

PHV Intern Final Week

Participant Notebook

September 2022

Office of Employee Experience and Development Center for Learning



Food Safety and Inspection Service			
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SUBJECT: Food Safety and Inspection Service (FSIS) Training Classes

Congratulations on being selected to attend FSIS training. This is an opportunity to gain significant knowledge about the skills and abilities needed to perform your job duties.

Please use these opportunities to learn as much as you can from the training and to actively participate by asking questions and engaging in class activities.

You represent FSIS and your conduct must reflect a high degree of professionalism. Improper conduct and unprofessional behavior will not be tolerated. Individuals exhibiting unprofessional behavior may be removed from class and returned to their duty station.

Although FSIS does not have a formal dress code, the goal is to project a positive professional image at all times. Shorts, flip flops, short skirts, crop tops, tank tops, clothing with a message that may be offensive to others, are not neat, clean, and free from holes or tears, are examples of inappropriate clothing in an FSIS worksite.

Finally, your feedback is very important. Please take the time to complete the evaluation forms and let us know what worked well and what could be improved.

Thank you for maintaining a positive and professional learning environment.

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FSIS STATUTES AND YOUR ROLE

OBJECTIVES

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

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

REFERENCES

Federal Meat Inspection Act Poultry Products Inspection Act

INTRODUCTION

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

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

Overview of the Statutes

The statutes related to FSIS activities include the:

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

The FMIA was enacted first, in 1906 after the public outrage stirred up by the writings of Upton Sinclair's book, "The Jungle." How many of you are familiar with this book? It contained graphic and detailed descriptions of the insanitary and abhorrent conditions that existed in meat establishments at the turn of the century in the city of Chicago, which was the heart of the meat processing industry at the time. Excerpts from the book were published in newspapers. With this information as a background, Congress enacted the FMIA. The PPIA was modeled after the FMIA. When you read it, you will see a number of similarities between the two statutes. The PPIA, enacted in 1957, was based on the growing poultry industry. Initially, there were two separate Agencies – one responsible for enforcing the provisions of the FMIA and one responsible for enforcing

the provisions of the PPIA. This explains why, in some cases, establishments that process both meat and poultry products have two establishment numbers. We will not be covering the EPIA in our review.

BASIS FOR FSIS AS A PUBLIC HEALTH REGULATORY AGENCY

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

FMIA Sec. 602. "Meat and meat food products are an important source of the Nation's total supply of food. It is essential in the <u>public interest</u> that the <u>health and welfare of consumers be protected</u> by assuring that meat and meat food products distributed are wholesome, not adulterated and properly marked, labeled, and packaged. It is hereby in found that all articles and animals which are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce, and that regulation by the Secretary and cooperation by the States and other jurisdictions as contemplated by this chapter are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to <u>protect the health and welfare of consumers.</u>"

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

- wholesome,
- not adulterated,
- properly marked/labeled, and packaged

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

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

PPIA Sec. 451. "It is essential in the <u>public interest</u> that the <u>health and welfare of</u> <u>consumers</u> be protected by assuring that poultry products distributed to them are wholesome, not adulterated and properly marked, labeled, and packaged."

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

PPIA Sec. 452. It is hereby declared to be the policy of Congress to provide for the inspection of poultry products and otherwise regulate their processing and distribution...to <u>prevent</u> the movement or sale in interstate or foreign <u>commerce</u> of, or the burden upon commerce by, poultry <u>products which are adulterated or misbranded</u>.

Remember, all the things you do or you supervise as part of your job can be traced back to the statutes to make sure that any meat, poultry, or egg product that is adulterated or

misbranded does not enter commerce to protect the public health. You will do that through the enforcement authorities that we will discuss later.

DEFINITION OF "ADULTERATED"

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

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

carcass, part thereof, meat or meat food product

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

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

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

The definition of adulterated product in 601 m(1) focuses on <u>added substances</u>. Two examples of added substances that have been declared to be adulterants in meat products include *Listeria monocytogenes (Lm)* and *E. coli* O157:H7. *Lm* is an example of an adulterant in ready-to-eat (RTE) products. It represents an added substance that renders the product injurious to health. Scientific studies have shown that this pathogen is present in the product due to the way in which product is handled or produced. For example, *Lm* is typically present in RTE products because of recontamination that occurs during the processing of product, such as through contact with the environment or with establishment employees, after an initial lethality treatment has been delivered. This pathogen is considered injurious to health because RTE products are not reheated by consumers before they are eaten. Therefore, if this substance is present, products are very likely to cause injury to human health and can even cause death. The only adulterant in non-intact raw meat or meat products is *E. coli* O157:H7.

Based on what we know from scientific studies, *E. coli* O157:H7 is considered to be an added substance because it is introduced into the product during processing. For example, it's spread from the hide or digestive tract of the animals during slaughter or processing. It's injurious to health because one of the normal ways of cooking this product includes "rare" which is not sufficient to destroy the pathogen. Again, the presence of this pathogen in the product under these conditions is likely to cause injury – and can even result in death.

FMIA Sec. 601(m)(2)(A): "If it bears or contains (by reason of administration of any substance to the live animal or otherwise) any <u>added poisonous or added deleterious</u> <u>substance</u> other than one which is (i) a pesticide chemical in or on a raw agricultural commodity (ii) a food additive, or (iii) color additive which may, in the judgment of the Secretary, make such article unfit for human food;"

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

FMIA Sec. 601(m)(2)(B): "If it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a <u>pesticide chemical</u> which is unsafe within the meaning of section 346a of this title;"

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

FMIA Sec. 601(m)(2)(C): "If it bears or contains any <u>food additive</u> which is unsafe within the meaning of section 348 of this title;"

Section 601(m)(2)(C) defines meat or meat products bearing any unsafe food additives to be adulterated. The FDA reviews all food additives for safety before use in food production. FDA establishes their conditions for use. An example of such a food additive approved under specified conditions is carcass washes used on the slaughter line. There are two types of food additives. One is direct and the other is indirect. Direct food additives are directly applied to the food, such as preservatives for meat products. Indirect food additives are those that are not used for food purposes, but come into contact with food; such as, sanitizers that are used on equipment or on food

contact surfaces. All food additives used in federal establishments must be approved by FDA. FSIS Directive 7140 lists all food additives that have been approved for use. So, again, FSIS enforces the policy that is set by FDA. The following definition in section 601(m)(2)(D), color additives, is not important in relation to your duties.

FMIA Sec. 601(m)(3): "If it consists in whole or in part of any filthy, putrid, or decomposed substances or is for any other reason unsound, <u>unhealthful</u>, <u>unwholesome</u>, or otherwise unfit for human food."

This next section, 601(m)(3), of the definition of adulteration emphasizes health. This is the definition that FSIS has used as the statutory basis for taking all actions against BSE. The reason this definition was used is that scientific studies have shown that infectivity of the disease exists within the animals before they show clinical signs of the disease. Legally, the burden is on FSIS to prove that these conditions – filthy, putrid, and decomposed – exist. This is why being graphic and accurate in descriptions of conditions is very important on the NRs. Some examples of filthy conditions include rail dust, rust, or rodent droppings on product.

Be aware that the adulteration provisions of the statutes are <u>not mutually exclusive</u>. For example, a product may be adulterated under 601(m)(3) AND 601(m)(1) because it is positive for *E. coli* O157:H7.

