# Statutes

## Objectives

Upon completion of this module the trainee will be able to:

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

## Legal Authority

The legal authority for FSIS activities can be traced all the way back to the United States Constitution because it grants to Congress the authority to regulate interstate commerce. From that authority, Congress enacted the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA).

Each of these Acts is intended to protect the health and welfare of the consuming public by preventing the introduction of adulterated or misbranded meat, poultry, or egg products into commerce. To illustrate, here's an example of a Congressional statement of findings from the FMIA (Section 602). The PPIA and EPIA contain similar statements of findings.

***"Meat and meat food products are an important source of the Nation's total supply of food. They are consumed throughout the Nation and the major portion thereof moves in interstate or foreign commerce. 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. Unwholesome, adulterated, or misbranded meat or meat products impair the effective regulation of meat and meat food products in interstate or foreign commerce, are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged meat and meat food products, and result in sundry losses to livestock producers and processors of meat and meat food products, as well as injury to consumers. The unwholesome, adulterated, mislabeled, or deceptively packaged articles can be sold at lower prices and compete unfairly with the wholesome, not adulterated, and properly labeled and packaged articles, to the detriment of consumers and the public generally."***

Another foundation principle is outlined in Section 452 of the PPIA which indicates that inspection is authorized to prevent products from entering commerce that are adulterated or misbranded.

Everything that FSIS does is based on these statutes and we must be able to trace the legal authority for enforcement actions back to a statutory basis.

## Key Definitions

Adulteration

One of the key provisions in the statutes is the definition of the word *"adulterated"* and how it applies to the work that FSIS does. It is found in the FMIA in Section 601, which contains all of the definitions for the statute. This definition actually has 9 parts but we are going to focus on the first few parts of the definition because they have the greatest bearing on daily FSIS activities.

The term "adulteration" applies to any carcass, part thereof, meat or meat food product under one or more of the following circumstances.

***(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 in or on such article does not ordinarily render it injurious to health."***

This definition focuses on *added substances*. An example of an added substance that has been declared to be an adulterant in ready-to-eat (RTE) meat products is *Listeria monocytogenes* (Lm). It represents an added substance that renders the product injurious to health. Scientific studies have shown that this pathogen is present in the product due to the way in which product is handled or produced. For example, Lm is present typically in RTE products because of recontamination that occurs during the processing of product – such as through contact with the environment or with plant employees after an initial lethality treatment has been delivered. This pathogen is considered injurious to health because RTE products are not cooked by consumers before they are eaten. If this substance is present, products are very likely to cause injury to human health. In non-intact raw meat or meat products, *E. coli* O157:H7 is an adulterant. Based on what we know from scientific studies, *E. coli* O157:H7 is considered to be an added substance because it is introduced to the product during processing. For example, it is spread from the hide or digestive tract of the animals during slaughter or processing. It is injurious to health because one of the normal ways of cooking this product includes "rare" which is not sufficient to destroy the pathogen. Again, the presence of this pathogen in the product under these conditions is likely to cause injury – and can even result in death.

***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;***

The second definition of the term "adulterated" in Section 601(m)(2)(A) of the FMIA relates to the *residues* of drugs in live animals It's a little bit tricky when you read this, because the things listed in (i), (ii), and (iii) are NOT covered in this definition. Based on its statutory authorities, the Food and Drug Administration (FDA), in its pre-market approval programs, considers what, if any, residues of animal drugs should be viewed as safe. FSIS is responsible for enforcing the levels that are established by FDA. Our inspectors conduct tests for animal drug residues, such as antibiotics, hormones, or sulfonamides. Because animal drug residues are not pesticides, food additives, or color additives, the Agency is left to find that the animal drug residue makes the meat product unfit for food. The regulations that cover animal drug residues are found in 21 CFR 556, which are FDA regulations.

