FSIS Statutes and Your Role

OBJECTIVES

Once you complete this module, you should be able to:

1. Understand the purpose of the Acts.
2. Identify key definitions from the Acts.
3. Understand the statutory authority for FSIS activities.
4. Understand how those activities plus authorities in the statutes support enforcement actions.

REFERENCES

1. Federal Meat Inspection Act
2. Poultry Products Inspection Act

IINTRODUCTION

The "Regulatory Framework" module provided an overview of the regulatory framework under which we operate in FSIS. This module will provide more detail about that regulatory framework and the statutory authority for day to day inspection, and verification activities.

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- Understand the purpose of the Acts.
- Identify key definitions from the Acts.
- Understand the statutory authority for FSIS activities.
- Understand how those activities; plus authorities in the statutes, support enforcement actions.

As we go through this module, keep in mind the inspection and verification activities you performed or supervised while in the plant working along side your mentor. Feel free to ask questions as we go. It's important for us to discuss some practical examples of how the statutory authorities apply to your work.

Overview of the Statutes

The statutes related to FSIS activities include the:

- Federal Meat Inspection Act (FMIA),
- Poultry Products Inspection Act (PPIA), and
- Egg Products Inspection Act (EPIA).

The FMIA was enacted first, in 1906 after the public outrage stirred up by the writings of Upton Sinclair's book, "The Jungle." How many of you are familiar with this book? It

contained graphic and detailed descriptions of the insanitary and abhorrent conditions that existed in meat plants at the turn of the century in the city of Chicago, which was the heart of the meat processing industry at the time. Excerpts from the book were published in newspapers. With this information as a background, Congress enacted the FMIA. The PPIA was modeled after the FMIA. When you read it, you will see a number of similarities between the two statutes. The PPIA enacted in 1957, was based on the growing poultry industry. Initially, there were two separate Agencies – one responsible for enforcing the provisions of the FMIA and one responsible for enforcing the provisions of the PPIA. This explains why, in some cases, establishments that process both meat and poultry products have two establishment numbers. We will not be covering the EPIA in our review.

Basis for FSIS as a Public Health Regulatory Agency

These Acts provide for the basis for FSIS's ability to perform as a public health agency. In Section 602 of the FMIA, Congressional statement of findings, states the following:

> **FMIA Sec. 602.** "*Meat and meat food products are an important source of the Nation's total supply of food. 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. It is hereby in found that all articles and animals which are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce, and that regulation by the Secretary and cooperation by the States and other jurisdictions as contemplated by this chapter are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers."*

These three things - verifying that meat or poultry products are:

1. wholesome,
2. not adulterated,
3. properly marked/labeled, and packaged

are the essentials of the job you have in protecting public health. All of your inspection and verification activities focus around one or more of these things that are covered in the Acts.

The Congressional statement of findings in the Poultry Products Act (Section 451) is almost identical to that of the FMIA. Again, it emphasizes public health, and it emphasizes the four essentials – wholesome, not adulterated, properly marked/labeled, and packaged. We'll be going into each of these in more detail as we continue.

> **PPIA Sec. 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."*

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.

> **PPIA Sec. 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.*

Remember, all the things you do or you supervise as part of your job can be traced back to the statutes to make sure that any meat, poultry, or egg product that is adulterated or misbranded does not enter commerce to protect the public health. You will do that through the enforcement authorities that we will discuss later.

Definition of "Adulterated"

One of the key provisions in the statutes is the provision related to the term "adulterated" product. What does the term "adulterated" mean, and how does it apply to the work that you do? The term "adulterated" is defined in the FMIA under Section 601, which contains all of the definitions for the statute. The definition is found in Section 601(m). This definition actually has 9 parts. We're going to focus on the first few parts of the definition because they have the greatest bearing on your daily work.

First, the term "adulteration" applies to any of the following:

- carcass,
- part thereof,
- meat or meat food product

under one or more of the circumstances described in Section 601(m) of the FMIA.

Now, let's look at some key parts of that definition.