FMIA Sec. 601(m)(4): "If it has been prepared, packed, or held under <u>insanitary</u> <u>conditions</u> whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;"

Section 601(m)(4) covers the definition of "adulterated" related to insanitary conditions. The SPS and Sanitation SOP regulations (9CFR 416) as well as the HACCP rule (regulation 417) are about ensuring that products are not adulterated through insanitary conditions. It's about ensuring that sanitary conditions are maintained throughout the production process. If we apply this to the slaughter process, establishments must ensure that their processes (such as de-hiding, and opening the digestive tract of livestock) do not create insanitary conditions that may contaminate the carcasses with filth. You will also be responsible for verifying that there are no insanitary conditions in the establishment.

The inspection duties that you and other inspection program personnel perform after slaughter, that can be trace back to this part of the FMIA are those covered by HACCP, Sanitation SOPs and the Sanitation Performance Standards. This is obviously the focal point of what you do. We'll come back to the HACCP regulation when we cover section 608 of the FMIA. Your inspection duties related to ensuring that the establishments maintain sanitary conditions are outlined thoroughly in FSIS Directive 5000.1, "Verifying an Establishment's Food Safety Systems." The remainder of Section 601 of the FMIA covers additional definitions of the term "adulterated." You can review these, including the ones dealing with the term "misbranded" on your own time.

There are parallel definitions of the term "adulterated" in the PPIA.

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

Like the FMIA, Section 453(g)(1) covers added substances that are poisonous or deleterious which may render a product injurious to health.

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

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

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

PPIA Sec. 453(g)(3): "If it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;"

Parallel to section 601(m)(3) of the FMIA, there is a section in the PPIA that emphasizes the importance of ensuring that poultry products do not injure human health in any way because they, "consist in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food. "

PPIA Sec. 453(g)(4): "If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;"

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

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

FMIA Sec. 601(m):

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

- (6) product in a container that is composed of poisonous or deleterious substance;

- (7) product that has been intentionally subjected to radiation that does not conform to regulatory requirements;

- (8) product from which a valuable constituent has been omitted or abstracted, or a substance has been substituted;

- (9) margarine containing animal fat that is filthy, putrid, or decomposed.

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

STATUTORY PROVISIONS FOR INSPECTION ACTIVITIES

Let's turn our attention to some our inspection activities.

Ante-mortem Inspection

Sections 603(a) of the FMIA, and 455(a) of the PPIA are the statutory authorities for the inspection activities you and other inspection personnel conduct during ante mortem inspection.

FMIA Sec. 603(A): "That hereafter, for the purpose of preventing the use in commerce, as hereinafter provide, of meat and meat food products which are adulterated, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all cattle, sheep, swine, goats, horses, mules, and other equines before they shall be allowed to enter into any slaughtering, packing, meat canning,"

These are the provisions upon which the regulations for ante mortem inspection were promulgated. For example, the regulation that corresponds with the statute 603(a) regarding ante mortem inspection in livestock is 9 CFR 309. This regulation contains more specific information that you should use in judging whether an official establishment that slaughters livestock is meeting the standard established by 603(a). For example, the inspection tasks include inspecting the livestock at rest; and then, in motion to detect abnormal conditions or symptoms of diseases that are identified in the regulations. If any of these animals are suspected of having abnormal conditions or diseases, they must be identified for further examination, and if necessary, identified for final disposition in post mortem inspection. Any animals found with symptoms of diseases must be disposed of properly. Remember, the authority for these actions as a result of ante mortem inspection comes from the section 603(a). Also remember that the purpose for conducting ante mortem inspection activities is to prevent animals that if slaughtered would result in adulterated product or would introduce insanitary conditions in the establishment from entering the establishment, and to ensure that if they do enter the establishment, they do not adulterate products.

Post-mortem Inspection

FMIA Sec. 604: "...the Secretary shall cause to be made by inspectors appointed for that purpose a post mortem examination and inspection of the carcasses and parts thereof of all (livestock)....to be prepared at any slaughtering...or similar establishment...which are capable of use as human food; and the carcasses and parts thereof all such animals found to be not adulterated shall be marked, stamped, tagged, or labeled as "Inspected and passed;" and...label, mark, stamp, or tag as "Inspected and condemned" all carcasses and parts...found to be adulterated;"

The statutory authorities for post mortem inspection are found in section 604 of the FMIA, and in section 455 (b) and (c) of the PPIA. These provisions cover two important concepts. One is the jurisdiction for inspection. The other is the requirement for inspection. For jurisdiction, post mortem inspection must be performed on all of the carcasses and parts <u>prepared</u> at an official establishment. The wording used in the poultry statutes is slightly different. Instead of "prepared" it uses the word "processed."

Regarding inspection tasks, this provision establishes the basis for the inspection tasks performed. As you recall from your training, post mortem inspection involves performing specific tasks that include observation and palpation or incision of lymph nodes in the head and viscera, and observation of the carcass. The purpose of inspection is to detect any carcasses or parts that exhibit signs of disease or conditions that otherwise make the carcass or parts unwholesome or unfit for human food. These tasks must be performed using methods that are safe and sanitary. The legal authority for these tasks can be traced directly back to this statutory provision.

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

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

The statutes continue by indicating that for those carcasses and parts that are found not to be adulterated, inspectors are to mark them as "inspected and passed." Inspectors are to mark those carcasses and parts that are found to be adulterated as "inspected and condemned." This is the statutory basis for your inspection duties. So, you apply the standards established by the definitions of adulteration; which, we have already discussed in making this judgment.

Exemptions from Inspection Requirements

The statutes also outline some exemptions to the inspection requirements. These are found in the FMIA in Section 623 and 624, and in Section 454 and 464 of the PPIA. For example, personal slaughtering and custom slaughter for personal, household, guest, or employee uses are exempt from inspection. However, the exempt products are still subject to the adulteration and misbranding provisions of the statutes (FMIA 623(d)).

In these exempt facilities, the establishment performs activities that constitute preparation of meat products, or processing of poultry products, but they have been exempted from inspection by Congress.

Marks of Inspection

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

Several times we have referred to labeling, marking, stamping, or tagging product as "Inspected and passed." We call these labels, marks, stamps, and tags the marks of inspection. The purpose of post mortem inspection is to determine whether the products are wholesome, not adulterated, and properly marked, labeled, and packaged, as required by the statutes. This ensures that the public health is protected. Remember in section 604 of the FMIA and in section 455 (b) and (c) of the PPIA, the statutes state that the carcasses and parts that are found NOT to be adulterated are to be marked as "inspected and passed." This same concept is covered again in more detail in Section 606 of the FMIA. These marks of inspection, stating "Inspected and passed", show that all meat products are cleared to enter commerce after they are found to be fit for human consumption. This is very important. Remember that product cannot move out of the establishment into commerce until it has been inspected and marked as passed. This means that you must be able to find that product is NOT adulterated. The burden of proof is on the establishment. If you have questions about whether or not to pass the product, don't pass it and don't stamp it as "Inspected and passed" unless; and until, you get satisfactory answers to your questions by the establishment. If you cannot find that the product is not adulterated, you must follow the Rules of Practice. So, Section 606 defines our product control authority.

