

Regulatory Framework

INTRODUCTION

This module covers an overview of the regulatory framework that is used by the Food Safety and Inspection Service (FSIS). This module provides you with information about the context in which you work. It is an overview of the regulatory framework for the Food Safety and Inspection Service (FSIS). As an agent of the federal government, you need to understand your legal responsibilities and the consequences that result when establishments do not comply with the laws and regulations governing meat, poultry, and egg products.

OBJECTIVES

The objectives of this training are as follows.

1. Understand where FSIS derives its authority.
2. Identify what is covered by the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA).
3. Understand what regulations are and where they come from.
4. Understand what Directives are and where they come from.
5. Understand what Notices are and where they come from.
6. Understand the relationship among statutes, regulations, directives, and notices.

Most of your daily work will be guided by the directives and notices. But these are based on regulations and the statutes.

Statutes

Let's go back to the first objective – to understand where FSIS gets the legal authority to regulate meat, poultry, and egg products. This legal authority can be traced all the way back to the United States Constitution. The Constitution grants the authority to regulate commerce among the states. The FMIA, PPIA, and EPIA were all adopted by Congress under that authority. 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).

“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.”

The PPIA and EPIA contain similar statements of findings.

Here are a few other things that you need to know to understand where FSIS derives its legal authority for regulating meat, poultry, and egg products. One is that FSIS is an Agency within the U.S. Department of Agriculture. Another is that FSIS is the agency in the office of the USDA’s Undersecretary for Food Safety. FSIS is a statutory agency in that the legal authority you carry out in your daily activities comes from the statute or the acts that we just mentioned. FSIS is charged by the Secretary of Agriculture with exercising her authority under the MIA, PPIA, and EPIA. The acts granted the legal authority for regulating meat, poultry, and egg products to the Secretary of Agriculture, who in turn has delegated it to FSIS. So, now you should understand that the authority for the actions that you take can be traced up through the Secretary of Agriculture and back to the statutes that were promulgated by Congress. As you go about your daily activities as a Public Health Veterinarian, you should be conscious of the fact that everything that you do is based on these statutes. We must be able to trace the legal authority for enforcement actions back to a statutory basis. You do not need to be a legal expert to perform your job duties effectively. But you do need to have an awareness of where these authorities come from. You can find the statutes on the web at <http://www.fsis.usda.gov/wps/portal/fsis/topics/rulemaking>.

Regulations

Let’s talk about how FSIS implements the statutes. Inspection personnel are charged with carrying out the Acts. However, you will not use the Acts to guide your day to day work. FSIS issues documents that define for inspection personnel, the regulated industry, and the public how these Acts will be carried out. These documents are the ones that will guide you in your daily activities. But, their basis is in the Acts.

These documents that clarify the statutes are called regulations. As mentioned earlier, most of your work will be guided by the regulations. You will use citations from regulations when you complete a Noncompliance Record. Regulations are adopted by a public process that involves notice, comment, and rule making.

Let’s talk about the steps involved in the rule making process. First, the Agency publishes a proposed rule. In this proposed rule, FSIS sets out its initial thinking on a topic. The proposed rule may result from legislation that requires the development of a rule, from a request by the Administrator or other federal management official, or some other reason (e.g., external event). A great deal of background work, including collecting and analyzing data, often goes into the development of a proposed rule. A proposed rule is developed by

a docket team. FSIS Directive 1232.4 describes how a docket team is established and the process used to develop a proposed rule. The proposed rule is published for public review in the Federal Register. You can see a current list of proposed rules on the FSIS web site under the section for Federal Register Publications at <http://www.fsis.usda.gov/wps/portal/fsis/topics/rulemaking>. Once the proposed rule has been posted, the public, including members of the regulated industry, academia, consumer groups, and private individuals have the opportunity to comment on the proposal. The comment period usually lasts sixty days.

After reviewing and considering all of the comments on the proposed rule, the Agency then publishes a final rule. Examples of some significant rules recently published include the Pathogen Reduction and HACCP rule (in 9 CFR section 417) and the Control of *Listeria monocytogenes* in Post-lethality Exposed Ready-to-eat Products (in 9 CFR 430.4).

