

**USDA – Food Safety and Inspection Service
Center for Learning**



Import Sanitation

Student Notes

Course Number 7100

November 2, 2020

Course Agenda

DAY 1	
9:00	Introduction / Registration / Tech Support
9:30	Statutes and Rules of Practice
11:00	Sanitation Performance Standards (SPS)
1:00	Lunch
2:00	Sanitation Standard Operating Procedures (SSOP)
5:00	Review
6:00	Adjourn

Table of Contents

Introduction	4
Statutes	5
Rules of Practice	9
--Rules of Practice Workshop	13
Sanitation Performance Standards (SPS)	15
Sanitation Standard Operating Procedures	29
--SSOP Workshop 1	32
--SSOP Workshop 2	36
--SSOP Workshop 3	39
--SSOP Workshop 4	41
Regulatory Process for Sanitation SOPs	43
Appendix	49
--Attachment 1 – Rules of Practice (9 CFR Part 500)	49
--Attachment 2 – Federal Meat Inspection Act (FMIA)(Excerpted)	53
--Attachment 3 – FSIS Directive 5,000.1 Revision 5 (Redacted)	Not attached
--Attachment 4 - Acronyms	61

Introduction

Before you can learn the terminology and methods associated with the inspection of imports, it is important that you develop an understanding of where FSIS derives its authority to regulate imports into the United States, and how regulations (rules) are created to hold all importers to a uniform standard. Along with this regulatory basis, we will familiarize you specifically with the regulations addressing sanitation in inspected establishments.

The Import Sanitation Course will cover the following three areas:

- Statutes and the Rules of Practice
- Sanitation Performance Standards (SPS)
- Sanitation Standard Operating Procedures (SSOP)

The way Import Inspectors verify sanitation in import establishments (or “I-Houses”) is somewhat more limited in scope than the way sanitation is verified in domestic establishments that slaughter and process meat, poultry, and egg products. Nevertheless, it is important you know from where the regulations and performance standards are derived and know what sanitation documents you *will* need to verify.

Most I-Houses are large, warehouse-type facilities. Meat and poultry products are not taken out of their containers and handled the way they are in domestic inspected establishments, meaning the facilities are (hopefully!) less messy and relatively easy to maintain in a sanitary condition. For certain tasks, you will need to remove product from shipping containers, thaw it, and either examine it or submit it for sampling, and for that you will only need a small designated room or compartment to conduct re-inspection and sampling, referred to as a Meat Inspection Department or “MID room.”

For this course, you should primarily follow along with the instructors’ presentation; however, this Student Notebook is intended for your use as a more detailed reference for the materials we will cover. It includes a few short workshops which will help gauge your understanding of the material as we go.

Statutes, Regulations, and Rules of Practice

Objectives:

1. Identify where FSIS derives its authority to regulate imported products.
2. Explain the relationship between regulations, directives, and notices.
3. Describe the purpose of the Rules of Practice.
4. List the three most common enforcement actions in order of severity.
5. Identify the conditions for taking each type of enforcement action.

Statutory Authority

Before we can discuss Import Sanitation and Import Inspection, you will need to develop an understanding of the regulatory basis for our authority in inspected establishments. FSIS's authority to conduct inspection activities is derived from the "Acts" (or "Statutes"), laws duly passed by Congress authorizing the Secretary of Agriculture to make regulations governing amenable establishments and products (the word "amenable" simply means "subject to the regulations").

- The Federal Meat Inspection Act (FMIA) was passed in 1906 in response to public outcry about the conditions in meat-packing plants exposed by author Upton Sinclair in "The Jungle." Section 620 of this Act specifically addresses imported product.
- The Poultry Products Inspection Act (PPIA) was passed in 1957 in response to the rapid growth of the poultry industry in this country. It is largely modeled directly after the FMIA. Section 466 of this Act specifically addresses imported product.
- The Egg Products Inspection Act (EPIA) was passed in 1970, directly addressing products made from egg (but not whole eggs). Section 1046 of this Act specifically addresses imported product.

For the purposes of this course, we will focus on the provisions of the FMIA, but understand that there are corresponding provisions in both the PPIA and EPIA. Section 620 of the FMIA specifically grants the Secretary of Agriculture ("the Secretary") the authority to make rules regarding imported product.

Section 620(a):

- (1) Prohibits "adulteration" and "misbranding" of imported products
 - (a) Adulteration is the introduction of contaminants or other deleterious substances to a product that would make it unwholesome, injurious to health of the consumer, or otherwise just unfit for human consumption
 - (b) Misbranding is the improper labeling or marking of product in such a way as to give the consumer a false impression of what is contained in the product packaging

Note: For all product, imported and domestic, Section 601(m) of the FMIA provides universal definitions of “adulteration” and Section 601(n) provides universal definitions of “misbranding.” See the attached excerpts from the Federal Meat Inspection Act.

- (2) Requires establishments to adhere to building construction and other provisions of the regulations
- (3) Requires imported product be derived from animals that were slaughtered humanely (in accordance with standards of the Humane Methods of Slaughter Act of 1958)
- (4) States that once imported, products are subject to and treated by the same standards as domestic products
- (5) Prescribe rules and standards for the marking and labeling of products
- (6) Exemption for items imported for personal consumption

Section 620(b) authorizes the Secretary to establish standards and conditions under which imported product may (or shall) be destroyed (except in cases in which the consignee exports the product to another country within a certain timeframe, or in cases in which the consignee satisfactorily corrects any misbranding errors on the product).

Section 620(f) states that imported products will be subject to the same regulatory standards as domestic product, and that any imported product that does not meet these standards will not be afforded entry into the United States.

Section 608 authorizes the Secretary to make rules (regulations) addressing sanitation for import establishments and products, i.e. prescribe sanitation standards (this will be the purview of the Import Sanitation Course).

Section 621 authorizes the Secretary to periodically make new or amended rules on an ongoing, as-needed basis.

Section 624 authorizes the Secretary to prescribe the conditions under which product may be stored or handled.

Regulations

Inspection activities are governed by the Code of Federal Regulations (CFR), specifically Title 9 (“Animals and Animal Products”), Parts 300 – 592 (stylized as “9 CFR 300 – 592”). The regulations are derived from the authorities granted to the Secretary by the Acts we just covered. As an example, the standards for sanitation are addressed in 9 CFR Part 416.

Obviously, the Secretary does not sit at his or her desk and write the regulations alone. For this, FSIS employs an entire Policy Development Staff, and continually seeks input from industry, consumers, and field personnel when proposing new or amended rules.

It is essential for you to understand the regulations, as these are what you will routinely verify, and what you will cite when documenting regulatory non-compliance.

Directives

These documents provide specific instruction to IPP on how to implement and enforce the rules, and how to verify establishments' compliance with those rules. Directives have **no expiration date**—they remain in effect until rescinded or until a revision is issued.

One example of a directive, FSIS Directive 5,000.1, instructs IPP in detail on how to verify compliance with virtually all of the routine inspection tasks assigned through the Public Health Information System (PHIS), i.e. "Inspection Methodology." However, there are *many* other directives covering topics ranging from finance to laboratory sampling (and of course there are directives related to imports and exports).

Notices

Notices are issued to inspection personnel to address specific problems or concerns that arise in the field. Occasionally, the Policy Development Division (PDD) will issue notices when they receive numerous questions from the field about a particular topic.

Notices are numbered sequentially based on the year in which they are issued (e.g, Notice 13-20 was the thirteenth notice issued during the year 2020), and typically **expire one year after the date of issue** (unless otherwise specified). On rare occasions, guidance in notices will remain in practice after the notice has officially expired; more commonly, such guidance may be later incorporated into a directive.

Enforcement Authorities

-Section 671 of the FMIA spells out our authority for **administrative enforcement**; that is, our ability to implement the Rules of Practice and affect the conditions under which establishments may operate and ship products in commerce. Most of our enforcement activity is administrative.

-Sections 672 and 673 of the FMIA spell out our authority for **civil enforcement**; that is, our authority to seize or detain product in commerce. This authority can have a direct economic impact on businesses, and thus must be used by FSIS judiciously.

-Section 676 of the FMIA spells out our authority for **criminal enforcement**. Fortunately, this authority is not often exercised, but is reserved for serious cases of misbranding product or endangerment of public health.

You do not need to memorize these regulations. Just understand that these are the basis for the regulatory enforcement actions inspection personnel undertake on a daily basis. We will discuss these under "Rules of Practice."

Constitutional Rights

Companies that slaughter, process, import, export, and distribute meat, poultry and egg products have a constitutional right to do business in the United States. The Rules of Practice are designed so that FSIS diligently affords companies “**due process**” in the daily implementation of inspection activities. “Due process” can roughly be defined as a fair proceeding before the government interferes with an establishment’s right to do business.

Inspected establishments have the right to appeal *all* enforcement actions, minutes, hours, or even years after they are implemented. This is why your understanding of your authority and the intent of the regulations is so important.

FSIS Obligations

In accordance with industry’s constitutional rights, establishments have the right to expect that FSIS will:

- Be fair and consistent in the enforcement of regulations
- Provide details about enforcement concerns
- Promptly respond to appeals
- Afford establishments the opportunity to implement corrective actions

Rules of Practice

Purpose

The Rules of Practice, as written in 9 CFR Part 500, are published to define the following:

- (1) The various types (and levels) of enforcement authorities FSIS maintains
- (2) The conditions under which FSIS may take enforcement actions
- (3) The enforcement process
- (4) The right of industry to appeal enforcement actions without fear of reprisal

Regulations

Section 500.1 – Defines “regulatory control action”, “withholding action”, and “suspension”

- Regulatory control actions (RCA) may be taken by IPP in order to prevent adulterated or misbranded product from entering commerce, or to prevent the use of insanitary rooms or equipment.
- Withholding actions refer to FSIS withholding the marks of inspection from being applied to specific products or processes (or all products in an establishment). IPP may take withholding actions but are advised to immediately notify their chain-of-command (Frontline Supervisor, etc.) when they do so.
- Suspension literally refers to the “suspension of assignment of inspection program personnel to an establishment.” Only the District Manager (DM) or designee may issue a suspension.

Section 500.2 – Lists the conditions under which IPP may take regulatory actions, instructs IPP to provide immediate notification, and affords establishments the right to appeal

- Insanitary conditions or practices
- Adulterated or misbranded product
- Conditions that preclude FSIS from determining that product is not misbranded or adulterated
- Inhumane handling of livestock

IPP may issue a regulatory control action (RCA) without prior notification but should immediately notify the establishment orally and/or in writing. Regulatory control actions most commonly take the form of the placement of a beige tag either retaining product or rejecting equipment or compartments. Establishments have the right to appeal any RCA.

