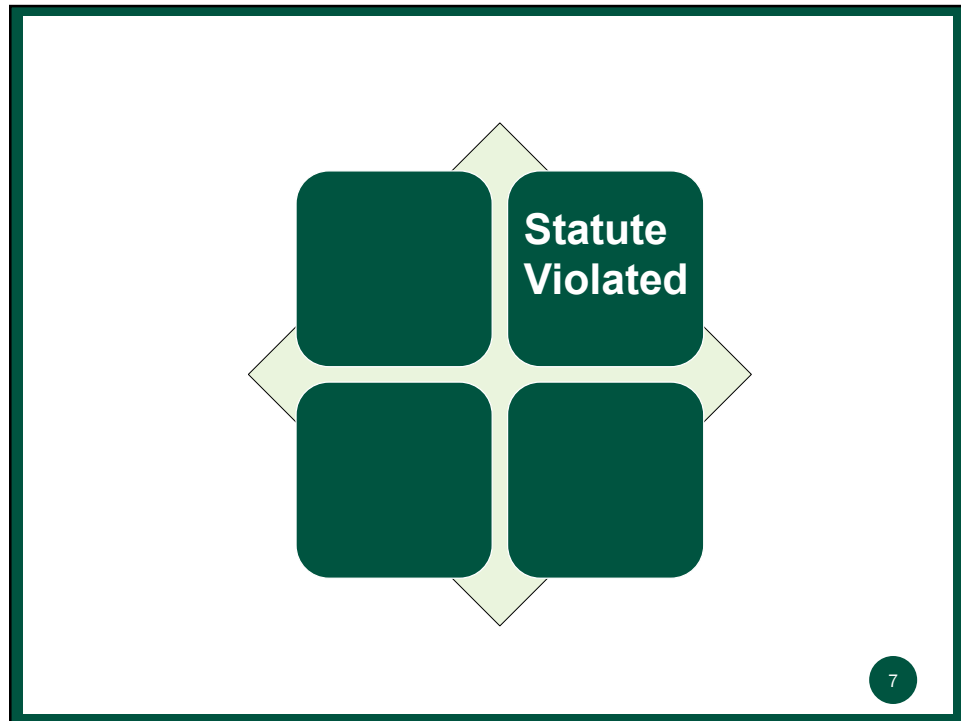
5

## 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 417.1**

6

6



7

### 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.*

8

8

## 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;...

9

9

## 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.

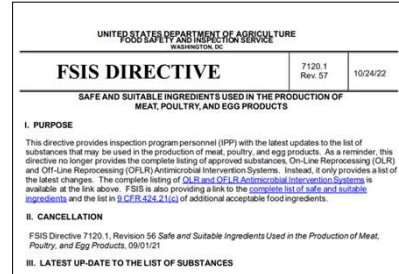
10

10

## 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



11

11

## 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.*



12

12

## Federal Meat Inspection Act: Adulterated Product

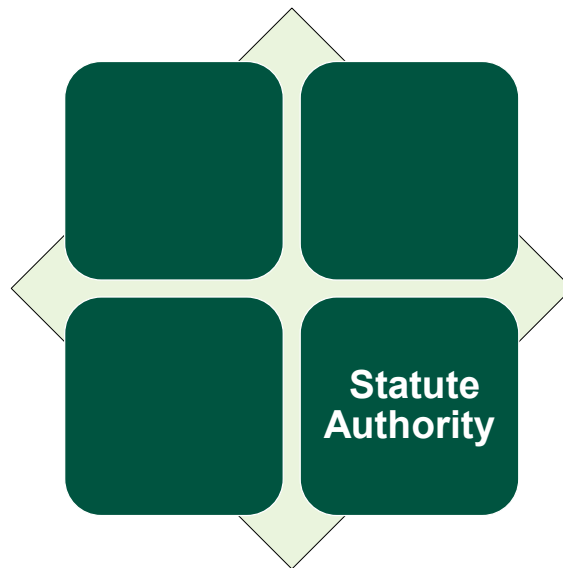
### Section 601 (m)(4):

- 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.*



13

13



14

14

## 21 U.S.C. 608

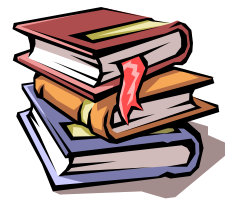
The Secretary shall cause to be made, by experts in **sanitation** or by other competent inspectors, such inspection of all slaughtering, meat canning, salting, packing, rendering, or similar establishments in which amenable species are slaughtered and the meat and meat food products thereof are prepared 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."**

15

15

## 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."



16

16



## 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



17

17

## 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."

18

18

## HACCP Bridge



19

19

## 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.

20

20

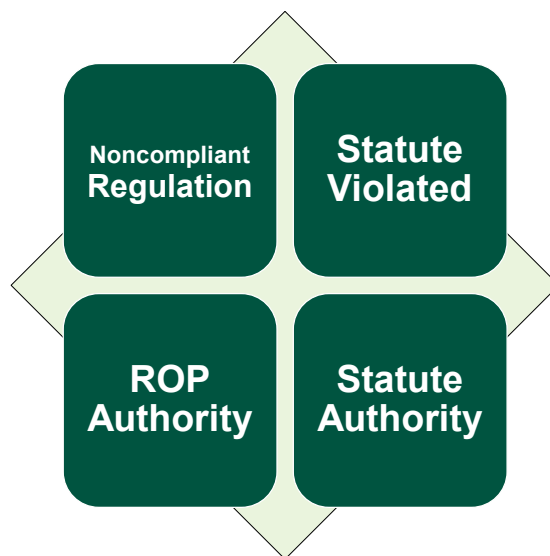
### 9 CFR 417.2(e) & 9 CFR 417.16 (a-e)

- **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

21

21

### Statutory / Regulatory Summary



22

22

### 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.



23

23

### Regulatory-Statutory Example 1.1

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.

24

24

## Regulatory-Statutory Example 1

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.

25

25

## 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.



26

26

### Regulatory-Statutory Example 2.2

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

27

27

### Regulatory-Statutory Example 2.1

What enforcement action is appropriate?

**NOIE**

What ROP gives us authority to take enforcement?

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

28

28

### Regulatory-Statutory Example 3

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

29

29

### Workshop



30

30

## 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?**

31

31

## Statutes for EIAOs

**Questions?**



33

33