***(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.***

The definition of the term "adulteration" found in Section 601(m)(2)(B) of the FMIA covers *pesticide chemicals*. The Environmental Protection Agency (EPA) has the statutory authority to consider what, if any, levels of pesticide residues found in food can be viewed as safe. FSIS is responsible for enforcing the tolerances that are established by EPA. The regulations related to pesticide chemicals are found in 40 CFR 180. An example of a pesticide chemical for which a tolerance has been established is Diazinon which is used in fields to eliminate fire ants, or the herbicide 2,4-D used in fields to eliminate undesirable grasses or weeds. These pesticides are not normally found in food animals. However, food animals may become exposed to them through drift in wind at the time when they are administered in a field, or through accidental ingestion. FSIS will sample products for pesticide residues and send the samples to the appropriate laboratory. In this case, if the residue level for the pesticide chemical is found to have exceeded the tolerance level set by EPA, the product (which may be a carcass or part) is considered to be adulterated based on this statutory definition.

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

Section 601(m)(2)(C) defines meat or meat products bearing any unsafe *food additives* to be adulterated. All food additives are reviewed for safety before use in food production by FDA and FDA establishes their conditions for use. An example of such a food additive approved for use under specified conditions is the antimicrobial carcass rinses used on the slaughter line. There are two types of food additives. One is direct and the other is indirect. Direct food additives are directly applied to the food, such as preservatives for meat products. Indirect food additives are those that are not used for food purposes but come into contact with food, such as sanitizers that are used on equipment or on food contact surfaces and packaging materials. All food additives used in federal establishments must be approved by FDA. FSIS Directive 7140 lists all food

additives that have been approved for use and it is updated on a regular basis. So, again, FSIS enforces the policy that is set by FDA.

***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.***

This next section, 601(m)(3), of the definition of adulteration emphasizes *health*. You should be aware that legally, the burden is on FSIS to prove that these conditions – filthy, putrid, or decomposed - exist. This is why it is very important that inspectors be graphic and accurate in descriptions of conditions in the Noncompliance Records (NRs). Some examples of filth include rail dust, rust, or rodent droppings on product. This is also the definition that FSIS is using as the statutory basis for taking all actions against BSE. The reason this definition was used is that scientific studies have shown that infectivity of the disease exists within the animals before they show clinical signs of the disease. Keep in mind that the adulteration provisions of the statutes are not mutually exclusive. For example, a product may be adulterated under 603(m)(1) AND 603(m)(3) because it is positive for *E. coli* O157:H7.

***(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;***

Section 601(m)(4) covers the definition of "adulterated" related to *insanitary conditions*. The HACCP rule (9 CFR 417) is about ensuring that products are not adulterated through insanitary conditions. It's about ensuring that sanitary conditions are maintained throughout the process. If we apply this to the slaughter process, establishments must ensure, for example, that their processes – such as de-hiding, opening the digestive tract of livestock – do not create insanitary conditions that may contaminate the carcasses with filth.

**Note** - Be aware that there are parallel provisions in the PPIA that contain the same definitions.

Additional definitions of "adulteration" in the FMIA include:

(5) The product of an animal which has died *otherwise than by slaughter*;

(6) A container that is composed of a *poisonous or deleterious* substance;

(7) Product intentionally subjected to *radiation* that does not conform to regulation;

(8) Product in which a *valuable constituent* has been omitted or abstracted, or substance has been substituted….;

(9) M*argarine* containing animal fat that is filthy, putrid, or decomposed

Misbranded

Another term that is defined in detail in the statutes is the term *"misbranded."* Most of these definitions deal with the label on the product. Section 601(o) and (p) define "label" to mean a display of written, printed, or graphic matter upon the immediate container, and the term "labeling" as all labels and other written, printed, or graphic matter upon an article, its container, or wrapper. Here are the twelve definitions of this term.

***(n) The term "misbranded" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:***

***(1) if its labeling is false or misleading in any particular;***

***(2) if it is offered for sale under the name of another food;***

***(3) if it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and immediately thereafter, the name of the food imitated;***

***(4) if its container is so made, formed or filled as to be misleading;***

***(5) if in a package or other container unless it bears a label showing (A) the name and place of business of the manufacturer, packer, or distributor; and (B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (B) of this subparagraph (5), reasonable variations may be permitted, and exemptions as to small packages may be established, by regulations prescribed by the Secretary;***

***(6) if any word, statement, or other information required by or under authority of this Act to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;***

***(7) if it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by regulations of the Secretary under section 7 of this Act 3 unless (A) it conforms to such definition and standards, and (B) its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;***

***(8) if it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by regulations of the Secretary under section 7 of this Act, and it falls below the standards of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;***