> **FMIA Sec. 601(m)(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;"*

The definition of adulterated product in 601 m(1) focuses on added substances. Two examples of added substances that have been declared to be adulterants in meat products include *Listeria monocytogenes (Lm*) and *E. coli* O157:H7. *Lm* is an example of an adulterant in ready-to-eat (RTE) products. 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 typically present 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 reheated by consumers before they are eaten. Therefore, if this substance is present, products are very likely to cause injury to human health and can even cause death. The only adulterant in non-intact raw meat or meat products is *E. coli* O157:H7.

Based on what we know from scientific studies, *E. coli* O157:H7 is considered to be an added substance because it is introduced into the product during processing. For example, it's spread from the hide or digestive tract of the animals during slaughter or processing. It's 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.

> **FMIA Sec. 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;"*

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 that have been declared to be harmful to human health. 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. Remember that the residue testing done by FSIS is based on the statutory authorities of the Food and Drug Administration (FDA). In its pre-market approval programs, FDA 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. In your duties, you will 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 prove 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 the FDA regulations.

> **FMIA Sec. 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;"*

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, in its pre-market approval programs, consider what, if any, levels of pesticide residues, if found on 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 Daizinon; 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 inadvertently; for example, through incidental contact such as drift in wind at the time when the pesticides are administered in a field, or through accidental ingestion. In your duties, you 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.

> **FMIA Sec. 601(m)(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. FDA establishes their conditions for use. An example of such a food additive approved under specified conditions is carcass washes 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. 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. So, again, FSIS enforces the policy that is set by FDA. The following definition in section 601(m)(2)(D), color additives, is not important in relation to your duties.

> **FMIA Sec. 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."*

This next section, 601(m)(3), of the definition of adulteration emphasizes health. This is the definition that FSIS has used 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. Legally, the burden is on FSIS to prove that these conditions – filthy, putrid, and decomposed – exist. This is why being graphic and accurate in descriptions of conditions is very important on the NRs. Some examples of filthy conditions include rail dust, rust, or rodent droppings on product.

Be aware that the adulteration provisions of the statutes are not mutually exclusive. For example, a product may be adulterated under 603(m)(3) AND 603(m)(1) because it is positive for *E. coli* O157:H7.

> **FMIA Sec. 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;"*

Section 601(m)(4) covers the definition of "adulterated" related to insanitary conditions. The HACCP rule (regulation 417) is about ensuring that products are not adulterated through insanitary conditions. It's about ensuring that sanitary conditions are maintained throughout the production process. If we apply this to the slaughter process, establishments must ensure; for example, that their processes – such as de-hiding, and opening the digestive tract of livestock – do not create insanitary conditions that may contaminate the carcasses with filth. You will also be responsible for verifying that there are no insanitary conditions in the plant.

The inspection duties that you and other inspection program personnel perform after slaughter, that can be traced back to this part of the FMIA are those covered by the HACCP rule; including SSOPs and the Sanitation Performance Standards. This is obviously central too much of what you do. We'll come back to the HACCP regulation when we cover section 608 of the FMIA. Your inspection duties related to ensuring that the establishments maintain sanitary conditions are outlined thoroughly in FSIS Directive 5000.1, Revision 1, "Verifying and Establishment's Food Safety Systems." The

remainder of Section 601 of the FMIA covers additional definitions of the term "adulterated." You can review these, including the ones dealing with the term "misbranded" on your own time.

> **PPIA Sec. 453(g)(1)**: *"If it bears or contains any poisonous or deleterious substance which may render it injurious to health;"*

There are parallel definitions of the term "adulterated" in the PPIA. Like the FMIA, Section 453(g)(1) covers added substances that are poisonous or deleterious which may render a product injurious to health.

Section 453(g) (2)(A)(B) covers adulteration caused by a pesticide chemical or article, which make the poultry products unfit for human food. Just like the corresponding section of the FMIA, this represents the statutory authority for the residue testing procedures that you perform. Although the substances and tolerance levels vary from those in meat products; again, you must be aware that EPA is responsible for setting the tolerances for these substances and FSIS is responsible for enforcing that policy through the residue testing program.