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

Reinspection

Reinspection is covered in 605 of the FMIA and 455(b) in the PPIA. Reinspection covers the situation when products are shipped from one establishment to another. For example, this could be carcasses coming from one establishment to be fabricated into special cuts at another establishment. It could be ground beef and trimmings coming from one establishment to another to be ground more finely, or to be used as a meat ingredient in a fully cooked product. When you work in an establishment that receives meat or poultry products from another establishment, part of your responsibility will be to ensure that those products entering the establishment are reinspected using the same standards that you use in the initial inspection – that products are wholesome, not adulterated, and properly marked, labeled, and packaged. Another condition requiring reinspection is when products are returned to the establishment for any reason. Again, your role is to ensure that these products are reinspected using the standards in the statutes, regulations, and Directives.

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

Sanitation

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

FMIA Sec. 608: "The Secretary shall prescribe the rules and regulations of sanitation under which establishments shall be maintained. The Secretary shall cause to be made by experts in sanitation or by other competent inspectors the inspection of all establishments where meat or meat products are prepared as may be necessary to inform concerning the sanitary conditions of these establishments."

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

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

- 1. Sanitation
- 2. Sanitary
- 3. Adulteration

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

The dictionary definition of the term "sanitation" shows that it means something broader than just keeping things clean. According to Webster's Collegiate Dictionary, the word "sanitation" means, "the development and application of sanitary measures for the sake of cleanliness, protecting health, etc." So, the dictionary drives us back to one of the two key terms that are common to the PPIA and the FMIA, which is the term "sanitary." The statutes talk about "sanitary practices", and "sanitary measures?" What doesn't this term "sanitary" mean? According to the dictionary, the term "sanitary" means, "of or pertaining to health or the conditions affecting health, especially with reference to cleanliness, precautions against disease, etc."

So, are the HACCP regulations and the sanitation regulations sanitary measures? Clearly they are, and we can demonstrate that fact to a court. To ensure that products are handled and held in a sanitary manner, establishments must follow the HACCP regulations. For example, the establishment must develop and implement a HACCP plan covering each product produced when the establishment's hazard analysis reveals one or more food safety hazards are reasonably likely to occur in the production process. This includes biological, chemical, and physical hazards.

The regulation outlines that establishments must follow the seven HACCP principles (417.2); which include conducting a hazard analysis, determining critical control points, establishing critical limits, establishing monitoring procedures, developing corrective action procedures, establishing recordkeeping and documentation procedures, and developing verification procedures. The regulation also specifies the conditions under which the establishment must reassess its HACCP plan. FSIS verification duties related to these regulations are described specifically in FSIS Directive 5000.1, "Verifying an Establishment's Food Safety System." It describes the inspection methods, regulatory decision making process, documentation, and enforcement tasks to use in relation to ensuring that the establishment complies with the regulations and statutes regarding sanitation. For example, the Hazard Analysis Verification (HAV) and HACCP Verification tasks are performed to verify that the establishment is meeting the requirements of 9 CFR 417.

The HACCP regulations require establishments to identify the hazards to health that may arise as a result of their operation and to address those that are reasonably likely to occur. If those hazards are not properly addressed and prevented, the result is adulterated product. As you will remember, the term "adulterated" is defined in the statutes. In enforcing the HACCP rules, what the Agency needs to show is why, in not complying with the regulations, the establishment is not complying with the statutory provisions that underlie the regulation. Section 608 gives the Agency authority for enforcing HACCP. So, if the Agency is to enforce the HACCP and sanitation rules (SPS and Sanitation SOP), we will need to show how an establishment's failure to follow the sanitary measures required by HACCP or sanitation rules creates insanitary conditions in its operation that resulted in the production of product that may be injurious to health.

It is important to note that under case law, the deleterious change in the product, that is, the change that may have the effect of making consumption of the product injurious to health, must occur while the product is being prepared, packed, or held; and, have occurred because of the insanitary conditions. How can we show that this is the case? We can show that having a sanitation standard operation procedure that is effective in preventing direct contamination of product with environment contaminants is a necessary precaution against producing product that may be injurious to health.

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

A parallel section is found in Section 456 of the PPIA.

PPIA Sec. 456: "Operation of premises, facilities, and equipment (a) Sanitary practices: Each official establishment slaughtering poultry...shall have such premises, facilities, and equipment, and be operated in accordance with such sanitary practices, as are required by regulations promulgated by the Secretary for the purpose of preventing the entry into or flow or movement in commerce or burdensome effect upon commerce, of poultry products which are adulterated."

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

Progression of Statutes

The statutes follow the processes that take place in the establishment. For example, Section 603 of the FMIA covers ante-mortem inspection. Section 604 covers post mortem inspection, and the carcasses. Section 606 covers the inspection of all meat products – the carcasses, the parts, processed products, and cut up products. Each product must be inspected. Section 608 covers the requirement for the establishment to maintain a sanitary environment for the slaughter and processing of animals to take place. The provisions in the PPIA follow this same progression.

Recordkeeping

The statutes outline requirements for recordkeeping related to the production of meat and poultry products. If you recall from your civics classes, the U.S. Constitution has a provision that protects citizens from unreasonable searches and seizure. The establishment has this same right, and just like other rights, it must be protected. However, it's important for inspection personnel to have access to establishment records (production, shipment, and other business records), particularly records related to the implementation of HACCP and Sanitation SOP. A review of those records can tell us important information about how product was handled, prepared, shipped, received, and stored to help us in making the determination about whether product that is being produced is wholesome, not adulterated, and properly labeled. Section 642 of the FMIA and Section 460(b) of the PPIA outline record keeping requirements and classes of businesses that are required to keep records; also, it gives FSIS the right to be in the establishment and to have access to the establishment facilities and records.

Establishments must maintain production records, and to provide the records within a reasonable amount of time when given notice. FSIS has issued regulations (9CFR 320.4 and 381.178) which further addresses entry into places of business and examination of records, including record keeping requirements. Tracing these

authorities in regulations, Directives, and Notices, remember that the HACCP and sanitation regulations (417, 416), which are promulgated under the Act, both outline more specific recordkeeping requirements. For example, the right of FSIS to access establishment records is reflected in the HACCP regulations in 417.5, which outlines the recordkeeping requirements related to HACCP plans. FSIS Directive 5000.1 outlines inspection methods covering these recordkeeping requirements. An example of a key directive dealing with establishment records is FSIS Directive 5000.2, "Review of Establishment Data by Inspection Personnel". It reminds inspection personnel that they have access to any type of record that the establishment maintains that relates to maintaining its food safety system, whether the records are referenced in the HACCP plan or not (e.g., records of microbiological sampling).

ENFORCEMENT AUTHORITIES AND ACTIONS

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

administrative, civil, and criminal

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

Administrative Authorities

Section 671 of the FMIA provides the authority to refuse or withdraw grants of inspection from federally inspected meat slaughter and processing establishments. Section 467 of the PPIA provides similar authority for the refusal and withdrawal of inspection services. Actions to refuse or withdraw grants of inspection can be initiated for such things as:

-violation of agency's sanitation, adulteration, and related requirements;

- conviction of an establishment or of a responsibly connected individual for certain crimes; and

- inhumane slaughter

In addition, under Section 607 of the FMIA and Section 457 of the PPIA, FSIS can rescind or refuse the approval of marks, labels, and containers.