***(9) if it is not subject to the provisions of subparagraph (7), unless its label bears (A) the common or unusual name of the food, if any there be, and (B) in case it is***

***fabricated from two or more ingredients, the common or unusual name of each such ingredient; except that spices, flavorings, and colorings may, when authorized by the Secretary, be designated as spices, flavorings, and colorings without naming each. Provided, That, to the extent that compliance with the requirements of clause (B) of this subparagraph (9) is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary;***

***(10) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary, after consultation with the Secretary of Health, Education, and Welfare, determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses;***

***(11) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: Provided, That, to the extent that compliance with the requirements of this subparagraph (11) is impracticable, exemptions shall be established by regulations promulgated by the Secretary; or***

***(12) If it fails to bear, directly thereon or on its container, as the Secretary may be regulations prescribe, the inspection legend and, unrestricted by any of the foregoing, such other information as the Secretary may require in such regulations to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition.***

## Inspection Activities

Inspection activities have their legal basis in the statutes. Sections 603(a) of the FMIA, and 455(a) of the PPIA are the statutory authorities for the inspection activities that we conduct during *antemortem inspection*. These are the provisions upon which the regulations for ante mortem inspection were promulgated. For example, the regulation that corresponds with the statute 603(a) regarding ante mortem inspection in livestock is 9 CFR 309. This regulation contains more specific information that inspection personnel are to use in judging whether an official establishment that slaughters livestock is meeting the standard established by 603(a). FSIS inspects the cattle at rest and then in motion to detect abnormal conditions or symptoms of diseases that are identified in the regulations. If any of these animals are suspected of having these abnormal conditions or diseases, identify them for further examination, and, if necessary, identify them for final disposition in post mortem inspection.

The statutory authorities for *postmortem inspection* are covered in section 604 of the FMIA, and in section 455 (b) and (c) of the PPIA. These provisions cover two important concepts. One is the *jurisdiction* for inspection. The other is *inspection procedures*. For jurisdiction, postmortem inspection must be performed on all of the carcasses and parts "prepared" at an official establishment. The wording used in the PPIA is slightly different. Instead of "*prepared*" it uses "*processed*." This provision also establishes the basis for the inspection procedures that are performed. Postmortem inspection involves performing specific procedures that include observation and palpation or incision of

lymph nodes in the head and viscera, and observation of the carcass. The purpose of inspection is to detect any carcasses or parts that exhibit signs of disease or conditions that otherwise make the carcass or parts unwholesome or unfit for human food. These procedures must be performed using methods that are safe and sanitary. These procedures can be traced directly back to this statutory provision.

This statute has been held by the courts to require that FSIS make a determination about each carcass during inspection. The statute says "all" carcasses. This is the "carcass by carcass" inspection legal requirement.

Postmortem inspection must be performed on all of the carcasses and parts ***prepared*** at an official establishment. The definition for the term "prepared" is found in Section 601(l) of the FMIA. It includes, "slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed." You should be aware that the only products FSIS inspects are those that are defined as "prepared" in the FMIA or "processed" in the PPIA. In other words, we don't have jurisdiction to "inspect" warehouses or distribution centers, although FSIS has the authority to visit and examine these facilities. The inspection of other types of products is covered by other federal agencies, such as FDA. You should also be aware that FSIS has statutory authorities to conduct activities other than inspection. For example, if we look at Section 624 of the FMIA, which is the same as section 453 of the PPIA, you'll see the authority to prescribe by regulations the conditions under which carcasses, parts, and meat products are stored or handled during buying, selling, freezing, storing, or transportation. While FSIS can conduct examinations at the out of plant locations where these processes are performed, these examinations are not "inspection."

The statutes continue by indicating that for those carcasses and parts that are found not to be adulterated, inspectors are to mark them as "***inspected and passed***." Inspectors are to mark those carcasses and parts that are found to be adulterated as "***inspected and condemned***." This is the statutory basis for inspection.

The statutes also outline some ***exemptions*** to inspection requirements. These are found in the FMIA in Section 623, and in Section 464 of the PPIA. For example, personal slaughtering and custom slaughter for personal, household, guest, or employee uses are exempt from inspection. However, the exempt products are still subject to the adulteration and misbranding provisions of the statutes. In these exempt facilities, the plant performs activities that constitute "preparation" of meat products or "processing" of poultry products but they have been exempted from inspection by Congress.

