

The Statutes and Your Role

EIAO Training

Objectives



Upon completion of this module, you will be able to:

- Describe where FSIS gets its legal authority.
- Identify which definition of adulteration under the statutes would apply in given situations.
- Identify the relevant sections of the statutes, as they would apply to various situations.
- Identify sections of the statutes that give FSIS various authorities.
- Identify the section of the statutes that gives FSIS the legal basis for the HACCP and SSOP regulations.

The Acts

- 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.)

Introduction to Organization of the Acts and Citing Statutory References

- Very important to understand the organization of the statutes and how to cite them in your documentation



Codified Statutes

- Congress organized or “codified” the Federal statutes into 50 Titles in the mid 1900’s



Citing the Codified Acts

- Title 21 - Food and Drugs contains FMIA, PPIA, EPIA
- FMIA begins with Section 601
- PPIA begins with Section 451
- Citation Example
 - 21 U.S.C. 601(m)(1)
 - 21 U.S.C. 454(a)(1)

Exercise

- Find and highlight the following citations in the FMIA and PPIA
 - 21 U.S.C. 601(m)(4)
 - 21 U.S.C. 455(b)
- How are regulations cited?



The Acts and Public Health



Background

- Our mission for protecting public health is directly tied to the FMIA, PPIA
- Acts give FSIS authority and responsibility to protect consumers by assuring products are:
 - Wholesome
 - Not adulterated
 - Properly labeled

The Acts and Public Health - Meat

- 21 U.S.C. 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 are wholesome, not adulterated and properly marked, labeled, and packaged.

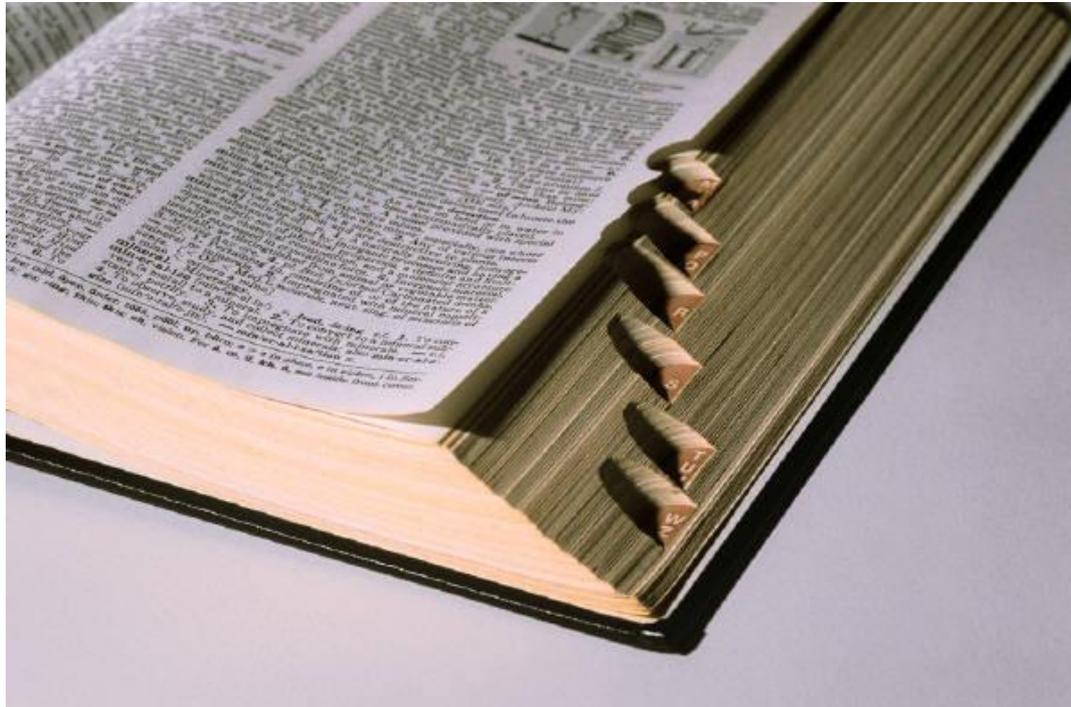
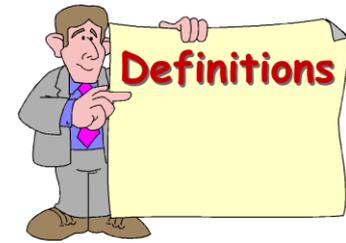
The Acts and Public Health - Poultry

- 21 U.S.C. 451
 - It is essential in the public interest that the health and welfare of consumers be protected by assuring that poultry products distributed to them are wholesome, not adulterated and properly marked, labeled, and packaged.