Each regulation has an effective date. Sometimes the effective date follows very closely with the publication of the regulation. At other times, there is a period of several months between the publication of the final regulation and the effective date to allow the regulated industry time to make changes to implement the provisions of the regulation. In some cases, the effective date for large establishments differs from the effective date for small and very small establishments. Upon the effective date of the regulation, the regulated industry must take steps to comply with the rule, and FSIS is responsible for ensuring that the rule is implemented appropriately by establishments.

Sometimes, even after being given the opportunity for comment, there is disagreement with the legal basis for the regulation. Even after the regulation has been implemented, interested parties have the opportunity to challenge the regulations in court. For example, a group challenged through court action the Agency's enforcement of the pathogen reduction regulation related to *Salmonella* testing. As a result of the court's ruling, FSIS changed the way it addressed sample set failures.

If you review the FMIA, PPIA, and EPIA, you will see that they are very general in nature. The regulations, on the other hand, are rules that take the general principles of the statutes and apply them to specific situations.

Let's walk through an example that shows how the Acts and the regulations are linked. Section 603(b) of the FMIA covers humane methods of slaughter for livestock. It states,

“For the purpose of preventing the inhumane slaughtering of livestock, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of the method by which cattle, sheep, swine, goats, horses, mules, and other equines are slaughtered and handled in connection with slaughter in the slaughtering establishments inspected under this chapter. The Secretary may refuse to provide inspection to a new slaughtering establishment or may cause inspection to be temporarily suspended at a slaughtering establishment if the Secretary finds that any cattle, sheep, swine, goats, horses, mules, or other equines have been slaughtered or handled in connection with slaughter at such establishment by any method not in accordance with the Act of August 27, 1958 (72 Stat. 862; 7 U.S.C. 1901-1906) until the establishment furnishes assurances satisfactory to the Secretary that all slaughtering and handling in connection with slaughter of livestock shall be in accordance with such a method.”

Note that this section of the Acts references the Humane Methods of Slaughter Act that is found in 7 U.S.C. 1901-1906. The regulation that provides more specific information for inspection personnel about how to carry out the Act is found in 9 CFR 313, “Humane Slaughter of Livestock.” A review of the information contained in this regulation will show that it covers specifics such as how livestock should be handled (e.g., driven at a walk with minimum excitement, no sharp objects used, dealing with disabled animals, access to water and feed) and permitted methods of stunning. It also outlines what inspection personnel must do if the establishment fails to comply with the regulation (e.g., notify the establishment, when to issue an NR, conditions under which inspection may be suspended).

Directives

When FSIS issues a regulation, we also issue at least one Directive. Directives contain instructions to inspection personnel about how to implement and enforce the rules. Directives provide information about inspection methods, regulatory decision making, documentation of noncompliance, and appropriate enforcement actions. You can find electronic copies of current FSIS Directives on the FSIS web site (search under key word “Directives” or go to the section for Regulations and Policies) – OR you can find the FSIS Directives on the web at [Regulations, Directives & Notices](#). Directives have no expiration date. Inspection personnel are to follow the information contained in the Directives until they are rescinded or replaced.

Remember that when a Directive is issued, it provides the specific instructions for how you and other inspection program personnel carry out a provision of the statute and the regulation. It’s the basis for conducting inspection. It may contain some attachments, such as Q&A’s, Compliance Guidelines for the industry, or specific instructions (e.g., for collecting samples) that clarify for inspection personnel and/or industry how the regulation is to be carried out. Please note that when the attachments to a Directive include Compliance Guidelines, these are not representative of regulatory requirements. Instead, they are exactly what their title suggests – guidelines to help industry understand how they can go about complying with the regulations.

Recently published Directives reflect the thought process you should use in carrying out inspection procedures – not black and white, yes/no answers. This is because the regulations now focus on providing performance standards that give industry room for innovation, rather than a command and control approach that requires all of industry to do the same thing to meet the requirements of a regulation. Let’s look back at FSIS Directive 6900.2 to see how it lays out the thought process you are to use in verifying regulatory requirements. The Directive discusses how inspection personnel are to verify compliance with regulation 313.2. This part of the regulation addresses driving livestock, dealing with disabled livestock, and stunning methods. The following questions are posed for inspection personnel to use in a thought process that will lead them to make a determination about whether the establishment is complying with the regulation.

Are animals driven from the unloading ramp to the holding pens with a minimum of excitement and not at a running pace?