> **PPIA Sec. 453(g)(2)(C):** *"If it bears or contains any food additive which is unsafe within the meaning of section 348 of this title;"*

Section 453(g)(2)(C) of the PPIA covers adulteration caused by a food additive. Again, remember that you will be responsible for ensuring that any food additives used by the plant in the processing of poultry products have been approved by FDA.

> **PPIA Sec. 453(g)(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;"*

Parallel to section 601(m)(3) of the FMIA, there is a section in the PPIA that emphasizes the importance of ensuring that poultry products do not injure human health in any way because they, "consist 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. "

> **PPIA Sec. 453(g)(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;"*

And finally, there is a parallel definition of "adulterated" in the PPIA that covers insanitary conditions.

We've highlighted the parts of the definition of adulteration in the Acts that are most relevant to your work. Now, let's briefly review the other parts of the definition. They include the following.

> FMIA Sec. 601(m):
> - (5) product of an animal which has died otherwise than by slaughter;
> - (6) product in a container that is composed of poisonous or deleterious substance;

- (7) product that has been intentionally subjected to radiation that does not conform to regulatory requirements;
- (8) product from which a valuable constituent has been omitted or abstracted, or a substance has been substituted;
- (9) margarine containing animal fat that is filthy, putrid, or decomposed.

This overview provides a very thorough basis for understanding what the statutory definition of "adulterated" is, and what it means in relation to FSIS inspection and verification activities. It is significant in relation to ensuring public health and food safety.

Statutory Provisions for Inspection Activities

Ante-mortem Inspection

Let's turn our attention to some our inspection activities. Sections 603(a) of the FMIA, and 455(a) of the PPIA are the statutory authorities for the inspection activities you and other inspection personnel conduct during ante mortem 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 you should use in judging whether an official plant that slaughters livestock is meeting the standard established by 603(a). For example, the inspection procedures include inspecting the livestock 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 abnormal conditions or diseases, they must be identified for further examination, and if necessary, identified for final disposition in post mortem inspection. Any animals found with symptoms of diseases must be disposed of properly. Remember, the authority for these actions as a result of ante mortem inspection comes from the section 603(a). Also remember that the purpose for conducting ante mortem inspection activities is to prevent animals that if slaughtered would result in adulterated product or would introduce insanitary conditions in the plant from entering the plant, and to ensure that if they do enter the plant, they do not adulterate products.

Post-mortem Inspection

> **FMIA Sec. 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; and the carcasses and parts thereof all such animals found to be not adulterated shall be marked, stamped, tagged, or labeled as "Inspected and passed;" and…label, mark, stamp, or tag as "Inspected and condemned" all carcasses and parts…found to be adulterated;"*

The statutory authorities for post mortem inspection are found 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 duties. For jurisdiction, post mortem inspection must be performed on all of the carcasses and parts prepared at an official establishment. The wording used in the poultry statutes is slightly different. Instead of "prepared" it uses the word "processed."

Regarding inspection procedures, this provision establishes the basis for the inspection procedures performed. As you recall from your training, post mortem 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. The legal authority for these procedures can be traced directly back to this statutory provision.

This statute has been held in the court system to require that FSIS make a determination about each carcass during inspection. You may hear this called a "carcass by carcass" inspection legal requirement.

Post mortem 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 processes." 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, FSIS does not have jurisdiction to inspect warehouses or distribution centers, although FSIS has the authority to visit 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 your inspection duties. So, you apply the standards established by the definitions of adulteration; which, we have already discussed in making this judgment.

Exemptions from Inspection Requirements

The statutes also outline some exemptions to the 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 except from inspection. However, the exempt products are still subject to the adulteration and misbranding provisions of the statutes.

In these except 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.

Marks of Inspection

> **FMIA Sec. 606:** *"…said inspectors shall mark, stamp, tag, or label as "Inspected and passed" all such product found to be NOT adulterated; and said inspectors shall label, mark, stamp, or tag as "Inspected and condemned" all such products found adulterated…."*

Several times we have referred to labeling, marking, stamping, or tagging product as "Inspected and passed." We call these labels, marks, stamps, and tags 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, as required by the statutes. This ensures 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 out of the plant into commerce until it has been inspected and marked as passed. This means that you must be able to find that product is NOT adulterated. The burden of proof is on the plant. If you 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.