The administrative enforcement authorities covered in the statutes include retaining product, withholding the marks of inspection, suspending inspection, and withdrawing inspection. Remember that the Rules of Practice, found in section 500 of the FSIS regulations, outline the due process that we must ensure takes place to protect the rights of establishments. Let's review these regulations briefly.

Section 500.2 of the regulations covers the <u>regulatory control actions</u> that take place in the establishment, such as tagging product, equipment, or facilities. Remember, under

the provisions contained in Section 608 of the FMIA, these actions are taken to prevent product that has been determined through inspection, to be unwholesome or adulterated from leaving the establishment and entering commerce. We are authorized to take regulatory control actions when we find insanitary conditions or practices, product adulteration, conditions that prevent us from determining that product is not adulterated or misbranded, and when there is inhumane handling or slaughter of livestock. When a regulatory control action is taken, you must notify the establishment immediately orally or in writing of the action and the reason for the action. Remember that for any type of enforcement action, the establishment has the right to appeal that action.

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

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

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

Civil Authorities

The civil authorities covered in the acts are found in Section 674 of the FMIA and 467(c) of the PPIA. Under these authorities, FSIS can enforce, prevent, and restrain violations of the acts. The actions involve U.S. District courts. The primary actions will be detention, and seizure of product. On rare occasions, FSIS can obtain an injunction in a federal court to prevent or restrain an establishment engaging in violations of the acts.

Detention authorities, found in Section 672 of the FMIA, and Section 467(a) of the PPIA, cover unwholesome, adulterated, or misbranded product that has left the establishment and has entered commerce. Detention actions are taken by Program Investigators (OIEA), Import Surveillance Liaison Officers (ISLO, OIEA – IID), or EIAOs (OFO). The role you might play in a detention action is that you might make a call about adulterated product that has left the establishment, which would lead to the detention action. For example, you may learn of test results that show product is adulterated with *E. coli* O157:H7. The detention action places the product on hold for 20 days. During this time, a decision is made on the ultimate disposition of the detained product.

The statutory authorities for seizure of product are found in FMIA section 673 and PPIA section 467(b). Seizure is also an action that is taken against product that is no longer in an establishment and has entered commerce. Typically, the first step in a civil action is detention, which is then followed by seizure and condemnation. It involves a court judgment that affirms that the product is in violation of the acts and must be condemned and destroyed. When the court determines that the product is to be condemned, it is released under bond to be destroyed. Court costs and fees, storage and other expenses are charged to the violator.

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

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

Criminal Authorities

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

The <u>prohibited acts</u> are listed in Section 610 of the FMIA and Section 458 of the PPIA and covers specific prohibited actions that are subject to criminal sanctions, including:

- Slaughter or preparation of product except in compliance with the Act.
- Inhumane slaughter or handling.
- Sale, transport, offering, or receipt, in commerce, of articles capable for use as human food that are either adulterated, misbranded, or not inspected.
- Causing products to become adulterated or misbranded.

- Misuse or unauthorized use of official marks, certificates, labels or devices of inspection.
- The knowing misrepresentation of any article as inspected and passed or exempt under the Act.

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

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

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

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

The Secretary may refer criminal violations to the Department of Justice for prosecution. The Secretary has discretion to forego criminal referral for minor violations where it is determined that the public interest will be served by a suitable written notice of warning. Discretion also applies to libel and injunction authorities. Violators of any provisions for which no other criminal penalty is provided shall be guilty of a misdemeanor, and subject to fine and up to one year imprisonment.

OTHER STATUTORY AUTHORITIES

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

Humane Handling of Livestock

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

Labeling

Labeling is also covered in the Acts. Remember that these authorities are secondary to your public health focus. The Agency is ensuring that inspection program personnel focus on food safety first (including Sanitation SOP, HACCP, Sanitation Performance Standards, and food safety sampling) followed by food security (when specific heightened security threat condition is declared), and into other activities we call "Nonfood Safety Consumer Protection" (NFSCP). Labeling is one of those NFSCP activities. The Directive that covers your inspection responsibilities for labeling is FSIS 7000.1 Verification of Non-Food Safety Consumer Protection Regulatory Requirements. Section 607 of the FMIA and Section 457 of the PPIA outline the following:

All meat and meat food products must be properly labeled, marked and packaged. Labels must not be false or misleading.

FSIS can withhold the use of any false or misleading labels or marks.

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

Exported Product

Section 615 of the FMIA covers exported product. The Act requires FSIS to inspect meat, and meat food products prior to export. Section 616 through 618 of the FMIA gives the Secretary broad authority to appoint inspectors and hold clearance of vessels until certificates of product wholesomeness are obtain from inspectors. It also covers the certification of products by FSIS prior to shipping.

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

SUMMARY

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

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

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

WORKSHOP

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

Scenario 1:

While performing ante mortem inspection, the PHV observes establishment personnel using a sharp object to drive hogs to slaughter. When questioned, the establishment employee says he did not know that he was not permitted to use the sharp object – in other words, he was not properly trained to perform his duties. The PHV verifies that the establishment takes immediate action to address this situation and necessary steps to prevent recurrence. The PHV also documents an NR in PHIS. The use of the sharp object is discontinued.

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

What is the regulation that relates to this scenario?

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

Scenario 2:

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

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

What is the regulation that relates to this scenario?

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

Scenario 3:

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

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

What regulations relate to this scenario?

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

Scenario 4:

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

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

What regulations relate to this scenario?

What is the	statutory	authority	that prov	vides F	-SIS	with t	the a	authority	to	address	this
scenario?	-		-					-			

Scenario 5:

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

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

What regulation relates to this scenario?

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

Scenario 6

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

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

What regulations relate to this scenario?

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

UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE

WASHINGTON, DC

FSIS DIRECTIVE

6900.2 Revision 3 9/24/20

HUMANE HANDLING AND SLAUGHTER OF LIVESTOCK

CHAPTER I - GENERAL

I. PURPOSE

This directive informs inspection program personnel (IPP) of the requirements, verification activities, and enforcement actions for ensuring that the handling and slaughter of livestock, including disabled livestock and livestock slaughtered by religious ritual methods, is humane. This directive provides instructions to IPP (e.g., public health veterinarian (PHV), consumer safety inspector (CSI)) for conducting humane handling activities randomly throughout their tour of duty and provides instructions to IPP, in establishments that assert that they have put in place a systematic approach, on how to assess whether that approach is robust. PHVs are to no longer perform a monthly verification task (*Verification of a Robust Systematic Approach*) to determine whether an establishment maintains a robust systematic approach for humane handling as they are expected to make this assessment on an ongoing basis and inform the establishment of any status change in this regard. FSIS has modified the definition of egregious inhumane treatment and instructs IPP to document egregious inhumane treatment on a noncompliance record (NR) instead of a memorandum of interview (MOI). This revision also updates instructions for entering humane handling verification data into the Public Health Information System (PHIS).

II. CANCELLATION

FSIS Directive 6900.2, Revision 2, Humane Handling and Slaughter of Livestock, 8/15/11

III. BACKGROUND

A. The Humane Methods of Slaughter Act (7 U.S.C. 1901, 1902, and 1906, see Attachment 1) requires that the slaughtering and handling of livestock be carried out only by humane methods. In this statute, Congress determined that the use of humane methods of handling and slaughtering livestock prevents needless suffering of animals and results in safer and better working conditions for employees in slaughter establishments. This includes:

- Slaughtering in accordance with the ritual requirements of the Jewish faith or of any other religious faith that prescribes a method of slaughter whereby the animal suffers loss of consciousness by anemia of the brain caused by the simultaneous and instantaneous severance of the carotid arteries with a sharp instrument and handling in connection with such slaughtering.
- 2. Using humane handling and slaughter practices for all livestock including non- ambulatory disabled livestock in accordance with the Humane Methods of Slaughter Act (HMSA). See Attachment 2 for FSIS humane handling regulations.