The Acts and Public Health - Poultry

- 21 U.S.C. Section 452
 - It is hereby declared to be the policy of Congress to provide for the inspection of poultry products and otherwise regulate their processing and distribution...to prevent the movement or sale in interstate or foreign commerce of, or the burden upon commerce by, poultry products which are adulterated or misbranded.

Definitions



Important Terms in the Acts

- The terms “misbranded” and “adulterated” play an important part in FSIS’ role of protecting public health and welfare.

Adulterated

Misbranded

Adulterated Product

- When is product adulterated?
- 21 U.S.C. 601(m) of the FMIA:
 - The term “adulterated” shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:”

Adulterated Product

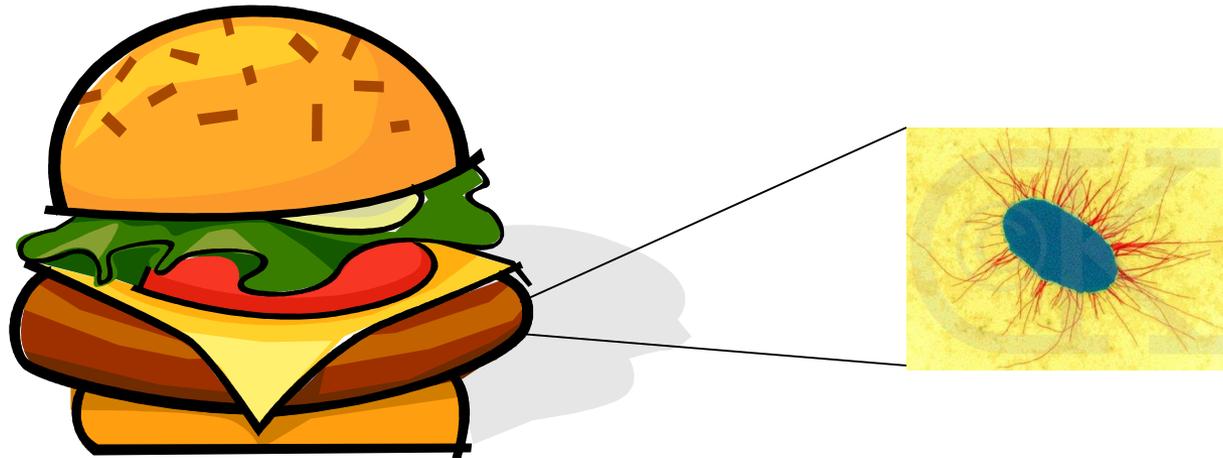
- 21 U.S.C. 601(m) of the FMIA:
 - (1) If it bears or contains any **poisonous or deleterious substance** which may render it injurious to health; but in case the substance is not an **added substance**, such article shall not be considered adulterated under this clause if the quantity of such substance does not ordinarily render it injurious to health;

Adulterated Product

- 21 U.S.C. 601(m)(1)
 - Focus is on “added substance”
 - Example
 - *Listeria monocytogenes* (Lm) findings in RTE product
 - *Lm* would be considered an added deleterious substance

Adulterated Product

- Another example of a “(m)(1)” case would be meat found positive for *E. coli* O157:H7 which can cause injury or even death



Adulterated Product

- 21 U.S.C. 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** other than one which is (i) a pesticide chemical in or on a raw agricultural commodity (ii) a food additive, or (iii) color additive which may, in the judgment of the Secretary, make such article unfit for human food;

Adulterated Product

- 21 U.S.C. 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 this title



Adulterated Product

- 21 U.S.C. 601(m)
 - (2)(C) if it bears or contains any **food additive** which is unsafe within the meaning of section 348 of this title



Adulterated Product

- 21 U.S.C. 601(m) :
 - (3) If it consists in whole or in part of any **filthy, putrid, or decomposed substances** or is for any other reason **unsound, unhealthful, unwholesome, or otherwise unfit** for human food.