Section 500.3 – Lists the conditions under which FSIS may issue a withholding action or suspension *without* prior notification to the establishment:

- Produced or shipped adulterated or misbranded product
- Establishment does not have a HACCP plan (does not apply to imports!)
- Establishment does not have Sanitation Standard Operating Procedures (SSOP)

- Egregious insanitary conditions
- Establishment violated the terms of an RCA (e.g., removed a tag placed by IPP)
- Establishment employee assaulted, threatened, intimidated, or interfered with IPP
- Establishment did not properly dispose of condemned product within 3 days of notification

For the purposes of this course, we are primarily concerned with insanitary conditions, the lack of a written SSOP, and the production or shipping of adulterated or misbranded product.

Section 500.4 – Lists the conditions under which FSIS may issue a withholding action or suspension *with* prior notification to the establishment

- Inadequate HACCP system (not applicable to imports!)
- Improper implementation or maintenance of SSOP
- Failure to maintain sanitary conditions; usually a trend of non-compliance
- Failure to perform testing or meet standards for control of certain foodborne pathogenic (harmful) bacteria (also, not usually applicable to imports!)

Again, for the purposes of this course, we will most be concerned with failures related to Sanitation Performance Standards (SPS) and Sanitation Standard Operating Procedures (SSOP).

Section 500.5 – Parts (a) and (b) prescribe the notification requirements and processes for withholding and suspension actions without or with prior notification, respectively; it also reiterates establishments' right to appeal and a fair hearing, and affords the District Manager the authority to hold a suspension in abeyance (i.e., delay implementation of a suspension to allow an establishment to implement corrective actions)

Section 500.5(b) lays out the conditions for what is called a Notice of Intended Enforcement (NOIE), issued by the District Manager (see below). It will state the type of enforcement action (withholding or suspension), the basis for the action, the products or processes affected, the establishment's right to appeal, and affords the establishment 3 days to respond with proposed corrective actions.

Section 500.6 – Defines the conditions under which FSIS may withdraw a grant of inspection from an establishment

Section 500.7 – Defines the conditions under which FSIS may refuse to issue a grant of inspection to an establishment

Section 500.8 – Includes procedures for FSIS to refuse or rescind approval of marks, labels, and containers

Notice of Intended Enforcement (NOIE)

Under conditions in which inspection personnel present the District Manager with justifiable grounds for a withholding action or suspension, the DM will issue a Notice of Intended Enforcement, or NOIE. The NOIE will include the following:

- The nature of the enforcement action (withholding or suspension)
- The regulatory basis for the enforcement action
- The products or processes affected
- Reiterates the establishment's right to appeal or contest the enforcement action
- Informs the establishment it has 3 days to respond in writing with proposed corrective actions; if the DM deems the proposed corrective actions to be inadequate, he or she may proceed to issue a Notice of Suspension (NOS), or may issue a Notice of Inadequate Response (NOIR), thus allowing the establishment one or more subsequent opportunities to propose adequate corrective actions

Once the District Manager has received the establishment's written response, one of the following may occur:

- (1) The DM may accept the response
- (2) The DM may reject the response and implement either
 - (a) The proposed withholding action
 - (b) The proposed suspension
 - (i) In some cases, the DM may elect to hold the suspension in abeyance, allowing the establishment some time to implement its planned corrective actions
- (3) The DM may defer enforcement and monitor implementation of corrective actions

Verification Plans

If the District Manager defers a decision on enforcement, or holds a suspension in abeyance, an Enforcement, Investigations, and Analysis Officer (EIAO) will be assigned to develop a Verification Plan (VP). The Verification Plan is a systematic plan for the in-plant inspector to verify the establishment's implementation of its corrective actions. These plans typically include increased frequency of certain relevant inspection tasks, as well as special weekly or bi-weekly documentation of findings for review at the District Office.

Review of Establishment History

Under any circumstances, upon entering a new assignment, you should be reviewing recent documented non-compliances, reviewing the results of any Food Safety Assessments (FSA) conducted at the establishment (think of an FSA as a kind of "audit" conducted by an EIAO), and review documents associated with any past enforcement actions at the establishment.

Appeals Process

Recall that the regulations (9 CFR Part 500) stipulate that establishments have the right to appeal any and all enforcement actions, regardless of extent or severity (this is a fundamental part of due process). They may appeal any regulatory decision of any FSIS program employee, and there is no time limit for making such appeals. Furthermore, establishments have the right to appeal without any fear of reprisal or retaliation from FSIS.

Establishments are to follow the FSIS chain of command when making appeals:

- (1) Program employee who made the regulatory determination
- (2) Frontline Supervisor (FLS)
- (3) District Manager (DM) – or designee, such as a Deputy District Manager (DDM)
- (4) Executive Associate for Regulatory Operations (EARO)
- (5) Assistant Administrator for Field Operations
- (6) FSIS Administrator

Rules of Practice Workshop

Using the module and Rules of Practice Regulations, answer the following questions. (Note that not all definitions are used.)

1. Match the following terms with their definition:

- | | |
|--------------------------------|---|
| ____ Compliance | A. Retention of product, rejection of equipment or facilities, refusal to allow the processing of specific product. |
| ____ Due process | B. DM suspends inspection; subsequently allows the establishment to operate after implementing corrective action |
| ____ Regulatory control action | C. Establishment processes are working properly in accordance with the laws and regulations. |
| ____ Withholding | D. Provides a systematic means for FSIS to verify that an establishment is effectively implementing the correctives measures. |
| ____ Suspension | E. The documentation that FSIS uses to provide prior notification of an intended enforcement action. |
| ____ NOIE | F. Refusal to allow the marks of inspection to be applied to products; may affect all or part of the product produced |
| ____ Abeyance | G. A fair proceeding must take place before the government interferes with an individual's property or actions. |
| ____ Verification plan | H. Interruption in the assignment of program employees to all or part of an establishment |
| | I. DM postpones an enforcement decision to allow establishment to implement proposed plan |

2. a. Who is authorized to take regulatory control action?
- b. Is prior notification of regulatory control action required?
- c. How is the establishment informed of regulatory control action?
- d. How is a regulatory control action documented?

3. For each of the circumstances below, indicate the most appropriate type of withholding action or suspension that should be taken. Use **WO** for without prior notification and **WP** for with prior notification

- ___ Produced and shipped adulterated product
- ___ Recurring insanitary conditions documented by FSIS
- ___ Egregious insanitary conditions involving food contact surfaces
- ___ Establishment has no HACCP plan

4. Read the following statements and mark T for true or F for false.

- a. An establishment may appeal any regulatory control action. ___
- b. There is no time limit to initiate an appeal. ___

Sanitation Performance Standards (SPS)

Objectives

1. Define “sanitation” and where FSIS derives its authority to verify sanitation regulations.
2. List the SPS regulations and describe where they apply in inspected establishments.
3. List examples of SPS non-compliance.
4. Apply knowledge of Rules of Practice to enforcement actions related to sanitation.

Background

Sanitation is defined by FSIS as “the formulation and application of procedures that establish an environmental state that promotes cleanliness and protects public health.” The Acts state multiple times that sanitation is vital to product wholesomeness and authorize the Secretary to make sanitation rules and standards and appoint inspectors to enforce them.

The sanitation regulations are all contained in 9 CFR Part 416. Some of these regulations address conditions in and around the establishment that may lead to adulteration of product if prudent measures are not taken—these are what we call **Sanitation Performance Standards**, or SPS, and are contained in 9 CFR 416.1 through 416.6. SPS regulations set goals or standards establishments must meet for sanitation, but they do not prescribe how they must meet the standards, and they do not require any written programs or recordkeeping system (though there are some forms of documentation that will need to be verified). The remaining regulations (9 CFR 416.11 through 416.17) require establishments to develop written procedures describing how they will protect product and food-contact surfaces on a daily basis. These are what we refer to as **Sanitation Standard Operating Procedures (SSOP)**.

It is important for you to understand how SPS and SSOP interrelate, and that they carry equal weight when it comes to regulatory significance.

The following types of establishments *all* must meet the sanitation regulatory requirements:

- Federal or State inspected establishments
- Import and Export facilities
- Identification (ID) warehouses
- Custom exempt slaughter or processing facilities

As an Import Inspector, there are some subtle differences from domestic inspected establishments to keep in mind. Often, you may only have “jurisdiction” over a small staging room or area within a large, warehouse-type facility, and in some cases, inspections may be conducted at the back of a truck or on a loading dock. While you may only be assessing food contact surfaces and possible direct product adulteration situations in that limited area (i.e., SSOP), you are still authorized to assess sanitary conditions in and around the area where import re-inspection is conducted (i.e., SPS addresses other parts of the building and grounds).

SPS Verification Task

To verify compliance with the Sanitation Performance Standards, you will routinely perform direct observation of the establishments' facilities and equipment for overall sanitary conditions, and you will periodically review certain documents associated with the SPS. Results of the SPS verification task—including any non-compliances observed—will be documented under the “SPS Verification” task in PHIS. Some of these documents include:

- Pesticide use information
- Certification of water potability
- Certification of private sewer or septic systems by State or local authorities
- Safety data related to cleaning compounds, sanitizers, and any other chemicals used in the establishment

When performing the SPS Verification task, you will select one or more of the 11 standards to verify. They may be selected at random, or they may be selected in response to recent problems or trends in non-compliance.

To determine compliance, you will use what we refer to as the “GAD” process:

- (1) **Gather** information by asking questions derived from the regulations
- (2) **Assess** the situation
 - (a) What is known for a fact?
 - (b) What is reasonable to conclude?
- (3) **Determine** if the situation creates an insanitary condition or contaminates or adulterates product, i.e., non-compliance

You are always to use sound reasoning and good judgement, and to follow precisely the procedures set out in FSIS Directive 5,000.1 for performing verification activities.

Some “GAD” questions you might ask yourself:

- Are the conditions you observed creating an insanitary condition?
- Are the conditions you observed contaminating product and/or food contact surfaces?

If SPS requirements are not being met, evaluate what is known and determine whether SSOP requirements are *also* not being met. This is how SPS and SSOP relate to one another. **Sometimes, what initially appears to be a non-compliance with one of the SPS standards actually is determined to be an SSOP non-compliance because product or food contact surfaces are affected.**

In all cases, non-compliance with one or more regulations should result in issuance of a non-compliance record (NR) to the establishment.

SPS Regulatory Requirements

Recall that the Sanitation Performance Standards address conditions in and around the official premises of an establishment that *may* result in insanitary conditions which *could* lead to adulteration of product. (The “official premises” of an establishment are usually determined during the grant approval process; however, conditions adjacent to or outside those boundaries can *still* affect sanitary conditions on the premises and in the establishment itself).

SPS non-compliance refers to “insanitary conditions,” *not* direct product contamination or adulteration situations.

Next, we will go through the SPS regulations individually and define all 11 Sanitation Performance Standards.

§416.1 General rules.

Each official establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated.