DISTRIBUTION: Electronic

B. PHVs are to notify establishments that they may choose to develop and implement a systematic approach for the humane handling and slaughtering of livestock. In 2004, FSIS published a notice in the Federal Register Notice (69 Fed. Reg. 54625) <u>Humane Handling and Slaughter Requirements and the Merits of a Systematic Approach to Meet Such Requirements</u>. This notice details the background on the humane handling and slaughter statutes issued by Congress and regulation of humane handling by FSIS. It also details steps industry should take to assure effective compliance with the Acts and regulations.

IV. IPP PERSONAL SAFETY

When IPP conduct humane handling verification activities of livestock, personal safety is paramount. IPP are to conduct this verification from a safe and suitable vantage point, taking into consideration the size and temperament of livestock and the type of stunning method employed by the establishment.

V. HUMANE HANDLING TERMINOLOGY

<u>A.</u> <u>Ambulatory Disabled Livestock</u>: Livestock capable of walking, but with physical impairment such as central nervous system signs, lameness, or similar conditions.

<u>B.</u> <u>Egregious inhumane treatment</u>: An egregious situation is an act or condition that results in severe harm to animals, for example:

- 1. Making cuts on or skinning conscious animals;
- 2. Excessive beating or prodding of ambulatory or nonambulatory disabled animals or dragging of conscious animals;
- 3. Driving animals off semi-trailers over a drop off without providing adequate unloading facilities (animals are falling to the ground);
- 4. Running equipment over conscious animals;
- 5. Stunning of animals and then allowing them to regain consciousness;
- 6. Failing to immediately (or promptly) render an animal unconscious after a failed initial stunning attempt (e.g., no planned corrective actions);
- 7. Multiple ineffective stun attempts (2 or more) that are due to one or more of the following establishment failures to properly handle or stun the animal:
 - a. Failure to immediately (or promptly) apply the corrective actions that demonstrates a blatant disregard for animal discomfort and excitement;
 - b. Failure to adequately restrain an animal;
 - c. Failure to use adequate stunning methods (e.g., inadequate air pressure, inadequate caliber, insufficient electric current) for the animal being stunned (e.g., species of animal, size of animal, etc.);
 - d. Poorly trained/untrained operator or inexperienced operator; or

- e. Prolonged discomfort and excitement of the animal due to the inability to render it insensible/unconscious after the application of the immediate (or prompt) corrective actions.
- 8. Dismembering conscious animals, for example, cutting off ears or removing feet;
- 9. Leaving disabled livestock exposed to adverse climate conditions while awaiting disposition, or
- 10. Otherwise causing unnecessary pain and suffering to animals, including situations on trucks.

<u>C.</u> <u>Falls</u>: When an animal loses an upright position suddenly, in which a part of the body other than the limbs touches the ground or floor.

<u>D.</u> <u>Humane Handling</u>: Handling and slaughter practices that cause a minimum of excitement, pain, injury, or discomfort to livestock.

<u>E.</u> <u>Hoisting</u>: The process whereby an animal after it is shackled, is raised, usually from a lying position, and suspended by a leg or legs.

<u>F.</u> <u>Non-Ambulatory Disabled Livestock</u>: Livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

<u>G.</u> <u>Shackling:</u> Livestock are shackled when a device (e.g., rope, chain) used to hoist the animal has been placed around the animal's leg, even if the device has not been drawn tight.

<u>H.</u> <u>Slips</u>: When a portion of the leg other than the foot touches the ground or floor, or a foot loses contact with the ground or floor in a non-walking manner.

<u>I.</u> <u>Suitable Equipment</u>: Establishment equipment that can enable establishment personnel to move nonambulatory disabled livestock with a minimum of excitement, pain, or injury. This type of equipment includes skid loaders and self-propelled tractors capable of pulling stone boats (sleds) or similar conveyances, those conveyances themselves, holding chutes, and a voltmeter or other suitable equipment that can verify voltage of electric prods attached to AC current.

<u>J. Suitable Restraints</u>: Establishment-provided restraints capable of effectively restraining livestock (including disabled livestock when necessary) and preventing injuries to Agency personnel when performing ante-mortem inspection. This includes inspections when conducted on a transport vehicle.

VI. SYSTEMATIC APPROACH TO HUMANE HANDLING AND SLAUGHTER (SYSTEMATIC APPROACH) IN A WRITTEN ANIMAL HANDLING PROGRAM

A. There is no regulatory requirement for a written systematic approach to humane handling. However, an establishment may choose to develop and implement a robust written animal handling program that effectively addresses the four aspects of a systematic approach that FSIS outlined in the Federal Register Notice [Docket No. 04-013N] <u>Humane Handling and Slaughter Requirements and the Merits of a Systematic Approach to Meet Such Requirements</u>.

B. These four steps are:

- 1. Conduct an initial assessment to determine where, and under what circumstances, livestock may experience excitement, discomfort, or accidental injury while being handled in connection with slaughter, and where, and under what circumstances, stunning problems may occur;
- 2. Design facilities and implement practices that will minimize excitement, discomfort, and accidental injury to livestock;
- 3. Evaluate periodically the handling methods the establishment employs to ensure that those methods minimize excitement, discomfort, or accidental injury and evaluate the stunning methods periodically to ensure that all livestock are rendered insensible to pain by a single blow; and
- 4. Respond to these evaluations, as appropriate, by addressing problems immediately and by improving those practices and modifying facilities when necessary to minimize excitement, discomfort, and accidental injury to livestock.

C. When establishment management believes they have an animal handling program that equates to a robust systematic approach and would like it reviewed by FSIS, IPP are to review the program and any records generated during its implementation.

- 1. The PHV, District Veterinary Medical Specialist (DVMS) and District Office (DO) management are to determine whether the information presented by establishment management meets the criteria for a robust systematic approach. If the criteria are met, the inspector-in-charge (IIC) is to inform the establishment that it has a robust systematic approach; and
- 2. The PHV is to document the determination in a MOI under the Livestock Humane Handling Verification task in PHIS. A copy of the MOI is to be emailed to the DVMS, Frontline Supervisor (FLS), and Deputy District Manager (DDM) and provided to establishment management.
- 3. IPP are to take into consideration whether the establishment has implemented and maintained a robust systematic approach in determining how to proceed in the circumstances set out in Chapter V, III, A (e.g., how to proceed when an incident occurs that involves egregious inhumane treatment of an animal).

D. The establishment is not required to provide IPP access to a written humane handling program. However, IPP will not be able to verify effective implementation of a program that the establishment believes reflects a robust systematic approach without access to the written program. Because a documented systematic approach is not a regulatory requirement, failure to implement provisions of such a program is not a noncompliance unless such failure to implement results in an identifiable failure to meet specific regulatory requirements.