Adulterated Product

- Some “(m)(3)” examples:
 - Meat product contaminated with rail dust, rust or rodent droppings
 - Meat products that are slimy and putrid due to spoilage

Adulterated Product

- “(m)(3)” is also the definition that FSIS is using as the statutory basis for taking actions against BSE
 - SRMs are considered “inedible” because of higher risk of infectivity for the BSE agent

Adulterated Product

- For “(m)(3)” cases it is very important to have graphic and accurate descriptions of conditions
 - Demonstrates product is filthy, putrid, or decomposed, or is for any other reason unsound, unhealthful, unwholesome, or unfit
 - Example – product in a warehouse is directly contaminated with rodent feces (product is observed to have feces on it)

Adulterated Product

- 21 U.S.C. 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;

Exercise

- A finished product storage warehouse, where meat product is stored, has significant amounts of rodent feces on the floor, but none was observed on the product.
- What adulteration provision(s) in the FMIA would apply?
- What regulations would apply?



Important Point

- The adulteration provisions of the statutes are not mutually exclusive.
 - For example, product may be adulterated under (m)(1), (m)(3) and (m)(4).

Adulterated Product - Poultry

- The definitions for “adulterated” in the PPIA are the same language found in the FMIA.
- Most commonly cited in enforcement actions =
 - (g)(1)
 - (g)(3)
 - (g)(4)



Adulterated Product

- Additional definitions
 - (5) product of an animal which has died otherwise than by slaughter;
 - (6) container is composed of poisonous or deleterious substance;
 - (7) intentionally subjected to radiation that does not conform to regulation;
 - (8) valuable constituent has been omitted or abstracted, or substance has been substituted....;
 - (9) margarine containing animal fat that is filthy, putrid, or decomposed (FMIA only)

Workshop

- Answer Questions 1 and 2 in the Statutes Workshop.
- Additional Question?
 - Are all adulterants a food safety hazard?



Misbranded Product

- FMIA 601(n); PPIA 453(h)
 - (1) False or misleading labeling
 - (2) Sold under the name of another food
 - (3) Imitation of another food

Misbranded Product

- FMIA 601(n); PPIA 453(h)
 - (4) Misleading container
 - (5) Unless it bears a label showing name/place of business of manufacturer with statement of weight or quantity
 - (6) If required information is not prominently displayed

Misbranded Product

- FMIA 601(n); PPIA 453(h)
 - (7) If it is represented as a food for which a standard of identity is prescribed but does not meet that standard
 - (8) If it falls below the fill standard for a container
 - (9) If the label results in unfair competition

Misbranded Product

- FMIA 601(n); PPIA 453(h)
 - (10) If there are special dietary claims but the dietary properties are not included in the label
 - (11) If artificial flavoring, coloring, or chemical preservatives are not included on the label
 - (12) If it requires special handling to maintain the wholesomeness of the product and that information is not included on the label

Inspection

- Statutory Basis



Antemortem Inspection

- 21 U.S.C. 603(a)
 - To prevent the use in commerce of adulterated products, the Secretary shall cause an examination and inspection of **all animals before** entering a slaughtering, canning or similar establishment.
- 21 U.S.C. 455(a)
 - Antemortem Inspection of Poultry

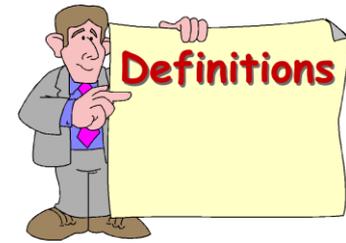
Antemortem Inspection

- Provides authority to identify animals suspected of having abnormal conditions or diseases and identifying them for further examination or final disposition



Postmortem Inspection

- 21 U.S.C. 604
 - ...the Secretary shall cause to be made by inspectors appointed for that purpose a post mortem examination and inspection of the carcasses and parts thereof of **all** (livestock)...to be **prepared** at any slaughtering...or similar establishment...which are capable of use as human food; (FMIA)