9 CFR 416.1 is the overall general rule that requires establishments to be operated and maintained in a sanitary condition and thereby prevent the adulteration of product. IPP are *not* to cite this regulation routinely when documenting non-compliance. This regulation is reserved for situations in which either (a) there is an egregious insanitary condition caused by obvious negligence by establishment management to address a sanitary concern or (b) there is a trend of repeated, uncorrected non-compliances leading to an egregiously insanitary condition. **In either case, this regulation is never cited without first compiling sufficient supporting documentation (e.g., prior NRs) and correlating with your Frontline Supervisor.**

§416.2 Establishment grounds and facilities.

(a) *Grounds and pest control.* The grounds about an establishment must be maintained to prevent conditions that could lead to insanitary conditions, adulteration of product, or interfere with inspection by FSIS program employees. Establishments must have in place a pest management program to prevent the harborage and breeding of pests on the grounds and within establishment facilities. Pest control substances used must be safe and effective under the conditions of use and not be applied or stored in a manner that will result in the adulteration of product or the creation of insanitary conditions.

9 CFR 416.2(a) sets the standard that establishments will maintain a pest control program to prevent the possible harborage and breeding of pests (e.g., mice, rats, flies, birds, etc.). Concerning observations might include tall grass and weeds near the premises, open or overflowing dumpsters, or piles of debris near or adjacent to buildings where products are handled or manufactured.

The pest control program does not need to be a written program, nor are establishments required to hire outside pest management contractors. However, they should maintain documents (labels or package inserts) for pest control substances describing the terms of their safe and effective use. IPP will periodically need to verify that

- These documents are maintained on premises.
- Pest control substances are being used safely in accordance with labeled instructions.
- Substances are not stored or applied in a manner which could adulterate product.

Also, note that while pest control is the main focus of this standard, it *also* prescribes that the grounds and premises must generally be maintained in a sanitary condition to prevent the adulteration of product. Trash, debris, spilled chemicals, and foul odors outside the establishment can have a direct effect on product held within, even if pest activity is not observed.

§416.2 Establishment grounds and facilities.

(b) *Construction.* (1) Establishment buildings, including their structures, rooms, and compartments must be of sound construction, be kept in good repair, and be of sufficient size to allow for processing, handling, and storage of product in a manner that does not result in product adulteration or the creation of insanitary conditions.

9 CFR 416.2(b)(1) prescribes standards for the construction, condition, and size of buildings, rooms, and compartments. Observations of concern might include

- Roofs that leak when it rains.
- Product handling areas not adequately separated by walls from break areas or locker rooms.
- Storage or manufacturing areas so small and cramped that edible and inedible product cannot be kept separated, or employee hygiene practices cannot be maintained.

§416.2 Establishment grounds and facilities.

(b) *Construction.*

(2) Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture and be cleaned and sanitized as necessary to prevent adulteration of product or the creation of insanitary conditions.

9 CFR 416.2(b)(2) specifically prescribes the standards for walls, floors, and ceilings. They must be of durable materials, i.e. not easily chipped, cracked, or broken, and they must be cleaned and sanitized as necessary—or as *often* as necessary—to prevent the creation of insanitary conditions.

Observations of concern might include

- Unsealed wood which might hold and soak in moisture and trapped food particles and bacteria
- Chipped floors where water containing organic material can pool and lie stagnant
- Flaking paint, rust, or other foreign materials that may fall on exposed product.

§416.2 Establishment grounds and facilities.

(b) *Construction.*

(3) Walls, floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice.

9 CFR 416.2(b)(3) specifically prescribes that walls, floors, ceilings, doors, windows, etc. must be constructed and maintained in such a way as to prevent pests from entering the establishment. It is not sufficient for establishments to trap mice, rats, flies, or other vermin *inside* the facilities where product is handled or stored—the pest management program must be designed to keep them *outside*.

Observations of concern might include

- Broken screens, windows, or curtain-type doors leading to outside docks
- Large gaps in doors leading outside (or open doors)
- Open air vents, or unused drain systems

§416.2 Establishment grounds and facilities.

(b) *Construction. ...*

(4) Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled, or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions.

9 CFR 416.2(b)(4) states establishments must adequately separate edible and inedible product by constructing rooms and compartments of adequate size and with clear separations. It should be noted that establishments may handle edible and inedible materials in the same compartments, if those materials are separated by **time and space**. That means they might handle them in the same room at different times of day (with cleaning and sanitation in between), or they may space them far enough apart that, in your sound judgement, edible product is not at risk of adulteration.

§416.2 Establishment grounds and facilities.

(c) *Light.* Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained and that product is not adulterated must be provided in areas where food is processed, handled, stored, or examined; where equipment and utensils are cleaned; and in hand-washing areas, dressing and locker rooms, and toilets.

9 CFR 416.2(c) prescribes the standard for lighting. Note that it does not prescribe any specific color or intensity of light, only that it be sufficient to facilitate visual inspection of all areas of the establishment and that employees are not prevented from taking measures to maintain sanitary conditions.

Example observations of concern might include

- Poor lighting in a staging area, so an Import Inspector cannot clearly see labels or the condition of containers or products
- No light in a lavatory, so employees are compelled to wash their hands in food processing sink immediately after using the restroom

§416.2 Establishment grounds and facilities.

(d) *Ventilation.* Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided.

9 CFR 416.2(d) requires that establishments maintain adequate ventilation to prevent adulteration of product by foul or noxious odors or vapors, or by dripping condensation from overhead structures. Condensation is always a concern when steam or humid air interacts with the cool dry air created by air conditioners and refrigeration units. Establishments must have measures in place to both prevent the buildup of condensation and control it when it does develop.

§416.2 Establishment grounds and facilities.

(e) *Plumbing.* Plumbing systems must be installed and maintained to:

- (1) Carry sufficient quantities of water to required locations throughout the establishment;
- (2) Properly convey sewage and liquid disposable waste from the establishment;
- (3) Prevent adulteration of product, water supplies, equipment, and utensils and prevent the creation of insanitary conditions throughout the establishment;
- (4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor;
- (5) Prevent back-flow conditions in and cross-connection between piping systems that discharge waste water or sewage and piping systems that carry water for product manufacturing; and*
- (6) Prevent the backup of sewer gases.

9 CFR 416.2(e) is a six-part regulation addressing plumbing in inspected establishments. The wording of each part is fairly self-explanatory, but in summary, the regulation prescribes that the plumbing system must do the following:

- Must provide **sufficient quantities of water** as needed throughout the establishment.
- Must properly **carry away sewage and liquid disposable waste**.
- Generally, **prevent adulteration of product, water supply, and equipment** (not contribute to an insanitary condition in any way);
- Provide **adequate floor drainage**.
- **Prevent back-flow conditions and cross-connections** between potable water and sewage; and
- **Prevent the backup of sewer gases**.

Observations of concern might include

- Floor drains in the staging area backing up after wash-down, with pallets of product sitting in an inch of stagnant water
- A hose with no valves laying in a pool of water on the floor
- An interruption in water supply preventing the proper washing of utensils and equipment

*We will see some examples of cross-connections and backflow in the slide presentation.

§416.2 Establishment grounds and facilities.

(f) *Sewage disposal.* Sewage must be disposed into a sewage system separate from all other drainage lines or disposed of through other means sufficient to prevent backup of sewage into areas where product is processed, handled, or stored. When the sewage disposal system is a private system requiring approval by a State or local health authority, the establishment must furnish FSIS with the letter of approval from that authority upon request.

9 CFR 416.2(f) addresses the matter of sewage disposal. Most import establishments likely are connected to municipal sewer authorities; therefore, you will only need to verify that the sewage disposal system is working properly (e.g., there is no backup of wastewater or sewage odor). However, some inspected establishments in isolated or rural locations may be connected to a private sewage system, such as a septic system. In these conditions, IPP should periodically verify that the establishment has on hand a current letter of approval from a State or local authority responsible for certifying such private sewage disposal systems (usually this is done semi-annually, or as needed).

§416.2 Establishment grounds and facilities.

(g) *Water supply and water, ice, and solution reuse.*

(1) A supply of running water that complies with the National Primary Drinking Water regulations (40 CFR part 141), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and packaging materials, for employee sanitary facilities, etc.). If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually.

While 9 CFR 416.2(e) requires that establishments have a supply of water sufficient in quantity, 9 CFR 416.2(g)(1) requires that establishments have a supply of potable water in compliance with the National Primary Drinking Water Act. It also specifies that the water must be supplied under a **suitable temperature and pressure** to maintain sanitary conditions.

If an establishment is connected to a municipal water supply (as is probably more common among import establishments), IPP will periodically review water reports or other documents issued by a State or local health authority attesting to the potability of the water supply (typically at least annually). If an establishment is connected to a well or other private water supply, IPP must review documentation certifying the potability of the water at least twice per year.

§416.2 Establishment grounds and facilities.

(g) *Water supply and water, ice, and solution reuse. ...*

(2) Water, ice, and solutions (such as brine, liquid smoke, or propylene glycol) used to chill or cook ready-to-eat product may be reused for the same purpose, provided that they are maintained free of pathogenic organisms and fecal coliform organisms and that other physical, chemical, and microbiological contamination have been reduced to prevent adulteration of product.

(3) Water, ice, and solutions used to chill or wash raw product may be reused for the same purpose provided that measures are taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. Reuse that which has come into contact with raw product may not be used on ready-to-eat product.

(4) Reconditioned water that has never contained human waste and that has been treated by an onsite advanced wastewater treatment facility may be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas, provided that measures are taken to ensure that this water meets the criteria prescribed in paragraph (g)(1) of this section. Product, facilities, equipment, and utensils coming in contact with this water must undergo a separate final rinse with non-reconditioned water that meets the criteria prescribed in paragraph (g)(1) of this section.

(5) Any water that has never contained human waste and that is free of pathogenic organisms may be used in edible and inedible product areas, provided it does not contact edible product. For example, such reuse water may be used to move heavy solids, to flush the bottom of open evisceration troughs, or to wash antemortem areas, livestock pens, trucks, poultry cages, picker aprons, picking room floors, and similar areas within the establishment.

(6) Water that does not meet the use conditions of paragraphs (g)(1) through (g)(5) of this section may not be used in areas where edible product is handled or prepared or in any manner that would allow it to adulterate edible product or create insanitary conditions.

9 CFR 416.2(g)(2) through (g)(6) address the conditions under which used water and solutions used in food processing may be reconditioned or re-circulated. It is unlikely this will be an important consideration in import establishments, so we will not discuss these in great detail. However, it is useful to understand that these provisions exist. Custom exempt establishments, however, are not permitted to reuse water, ice, and solutions.

§416.2 Establishment grounds and facilities.

(h) Dressing rooms, lavatories, and toilets.

(1) Dressing rooms, toilet rooms, and urinals must be sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms and compartments in which products are processed, stored, or handled.

(2) Lavatories with running hot and cold water, soap, and towels, must be placed in or near toilet and urinal rooms and at such other places in the establishment as necessary to ensure cleanliness of all persons handling any product.