E. If the establishment develops and implements what it considers to be a robust systematic approach and IPP have informed the establishment that the Agency agrees, IPP are to verify implementation of the establishment's robust systematic approach, as described in Chapter IV. II. F.

NOTE: If an establishment is suspended (Notice of Suspension (NOS)) or receives a Notice of Intended Enforcement Action (NOIE) due to an egregious inhumane handling and slaughter event, they will no longer be considered by FSIS to have a robust systematic approach. The establishment will need to proffer corrective actions and preventive measures to the DO in order to develop a verification plan (Refer to: <u>FSIS Directive 5100.3</u> "Administrative Enforcement Action Decision-Making and

UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC

FSIS DIRECTIVE

5000.2 Revision 2 12/4/08

REVIEW OF ESTABLISHMENT TESTING DATA BY INSPECTION PROGRAM PERSONNEL

I. PURPOSE

The purpose of this directive is to clarify that inspection program personnel have access to a wide range of records under the Hazard Analysis and Critical Control (HACCP) regulations (9 CFR part 417), and that they are to use that access to review certain types of records on a regular basis.

II. CANCELLATION

FSIS Directive 5000.2, Revision 1, Review of Establishment Data by Inspection Program Personnel, dated 6/19/08

III. REASON FOR REISSUANCE

FSIS is reissuing this directive to clarify what records inspection program personnel are to review and how they are to document the review. Specifically, FSIS has attached a question and answer that explains what data are available to the Agency.

IV. REFERENCES

9 CFR part 417 FSIS Directive 5000.1

V. BACKGROUND

Under the HACCP regulations, an establishment is required to keep records related to the HACCP plan, including all decisionmaking documentation associated with its development and all records associated with its operation (i.e., monitoring, verification, and corrective action). To develop a HACCP plan, under 9 CFR 417.2(a)(1), an establishment is to have a written hazard analysis that reflects its determination of the food safety hazards that are reasonably likely to occur in the production process and to identify the preventive measures that the establishment will employ to control those hazards. The establishment develops a flow chart that lists the steps of each process and product flow in the establishment and that identifies the intended use or consumers

of the finished product (9 CFR 417.2(a)(2)). In addition, under 9 CFR 417.5(a)(1), establishments are to maintain "...the written hazard analysis prescribed in 9 CFR 417.2(a) ..., including all supporting documentation."

Given these regulatory requirements, the results of any testing that is performed by the establishment that may have an impact on the establishment's hazard analysis, whether or not such testing is incorporated into an actual HACCP plan, referenced in a HACCP plan, or considered in assessing a prerequisite program, are subject to FSIS review and are to be available to FSIS personnel.

The activities in this directive are directly related to those found in FSIS Directive 5000.1, Chapter II - HACCP. Inspection program personnel are to verify the proper execution of an establishment's HACCP plans and any prerequisite programs as set out in FSIS Directive 5000.1. Examples of such test results include, but are not limited to, testing records, data, and supporting documentation associated with testing associated with prerequisite programs and good manufacturing procedures; and testing conducted for the establishment's business customers that could bear on the hazard analysis.

VI. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES

A. Inspection program personnel are to be aware of any testing that is performed by the establishment that may have an impact on the establishment's hazard analysis and are to ask establishment management to make available for review the data that is generated by such testing so that it is available when inspection program personnel are verifying HACCP records.

B. At least once a week during the performance of an HACCP 01 procedure, inspection program personnel are to review the results of any testing that the establishment has performed that may have an impact on the establishment's hazard analysis.

C. When reviewing these test results, inspection program personnel are to seek answers to questions such as:

NOTE: Inspection program personnel are not to request that the establishment provide a written response to these questions.

1. Is there documentation that supports the frequency of the testing that the establishment employs?

2. If the testing is used by the establishment to reflect the effects of a prerequisite program do the results support the decision-making for the design of the program? (also see FSIS Directive 5000.1, Chapter II).

This Directive deliberately truncated for training purposes

UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON. DC

FSIS DIRECTIVE

6420.2 Revison 2

12/19/19

VERIFICATION OF PROCEDURES FOR CONTROLLING FECAL MATERIAL, INGESTA, AND MILK IN LIVESTOCK SLAUGHTER OPERATIONS

CHAPTER I -- GENERAL

I. PURPOSE

This directive provides inspection program personnel (IPP) with the current method for protecting public health by verifying, documenting, and enforcing the requirement that there be no visible fecal material, milk, or ingesta on livestock carcasses at or immediately after the final rail, and for verifying that feces, ingesta, and milk are not present on head, cheek, and weasand meat at packing. In this revision, FSIS increased the livestock carcass sample size in Attachment 1. This change will help the Agency better analyze data from establishments that operate under traditional inspection and the New Swine Slaughter Inspection System (NSIS).

II. CANCELLATION

FSIS Directive 6420.2, Rev. 1, Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Livestock Slaughter Operations, 4/27/17

III. BACKGROUND

A. In slaughter establishments, contamination of carcasses and parts from feces, ingesta, and milk are primary avenues for the spread of pathogens. Pathogens may reside in fecal material, both in the gastrointestinal tract and on the exterior surfaces of the animal going to slaughter. Without care being taken in handling and dressing procedures during slaughter and processing, the edible portions of the carcass can become contaminated with bacteria capable of causing illness in humans. Once introduced into the establishment environment, the organisms may be spread from carcass to carcass or by other means. FSIS enforces a "zero tolerance" standard for visible fecal material, ingesta, or milk on carcasses and parts at the time of inspection.

B. One approach that FSIS takes to minimize the occurrence of pathogens on meat is to verify that feces, ingesta, and milk do not contaminate livestock carcasses and parts, or if they do, that they are properly removed. FSIS provides instructions to IPP on how to verify that meat from heads, cheeks, and weasands - livestock carcass parts used in the manufacture of ground meat (e.g., ground beef) - that may become contaminated with feces, ingesta, or milk - are not contaminated with these substances. If the meat from these parts is contaminated, it represents a way of introducing pathogens into ground meat products. FSIS is reissuing this directive as one of a number of steps that it is taking to ensure that the possibility of contamination with pathogens is reduced to the extent possible.

C. Some ground meat components (e.g., head, cheek, and weasand meat) may not be attached to the carcass at the time that the carcass passes the final rail. IPP are to verify that these parts are not contaminated by fecal material, ingesta, or milk at the end of the harvesting process e.g., at the packaging step or when the product is placed into a container for storage.

D. FSIS has instructed IPP that they have access to the results of any testing and of any monitoring activities that are performed that may have an impact on the establishment's hazard analysis (See FSIS Directive 5000.2). IPP must review results on at least a weekly basis.

E. In addition to zero tolerance verification, IPP verify compliance with HACCP requirements and verify that establishment controls incorporated into the establishment's HACCP system ensure all meat and meat by-products (e.g. offal) are safe, wholesome, clean, and free of contamination using the Slaughter HACCP Verification task. See instructions in <u>FSIS Directive</u> <u>5000.1</u>, Verifying an Establishment's Food Safety System.

F. For additional instructions on how IPP are to verify Livestock Zero Tolerance requirements in official establishments operating under the New Swine Inspection System (NSIS), see FSIS Directive 6,600.1, Ante-mortem and Post-mortem Inspection and Verification of Ready-To-Cook Requirements.