Are electronic prods and other implements used as little as possible to move animals within the establishment?

Are animals driven by using an object that would not cause unnecessary pain?

Are disabled animals separated from ambulatory animals and placed in a covered pen?

Do animals have access to water?

Is there sufficient room in holding pens for animals held over night?

Notice that these questions allow the establishment latitude on how they comply with the regulations. If they were written in a command and control format, they would list specifics, such as how often (hours, minutes) animals must have access to water, or detail the amount of water that must be available in relation to the number of cattle in a pen (e.g., so many gallons of water provided per so many head of cattle). However, the black and white, or command and control approach takes away industry's ability to innovate and make improvements in the manner in which they comply with the regulations. Using the thought process often means that you have to work a little harder to make a determination about regulatory compliance. But, it is better overall in terms of the results that are obtained for public health.

In following through with our example of humane slaughter, to show the link between the Acts, regulations, and Directives, FSIS Directive 6900.2 covers humane slaughter. It's titled "Humane Handling and Slaughter of Livestock." If you look at the references section on the first page of the Directive, you'll see that the Act 7 U.S.C.1901, 1902, 1906, and the regulation 9 CFR 313 are cited. The background section also covers the Humane Methods of Slaughter Act of 1978, and the regulation 9 CFR 313. Then, the directive provides specific instructions on the verification methods inspection program personnel should perform associated with each part of 9 CFR 313. It outlines questions that inspection program personnel should use to verify that establishments are complying with the regulations, and thus with the Acts. It discusses specific situations, such as ritual slaughter (e.g., Kosher, Halal). Then, it discusses exactly what inspection program personnel are to do if the establishment fails to comply with the regulations. For example, it indicates the type of information to be included on the NR, such as the Humane Activities Tracking System (HATS) category. It outlines the specific circumstances under which inspection should be suspended.

Remember, the Acts provide FSIS with the legal authority to ensure humane handling and slaughtering of animals. Regulation 313 provides more detail about what is required of the industry. FSIS Directive 6900.2 provides specific instructions for inspection program personnel on verifying that industry complies with the regulations. When you determine that there is noncompliance in relation to humane handling, it must relate to a provision in the regulations. You will document this regulation citation on the NR that you write describing the noncompliance. You must be guided by the regulations when determining noncompliance. It is unacceptable and inappropriate to make a determination that there is noncompliance if it cannot be linked to a regulation.

Notices

Now that you have a good understanding about FSIS Directives, let's talk about FSIS Notices. Notices are instructions to FSIS inspection personnel to address a particular

problem that has arisen. The need for Notices is often identified by the Policy Development Division as a result of a number of questions about a specific topic from the field. You can find FSIS Notices on the web at [Regulations, Directives & Notices](#). Notice 12-05, “Documentation of Humane Handling Activities” was issued on February 18, 2005. Among the reasons for its issuance was to provide inspection program personnel with clarification regarding what information they are to record in the HATS tab under the Livestock Humane Handling task in the Public Health Information System (PHIS), and what information they are to include on noncompliance records (NRs) issued for humane handling noncompliance. Notices are numbered based on the fiscal year in which they are issued, and the number of other Notices issued. For example, Notice 12-05 was issued in fiscal year 05 (February 2005), and it was the 12th technical notice issued for 2005. Notices specify an expiration date. For Notice 12-05, the expiration date (shown at the bottom of page 1) was 03/01/05. They are often used as temporary measures until a more comprehensive policy is developed, which may include the issuance of a new regulation and a Directive or Directives. Notices are the shortest and most focused type of direction provided to inspection program personnel. Note that Notice 12-05 references 9 CFR 313 and 500 (Humane Slaughter of Livestock and Rules of Practice regulations, respectively) and FSIS Directive 6900.2. The Notice is only seven pages long, and it has one attachment.