To summarize, those carcasses and parts that are found to be adulterated are to be marked "inspected and condemned." They must be either reprocessed or destroyed, and cannot leave the plant to enter commerce to be used for human food. They must be destroyed in the presence of a USDA inspector. The statute also specifies that if the establishment fails to destroy a condemned carcass or part, the Secretary may remove the inspectors from the establishment. We call this removal of inspection "suspension" of inspection. We'll discuss this further in a few minutes when we talk about enforcement authorities.

Reinspection

Reinspection is covered in 605 of the FMIA and 455(b) in the PPIA. Reinspection covers 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 you work in an establishment that receives meat or poultry products from another plant, part of your responsibility will be to ensure that those products entering the establishment are reinspected using the same standards that you use in the initial inspection – that products are wholesome, not adulterated, and properly marked, labeled, and packaged. Another condition requiring reinspection is when products are returned to the establishment for any reason. Again, your role is to ensure that these products are reinspected using the standards in the statutes, regulations, and Directives.

Under both of these conditions you should ask a lot of questions to ensure that the product is wholesome, not adulterated, and properly marked, labeled, and packaged. For example, if the product has been transported to the establishment, was it held under conditions in a manner that would ensure that it did not become filthy, putrid, or decomposed, or for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food. Here are some examples of questions you might ask to make this determination. Was the temperature of the product controlled throughout transportation? Are there measures to prevent cross contamination of the product with the environment? These questions should be part of the decision making process you use in determining if product is wholesome and not adulterated.

Sanitation

Another statutory provision that is very important to your daily activities 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.

> **FMIA Sec. 608:** *"The Secretary shall prescribe the rules and regulations of sanitation under which establishments shall be maintained. 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 as may be necessary to inform concerning the sanitary conditions of these establishments."*

Let's look at the provision 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.

First, let's look at the meaning of three key words. They are:

- Sanitation
- Sanitary
- Adulteration

We've talked about the definition of the term "adulterated." Remember that it has several definitions in the statute. But, the word "sanitation" is not defined in either the FMIA or the PPIA. Because the term is not defined in the statute, we have to look to its common meaning. A common definition of the term "sanitation" is, "keeping things clean." This definition is supported by FSIS regulations, which distinguish between sanitation and HACCP. When a term, such as "sanitation" is not defined in the statutes, the courts are required to turn to the common meaning for evidence. This is typically done by consulting the dictionary.

The dictionary definition of the term “sanitation” shows that it means something broader than just keeping things clean. According to Webster’s Collegiate Dictionary, the word “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 the term “sanitary.” The statutes talk about “sanitary practices”, and “sanitary measures?” What doesn’t this term “sanitary” mean? According to the dictionary, the term “sanitary” means, “of or pertaining to health or the conditions affecting health, especially with reference to cleanliness, precautions against disease, etc.”

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 the HACCP 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. FSIS verification duties related to these regulations are described specifically in FSIS Directive 5000.1, Revision 1, “Verifying an Establishment’s Food Safety System.” It describes the inspection methods, regulatory decision making process, documentation, and enforcement procedures to use in relation to ensuring that the establishment complies with the regulations and statutes regarding sanitation. For example, the 01 and 02 HACCP procedures are performed to verify that the establishment is meeting the requirements of 9 CFR 417.

The HACCP regulations require establishments to identify the hazards to health 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, the term “adulterated” is defined in the statutes. 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 the 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.

It is important to note that under case law, 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. How can we show that this is the case? We can show that having a sanitation standard operation procedure that is effective in preventing direct contamination of product with environment contaminants is a

necessary precaution against producing product that may be injurious to health. Moreover, a failure to implement an effective SSOP, or to ensure the on going effectiveness of the SSOP would create conditions under which such contamination may occur; and thus, product is rendered injurious to health. Similarly, a failure by on establishment to perform an adequate hazard analysis would create insanitary conditions because, without such an analysis, the establishments cannot be sure that it has identified and addressed conditions that could cause the product to be injurious to health.