***Reinspection*** is covered in 605 of the FMIA and 455(b) in the PPIA. Reinspection is required in the situation when products are shipped from one plant to another. For example, this could be carcasses coming from one plant to be fabricated into special cuts at another establishment. It could be ground beef and trimmings coming from one establishment to another to be ground more finely, or to be used as a meat ingredient in a fully cooked product. When an inspector works in an establishment that receives meat or poultry products from another plant, part of his/her responsibility is to ensure that those products entering the establishment are reinspected using the same standards that are used in the initial inspection. Another condition requiring reinspection is when products are returned to the establishment for any reason. Again, the inspector's role is to ensure that these products are reinspected using the standards in the statutes, regulations, and directives.

Section 606 covers *inspection* of all meat products, including further processed products. It begins by indicating that inspectors examine all meat food products prepared for commerce, including meat products prepared in any slaughtering meat-canning, salting, packing, rendering, or similar establishment. It also indicates that inspectors shall have access at all times, day or night, whether the establishment is operating or not, to every part of the establishment.

Section 606 of the FMIA gives additional information about the *marks of inspection*. The purpose of post mortem inspection is to determine whether the products are wholesome, not adulterated, and properly marked, labeled, and packaged. This insures that the public health is protected. Remember in section 604 of the FMIA, and in section 455 (b) and (c) of the PPIA, the statutes state that the carcasses and parts that are found NOT to be adulterated are to be marked as "inspected and passed." This same concept is covered again in more detail in Section 606 of the FMIA. These marks of inspection stating "inspected and passed" show that all meat products are cleared to enter commerce after they are found to be fit for human consumption. This is very important. Remember that product cannot move in commerce unless it has been inspected and marked as passed. This means that inspectors must be able to find that product is NOT adulterated. The burden of proof is on the plant. What we are training our inspectors is if they have questions about whether or not to pass the product, don't pass it and don't stamp it as "inspected and passed" unless and until you get satisfactory answers to your questions by the plant. If you cannot find that the product is not adulterated, you must follow the Rules of Practice. So, Section 606 defines our product control authority. This important principle is illustrated in the diagram below.

**Not Adulterated → Mark Product as "U.S. Inspected and Passed"**

**Adulterated → Mark Product as "U.S. Inspected and Condemned"**

**Cannot Determine → Do Not Mark Product as "U.S. Inspected and Passed"**

## Sanitation

Another statutory provision that is very important is the one dealing with the requirement for the establishment to maintain *sanitary conditions* – Section 608 of the FMIA and 456(a) of the PPIA. To paraphrase the FMIA, the statute indicates that if the sanitary conditions are found by inspectors to be such that the meat or meat food products are rendered adulterated, inspectors shall refuse to allow the meat or meat food products to be labeled, marked, stamped, or tagged as "inspected and passed." These statutes give FSIS the ability to ensure that product is handled and held in a sanitary manner. This is one of the provisions upon which the HACCP regulations (417), the Sanitation Performance Standard Regulation and the Sanitation Standard Operating Procedures Regulation (both covered in 416) are based.

Let's look at the provision - Section 608 - that sets forth the requirements for sanitation in meat plants a little closer. First, it authorizes the Secretary of Agriculture to promulgate regulations that describe what establishments must do to maintain sanitary conditions. It also authorizes inspections to ensure that establishments are in compliance. If insanitary

conditions are found the marks of inspection may be withheld. The provisions of Section 608 may be summarized by the following diagram.

**Secretary (Agency) writes rules (Ex. HACCP/SSOP)**
↓
**Inspections are made**
↓
**Insanitary conditions exist**
↓
**Refuse to allow the marks of inspection**

First, let's look at the meaning of the words, "sanitation," "sanitary," and "adulteration." We've talked about the definition of the term "adulterated." Remember that it has several definitions. The term sanitation is not defined in the statute so we have to look to its common meaning. If you think about what the term "*sanitation*" means, just off the top of your head, you would say that it means keeping things clean. This definition is supported by FSIS regulations, which distinguishes between sanitation and HACCP. If you look in the dictionary, which is what courts are supposed to do for evidence of the common meaning when there is no statutory definition, you will find that "sanitation" means something broader than just keeping things clean. According to Webster's Collegiate Dictionary, "sanitation" means "the development and application of sanitary measures for the sake of cleanliness, protecting health, etc." So, the dictionary drives us back to one of the two key terms that are common to the PPIA and the FMIA which is "*sanitary*." The statutes talk about "sanitary practices" and "sanitary measures?" What does "sanitary" mean? Webster defines sanitary" as "pertaining to health or the conditions affecting health, especially with reference to cleanliness, precautions against disease, etc." So to summarize our discussion consider the following diagram.