Livestock Defined

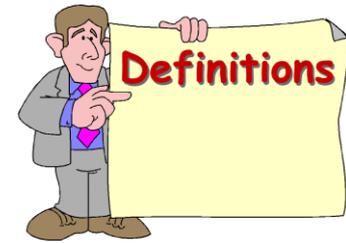
- Species covered by the FMIA
 - Often called “amenable to”
- “Livestock” identified as:
 - Cattle
 - Swine
 - Sheep
 - Goats
 - Horses
 - Mules
 - Other Equine
 - And, all fish of the order Siluriformes

What Meat Products Must Be Inspected?

- Must be inspected if livestock are “**prepared**” and not given an exemption by Congress such as custom
 - “Prepared” – includes “slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.”

Postmortem Inspection

- 21 U.S.C. 455(b)
 - The Secretary, whenever **processing** operations are being conducted, shall cause to be made by inspectors postmortem inspection of the carcass of **each bird** processed....



Poultry Defined

- Species covered by the PPIA
- “Any domesticated bird” – PPIA
 - Chickens
 - Turkeys
 - Ducks
 - Geese
 - Guineas
 - Ratites
 - Squabs (young pigeons)

What Poultry Products Must Be Inspected?

- If poultry are “**processed**” they must be inspected unless exempted in some way
 - “Processing - slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.”

Exemptions from Inspection

- 21 U.S.C. 623 and 464
- “Prepare” or “Process” otherwise amenable products but given an exemption in the Acts
 - Custom Exempt (FMIA)
 - Retail Exempt
 - Restaurants
 - Central Kitchens

Voluntary Reimbursable Services

- Ag Marketing Act of 1946
- Non-amenable species slaughter and processing inspection services
 - Example: Bison slaughter and processing
- Reimbursable fee-for-service basis
- Other Activities
 - ID Services
 - Certification Services
 - Food inspection



Product Reinspection

- 21 U.S.C. 605 and 455(b)



Further Processed Products Inspection

- 21 U.S.C. 606
 - “For the purposes hereinbefore set forth the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all meat food products **prepared** for commerce”

Marks of Inspection

- What products receive the mark of inspection?
 - 21 U.S.C. 604, 606, and 455
 - Found to be “not adulterated”



Marks of Inspection

- If a determination is made the product is adulterated
 - Condemned (or reconditioned in some cases)
- If there is some reason a determination of the product status cannot be made
 - Retain the product – do not allow marks to be applied
 - Example – Cow with fresh injection lesion

Sanitation

- 21 U.S.C. Section 608 and 456(a)
- Provides legal basis for 9 CFR 416, 417



21 U.S.C. 608 - FMIA

- The Secretary shall cause to be made by experts in sanitation or by other competent inspectors the **inspection of all establishments** where meat or meat products are prepared.....necessary to inform concerning the sanitary conditions of these establishments.
- The Secretary shall **prescribe the rules and regulations of sanitation.....**

21 U.S.C. 608

- Secretary prescribes regulations



- Causes inspections to be made



- If insanitary conditions found



- Marks of inspection may be withheld

21 U.S.C. 608

- Key words related to Agency's authority
 - "Sanitation"
 - "Sanitary"
 - "Adulteration"

Pop Quiz

- Is the term “sanitation” defined in the statute?



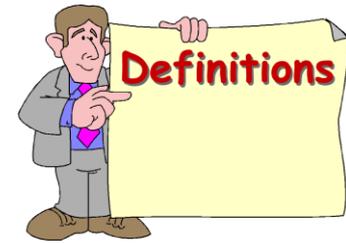
Pop Quiz

- Is the term “sanitation” defined in the statute?

No!