CHAPTER II -- LIVESTOCK FECAL MATERIAL, INGESTA, AND MILK INSPECTION

I. GENERAL

9 CFR 310.18(a) states: Carcasses, organs, and other parts shall be handled in a sanitary manner to prevent contamination with fecal material, urine, bile, hair, dirt, or foreign matter; however, if contamination occurs, it shall be promptly removed in a manner satisfactory to the inspector.

A. Under 9 CFR 417, a HACCP plan must include, as appropriate, critical control points (CCPs) that are designed to control identified food safety hazards (9 CFR 417.2(c)(2)). Because fecal material is a vehicle for pathogens, and because virtually all slaughter establishments recognize that contamination of meat by pathogenic microorganisms from fecal material, ingesta, or milk is a food safety hazard that is reasonably likely to occur in the slaughter production process, IPP are to verify that slaughter establishments have adopted controls that they can demonstrate are effective in reducing the occurrence of pathogens, including controls that prevent contamination of carcasses with fecal contamination, milk and ingesta.

B. In each establishment slaughtering livestock, IPP inspection activities include verification checks to determine whether the establishment is producing carcasses and head, cheek, and weasand meat that are not contaminated with fecal material, ingesta, or milk. (See 9 CFR 307.2(g), 310.3, 310.17(a), 310.18(a), and 318.2(b) and (d).)

II. ON-LINE INSPECTION RESPONSIBILITIES

A. When on-line IPP find feces, ingesta, or milk on the carcass and its parts during the postmortem inspection of each carcass and its parts, they are to verify the satisfactory removal of contamination before passing each carcass or part.

B. When the on-line inspectors find feces, ingesta, or milk on the carcass, they are to stop the slaughter line to allow for trimming of the carcass by establishment personnel and reinspection of the carcass by the inspector unless the establishment has provided a rail-out loop:

- 1. For the purpose of moving contaminated carcasses off-line for trimming, reexamination, and positioning back on the line for final inspection; and
- 2. Determined by the Inspector-in-Charge (IIC) to be adequate to prevent accumulation of contaminated carcasses or cross-contamination of other carcasses.

C. On-line IPP who retain a carcass for veterinary disposition for pathology are not to authorize establishment trimming of such carcass until after disposition by a public health veterinarian (PHV).

D. On-line IPP are to notify the IIC or the off-line inspector as directed by the IIC when they believe that the:

- 1. Establishment's rail-out procedure is inadequate to prevent carcass accumulation or cross-contamination of other carcasses; or
- 2. Establishment's slaughter or dressing processes are not under control based on repeated presentation of contaminated carcasses for post-mortem inspection.

E. If the on-line head or viscera inspector finds contamination, the establishment must remove the contamination before the head or affected viscera or part can be passed. If the on-line head or viscera inspector repeatedly finds contamination at the point of inspection, he or she is to notify the IIC or the off-line inspector as directed by the IIC.

III. LIVESTOCK VERIFICATION PROCEDURES

A. Off-line IPP are to select carcasses for examination at the post-mortem rail inspection station to verify the adequacy of the establishment's procedures in preventing carcass contamination with fecal material, ingesta, or milk, and that head, cheek, and weasand meat are not contaminated with fecal material, ingesta, or milk at the completion of the harvesting process using the Livestock Zero Tolerance Verification task. Livestock Zero Tolerance Verification tasks are to be scheduled once per day per shift, at a minimum, in the Public Health Information System (PHIS). Additional directed tasks may be performed by the off-line inspector if the IIC determined that the establishment has lost process control.

B. When performing a Livestock Zero Tolerance Verification inspection task, off-line IPP are to select carcass units at the post-mortem rail inspection station for examination on-line, or after the post-mortem rail inspection station (see <u>Attachment 1</u> for selection of carcass units) and before the final wash.

NOTE: To address any issues related to a less than ideal slaughter floor design, inspectors' safety, or presentation of carcasses or parts, the IIC and Front Line Supervisor (FLS) can develop appropriate temporary or alternate procedures or arrangements with establishment management in order for IPP to properly conduct this inspection task per <u>9 CFR 307.2</u>.

C. Verifying that the establishment's HACCP process is controlling fecal material, ingesta, or milk contamination during the carcass production process, off-line IPP are to:

- 1. Determine the expected slaughter volume for that day;
- Determine the number of carcass units based on daily slaughter volume (see <u>Attachment 1</u>);

UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC

FSIS DIRECTIVE

10,800.1 Rev. 1

3/3/14

RESIDUE SAMPLING, TESTING AND OTHER VERIFICATION PROCEDURES UNDER THE NATIONAL RESIDUE PROGRAM FOR MEAT AND POULTRY PRODUCTS

CHAPTER ONE – GENERAL

I. PURPOSE

A. This directive provides instructions to inspection program personnel (IPP), including Public Health Veterinarians (PHVs) and Consumer Safety Inspectors (CSIs), on selecting animals and performing chemical residue sample collection and testing procedures in accordance with the National Residue Program (NRP) for meat, and poultry products. This directive addresses the role of IPP in the collection of animal identification (ID) and producer information, in conducting in-plant residue screening tests, and in completing residue sampling tasks using the Public Health Information System (PHIS).

B. This directive advises IPP about their responsibilities, as part of the NRP, to verify that the establishment is controlling residues in its food safety system. It also advises them on actions to take when a residue violation is suspected or identified through sampling, when a residue repeat violator is identified, and when an establishment fails to collect animal ID information or to maintain animal ID identifiable with the carcass pending FSIS residue test results.

KEY POINTS:

- IPP select carcasses for NRP scheduled (directed) sampling from all animals that pass antemortem inspection, regardless of post-mortem disposition.
- Establishments that do not have an effective residue control program in place in their Hazard Analysis and Critical Control Point (HACCP) system when slaughtering cull dairy cows and bob veal calves are targeted for in-plant testing for chemical residues at an increased rate.
- FSIS condemns an entire carcass and its parts when there is no Food and Drug Administration (FDA) or Environmental Protection Agency (EPA) established tolerance or action level for the identified chemical residue in muscle, whether the chemical residue is found in muscle, organ, or other tissue.
- IPP will take action in an establishment that receives animals from a producer who has been determined to have more than one (1) FSIS laboratory-confirmed residue violation within a twelve (12) month period.
- The Kidney Inhibition Swab (KIS™) test has replaced the Fast Antimicrobial Screen Test (FAST) in all slaughter establishments

- FSIS laboratories now use multi-residue screening methods on tissue samples submitted from positive KIS[™] tests.
- The sample size for muscle tissue collected for directed livestock and poultry residue samples submitted to FSIS Laboratories has increased from one (1) pound to two (2) pounds.
- FSIS requires livestock slaughter establishments to hold or control livestock carcasses and parts selected for FSIS directed residue testing and not to allow them to enter commerce until the FSIS laboratory reports negative or non-violative test results.

II. SIGNIFICANT CHANGES

FSIS is reissuing this directive to incorporate instructions from FSIS notices and other FSIS directives related to residue verification and to provide instructions for completing residue verification tasks using PHIS. It also provides clarification on actions that IPP are to take when an establishment fails to provide information on the violator upon reporting of a violative residue.