**"Sanitation"→ "Sanitary Measures"→ "Pertaining to Health"→ HACCP/SSOP**

So, are the HACCP regulations and the sanitation regulations sanitary measures? Clearly they are, and we can demonstrate that fact to a court. To ensure that products are handled and held in a sanitary manner, plants must follow these regulations. For example, the establishment must develop and implement a HACCP plan covering each product produced when the establishment's hazard analysis reveals one or more food safety hazards are reasonably likely to occur in the production process. This includes biological, chemical, and physical hazards. The regulation outlines that establishments must follow the seven HACCP principles (417.2), which include conducting a hazard analysis, determining critical control points, establishing critical limits, establishing monitoring procedures, developing corrective action procedures, establishing recordkeeping and documentation procedures, and developing verification procedures. The regulation also specifies the conditions under which the establishment must reassess its HACCP plan.

The HACCP regulations require establishments to identify the food safety hazards that may arise as a result of their operation and to address those that are reasonably likely to occur. If those hazards are not properly addressed and prevented, the result is adulterated product. As you will remember, one definition of the term "*adulterated*" in 601(m)(4) is " *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".* In enforcing the HACCP rules, what the Agency needs to

show is why, in not complying with the regulations, the establishment is not complying with the statutory provisions that underlie the regulation. Section 608 gives the Agency authority for enforcing HACCP.

So, if the Agency is to enforce its HACCP and sanitation rules, we will need to show how an establishment's failure to follow the sanitary measures required by HACCP or sanitation rules creates insanitary conditions in its operation that resulted in the production of product that may be injurious to health. To summarize, consider the following diagram.

**HACCP/SSOP Failure→ Insanitary conditions→ Product may be injurious to health**

It is important to note that the deleterious change in the product, that is, the change that may have the effect of making consumption of the product injurious to health, must occur while the product is being prepared, packed, or held and have occurred because of the insanitary conditions.

Note: The PPIA has a parallel section – Section 456 – which contains similar language.

**Review of Key Provisions**

Let's quickly review the statutes we've covered. Section 603 covers ante mortem inspection. Section 604 covers post mortem inspection, and the carcasses. Section 605 covers reinspection of product. Section 606 covers the inspection of all meat products – the carcasses, the parts, processed products, and cut up products. Each product must be inspected. Section 608 covers the requirement for the plant to maintain a sanitary environment for the slaughter and processing of animals to take place. The provisions in the PPIA follow this same progression.

**Recordkeeping Requirements**

Now, let's look at the requirements in the statutes for recordkeeping related to the production of meat and poultry products. The fourth Amendment to the U.S. Constitution protects citizens from unreasonable searches and seizure. The plant has this same right, and just like other rights, it must be protected. However, it's important for us to have access to plant records, particularly under HACCP. A review of those records can tell us important information about how product was handled and prepared to help us in making the determination about whether product that is being produced is wholesome and not adulterated. Section 642 of the FMIA and 460(b) of the PPIA gives FSIS the right to be in the plant and to have access to the plant facilities and records.

Establishments must maintain production records and to provide the records within a reasonable amount of time when given notice. Tracing these authorities in regulations, directives, and notices, remember that the HACCP and sanitation regulations (417, 416) both outline more specific recordkeeping requirements. For example, this right of FSIS to access plant records is reflected in the HACCP regulations in 417.5, which outlines the recordkeeping requirements related to HACCP plans. FSIS Directive 5000.1, Revision 1, outlines inspection methods covering these recordkeeping requirements. An example of a key directive dealing with plant records is FSIS Directive 5000-2, which reminds inspection personnel that they have access to any type of record that the plant

maintains if it relates to maintaining its food safety system, whether the records are referenced in the HACCP plan or not (e.g., records of microbiological sampling).