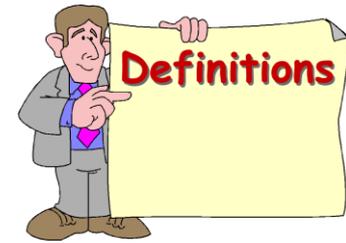
21 U.S.C. 608



- What is the common meaning of “sanitation”?
- Keeping things clean (supported by the regulations)



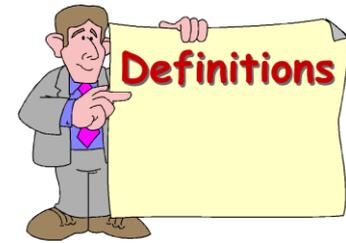
21 U.S.C. 608



- Webster's definition of "sanitation:"
 - ...development and application of sanitary measures for the sake of cleanliness, protecting health, etc."



21 U.S.C. 608



- Webster's definition of "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 and sanitation regulations are **sanitary measures** necessary to protect public health

HACCP

SSOP

SPS

21 U.S.C. 608

- Provides FSIS the ability to ensure product is handled and held in a sanitary manner
- Key provision upon which the HACCP, SPS, and SSOP regulations are based



Consider This

- If hazards are not properly addressed and prevented will product be “adulterated?”



Key Principle

- To enforce the HACCP rule, we must show that the establishment is not complying with the statutory provisions that support the regulation.



Key Principle

- We must show how an establishment's failure to follow the **sanitary measures** required by HACCP or sanitation rules created **insanitary conditions** in its operation that resulted in the production of product that may be injurious to health.

Key Principle

- How can we show this is the case for SSOPs?
 - Show that the SSOP is a necessary precaution against producing product that may be injurious to health
 - Failure to implement or maintain SSOP's may create conditions under which contamination occurs, rendering product injurious

Key Principle

How can we show this is the case for HACCP?

- Show that failure to perform an adequate hazard analysis creates insanitary conditions that could lead to production of product which is injurious to health
 - Without such an analysis, plants cannot be sure they have identified and addressed conditions that could cause product to be injurious to health

Key Principle

- Change in the product must occur while the product is being prepared, packed, or held in the establishment and have occurred because of the insanitary conditions in that establishment



21 U.S.C. 456 - PPIA

- Parallel to FMIA Section 608
 - Each official establishment slaughtering poultry...shall have such premises, facilities, and equipment, and be operated in accordance with such sanitary practices, as are required by regulations promulgated by the Secretary for the purpose of preventing the entry into or flow or movement in commerce or burdensome effect upon commerce, of poultry products which are adulterated.

Tying it all together

- HACCP regulations that build the statutory-regulatory thought process
 - 417.2(e)- (aka ‘the bridge’) “Pursuant to 21 U.S.C. 456, 463, 608, and 621, the failure of the establishment to develop and implement a HACCP plan...”
 - 417.6 (a-e) – A HACCP plan may be found to be inadequate if: ...



Workshop

- Answer question 3 of the workshop in your notebook.



Review

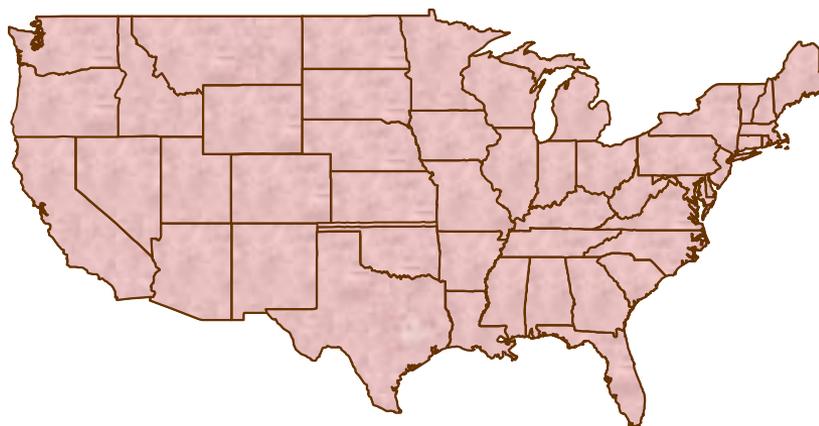
- Statutes reflect plant processes
 - 603 – Antemortem
 - 604 – Postmortem
 - 605 – Reinspection
 - 606 – Inspection of all meat products
 - 608 – Sanitary conditions