> **PPIA Sec. 456:** *"Operation of premises, facilities, and equipment (a) Sanitary practices: 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."*

A parallel section is found in Section 456 of the PPIA. This section clearly gives FSIS the authority to adopt regulations to ensure that there are sanitary conditions in establishments where poultry products are prepared and packed so that the resulting product is not injurious to health.

Progression of Statutes

The statutes follow the processes that take place in the plant. For example, Section 603 of the FMIA covers ante-mortem inspection. Section 604 covers post mortem inspection, and the carcasses. 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

The statutes outline requirements for recordkeeping related to the production of meat and poultry products. If you recall from your civics classes, the U.S. Constitution has a provision that 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 inspection personnel to have access to plant records, particularly records related to the implementation of 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 Section 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, the 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 that relates to maintaining its food safety system, whether the records are referenced in the HACCP plan or not (e.g., records of microbiological sampling).

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

Among these, most of the enforcement actions in plant personnel are involved with are the ones that come from the administrative authority. For example, you or other inspection personnel may withhold the marks of inspection or retain product. Let's review each of these authorities in more detail.

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, which is found in section 500 of the FSIS regulations, outline the due process that we must ensure takes place to protect the rights of establishments. Let's review these regulations briefly.

Section 500.2 of the regulations covers the regulatory control actions that take place in the plant, such as tagging product, equipment, or facilities. Remember that these actions are taken to prevent product that has been determined through inspection, to be unwholesome or adulterated from leaving the plant and entering commerce. We are authorized to take these regulatory control actions when we find insanitary conditions or practices, product adulteration, 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, you 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.

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, 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.

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. The prior notification is called a "Notice of Intended Enforcement Action," or NOIE. Specifics about what is contained in the NOIE are 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. Here's 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, you will provide 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 you provide in the NRs that you write are the evidentiary basis upon which this action is taken.

Civil Authorities

The civil authorities covered in the acts are found in Section 677 of the FMIA and 467(c) of the PPIA. Under these authorities, FSIS can enforce, prevent, and restrain violations of the acts. The actions involve U.S. District courts. The primary actions will be detention, and seizure of product. On rare occasions, FSIS can obtain an injunction in a federal court to prevent or restrain an establishment engaging in violations of the acts.

Detention authorities, found in Section 672 of the FMIA, and Section 467(a) of the PPIA, 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 role you might play in a detention action is that you might make a call about adulterated product that has left the establishment, which would lead to the detention action. For example, you may learn of test results that show product is adulterated with *E. coli* O157:H7. The detention action places the product on hold for 20 days. During this time, a decision is made on the ultimate disposition of 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 that affirms that the product is in violation of the acts and must be condemned and 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 are violations of the Acts that are civil in nature, FSIS 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.

Although you will not be involved in taking any civil enforcement action, some of the documentation created in the establishment, such as NRs or memoranda, may be included in a case file that is submitted to the court. Therefore, it's very important that you, and the inspection personnel you supervise, follow the instructions in the Directives; such as those in FSIS Directive 5000.1, on completing NRs accurately, completely, and in a timely manner. They are important pieces that may make a difference in court decisions.

Criminal Authorities

In addition to the administrative and civil authorities, there are criminal authorities granted under the acts. Again, you will probably not have a direct involvement in these kinds of actions. However, the documentation that you; and inspection personnel you supervise produce, may be used in actions. The acts cover the criminal acts of assault and intimidation of a person engaged in official duties, intent to defraud the public by distributing adulterated articles, and bribing or offering a bribe to an inspection official. All of these are prohibited acts. Let's look at each of these closer.