**State – Federal Cooperation**

Not all inspection is done by FSIS. The Acts provide for FSIS support of State programs. Section 661 of the FMIA requires that the State program cover antemortem inspection, postmortem inspection, sanitation, and reinspection in a manner that is equal to the federal program. Note that the State programs are subject to certain chapters of the Acts – adulteration/misbranding, recordkeeping, and the auxiliary provisions (671) that cover provisions for withdrawal of inspection.

**Imported Product**

Imported product is product that is manufactured in another country and shipped into the U.S. The Acts state in Section 620 of the FMIA that the foreign country must have a program that is equivalent to that of the U.S. and that the products that are offered for import into the U.S. must be inspected before they can enter the U.S.

**Rulemaking Authority**

Three sections of the statutes – FMIA 608 and 621, and PPIA 456 – are the basis upon which FSIS establishes regulations. Section 621 of the FMIA gives FSIS the authority to adopt regulations for effectively enforcing the Act. As an example of this, when FSIS adopted the HACCP rule we used the general rulemaking authority (FMIA 621) to make sure the establishments operate in a sanitary environment (FMIA 608).

**Enforcement Authorities and Actions**

Now, let's review the statutory authority for taking enforcement action when establishments fail to comply with provisions outlined in the Acts. There are three basic enforcement authorities covered in the Acts: *administrative, civil, and criminal*.

Administrative Authorities

The administrative enforcement authorities covered in the statutes include retaining product, withholding the marks of inspection, suspending inspection, and withdrawing inspection. Remember that the Rules of Practice outline the due process that we must provide to protect the rights of establishments.

Section 500.2 covers *regulatory control actions*, such as tagging product, equipment, or facilities. Remember that these kind of actions are taken to prevent product that has been determined through inspection to have a problem that appears to have rendered it to be unwholesome or adulterated from entering commerce. We are authorized to take these regulatory control actions when we find insanitary conditions or practices, adulterated product, conditions that prevent us from determining that product is not adulterated or misbranded, and when there is inhumane handling or slaughter of livestock. When a regulatory control action is taken, FSIS must notify the establishment immediately orally or in writing of the action and the reason for the action. Remember that for any type of enforcement action, the plant has the right to appeal that action.

When an inspector retains product, the establishment can either take corrective action or appeal the retention to the next level of supervision.

Section 500.3 of the Rules of Practice covers situations that warrant a *withholding action* or *suspension* without prior notification to the establishment. These actions are authorized when the establishment has produced and shipped adulterated or misbranded product and there is an imminent hazard to health. For example, the establishment does not have a HACCP plan, the establishment does not have an SSOP, sanitary conditions are such that products in the establishment are or would be rendered adulterated, the establishment violated the terms of a regulatory control action, someone associated with the establishment assaults or threatens to assault or intimidate or interfere with an FSIS employee or FSIS inspection, the establishment fails to destroy condemned product according to regulatory requirements, or the establishment handles or slaughters animals inhumanely. Section 500.5(a) covers the notification that must be provided to the establishment as promptly as circumstances permit. Again, the establishment has the same choices – correct or appeal.

Section 500.4 of the Rules of Practice covers the conditions under which withholding actions are taken or when suspensions occur with prior notification to the establishment. We call the prior notification a "Notice of Intended Enforcement Action," or NOIE. The NOIE is covered in 500.5(b). The conditions that require prior notification include an inadequate HACCP plan, an SSOP has not been properly implemented or maintained, failure to maintain sanitary conditions due to multiple or recurring noncompliance, failure to collect generic *E. coli* samples, and failure to meet the *Salmonella* performance standards. Let's walk through a simple, practical example. According to the Rules of Practice, if there is a condition that requires prior notice before the marks of inspection are withheld, FSIS provides the establishment a written notice of the enforcement action. The written notice (NOIE) gives the establishment three days to respond. During this time, the establishment can provide a corrective action plan, which if judged to be adequate will result in putting the suspension in abeyance. Or, the establishment can challenge the validity of FSIS actions through the appeals process.

Withdrawal of inspection, covered in 500.6, is a formal legal process that involves filing a complaint in an administrative proceeding at the Department level. This will be handled by a Program Investigator, however, the documentation inspectors provide in the NRs are the evidentiary basis upon which this action is taken.