(3) Refuse receptacles must be constructed and maintained in a manner that protects against the creation of insanitary conditions and the adulteration of product.

9 CFR 416.2(h) is a critically important regulation. All inspected facilities—domestic, import, custom, or other—must be equipped with functioning lavatories and toilets (in FSIS terms, the word “lavatory” refers to a sink used for handwashing and personal hygiene), and dressing rooms or locker rooms as needed. As the regulation states, these compartments must meet the following standards:

- Be sufficient in number for the size of the facility and the number of employees working therein. There is no specific formula for the number of toilets, sinks, etc. per person, but it must be apparent in the judgement of IPP that they are sufficient to maintain sanitary conditions.
- Toilets and lavatories must, of course, be separate from compartments in which product is stored or handled.
- Lavatories must have running hot and cold water with soap and disposable hand towels, and they must be placed in or near toilets.
- 9 CFR 416.2(h)(3) addresses the placement and condition of trash receptacles.

Examples of observations of concern might include

- One functioning bathroom for a large facility with over 100 employees with overflowing trash cans that cannot be adequately maintained.
- A bathroom with an overflowing toilet or sink that is being used by employees during operations.
- A lack of running hot water in establishment handwash sinks, or empty soap or towel dispensers; or
- Overflowing trash receptacles in the processing area.

§416.3 Equipment and utensils.

(a) Equipment and utensils used for processing or otherwise handling edible product or ingredients must be of such material and construction to facilitate thorough cleaning and to ensure that their use will not cause the adulteration of product during processing, handling, or storage. Equipment and utensils must be maintained in sanitary condition so as not to adulterate product.

(b) Equipment and utensils must not be constructed, located, or operated in a manner that prevents FSIS inspection program employees from inspecting the equipment or utensils to determine whether they are in sanitary condition.

(c) Receptacles used for storing inedible material must be of such material and construction that their use will not result in the adulteration of any edible product or in the creation of insanitary conditions. Such receptacles must not be used for storing any edible product and must bear conspicuous and distinctive marking to identify permitted uses.

You may only need to verify this regulation infrequently in I-houses, as there is minimal handling of product by employees, and often very little equipment involved. While the act of contaminating or adulterating product with insanitary equipment or utensils would be covered under the SSOP regulations, which we will discuss later, 9 CFR 416.3 addresses generally how equipment and utensils shall be constructed and maintained, and specifies the requirements for receptacles for inedible materials (sub-part 416.3(c)).

“Equipment” refers to items like prep tables, table saws, sinks, pallets, hoses, hand carts or totes, or other items upon which product might be placed, or which might touch product indirectly. “Utensils” refers to items like knives or hooks, or even handheld thermometers, which employees may use to directly handle product.

In general, establishments must be able to thoroughly clean and sanitize equipment and utensils, i.e., they must be impermeable to moisture and they must be able to access all parts of the equipment which may conceal scraps of product from previous days’ production. They also must allow FSIS access to inspect all parts of such equipment and utensils.

Example observations of concern might include

- Knives with unsealed wooden handles that may soak in moisture and bacteria
- Plastic cutting boards with deep grooves that may harbor bacteria
- Rusty carts or tables or dirty hoses, which may be touched by employees who then proceed to touch product
- Being unable to inspect the inner housing of a table saw for scraps of meat and fat from a previous days’ production
- Unmarked inedible bins being used to hold edible product

§416.4 Sanitary operations.

(a) All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

(b) Non-food-contact surfaces of facilities, equipment, and utensils used in the operation of the establishment must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

(c) Cleaning compounds, sanitizing agents, processing aids, and other chemicals used by an establishment must be safe and effective under the conditions of use. Such chemicals must be used, handled, and stored in a manner that will not adulterate product or create insanitary conditions. Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection program employees for review.

(d) Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.

9 CFR 416.4 is a critical regulation that is frequently cited in situations of SPS non-compliance.

As you can see above, sub-parts (a) and (b) prescribe that food contact surfaces and non-food contact surfaces, respectively, must be cleaned and sanitized *as frequently as necessary* to maintain sanitary conditions. (For example: 416.4(a) might be cited for the discovery of insanitary knives, whereas 416.4(b) might be cited for the finding of a rusty or dirty handcart used to transport product, or even a dirty wall or overhead pipe).

While 9 CFR 416.2(a) governs the safe storage, handling, and use of pesticides, 9 CFR 416.4(c) addresses the safe handling and use of cleaning compounds, processing aids, or any other chemicals routinely used. It also requires the maintenance of documentation—which IPP should periodically verify—describing the safe handling and use of such chemicals. (A common example would be having Safety Data Sheets on file for all chemicals).

9 CFR 416.4(d) is perhaps one of the most critical of all SPS regulations. It prescribes that product *must be protected at all times*, starting when it is first unloaded at the establishment and not ending until product is delivered to its end-consumer or consignee in commerce (i.e., in transit to its final place of delivery). This is why IPP have the authority under SPS to inspect the conditions of truck trailers and other conveyances at official establishments. This regulation is often cited in conjunction with SSOP regulations when it can be demonstrated that an establishment failed to protect product from adulteration.

§416.5 Employee hygiene.

(a) *Cleanliness.* All persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions.

(b) *Clothing.* Aprons, frocks, and other outer clothing worn by persons who handle product must be of material that is disposable or readily cleaned. Clean garments must be worn at the start of each working day and garments must be changed during the day as often as necessary to prevent adulteration of product and the creation of insanitary conditions.

(c) *Disease control.* Any person who has or appears to have an infectious disease, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, must be excluded from any operations which could result in product adulteration and the creation of insanitary conditions until the condition is corrected.

There is only limited handling of product by employees in import establishments; however, 9 CFR 416.5 gives IPP the authority to observe and verify that establishment employees involved in the handling of product undertake prudent personal hygiene measures to protect product and food contact surfaces from contamination.

Sub-part (a) prescribes general cleanliness for all personnel, while sub-part (b) specifically addresses the conditions of clothing and outer garments, such as gloves, frocks, aprons, hairnets, etc. Sub-part (b) also requires employees to start the day with clean clothing, and to wash or change it as frequently as necessary to maintain sanitary conditions.

Sub-part (c) explicitly states that employees with outward signs of disease or illness, including open sores or wounds, shall not be involved in operations. If, for example, an employee has a cut or sore on their hand, they would be required to wash their hand, apply a clean bandage, and wear clean gloves both to protect the wound *and* protect the product. Similarly, IPP are to verify that supervisors are excusing from operations employees who are exhibiting coughing, sneezing, vomiting, diarrhea, fever, or other clinical signs of illness.

What is unique about the employee hygiene regulations is that they apply equally to FSIS personnel. IPP are expected to maintain the same standards of personal hygiene and cleanliness and are not to be in and around establishments and product when they exhibit signs of illness.

§416.6 Tagging insanitary equipment, utensils, rooms or compartments.

When an FSIS program employee finds that any equipment, utensil, room, or compartment at an official establishment is insanitary or that its use could cause the adulteration of product, he will attach to it a “U.S. Rejected” tag. Equipment, utensils, rooms, or compartments so tagged cannot be used until made acceptable. Only an FSIS program employee may remove a “U.S. Rejected” tag.

9 CFR 416.6 addresses the use of the beige “U.S. Rejected” tag to take regulatory control over insanitary rooms, compartments, or equipment. Note that in FSIS, we use these tags to REJECT rooms and equipment and to RETAIN product (which is only applied when product contamination or adulteration has occurred). Because SPS refers to conditions **in and around** the establishment, only the REJECT component applies here. Once a “U.S. Rejected” is applied, IPP should always follow the Rules of Practice by informing establishment management orally, then issuing a non-compliance record (NR) to document the finding(s) in writing.

The last clause states that *only* an FSIS employee may remove a “U.S. Rejected” tag. Removal of such a tag by establishment personnel without permission of IPP is considered interference with inspection activities, and could result in withholding actions (or more severe enforcement).

In summary, the 11 standards of SPS are as follows:

- | | |
|----------|---|
| 416.2(a) | Grounds and pest control |
| 416.2(b) | Construction |
| 416.2(c) | Lighting |
| 416.2(d) | Ventilation |
| 416.2(e) | Plumbing |
| 416.2(f) | Sewage disposal |
| 416.2(g) | (Potable) water supply and water/ice/solution reuse |
| 416.2(h) | Dressing rooms, lavatories, and toilets |
| 416.3 | Equipment and utensils |
| 416.4 | Sanitary Operations |
| 416.5 | Employee hygiene |

IPP are to select one or more standards to verify when performing the SPS Verification task. These may be selected at random, or on a rotating basis, or they may be selected in response to specific ongoing concerns or recent trends non-compliance.

Though we have discussed the Sanitation Performance Standards in great detail, it is first essential that you understand what the standards are, and that the SPS only prescribe the goals, not how establishments are to achieve them. Establishments may take whatever methods they deem prudent to achieve the SPS.

SPS is primarily focused on observation in and around the establishment—only occasionally is there documentation that you may need to review (this is a significant difference from SSOP).

Sanitation Standard Operating Procedures (SSOP)

Objectives

1. Define SSOPs and understand their relationship to SPS.
2. List the 4 regulatory requirements of SSOP.
3. Understand the 4 tasks IPP use to verify compliance with the SSOP regulations.
4. Describe how IPP verify establishment corrective actions following SSOP non-compliance.

Background

SPS defines 11 sanitation standards (goals) for conditions in and around establishments which must be met to remain in compliance with FSIS regulations. Sanitation Standard Operating Procedures (SSOP) are the basis for specific daily activities establishments will conduct before and during operations to ensure that sanitary conditions are maintained and that product is not adulterated.

Unlike SPS, Sanitation SOPs must be written, and establishments must maintain daily records associated with their implementation. SSOPs are addressed by regulations 9 CFR 416.11 through 416.17. The basic regulatory provision for SSOP is as follows:

§416.11 General rules.

Each official establishment shall develop, implement, and maintain written standard operating procedures for sanitation (Sanitation SOP's) in accordance with the requirements of this part.

As we hinted at, there are four regulatory requirements related to SSOP, three of which are mentioned in the general rules:

- Implementation
- Maintenance
- Corrective Actions
- Recordkeeping

Each of the subsequent regulations spells out the requirements in greater detail.

Development

9 CFR 416.12 directs each inspected establishment to develop SSOPs to maintain sanitary conditions and prevent the adulteration of product. In fact, Frontline Supervisors are tasked with ensuring establishments have developed written SSOPs before even recommending the District Manager issue a grant of inspection. Let's look at each part individually:

§416.12 Development of Sanitation SOP's.

(a) The Sanitation SOP's shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).

9 CFR 416.12(a) states that the Sanitation SOPs will define procedures conducted daily, before *and* during operations to prevent contamination or adulteration of product. The key words here are "daily", "before", and "during."