The statutory authority for criminal acts are outlined in the sections of the statutes dealing with the prohibited acts. The prohibited acts are listed in Section 610 of the FMIA and Section 458 of the PPIA. The acts that are prohibited include the following:

- Slaughter or preparation except in compliance with the Act.
- Inhumane slaughter or handling.
- Sale, transport, offering, or receipt, in commerce, of articles capable for use as human food that are either adulterated, misbranded, or not inspected.
- Causing products to become adulterated or misbranded.
- Misuse or unauthorized use of official marks, certificates, labels or devices of inspection.
- The knowing misrepresentation of any article as inspected and passed or exempt under the Act.

These prohibitions apply to persons, firms and corporations. Perpetrators of any violation of these prohibited acts are subject to fines and other penalties.

FMIA Sec. 675; PPIA Sec. 461(c) covers criminal acts related to assault, and intimidation of inspection personnel. Under these statutes, no person shall forcibly assault, resist, oppose, impede, intimidate, or interfere with any USDA employee engaged in or on account of official duties. Therefore, it is prohibited for plant employees to impede you, or interfere in any way with your work. Assault and intimidation are conditions result in immediate withdrawal of inspection with no requirement to notify the establishment (Rules of Practice, 9 CFR 500). If you or any other inspection personnel in the plant are threatened in any way by a person at the establishment, consider safety first. Report it immediately to your supervisor as you have been instructed. The acts outline that these conditions can result in fines and prison time for violators. These types of violations may result in a $5,000 fine, 3 years

prison or both. There are more severe penalties for use of a deadly or dangerous weapon. These statutes also cover the murder of FSIS employees on duty.

Section 676 of the FMIA and Section 461(a) of the PPIA define that persons who intend to defraud or distribute, or attempt to distribute a meat or poultry article that is adulterated is subject to fines, imprisonment, or both.

Section 622 of the FMIA covers the criminal act of bribery. It 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. Bribery is defined as a felony act, and violators are subject to a fine ranging from $5,000 to $10,000, and imprisonment for 1 to 3 years. In addition to these penalties, FSIS will withdraw inspection. This section also prohibits FSIS employees from accepting or receiving money or something of value from representatives of the establishment, or industry. As you may recall from the unit on ethics, you are not to accept any item of value from a plant employee. Other felonies include failing to destroy condemned product, having an owner/operator who has been convicted on a felony, or two or more misdemeanors. Be aware that the USDA's Office of the Inspector General (OIG) conduct investigations into allegations of bribery. The investigations are usually initiated as a result of an anonymous call to the OIG's hotline.

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.

Other Statutory Authorities

In the previous sections, we covered the statutory authorities that were most significant in relation to ensuring the protection of public health. In this section, we will review some additional statutory authorities that relate to your work.

Humane Handling of Livestock

Section 603(b) covers the authorities related to the humane handling of livestock. The Section outlines inspection authority over the methodology of humane handling, and slaughtering of animals. It states that FSIS can establish rules and regulations to oversee that the requirements of the Humane Methods of Slaughter Act are being met at establishments. It also gives FSIS authority to suspend or refuse inspection for violations of the Humane Methods of Slaughter Act. FSIS may refuse to grant inspection, or temporarily suspend inspection for slaughter or handling; other than, in accord with Humane Methods of Slaughter Act.

Labeling

Labeling is also covered in the Acts. Remember that these authorities are secondary to you in your focus. The Agency policy is that we put 90% of our inspection resources into food safety issues (including SSOP, HACCP, Sanitation Performance Standards, and food safety sampling), and 10% into other activities we call "other consumer protection"

activities. Labeling is one of those other consumer protection activities, as is exports. The Directive that covers your inspection responsibilities for labeling is the 7000. Section 607 of the FMIA and Section 457 of the PPIA outline the following:

- All meat and meat food products must be properly labeled, marked and packaged.
- Labels must not be false or misleading.
- FSIS can withhold the use of any false or misleading labels or marks.

As is true of any other provision, these statutes provide for hearing and appeal rights on FSIS decisions.

Exported Product

Section 606 of the FMIA covers exported product. The Act 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 covers the certification of products by FSIS prior to shipping.