Civil Authorities

The most common civil authorities exercised by FSIS are the detention and seizure of product.

*Detention* authorities cover unwholesome, adulterated, or misbranded product that has left the establishment and has entered commerce. Detention actions are taken by Program Investigators or EIAOs. The detention action places the product on hold for 20 days. During this time, a decision is made on whether to seize the detained product.

The statutory authorities for *seizure* of product are found in FMIA section 673 and PPIA section 467(a). Seizure is also an action that is taken against product that is no longer in an establishment and has entered commerce. Typically, the first step in a civil action is detention, which is then followed by seizure and condemnation. It involves a court

judgment as to whether the product is adulterated and must be condemned or destroyed. When the court determines that the product is to be condemned, it is released under bond to be destroyed. Court costs and fees, storage and other expenses are charged to the violator.

When there violations of the Acts that are civil in nature, FSIS also has the authority to obtain an *injunction* from a court to keep the plant from doing something (e.g., continuing its operations) – although this rarely occurs.

Criminal Authorities

The statutory authority for criminal acts comes from the sections dealing with the *prohibited acts*. Both the FMIA and the PPIA list prohibited acts.

Section 610 of the FMIA and Section 458 of the PPIA prohibit causing products to become adulterated or misbranded. This applies to persons, firms and corporations.

Section 611 of the FMIA and 458(c) prohibits the misuse or unauthorized use of official marks, certificates, labels or devices of inspection and prohibits the knowing misrepresentation of any article as inspected and passed or exempt under the Act. Section 675 and 471(c) prohibit any person from forcibly assaulting, resisting, opposing, impeding, intimidating, or interfering with any USDA employee engaged in or on account of official duties.

The FMIA Sec. 676 and PPIA Sec. 461(a) involve the intent to defraud, or any distribution or attempted distribution of an article that is adulterated.

FMIA Sec. 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. It also prohibits employees from accepting or receiving money or something of value.

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.

Violators of any provisions for which no other criminal penalty is provided shall be guilty of a misdemeanor, and subject to fine and up to one year imprisonment. Felony, if intent to defraud or distribution of adulterated product (except m(8)), subject to substantial fine and imprisonment.

**Other Statutory Authorities**

The *Humane Methods of Slaughter Act* (HMSA) is incorporated by reference in the FMIA. The Secretary shall cause an examination and inspection of the method by which animals are slaughtered and handled in connection with slaughter at such establishments. FSIS may refuse to grant inspection or temporarily suspend inspection for slaughter or handling other than in accord with HMSA.

All meat and meat food products must be properly *labeled, marked and packaged*. Labels must not be false or misleading. The statutes give FSIS broad authority to prescribe regulations to protect the public. FSIS withholds the use of any false or

misleading labels or marks. The statutes also provide hearing and appeal rights to the establishment on FSIS decisions.

The FMIA, in Section 606, requires FSIS to inspect meat and meat food products prior to *export.* It gives the Secretary broad authority to determine time and manner of inspection. It also provides for the certification of products by FSIS prior to shipping.

Section 677 of the FMIA indicates that *other federal laws* may be applied in the administration and enforcement of the FMIA.

# Workshop

1. Where does FSIS derive its legal authority from?

2. List some common adulterants that may affect products regulated by FSIS and give the proper statutory reference (i.e., 21 U.S.C.) to the appropriate definition of adulteration that would apply.

3. What section(s) of the statute (21 U.S.C.) provides the legal basis for the following?

a. Antemortem Inspection

b. Humane Slaughter

c. Postmortem Inspection

d. Reinspection

e. Marking of Products

f. Inspection of Processed Products

g. Sanitation Inspection

4. Identify the relevant section(s) of the FMIA (21 U.S.C.) as they would apply to the following situations.

a. Bribery

b. Knowingly shipping adulterated product

c. Causing product to become adulterated

d. Intimidation of inspection personnel

e. Improper use of marks of inspection

5. Identify the section(s) of the FMIA (21 U.S.C.) that gives FSIS the following authorities.

a. Inspection and certification of export product

b. Inspection of imported product

c. Detention of adulterated product in commerce

d. Review records at a distribution warehouse

e. Cooperate with State Inspection Programs

f. Publish a final rule (regulation)

6. What section(s) of the FMIA form the legal basis of the HACCP and SSOP regulations?