21 U.S.C. 642 and 460(b)

- Requires all persons/entities subject to the Act to afford access to their place of business, facilities and examination of records to an authorized representative of the Secretary.
- Requires...to maintain records of productions...and correctly disclose all transactions
- Records available to FSIS in a reasonable time upon notice

21 U.S.C. 661 and 454 -States

- States have the right to develop a State inspection program “equal to” the federal program
- Acts outline conditions under which State programs are permitted



21 U.S.C. 620 and 466 - Import

- “No carcasses, parts of carcasses, meat or meat food products of cattle, sheep, swine, goats, horses, mules, or other equines which are capable of use as human food, shall be **imported** into the United States if such articles are adulterated or misbranded and unless they comply with all the inspection...provisions.....”

Pop Quiz

- What is the statutory authority for enforcing HACCP, SSOP, and SPS Regs?



Pop Quiz

- What is the statutory authority for enforcing the HACCP, SSOP, and SPS Regulations?

21 U.S.C. 608 and 456



Rulemaking Authority

- Where in the statutes does it provide for regulations to be made ?



Rulemaking Authority

- 608 – “...and to prescribe the rules and regulations of sanitation under which such establishments shall be maintained....”
- 456 – “...as required by regulations promulgated by the Secretary for the purpose of preventing the entry into or flow or movement in commerce of burdensome effect upon commerce of poultry products which are adulterated.....”

Rulemaking Authority

- 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.”
- 463 – “...Secretary shall promulgate such or other rules and regulations...to carry out the provisions of the Act.”

Rulemaking Authority

- Rulemaking example:
 - HACCP rule



Regulatory-Statutory Thought Process

- Example
 - An establishment fails to follow its preoperational SSOPs and IPP find numerous noncompliances on preop inspection over a period of weeks in which food contact surfaces were found in an insanitary condition.
 - What would the regulatory –statutory thought process be if further enforcement were to be considered?

Regulatory-Statutory Thought Process

- **416.13(a) &/or (c)** SSOP pre-op noncompliance
- **416.14** Failure to routinely evaluate the effectiveness of the SSOPs
- Insanitary conditions in the establishment may result in product being adulterated under **21 U.S.C. 601(m)(4)**
- Under **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

Enforcement Authority and Actions



Enforcement Authorities

- Administrative
- Civil
- Criminal



Administrative Enforcement

- 9 CFR 500 Rules of Practice
 - 500.2 – Regulatory control actions
 - 500.3 – Withholding actions or suspensions without prior notification
 - 500.4 – Withholding actions or suspensions with prior notification
 - 500.6 – Withdrawal of inspection

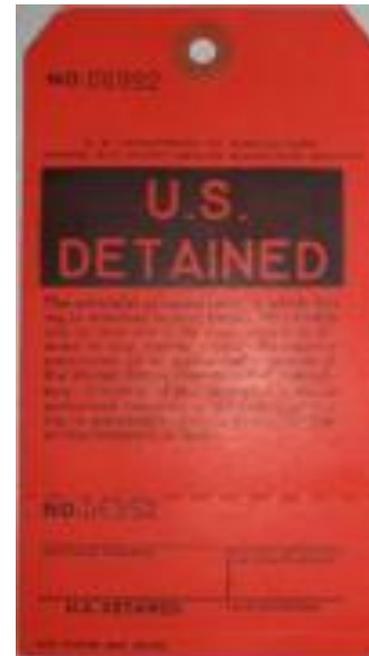
Civil Authorities

- 21 U.S.C. 674 and 467(c)
- U.S. District Courts have jurisdiction



Civil Authorities

- Detention of product
- Seizure of product
- Injunctions



Detention Authority

- 21 U.S.C. 672 and 467(a)
- Authority to detain adulterated, misbranded or non-inspected products.
- For a period not exceeding 20 days
- Product may not be moved unless released by agency

Seizure Authority

- 21 U.S.C. 673 and 467(b)
- Seizure of adulterated/misbranded product
 - Court action against product not violator



Injunction Authority

- Court actions used to restrain or prevent an establishment from violations of the acts



Prohibited Acts



- 21 U.S.C 610, 611, and 458
 - Prohibits slaughter or preparation except in compliance with the Act.
 - Prohibits inhumane slaughter or handling.
 - Prohibits sale, transport, offering, or receipt, in commerce, of articles capable for use as human food that are either adulterated, misbranded or not inspected.