§416.12 Development of Sanitation SOP's.

(b) The Sanitation SOP's shall be signed and dated by the individual with overall authority on-site or a higher-level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOP's as specified and will maintain the Sanitation SOP's in accordance with the requirements of this part. The Sanitation SOP's shall be signed and dated upon initially implementing the Sanitation SOP's and upon any modification to the Sanitation SOP's.

9 CFR 416.12(b) specifies that an establishment's written SSOP will be signed and dated (authenticated) by a responsible establishment official, and that that official will be responsible for the ongoing maintenance of the SSOPs. Additionally, an establishment official will sign and date the SSOP any time it is modified.

§416.12 Development of Sanitation SOP's.

(c) Procedures in the Sanitation SOP's that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.

9 CFR 416.2(c) essentially establishes the basis for what we refer to as Pre-Operational SSOP. Establishments must define, in writing, the steps they will take to make food contact surfaces sanitary prior to the start of daily operations.

§416.12 Development of Sanitation SOP's.

(d) The Sanitation SOP's shall specify the frequency with which each procedure in the Sanitation SOP's is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s).

9 CFR 416.2(d) requires that the written SSOP specify the frequency with which each procedure or activity is to be conducted daily, and must identify which employee(s) will be responsible for these procedures.

In import establishments, there are limited situations in which you will verify SSOPs *during* operations, because there are no ongoing processing operations. Nevertheless, you will need to perform the Operation SSOP tasks whenever product is handled and food contact surfaces are used.

Note: In some instances, establishments may state that some procedures are to be conducted less frequently than daily; however, in these cases, they still must demonstrate to IPP that their measures are sufficient to maintain sanitary conditions of food contact surfaces before and during operations.

WORKSHOP #1- Identifying the Basic Elements of the SSOPs

Objective: Carefully read the sample Sanitation SOP. Evaluate the Sanitation SOP for compliance with §416.11 and §416.12. After you have evaluated the Sanitation SOP, answer the questions listed in the worksheet.

GSP Warehouse—Sanitation SOP

Owner – Mike Adams

This Sanitation SOP is for GSP Warehouse and became effective on January 28, 2015.

Pre-operational

All food contact surfaces of the facility, equipment, and utensils used in the inspection room will be cleaned daily after conclusion of all re-inspections by rinsing, soaping, and sanitizing. All cleaning will be monitored daily by Diana Popadoupolis before re-inspections begin the next day. Records will be kept on Form Pre-Op I by Diana Popadoupolis.

Operational

Every day all equipment and surfaces in the inspection room will be kept as sanitary as necessary to prevent contamination or adulteration of product. Every day all employees will follow hygienic practices to keep themselves from contaminating or adulterating product.

These actions will be monitored by Diana Popadoupolis once each day. Records of this monitoring will be kept on Form Ops I by Diana Popadoupolis.

Corrective actions taken during pre-operational sanitation inspection or during operations will be written on the back of the Form Pre-Op I or Form Ops I as necessary.

(Signature and date of 1/28/15) Mike Adams

WORKSHOP #1- Identifying the Basic Elements of the SSOPs

Objective: Verification of compliance with the basic development of SSOPs

For Training Purposes Only

PHIS Task: preoperational & operational SSOP record review task			
Relevant Regulatory Question	Yes	No	Student's comments
Does the establishment have written Sanitation SOP's that describe the procedures the establishment conducts daily to prevent direct contamination or adulteration of product(s)? [§416.12 (a)]			
Do the establishment's SSOPs identify which of the procedures are pre-operational procedures? [§416.12 (c)]			
Do the establishment's pre-operational SSOP procedures address (at a minimum) the cleaning of food contact surfaces of facilities, equipment, and utensils? [§416.12 (c)]			
Do the establishment's SSOPs specify the frequency with which the establishment will conduct each procedure? [§416.12(d)]			
Do the establishment's SSOPs identify the establishment employee or employees responsible for implementing and maintaining specified procedures? [§416.12 (d)]			

<p>Does the establishment have records that identify the documentation and the implementation and monitoring of the SSOPs on a daily basis and any corrective actions taken? [§416.16 (a)]</p>			
<p>Did the individual with overall authority on-site or a higher-level official of the establishment sign and date the Sanitation SOP's</p> <p>(1) Upon initial implementation, or</p> <p>(2) Upon modification [§416.12 (d)]</p> <p>Are there any failures to comply?</p>			

Implementation

§416.13 Implementation of SOP's.

(a) Each official establishment shall conduct the pre-operational procedures in the Sanitation SOP's before the start of operations.

(b) Each official establishment shall conduct all other procedures in the Sanitation SOP's at the frequencies specified.

(c) Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOP's.

The implementation requirement spelled out in 9 CFR 416.13 stipulates when establishments will conduct their pre-operational and operational (before and during) SSOPs, *and* very importantly, stipulates that they will **monitor** the implementation of these procedures on a daily basis. This means that responsible designated establishment employee(s) will actually perform the SSOP procedures even before IPP are physically present to verify their effectiveness.

Note that the *act* of monitoring might include filling out one or more daily records. However, IPP will actually verify recordkeeping as a separate regulatory requirement (to be discussed shortly).

Maintenance

§416.14 Maintenance of Sanitation SOP's.

Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOP's and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.

The maintenance regulatory requirement directs establishments to treat their SSOP as a “living document,” subject to regular review and revision to maintain their effectiveness. Changes may occur as a result of new processes or equipment, as a result of non-compliance issues, or may be prescribed for the responsible authority to conduct on a routine basis regardless of whether or not changes need to be made. **Note that establishments are not required to inform FSIS when they make changes to their SSOPs—it is your responsibility to review the SSOP regularly.**

Corrective Actions

§416.15 Corrective Actions.

(a) Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOP's or the procedures specified therein, or the implementation or maintenance of the Sanitation SOP's, may have failed to prevent direct contamination or adulteration of product(s).

9 CFR 416.15(a) is the requirement that establishments *plan* for the eventuality that some aspect of SSOP implementation or monitoring might break down, resulting in potential or actual contamination of food contact surfaces or adulteration of product. They must prescribe, in writing, the measures employees will take when either establishment monitors or IPP identify failures in the SSOP system.

§416.15 Corrective Actions.

(b) Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOP's and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOP's or the procedures specified therein.

9 CFR 416.15(b) spells out three things establishments must accomplish when implementing their SSOP corrective actions. In FSIS, we like to use the acronym “DRiP” to remember the requirements IPP must verify when verifying SSOP corrective actions.

- Ensure appropriate **disposition** of product (condemn, trim, wash, etc.)
- **Restore** sanitary conditions
- Prevent the **recurrence** of direct contamination or adulteration of product (including reevaluation or modification of the SSOPs as necessary)

Whenever IPP observe and document non-compliance in the course of performing any SSOP verification task, corrective actions *must* be verified before the task can be completed.

****It is important for you, as an Import Inspector, to understand that there are limits to your jurisdiction when verifying and enforcing SSOPs. Product that has been exposed and/or contaminated in transit to your establishment would be refused entry and would need to be destroyed. Thus, in a sense, it has not technically “arrived” in the country yet and is not subject to your jurisdiction. On the other hand, product that has been exposed and/or contaminated in the process of staging by the establishment (such as for physical examination) *would* be subject to your jurisdiction, and therefore SSOP verification. Additionally, product that has passed your inspection and is allowed entry into the United States is now considered domestic product. This product would no longer be under your jurisdiction—it would be subject to verification by domestic inspection personnel. Any contamination or adulteration you discover at this point would need to be reported to FSIS Compliance via your Frontline Supervisor.**

Recordkeeping

The recordkeeping requirement of the SSOP regulations is one major way SSOP is distinguished from SPS. In addition to conducting daily procedures to ensure that food contact surfaces are maintained in a sanitary condition, establishments must develop and maintain a system for authenticating that such procedures take place. These are spelled out in 9 CFR 416.16.

§416.16 Recordkeeping requirements.

(a) Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOP's as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOP's shall authenticate these records with his or her initials and the date.

As you can see, recordkeeping exists as documentation of the implementation (and monitoring) and corrective actions regulatory requirements. The establishment employee(s) the SSOPs designate as being responsible for implementation and monitoring are responsible for authenticating all SSOP records with their **initials** and the **date**. (Note that these designees do not need to be same person as the responsible establishment official who developed and signed the SSOP).

§416.16 Recordkeeping requirements.

(b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.

9 CFR 416.16(b) permits establishments to maintain SSOP records on computer, provided they have sufficient controls in place to maintain integrity and security of them.

§416.16 Recordkeeping requirements.

(c) Records required by this part shall be maintained for at least 6 months and made available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

9 CFR 416.16(c) requires that establishments must maintain SSOP records for a minimum of **6 months**, that they must maintain them on-hand at the establishment for **48 hours**, and that they must make them available to FSIS personnel for review upon request.

After the 48 hours, if they so choose, establishments may store SSOP records off the official premises, provided they can present them to FSIS personnel for review within 24 hours of being requested.

Agency Verification

§416.17 Agency verification.

FSIS shall verify the adequacy and effectiveness of the Sanitation SOP's and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:

- (a) Reviewing the Sanitation SOP's;
- (b) Reviewing the daily records documenting the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken;
- (c) Direct observation of the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken; and
- (d) Direct observation or testing to assess the sanitary conditions in the establishment.

9 CFR 416.17 defines for FSIS the methods we will undertake to verify effective of SSOPs. If at any time, IPP determine through their observations that an establishment has failed to properly develop, implement, or maintain their SSOPs, they should immediately contact their FLS for further guidance, as further enforcement actions may result.

We will discuss the Agency Verification requirements further as part of our discussion of the Regulatory Process.

Regulatory Process for Sanitation SOPs

Objectives

1. Understand FSIS responsibilities in verifying establishment SSOPs.
2. Describe the regulatory thought process used in performing SSOP verification tasks.
3. List the four SSOP verification tasks.
4. List the two components of each SSOP verification task.

FSIS Responsibilities

FSIS Directive 5,000.1 Revision 5 is the document that prescribes the universal inspection methodology for all IPP. Sanitation SOP inspection verification responsibilities are spelled out in Sections II and V of the directive.

The Regulatory Process

The model we use for performing regulatory compliance verification is summed up in the acronym “I.D.D.E.” which stands for

- **Inspection Methodology** – Described in FSIS Directive 5,000.1
- **Decision-making** – Regulatory conclusions reached using the “GAD” process
- **Documentation** – Includes PHIS tasks, NRs, and MOIs, as needed
- **Enforcement** – If necessary, implementation of RCAs, withholding actions, or suspension

IPP perform inspection methodology under four different verification tasks in PHIS. Two fall under the Pre-Operational SSOP, and two fall under Operational SSOP. Thus, the tasks are organized as follows:

Inspection Tasks	General Description
<u>Pre-Operational</u> Sanitation SOP Record Review	Use the Recordkeeping verification activity to verify that the establishment implements the procedures in the Sanitation SOP effectively to prevent contamination of food contact surfaces or adulteration of products prior to operations.
<u>Pre-Operational</u> Sanitation SOP Review and Observation	Use the Review and Observation verification activity and the Recordkeeping verification activity to verify that the establishment implements the procedures in the Sanitation SOP effectively to prevent contamination of food contact surfaces or adulteration of products prior to operations. In PHIS, IPP should select the “Both” option on the Activity tab.