The Directive that relates to your inspection responsibilities for exported product is 9000.1. This directive describes what you should do to access the Export Library on the FSIS web site to check the current export requirements. You should do this frequently, as the requirements change regularly. It also covers your role in export certification. The forms that you are to use when performing your inspection duties related to exported products are also found in this Directive.

Summary

Now that we have completed our review of the statutes, you should be able to:

- Understand the purpose of the Acts.
- Identify key definitions from the Acts.
- Understand the statutory authority for FSIS activities.
- Understand how those activities plus authorities in the statutes support enforcement actions.

These Acts provide for the basis for FSIS's ability to perform as a public health agency. Although you find direction for your day-to-day activities in FSIS Directives, the statutes we have reviewed underlie all of these activities and provide the legal basis for them. As you perform your inspection and verification duties, you should always be conscious of the Acts, as they are the foundation for all that we do.

WORKSHOP

Instructions: For each scenario, describe the statutory authority, regulation, and Directive that is associated with it.

Scenario 1:

While performing ante mortem inspection, he PHV observes establishment personnel using a sharp object to drive hogs to slaughter. When questioned, the establishment employee says he did not know that he was not permitted to use the sharp object – in other words he was not properly trained to perform his duties. The PHV verifies that the establishment takes immediate and further preventive actions to address this situation. The PHV also completes an NR using procedure code 04C02 with the trend indicator of "protocol." The use of the sharp object is discontinued.

What is the Directive that guides your activities for this scenario? _____

What is the regulation that relates to this scenario? _____

What is the statutory authority that provides FSIS with the authority to address this scenario? _____

Scenario 2:

The PHV is performing a review of plant records. As directed, the PHV reviews the records associated with the establishment's testing program for E. coli O157:H7 in its raw ground product. The establishment records indicate that no positive results have been found this week.

What is the Directive that guides your activities for this scenario? _____

What is the regulation that relates to this scenario? _____

What is the statutory authority that provides FSIS with the authority to address this scenario? _____

Scenario 3:

The PHV observes the off-line inspectors to determine if they are using the appropriate inspection methods and decision making to verify that the meat from heads, cheeks, and weasands of beef are free of fecal material, ingesta, and milk.

What is the Directive that guides your activities for this scenario? _____

What regulations relate to this scenario? _____
What is the statutory authority that provides FSIS with the authority to address this scenario? _____

Scenario 4:

The PHV observes a cow during ante mortem inspection in very poor condition. The animal is identified as a Suspect. At post mortem inspection, the PHV observes a lesion in the carcass suggestive of an injection site. The PHV retains the carcass, collects kidney tissue samples and conducts the FAST test. After a presumptive positive FAST test, the PHV proceeds to follow the unified sampling directive 10,210.1 to process all the tissues collected. After freezing, all samples with the form are packaged for shipping to the Midwest Lab in St. Louis MO.

What is the Notice that guides your activities for this scenario? _____

What regulations relate to this scenario? _____

What is the statutory authority that provides FSIS with the authority to address this scenario? _____

Scenario 5:

The Consumer Safety Inspector (CSI) comes into the government office and tells the PHV the following: After the establishment had completed its preoperational sanitation procedures, the CSI observed residue of the previous day's operation on the conveyor belt that comes into direct contact with product. The CSI took a regulatory control action and issued an NR.

What is the Directive that guides your activities for this scenario? _____

What regulation relates to this scenario? _____

What is the statutory authority that provides FSIS with the authority to address this scenario? _____

Scenario 6

You are performing the 03J01 procedure in a poultry slaughter operation, and have randomly selected to verify the establishment's verification requirements for the chilling CCP. You review the establishment's HACCP plan, and find that it specifies verification personnel will review the temperature records and observe the monitoring procedures at this CCP once per shift. It also specifies that maintenance personnel will verify the accuracy of the temperature recording charts once per shift by taking an independent temperature check. Based upon your review of the HACCP plan, you determine that the establishment is in compliance with regulatory requirements.

What is the Directive that guides your activities for this scenario? _____

What regulations relate to this scenario? _____

What is the statutory authority that provides FSIS with the authority to address this scenario? _____