Correspondence between acts, regulations, directives, and notices

You should understand that there is not a one-to-one correspondence between statutory provisions, regulations, Directives, and Notices. For example, a small (or short) statutory provision may result in a very detailed regulation, with multiple Directives, and perhaps Notices as well. Let’s look at the statutory provision covering ante mortem inspection – Section 603(a) of the FMIA. This provision reads,

“Examination of animals before slaughtering: diseased animals slaughtered separately and carcasses examined. For the purpose of preventing the use in commerce of meat and meat food products which are adulterated, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all cattle, sheep, swine, goats, horses, mules, and other equines before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce; and all cattle, sheep, swine, goats, horses, mules, and other equines found on such inspection to show symptoms of disease shall be set apart and slaughtered separately from all other cattle, sheep, swine, goats, horses, mules, or other equines, and when so slaughtered the carcasses of said cattle, sheep, swine, goats, horses, mules, or other equines shall be subject to a careful examination and inspection, all as provided by the rules and regulations to be prescribed by the Secretary, as provided for in this subchapter.”

This short statutory provision is the basis for an extensive regulation, 9 CFR 309. This regulation includes subparts 1 through 18. It covers a range of topics including ante mortem inspection of livestock in pens, identifying disease conditions, dealing with dead and dying animals, disposal of condemned animals, specific diseases, residues, livestock used for research purposes, and official marks of inspection.

Acts → Regulations → Directives → Notices

Summary

To summarize what we've covered, the statute is the legal foundation for our activities. More details about regulatory requirements are set forth in regulations. FSIS Directives and Notices provide specific instructions for your daily work to verify that establishments are complying with the regulations.

When you determine that there is noncompliance, you link it to a regulation and you list the citation of that regulation on the NR. The regulations are based on the statutes. The statutes are used when there are legal challenges to actions taken by FSIS. If the action taken is challenged in court, an FSIS Program Investigator will add statutory citations to the ones you have provided based on the regulations.

REFERENCES

1. Federal Meat Inspection Act
2. Poultry Products Inspection Act
3. Human Methods of Slaughter Act
4. Regulation 313
5. Regulation 500
6. Directive 6900.2
7. Notice 12-05

WORKSHOP

Statute – 603(b) included in the student handout

Regulation – 313.1

Directive – 6900.2

Notice 12-05

What does statute 603(b) cover?

What is the relationship between statute 603(b) and regulation 313.1?

What is the relationship between regulation 313.1 and Directive 6900.2?

What is the relationship between Directive 6900.2 and Notice 12-05?

Supplement for Workshop

REGULATION

PART 313—HUMANE SLAUGHTER OF LIVESTOCK

Sec.

313.1 Livestock pens, driveways and ramps.

313.2 Handling of livestock.

313.5 Chemical; carbon dioxide

313.15 Mechanical; captive bolt.

313.16 Mechanical; gunshot.

313.30 Electrical; stunning or slaughtering with electric current.

313.50 Tagging of equipment, alleyways, pens or compartments to prevent inhumane slaughter or handling in connection with slaughter.

313.90 [Reserved]

AUTHORITY: 7 U.S.C. 1901–1906; 21 U.S.C. 601–

695; 7 CFR 2.17, 2.55.

SOURCE: 44 FR 68813, Nov. 30, 1979, unless otherwise noted.

§ 313.1 Livestock pens, driveways and ramps.

(a) Livestock pens, driveways and ramps shall be maintained in good repair. They shall be free from sharp or protruding objects which may, in the opinion of the inspector, cause injury or pain to the animals. Loose boards, splintered or broken planking, and unnecessary openings where the head, feet, or legs of an animal may be injured shall be repaired.

(b) Floors of livestock pens, ramps, and driveways shall be constructed and

maintained so as to provide good footing for livestock. Slip resistant or waffled floor surfaces, cleated ramps and the use of sand, as appropriate, during winter months are examples of acceptable construction and maintenance.

(c) U.S. Suspects (as defined in § 301.2(xxx)) and dying, diseased, and disabled livestock (as defined in § 301.2(y)) shall be provided with a covered pen sufficient, in the opinion of the inspector, to protect them from the adverse climatic conditions of the locale while awaiting disposition by the inspector.

(d) Livestock pens and driveways shall be so arranged that sharp corners and direction reversal of driven animals are minimized. [44 FR 68813, Nov. 30, 1979, as amended at 53

FR 49848, Dec. 12, 1988]

§ 313.2 Handling of livestock.

(a) Driving of livestock from the unloading ramps to the holding pens and from the holding pens to the stunning area shall be done with a minimum of excitement and discomfort to the animals. Livestock shall not be forced to move faster than a normal walking speed.

(b) Electric prods, canvas slappers, or other implements employed to drive animals shall be used as little as possible in order to minimize excitement