Inspection Tasks	General Description
<u>Operational</u> Sanitation SOP Record Review	Use the Recordkeeping verification activity to verify that the establishment implements the procedures in the Sanitation SOP effectively to prevent contamination of food contact surfaces or adulteration of products during operations.
<u>Operational</u> Sanitation SOP Review and Observation	Use the Review and Observation verification activity and the Recordkeeping verification activity to verify that the establishment implements the procedures in the Sanitation SOP effectively to prevent contamination of food contact surfaces or adulteration of products during operations. In PHIS, IPP should select the “Both” option on the Activity tab.

Note that under each “Pre-Operational SSOP” and “Operational SSOP”, there are both recordkeeping and review and observation components. **Review** refers to actual hands-on measurement of certain factors related to SSOPs. It might involve taking actual measurements, for example, room or product temperatures, but most commonly it involves organoleptic (senses of sight, smell, and touch) inspection on and around product. **Observation** refers to situations in which you watch establishment personnel implement and monitor their Sanitation SOPs in real time.

You will learn more about performing inspection verification tasks in PHIS during the Import Inspection Course, but it is useful to understand now that they exist and how they are executed in your import establishments.

The Record Review Tasks: Pre-Operational and Operational

IPP use the recordkeeping verification activity to verify all **four** Sanitation SOP requirements (implementation, maintenance, corrective actions, and recordkeeping) while performing the Pre-Operational and Operational Sanitation SOP Record Review tasks.

During the Sanitation SOP record review tasks, IPP perform the following:

- 1) **Review the written Sanitation SOP** to be familiar with the establishment’s current pre-operational or operational sanitation procedures.
- 2) **Verify that the SSOP continues** to meet the design requirements of §416.12.
- 3) **Verify that the establishment has maintained daily records** that demonstrate that the establishment has implemented the pre-operational and operational procedures as written, monitored those procedures at least daily or at the specified frequency, and taken immediate or corrective action when necessary.

-For instance, **IPP verify that the records** indicate that the establishment conducted monitoring daily prior to the start of operations. If the establishment observed a contaminated food contact surface (residue from previous day’s product) during pre-operational inspection, IPP verify that the establishment documented that the contaminated surface was re-cleaned, re-inspected and released before product passed

over the surface. Similarly, if the establishment has documented the finding of contaminated product or food contact surfaces during operations, IPP verify that the documented corrective actions meet regulatory requirements.

- 4) Verify all the **recordkeeping** requirements of §416.16.

-For instance, IPP verify that the establishment employee responsible for the implementation and monitoring of the procedure has authenticated the records with their initials and date.

The Review and Observation Tasks: Pre-Operational and Operational

IPP use **both** the review and observation verification activity and the recordkeeping verification activity when performing the Pre-Operational and Operational Sanitation SOP Review and Observation tasks. IPP are to verify that all **four** Sanitation SOP requirements (implementation, maintenance, corrective actions, and recordkeeping).

Each time IPP perform the review and observation tasks, they:

- 1) **Should review the written Sanitation SOP** so they are familiar with the establishment's current pre-operational or operational sanitation procedures;
- 2) **Verify** that the SSOP continues to meet the design requirements of §416.12;
- 3) **Observe the establishment conducting its monitoring** activities and implementing corrective action when they find that the pre-operational or operational procedures have failed to effectively clean and sanitize food contact surfaces;
- 4) **Inspect one or more areas** and perform an organoleptic examination of some of the establishment's facilities, equipment, and utensils to assess sanitary conditions (sometimes referred to as "hands-on" inspection);
- 5) Compare their findings with the establishment records/findings, (which may not be documented until the start of the next production day for that specific shift), and
- 6) **Verify that the establishment meets the corrective action requirement** of 9 CFR 416.15 when they find that the establishment's Sanitation SOP has failed to prevent product contamination or adulteration.

To perform the Pre-Op or Operational Sanitation SOP Review and Observation task, IPP should have:

- A pen or pencil.
- U.S. Rejected/U.S. Retained tags and some means (tape, string, rubber bands) of affixing these tags to equipment, departments, product, etc.
- A notepad to record their pre-operational findings.

Pre-Op Sanitation SOP Review and Observation Task

- IPP not trained in lockout/tagout (FSIS Directive 4791.11) methodology shall not perform pre-op sanitation inspection on any piece of equipment requiring lock out. (Lockout/tagout is a systematic method of isolating and cutting off power supply to equipment with dangerous moving parts so that they can be manually inspected).
- After establishment management informs IPP that an area is ready for FSIS pre-op inspection, IPP perform the review component of Pre-Op Sanitation SOP Review and Observation verification task. They are to inspect areas in the establishment, equipment and utensils, and places on equipment that, if insanitary, would present the greatest risk of transferring pathogens or other contaminants to product (e.g., direct food contact surfaces that are difficult to clean or may serve as microbial harborage sites).

When performing the Pre-Operation SSOP Review and Observation task, IPP are also to review **FSIS Directive 5,000.4**. This directive provides detailed instruction on pre-op sanitation; in particular, the thought process on how to select areas or equipment to inspect. In short, the thought process requires IPP to focus on the areas and equipment that are at **highest risk** for becoming insanitary and potentially contaminating product during operations.

For example: While IPP should inspect all production areas and equipment over time, they should be somewhat more likely to select cutting boards, knives, grinders, or the inner machinery of table saws for organoleptic inspection, over such items as walls, storage shelves, or infrequently used hand tools.

IPP should ask themselves the following:

- (1) Which pieces of equipment directly contact exposed product?
- (2) Which pieces of equipment directly contact ready-to-eat (RTE) product after lethality treatment (cooking, heating, or other treatment to kill harmful bacteria)?
- (3) Which pieces of equipment are hardest to clean?
- (4) Is there a history of pre-operational non-compliance documented by either FSIS or the establishment?

IPP should review the following:

- (1) The establishment's SSOP records
- (2) Microbial testing records (if available)
 - (a) Establishments are not required to include environmental or product sampling into their SSOPs
 - (b) If your establishment *does* include sampling as part of its SSOPs, you should
 - Observe establishment personnel collecting samples
 - Review laboratory results
 - Verify corrective actions are taken in response to positive or abnormal sample results
- (3) NRs

- When IPP have completed their examination of the selected area(s) and equipment, IPP should compare their findings to the establishment's sanitation findings. If the written records are not yet completed, IPP may ask the establishment about its pre-operational findings and any actions taken. However, IPP must verify the recordkeeping requirements before completing the task.
- **When IPP observe contaminated direct food contact surfaces** during the pre-op sanitation verification, they are to:
 - **Reject** the affected equipment by placing a "U.S. Rejected" tag;
 - **Notify** the establishment, and
 - **Document** the noncompliance on NR.
- The establishment has the responsibility to restore sanitary conditions (clean the contaminated food contact surface) and document the restoration of sanitary conditions under §416.16(a). **Preventive measures do not need to be developed and documented unless product has been contaminated or adulterated by the unclean surface.** IPP should not remove the "U.S. Rejected" tag until the establishment has restored sanitary conditions.

Operational Sanitation SOP Review and Observation Task

- IPP should select area(s) of the establishment and equipment that presents the **highest risk** for insanitary conditions or product contamination.
- IPP should observe the equipment, employees, and facilities to verify that product contamination is not occurring during operation.
- If IPP observe contaminated direct food contact surfaces or contaminated product, there is Sanitation SOP noncompliance whether there is a procedure written in the establishment's Sanitation SOP to cover that situation or not.
- IPP should inspect direct food contact surfaces of equipment, facilities, and utensils.
- IPP should be aware of other potential sources of product contamination such as condensation, peeling paint, dead-end pipes and scaling rust from overhead fixtures where products are processed, handled, or stored can contaminate products.
- When possible, IPP should also observe the establishment conducting its monitoring activity.
- When IPP have completed their assessment of the sanitation in one or more areas of the establishment, they should compare their findings with the establishment's sanitation findings. If the records are not complete at the time, IPP might ask the establishment if it has conducted monitoring and what observations were made. However, IPP must verify the recordkeeping requirements prior to completion of the task.

- IPP should be aware that there are times the responsible establishment employee might not be able to propose permanent preventive measures immediately (i.e., repairs cost money!). However, in these situations, the establishment should propose a tentative preventative measure until they determine a permanent solution.

Note: Even if there is only sufficient time on a given day to perform the review and observation component of a Pre-Operational or Operational SSOP task, IPP are still to make time to review the establishment's Sanitation SOPs regularly. Establishments are not required to inform FSIS when they make modifications to their SSOPs.

Documentation and Enforcement

We will further discuss how to perform and document both compliance and non-compliance while performing tasks in PHIS during the Import Inspection Course. However, it will be useful for you to understand the basic procedures to follow when you observe non-compliance during the performance of SSOP verification tasks.

- (1) Take a regulatory control action
 - (a) Apply a "U.S. Rejected" tag to any food contact surface that is found to be in an insanitary condition, or
 - (b) Apply a "U.S. Retained" tag to any product found to be contaminated by employees' failure to follow SSOPs or other sanitary practices
- (2) Verbally inform establishment management of the non-compliance as soon as possible
- (3) Document a non-compliance record (NR) and issue it to the establishment
- (4) Do not relinquish regulatory control over the affected products or equipment until sanitary conditions are restored and corrective actions are completed

Summary

- The Statutes (or Acts)—FMIA, PPIA, EPIA, etc.—are laws enacted by Congress governing the inspection of meat, poultry, and egg products.
- Regulations are promulgated by the Secretary of Agriculture to meet the requirements of the Acts.
- Directives are issued by FSIS to instruct IPP how to conduct various activities; they remain in effect until revised or cancelled.
- Notices are issued by FSIS in response to issues that arise, or when the Policy Division receives numerous questions from the field on a particular topic; they typically expire after 1 year, unless renewed.
- IPP follow the Rules of Practice (9 CFR Part 500) to afford establishments due process.
- Inspection Methodology for sanitation (and other areas of verification) is addressed in FSIS Directive 5,000.1.
- Sanitation Performance Standards (SPS) are 11 standards establishments must meet, by whatever means they deem prudent and effective, to remain in regulatory compliance—9 CFR 416.1 through 416.6.
- Sanitation Standard Operating Procedures (SSOP) are written procedures developed by establishments specifically to protect product and food contact surfaces from contamination or adulteration—9 CFR 416.11 through 416.17.