Prohibited Acts



- Prohibits causing products to become adulterated or misbranded.
- Prohibits misuse or unauthorized use of official marks, certificates, labels or devices of inspection.
- Prohibits the knowing misrepresentation of any article as inspected and passed or exempt under the Act.

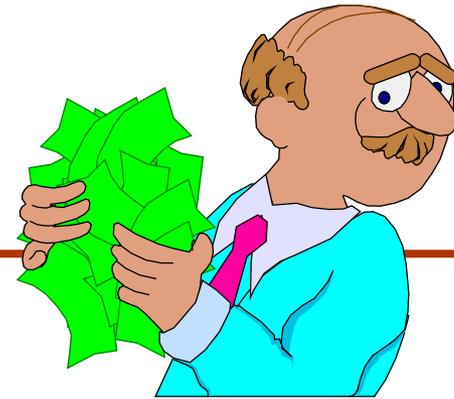
Assault and Intimidation

- 21 U.S.C. 675 and 461(c)
 - No person shall forcibly assault, resist, oppose, impede, intimidate, or interfere with any USDA employee
 - \$5,000 fine, 3 years prison or both.
 - More severe penalties for use of a deadly or dangerous weapon.
 - Also covers murder of employees on duty.

Attempt to Defraud

- 21 U.S.C. 676 and 461(a)
 - Involves intent to defraud, or any distribution or attempted distribution of an article that is adulterated
 - Subject to fines and imprisonment or both

Bribery



- 21 U.S.C. 622
 - Prohibits any person, firm or corporation from paying or offering to pay any money or other thing of value to an agency employee with the intent to influence his/her discharge of duties.
 - Felony, \$5,000 to \$10,000 fine, and imprisonment for 1 to 3 years.
 - Also prohibits employees from accepting or receiving money or something of value.

Criminal Authorities

- The Secretary may refer criminal violations to the Department of Justice for prosecution.
- The Secretary has discretion to forego criminal referral for minor violations where it is determined that the public interest will be served by a suitable written notice of warning.
- Discretion also applies to libel and injunction authorities.

Other Statutory Authorities



Humane Methods



- 21 U.S.C. 603(b)
 - Humane Methods of Slaughter Act incorporated by reference.
 - Secretary shall cause an examination and inspection of the method by which animals are slaughtered and handled
 - FSIS may refuse to grant inspection or temporarily suspend inspection

Humane Methods



- 7 U.S.C. 1901-1907
 - Must be slaughtered in a humane manner to prevent needless suffering.
 - Ritual slaughter exempted
- 9 CFR 313.1-50
 - Humane handling regulations, example, stunning must produce immediate unconsciousness, with minimum excitement and discomfort
- FSIS Directive 6900.2
 - In-plant verification and enforcement policies for egregious and non-egregious non-compliance

Workshop

- An inspector has observed egregious inhumane handling, multiple ineffective stunning attempts, and has taken RCA to stop the process.
- What would be the statutes and regulations that apply? What should happen next, and how will you support it?

Labeling Authorities



- 21 U.S.C. 607 and 457
 - All meat and meat food products must be properly labeled, marked and packaged
 - Labels must not be false or misleading
 - Gives FSIS broad authority to prescribe regulations to protect the public
 - FSIS withholds the use of any false or misleading labels or marks
 - Hearing and appeal rights on FSIS decisions

Export Authorities

- 21 U.S.C. 615-619
 - Requires FSIS to inspect meat and meat food products prior to export
 - Gives the Secretary broad authority to determine time and manner of inspection
 - Provides for certification of products by FSIS prior to shipping



Notification – Adulterated Product

- 21 U.S.C. 612
 - Requires establishment to notify FSIS if adulterated product received or shipped
 - Must give type of product, amount, origin and destination



Recall Plans and Reassessments

- 21 U.S.C. 613
 - Establishments must have recall plans
 - Document reassessments
 - Make these documents available to inspectors upon request.



Workshop

- Answer questions 4-5 in your workshop.