Attachment 1 – Rules of Practice

Code of Federal Regulations

Page 1 of 4

Code of Federal Regulations

Title 9 - Animals and Animal Products

Volume: 2

Date: 2011-01-01

Original Date: 2011-01-01

Title: PART 500 - RULES OF PRACTICE

Context: Title 9 - Animals and Animal Products. CHAPTER III - FOOD SAFETY AND INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE. SUBCHAPTER E - REGULATORY REQUIREMENTS UNDER THE FEDERAL MEAT INSPECTION ACT AND THE POULTRY PRODUCTS INSPECTION ACT.

Pt. 500

PART 500—RULES OF PRACTICE

Sec.

500.1 Definitions.

500.2 Regulatory control action.

500.3 Withholding or suspension of inspection without prior notification.

500.4 Withholding action or suspension of inspection with prior notification.

500.5 Notification, appeals, and actions held in abeyance.

500.6 Withdrawal of inspection.

500.7 Refusal to grant inspection.

500.8 Procedures for rescinding or refusing approval of marks, labels, sizes, and containers.

Authority: 21 U.S.C. 451-470, 601-695; 7 U.S.C. 450, 1901-1906; 7 CFR 2.18, 2.53.

Source: 64 FR 66546, Nov. 29, 1999, unless otherwise noted.

§ 500.1 Definitions.

(a) A "regulatory control action" is the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product.

(b) A "withholding action" is the refusal to allow the marks of inspection to be applied to products. A withholding action may affect all product in the establishment or product produced by a particular process.

(c) A "suspension" is an interruption in the assignment of program employees to all or part of an establishment.

§ 500.2 Regulatory control action.

(a) FSIS may take a regulatory control action because of:

(1) Insanitary conditions or practices;

(2) Product adulteration or misbranding;

(3) Conditions that preclude FSIS from determining that product is not adulterated or misbranded; or

(4) Inhumane handling or slaughtering of livestock.

(b) If a regulatory control action is taken, the program employee will immediately notify the establishment orally or in writing of the action and the basis for the action.

<http://www.gpo.gov/fdsys/pkg/CFR-2011-title9-vol2/xml/CFR-2011-title9-vol2-part500.xml> 5/5/2015

(c) An establishment may appeal a regulatory control action, as provided in §§ 306.5 and 381.35 of this chapter.

§ 500.3 Withholding action or suspension without prior notification.

(a) FSIS may take a withholding action or impose a suspension without providing the establishment prior notification because:

- (1) The establishment produced and shipped adulterated or misbranded product as defined in 21 U.S.C. 453 or 21 U.S.C. 602;
- (2) The establishment does not have a HACCP plan as specified in § 417.2 of this chapter;
- (3) The establishment does not have Sanitation Standard Operating Procedures as specified in §§ 416.11-416.12 of this chapter;
- (4) Sanitary conditions are such that products in the establishment are or would be rendered adulterated;
- (5) The establishment violated the terms of a regulatory control action;
- (6) An establishment operator, officer, employee, or agent assaulted, threatened to assault, intimidated, or interfered with an FSIS employee; or
- (7) The establishment did not destroy a condemned meat or poultry carcass, or part or product thereof, in accordance with part 314 or part 381, subpart L, of this chapter within three days of notification.

(b) FSIS also may impose a suspension without providing the establishment prior notification because the establishment is handling or slaughtering animals inhumanely.

§ 500.4 Withholding action or suspension with prior notification.

FSIS may take a withholding action or impose a suspension after an establishment is provided prior notification and the opportunity to demonstrate or achieve compliance because:

- (a) The HACCP system is inadequate, as specified in § 417.6 of this chapter, due to multiple or recurring noncompliances;
- (b) The Sanitation Standard Operating Procedures have not been properly implemented or maintained as specified in §§ 416.13 through 416.16 of this chapter;
- (c) The establishment has not maintained sanitary conditions as prescribed in §§ 416.2-416.8 of this chapter due to multiple or recurring noncompliances;
- (d) The establishment did not collect and analyze samples for *Escherichia coli* Biotype I and record results in accordance with § 310.25(a) or § 381.94(a) of this chapter;
- (e) The establishment did not meet the *Salmonella* performance standard requirements prescribed in § 310.25(b) or § 381.94(b) of this chapter.

§ 500.5 Notification, appeals, and actions held in abeyance.

(a) If FSIS takes a withholding action or imposes a suspension, the establishment will be notified orally and, as promptly as circumstances permit, in writing. The written notification will:

- (1) State the effective date of the action(s),
- (2) Describe the reasons for the action(s),
- (3) Identify the products or processes affected by the action(s),
- (4) Provide the establishment an opportunity to present immediate and corrective action and further planned preventive action; and
- (5) Advise the establishment that it may appeal the action as provided in §§ 306.5 and 381.35 of this chapter.

(b) The prior notification provided for in § 500.4 of this part will:

- (1) State the type of action that FSIS may take;
- (2) Describe the reason for the proposed action;
- (3) Identify the products or processes affected by the proposed action;
- (4) Advise the establishment of its right to contact FSIS to contest the basis for the proposed action or to explain how compliance has been or will be achieved; and
- (5) Advise the establishment that it will have three business days from receipt of the written notification to respond to FSIS unless the time period is extended by FSIS.

(c) An establishment may appeal the withholding action or suspension, as provided in §§ 306.5 and 381.35 of this chapter.

(d) If FSIS suspends inspection and does not hold the suspension action in abeyance as provided in paragraph (e) of this section, the establishment may request a hearing pursuant to the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H. Upon such request, the Administrator will file a complaint that will include a request for an expedited hearing.

(e) FSIS may hold a suspension in abeyance and allow the establishment to operate under the conditions agreed to by FSIS and the establishment.

§ 500.6 Withdrawal of inspection.

The FSIS Administrator may file a complaint to withdraw a grant of Federal inspection in accordance with the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H because:

- (a) An establishment produced and shipped adulterated product;
- (b) An establishment did not have or maintain a HACCP plan in accordance with part 417 of this chapter;
- (c) An establishment did not have or maintain Sanitation Standard Operating Procedures in accordance with part 416 of this chapter;
- (d) An establishment did not maintain sanitary conditions;
- (e) An establishment did not collect and analyze samples for *Escherichia coli* Biotype I and record results as prescribed in § 310.25(a) or § 381.94(a) of this chapter;
- (f) An establishment did not comply with the Salmonella performance standard requirements as prescribed in §§ 310.25(b) and 381.94(b) of this chapter;
- (g) An establishment did not slaughter or handle livestock humanely;
- (h) An establishment operator, officer, employee, or agent assaulted, threatened to assault, intimidated, or interfered with an FSIS program employee; or
- (i) A recipient of inspection or anyone responsibly connected to the recipient is unfit to engage in any business requiring inspection as specified in section 401 of the FMIA or section 18(a) of the PPIA.

§ 500.7 Refusal to grant inspection.

(a) The FSIS Administrator may refuse to grant Federal inspection because an applicant:

- (1) Does not have a HACCP plan as required by part 417 of this chapter;
- (2) Does not have Sanitation Standard Operating Procedures as required by part 416 of this chapter;
- (3) Has not demonstrated that adequate sanitary conditions exist in the establishment as required by part 308 or part 381, subpart H, and part 416 of this chapter;
- (4) Has not demonstrated that livestock will be handled and slaughtered humanely; or

(5) Is unfit to engage in any business requiring inspection as specified in section 401 of the FMIA or section 18(a) of the PPIA.

(b) If the Administrator refuses to grant inspection, the applicant will be provided the opportunity for a hearing in accordance with the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H.

§ 500.8 Procedures for rescinding or refusing approval of marks, labels, and containers.

(a) FSIS may rescind or refuse approval of false or misleading marks, labels, or sizes or forms of any container for use with any meat or poultry product under section 7 of the FMIA or under section 8 of the PPIA.

(b) FSIS will provide written notification that:

(1) Explains the reason for rescinding or refusing the approval;

(2) Provides an opportunity for the establishment to modify the marking, labeling, or container so that it will no longer be false or misleading; and

(3) Advises the establishment of its opportunity to submit a written statement to respond to the notification and to request a hearing.

(c) If FSIS rescinds or refuses approval of false or misleading marks, labels, or sizes or forms of any container for use with any meat or poultry product, an opportunity for a hearing will be provided in accordance with the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H.

Attachment 2 – Federal Meat Inspection Act (FMIA)(excerpt)

§620. Imports

(a) Adulteration or misbranding prohibition; compliance with inspection, building construction standards, and other provisions; humane methods of slaughter; treatment as domestic articles subject to this chapter and food, drug, and cosmetic provisions; marking and labeling; personal consumption exemption

No carcasses, parts of carcasses, meat or meat food products of cattle, sheep, swine, goats, horses, mules, or other equines which are capable of use as human food, shall be imported into the United States if such articles are adulterated or misbranded and unless they comply with all the inspection, building, construction standards, and all other provisions of this chapter and regulations issued thereunder applicable to such articles in commerce within the United States. No such carcasses, parts of carcasses, meat or meat food products shall be imported into the United States unless the livestock from which they were produced was slaughtered and handled in connection with slaughter in accordance with the Act of August 27, 1958 (72 Stat. 862; 7 U.S.C. 1901–1906). All such imported articles shall, upon entry into the United States, be deemed and treated as domestic articles subject to the other provisions of this chapter and the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.]: *Provided*, That they shall be marked and labeled as required by such regulations for imported articles: *Provided further*, That nothing in this section shall apply to any individual who purchases meat or meat products outside the United States for his own consumption except that the total amount of such meat or meat products shall not exceed fifty pounds.

(b) Terms and conditions for destruction

The Secretary may prescribe the terms and conditions for the destruction of all such articles which are imported contrary to this section, unless (1) they are exported by the consignee within the time fixed therefor by the Secretary, or (2) in the case of articles which are not in compliance with the chapter solely because of misbranding, such articles are brought into compliance with the chapter under supervision of authorized representatives of the Secretary.

(c) Payment of storage, cartage, and labor charges by owner or consignee; liens

All charges for storage, cartage, and labor with respect to any article which is imported contrary to this section shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against such article and any other article thereafter imported under this chapter by or for such owner or consignee.

(d) Prohibition

The knowing importation of any article contrary to this section is prohibited.

(e) Omitted

(f) Inspection and other standards; applicability, enforcement, etc.; certifications

Notwithstanding any other provision of law, all carcasses, parts of carcasses, meat, and meat food products of cattle, sheep, swine, goats, horses, mules, or other equines, capable of use as human food, offered for importation into the United States shall be subject to the inspection, sanitary, quality, species verification, and residue standards applied to products produced in the United States. Any such imported meat articles that do not meet such standards shall not be

permitted entry in to the United States. The Secretary shall enforce this provision through (1) the imposition of random inspections for such species verification and for residues, and (2) random sampling and testing of internal organs and fat of the carcasses for residues at the point of slaughter by the exporting country in accordance with methods approved by the Secretary. Each foreign country from which such meat articles are offered for importation into the United States shall obtain a certification issued by the Secretary stating that the country maintains a program using reliable analytical methods to ensure compliance with the United States standards for residues in such meat articles. No such meat article shall be permitted entry into the United States from a country for which the Secretary has not issued such certification. The Secretary shall periodically review such certifications and shall revoke any certification if the Secretary determines that the country involved is not maintaining a program that uses reliable analytical methods to ensure compliance with United States standards for residues in such meat articles. The consideration of any application for a certification under this subsection and the review of any such certification, by the Secretary, shall include the inspection of individual establishments to ensure that the inspection program of the foreign country involved is meeting such United States standards.

(g) Administration of animal drugs or antibiotics; terms and conditions; entry order violations

The Secretary may prescribe terms and conditions under which amenable species that have been administered an animal drug or antibiotic banned for use in the United States may be imported for slaughter and human consumption. No person shall enter amenable species into the United States in violation of any order issued under this subsection by the Secretary.

(h) Reciprocal meat inspection requirement

(1) As used in this subsection:

(A) The term "meat articles" means carcasses, meat and meat food products of cattle, sheep, swine, goats, horses, mules, or other equines, that are capable of use as human food.

(B) The term "standards" means inspection, building construction, sanitary, quality, species verification, residue, and other standards that are applicable to meat articles.

(2) On request of the Committee on Agriculture or the Committee on Ways and Means of the House of Representatives or the Committee on Agriculture, Nutrition, and Forestry or the Committee on Finance of the Senate, or at the initiative of the Secretary, the Secretary shall, as soon as practicable, determine whether a particular foreign country applies standards for the importation of meat articles from the United States that are not related to public health concerns about end-product quality that can be substantiated by reliable analytical methods.

(3) If the Secretary determines that a foreign country applies standards described in paragraph (2)—

(A) the Secretary shall consult with the United States Trade Representative; and

(B) within 30 days after the determination of the Secretary under paragraph (2), the Secretary and the United States Trade Representative shall recommend to the President whether action should be taken under paragraph (4).

(4) Within 30 days after receiving a recommendation for action under paragraph (3), the President shall, if and for such time as the President considers appropriate, prohibit imports into the United States of any meat articles produced in such foreign country unless it is determined

that the meat articles produced in that country meet the standards applicable to meat articles in commerce within the United States.

(5) The action authorized under paragraph (4) may be used instead of, or in addition to, any other action taken under any other law.

§621. Inspectors to make examinations provided for; appointment; duties; regulations

The Secretary shall appoint from time to time inspectors to make examination and inspection of all amenable species, inspection of which is hereby provided for and of all carcasses and parts thereof, and of all meats and meat food products thereof, and of the sanitary conditions of all establishments in which such meat and meat food products hereinbefore described are prepared; and said inspectors shall refuse to stamp, mark, tag, or label any carcass or any part thereof, or meat food product therefrom, prepared in any establishment hereinbefore mentioned, until the same shall have actually been inspected and found to be not adulterated; and shall perform such other duties as are provided by this chapter and by the rules and regulations to be prescribed by said Secretary; and said Secretary shall, from time to time, make such rules and regulations as are necessary for the efficient execution of the provisions of this chapter, and all inspections and examinations made under this chapter, shall be such and made in such manner as described in the rules and regulations prescribed by said Secretary not inconsistent with provisions of this chapter.

§601. Definitions

As used in this chapter, except as otherwise specified, the following terms shall have the meanings stated below:

(a) The term "Secretary" means the Secretary of Agriculture of the United States or his delegate.

(b) The term "firm" means any partnership, association, or other unincorporated business organization.

(c) The term "meat broker" means any person, firm, or corporation engaged in the business of buying or selling carcasses, parts of carcasses, meat, or meat food products of cattle, sheep, swine, goats, horses, mules, or other equines on commission, or otherwise negotiating purchases or sales of such articles other than for his own account or as an employee of another person, firm, or corporation.

(d) The term "renderer" means any person, firm, or corporation engaged in the business of rendering carcasses or parts or products of the carcasses, of cattle, sheep, swine, goats, horses, mules, or other equines, except rendering conducted under inspection or exemption under this subchapter.

(e) The term "animal food manufacturer" means any person, firm, or corporation engaged in the business of manufacturing or processing animal food derived wholly or in part from carcasses, or parts or products of the carcasses, of cattle, sheep, swine, goats, horses, mules, or other equines.

(f) The term "State" means any State of the United States and the Commonwealth of Puerto Rico.

(g) The term "Territory" means Guam, the Virgin Islands of the United States, American Samoa, and any other territory or possession of the United States, excluding the Canal Zone.

(h) The term "commerce" means commerce between any State, any Territory, or the District of Columbia, and any place outside thereof; or within any Territory not organized with a legislative body, or the District of Columbia.

(i) The term "United States" means the States, the District of Columbia, and the Territories of the United States.

(j) The term "meat food product" means any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, excepting products which contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and which are exempted from definition as a meat food product by the Secretary under such conditions as he may prescribe to assure that the meat or other portions of such carcasses contained in such product are not adulterated and that such products are not represented as meat food products. This term as applied to food products of equines shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

(k) The term "capable of use as human food" shall apply to any carcass, or part or product of a carcass, of any animal, unless it is denatured or otherwise identified as required by regulations prescribed by the Secretary to deter its use as human food, or it is naturally inedible by humans.

(l) The term "prepared" means slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.

(m) The term "adulterated" shall apply 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;

(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) a color additive) which may, in the judgment of the Secretary, make such article unfit for human food;

(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,

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

(D) if it bears or contains any color additive which is unsafe within the meaning of section 379e of this title: *Provided*, That an article which is not adulterated under clause (B), (C), or (D) shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive in or on such article is prohibited by regulations of the Secretary in establishments at which inspection is maintained under this subchapter;

(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;

(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;

(5) if it is, in whole or in part, the product of an animal which has died otherwise than by slaughter;

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title;

(8) if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is; or

(9) if it is margarine containing animal fat and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance.

(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 chapter 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 607 of this title unless (A) it conforms to such definition and standard, 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 607 of this title, and it falls below the standard 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 usual name of the food, if any there be, and (B) in case it is fabricated from two or

more ingredients, the common or usual 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 and Human Services, 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 by 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.

(o) The term "label" means a display of written, printed, or graphic matter upon the immediate container (not including package liners) of any article.

(p) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(q) The term "Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.]" means the Act so entitled, approved June 25, 1938 (52 Stat. 1040), and Acts amendatory thereof or supplementary thereto.

(r) The terms "pesticide chemical," "food additive," "color additive," and "raw agricultural commodity" shall have the same meanings for purposes of this chapter as under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(s) The term "official mark" means the official inspection legend or any other symbol prescribed by regulations of the Secretary to identify the status of any article or animal under this chapter.

(t) The term "official inspection legend" means any symbol prescribed by regulations of the Secretary showing that an article was inspected and passed in accordance with this chapter.

(u) The term "official certificate" means any certificate prescribed by regulations of the Secretary for issuance by an inspector or other person performing official functions under this chapter.

(v) The term "official device" means any device prescribed or authorized by the Secretary for use in applying any official mark.

(w) The term "amenable species" means—

(1) those species subject to the provisions of this chapter on the day before November 10, 2005;

(2) all fish of the order Siluriformes; and

(3) any additional species of livestock that the Secretary considers appropriate.

§608. Sanitary inspection and regulation of slaughtering and packing establishments; rejection of adulterated meat or meat food products

The Secretary shall cause to be made, by experts in sanitation or by other competent inspectors, such inspection of all slaughtering, meat canning, salting, packing, rendering, or similar establishments in which amenable species are slaughtered and the meat and meat food products thereof are prepared for commerce as may be necessary to inform himself concerning the sanitary conditions of the same, and to prescribe the rules and regulations of sanitation under which such establishments shall be maintained; and where the sanitary conditions of any such establishment are such that the meat or meat food products are rendered adulterated, he shall refuse to allow said meat or meat food products to be labeled, marked, stamped or tagged as "inspected and passed."

§624. Storage and handling regulations; violations; exemption of establishments subject to non-Federal jurisdiction

The Secretary may by regulations prescribe conditions under which carcasses, parts of carcasses, meat, and meat food products of cattle, sheep, swine, goats, horses, mules, or other equines, capable of use as human food, shall be stored or otherwise handled by any person, firm, or corporation engaged in the business of buying, selling, freezing, storing, or transporting, in or for commerce, or importing, such articles, whenever the Secretary deems such action necessary to assure that such articles will not be adulterated or misbranded when delivered to the consumer. Violation of any such regulation is prohibited. However, such regulations shall not apply to the storage or handling of such articles at any retail store or other establishment in any State or organized Territory that would be subject to this section only because of purchases in commerce, if the storage and handling of such articles at such establishment is regulated under the laws of the State or Territory in which such establishment is located, in a manner which the Secretary, after consultation with the appropriate advisory committee provided for in section 661 of this title, determines is adequate to effectuate the purposes of this section.

Acronyms and Definitions

USDA	United States Department of Agriculture
FSIS	Food Safety and Inspection Service
APHIS	Animal and Plant Health Inspection Service (a sister agency of FSIS under USDA)
IPP	Inspection Program Personnel
FI	Food Inspector
CSI	Consumer Safety Inspector
SCSI	Supervisory Consumer Safety Inspector
PHV	Public Health Veterinarian
SPHV	Supervisory Public Health Veterinarian
FLS	Frontline Supervisor
EIAO	Enforcement, Analysis, and Investigations Officer
SEIAO	Supervisory Enforcement, Analysis, and Investigations Officer
CI	Compliance Investigator
DVMS	District Veterinary Medical Specialist
DCS	District Case Specialist
DDM	Deputy District Manager
DM	District Manager
EARO	Executive Associate for Regulatory Operations
AA	Assistant Administrator
OFO	Office of Field Operations
FMIA	Federal Meat Inspection Act
PPIA	Poultry Products Inspection Act
EPIA	Egg Products Inspection Act
HMSA	Humane Methods of Slaughter Act
CFR	Code of Federal Regulations
ROP	Rules of Practice
NOIE	Notice of Intended Enforcement
NOIR	Notice of Inadequate Response
NOS	Notice of Suspension
NOD	Notice of Deferral
VP	Verification Plan
FSA	Food Safety Assessment
RCA	Regulatory Control Action
PHIS	Public Health Information System
NR	Non-compliance Record
MOI	Memorandum of Interview (documents any non-regulatory concerns or discussions)
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures
HACCP	Hazard Analysis Critical Control Points
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
SDS	Safety Data Sheet
FCS	Food contact surface
MID	Meat Inspection Department