III. CANCELLATIONS

- FSIS Directive 10,800.1, Procedures For Residue Sampling, Testing, And Other Responsibilities For The National Residue Program, dated 7/12/07
- FSIS Directive 10,220.2, Use of CAST and FAST Screening Tests for Bob Veal Calves, dated 4/9/96 FSIS Directive 10,220.3, Using the FAST Antimicrobial Screen Test (FAST) to Detect Antimicrobial
- Drug Residues in Swine and Cattle, dated 8/23/06
- FSIS Notice 54-13, Inspection Responsibilities When a Chemical Residue Does not Have an Established Tolerance, dated 8/14/13
- FSIS Notice 52-13, Level of In-Plant Targeted Testing For Chemical Residues in Cull Dairy Cows and Bob Veal, dated 8/12/13
- FSIS Notice 73-13, Instructions for Carcass Selection for the National Residue Program Scheduled Samples, dated 11/4/13

IV. BACKGROUND

A. The United States has a complex residue control system, with rigorous processes for approval, sampling, testing, and enforcement activities. Three principal agencies are involved in the control of residues in meat and poultry products: FSIS, FDA, and EPA. FSIS works with EPA and FDA to implement the NRP. The primary responsibility of FSIS in the NRP is to verify that establishments control animal drug residues, pesticides, environmental contaminants, and any other chemical hazards in and on meat and poultry products through sampling programs within the NRP. The NRP also provides national data on chemical residue testing results to support risk assessment, enforcement, and educational activities. In accordance with FDA and EPA regulations, the NRP is designed to prevent the occurrence of violative levels of chemical residues in meat and poultry products.

B. Under 9 CFR 417.2, establishments are to conduct a hazard analysis and consider the food safety hazards that are reasonably likely to occur in their production processes and establish steps to prevent, eliminate, or reduce those hazards to an acceptable level. A food safety hazard is any biological, chemical, or physical hazard that may cause a food to be unsafe for human consumption. The possible sources from which chemical food safety hazards may arise include chemical contamination, drug residues, and pesticides. Establishments are also required to maintain documentation that supports the decisions made in their hazard analysis as a part of their records under 9 CFR 417.5(a)(1).

Meat, Poultry, and Egg Products Recalls

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SUMMARY

Slides	LEARNING OBJECTIVES
N/A	Scientific:
	[None for this topic in this context.]
	Regulatory/Administrative:
	 Explain the key steps in the product recall process, i.e., identification, outbreak notification, investigation, evidence collection, decision document, recall committee, recall, and follow-up.
	Identify the points in the product recall process at which a PHV would become involved and the PHV's role at those points in the process.
	3. Explain how the PHV interacts with other entities involved in a recall.

Slides	RECALLS DEFINED		
3	References		
	Relevant Directives:		
	5000.8 - Verifying Requirements for Written Recall Procedures		
	8080.1 - Recall of Meat & Poultry Products		
	8080.3 - Foodborne Illness Investigations		
	8091.1 - Procedures for Health Hazard Evaluation Board		
	8410.1 - Detection and Seizure		
	10,010.3 - Traceback Methods for E. coli O157:H7		
	Small Plant Recall Plan Guidebook		

4	Definition
	 Voluntary removal of FSIS regulated products from commerce Adulterated or misbranded product Initiated by manufacturer or distributer May be requested by FSIS If company does not recall: Office of Investigation Enforcement and Audit (OIEA) and EIAO's may detain and seize product in commerce Initiated by and seize product in commerce
5	Question: Adulterated or Misbranded Where do you find the legal definition of adulterated or misbranded product?

6	Examples: Adulterated in Statutes
	 Poultry Products Inspection Act – 21 U.S.C. 453 (g) Federal Meat Inspection Act – 21 U.S.C. 601 (m)
	What are some examples of "adulterated" in the real world?
7	Examples: Misbranded in Statutes
	 Poultry Products Inspection Act – 21 U.S.C. 453 (h) Federal Meat Inspection Act – 21 U.S.C. 601 (n)
	What are some examples of "misbranded" in the real world?

8	Recall Classes (Decided by Recall Committee)
	Class I • Reasonable probability of serious, adverse health consequences or death Class II • Remote probability of adverse health consequences Class III • No adverse health consequences
9	 Potential Sources for Recalls Establishment records and data FSIS inspections FSIS laboratory sampling data Epidemiological data CDC, FDA, and State Agences or sources

Office: Meat, Poultry, and Egg Products Recalls

-	Recalls are also class Scope: the am Depth: the leve Types of Recalls To find information ab	sified by: nount and type of product in q el of product distribution	question
	Types of Recalls		
	Types of Recalls		
		oout recalls on the USDA web	osite:
	United States Department of Food Safety and Inspection	of Agriculture About FSIS Districe Service Service Services Newsroom Forms	ct Offices Careers Contact Us Ask Karen ask FSIS En Español Search FSIS O Site Map A-Z Index Help
	Topics / Recalls and Public Health Alerts / C > Careers > Fact Sheets > Food Safety Education > Data Collection and Reports > Food Defense and Emergency Response > Inspection > International Affairs > Regulatory Compliance > Regulations, Directives and Notices > Rulemaking > Science	Current Recalls and Alerts Current Recalls and Alerts This page contains summary data on ACTIVE recall cases Receive email notification when recalls or public health a FSIS Issues Public Health Alert for Empire Kosher Poult Contamination (Aug 24, 2018) FSIS Issues Public Health Alert for Beef, Pork and Poult 30, 2018) FSIS Issues Public Health Alert for Products Containing Salmonella Contamination (Jul 20, 2018) En Español FSIS Issues Public Health Alert for Chicken and Pork Pr Español Frior Years	 Image: Solution of the second seco

Office: Meat, Poultry, and Egg Products Recalls

	Typical recall types:
12	Recall Process: Overview
	You are one of the first lines of defense!
	What role does the in-plant PHV have?

Wha	type of information will you gather?	

Office: Meat, Poultry, and Egg Products Recalls



14 **Recall Regulations**

§ 418.2 Notification.

"Each official establishment must promptly notify the local FSIS District Office within 24 hours of learning or determining that an adulterated or misbranded meat, meat food, poultry, or poultry product received by or originating from the official establishment has entered commerce, if the official establishment believes or has reason to believe that this has happened. The official establishment must inform the District Office of the type, amount, origin, and destination of the adulterated or misbranded product."

- Establishments must notify the District within 24 hours when adulterated or misbranded product has entered commerce
- Information must include the type, amount, origin, and destination of the product

§ 418.3 Preparation and maintenance of written recall procedures.

Each official establishment must prepare and maintain written procedures for the recall of any meat, meat food, poultry, or poultry product produced and shipped by the official establishment. These written procedures must specify how the official establishment will decide whether to conduct a product recall, and how the establishment will effect the recall, should it decide that one is necessary.

• Establishments must prepare and maintain written recall procedures

15	In-plant Verification of Recall Plan
	 At least once a year, use a directed Other Inspection Requirements task to verify establishments have written recall procedures. If there are written recall procedures, mark 418.3 as verified and complete the task in PHIS. If there are no written recall procedures, document noncompliance in PHIS on an NR citing 418.3 Refer to FSIS Directive 5000.8
Slides	RECALL SCENARIOS
17	Scenario 1 The District Office has provided the PHV with a heads up electronic mail message regarding a potential recall situation. A federally inspected establishment received three complaints from customers regarding the presence of plastic pieces in their fully cooked, not shelf stable, ready-to-eat Bologna. The complaints did not indicate the plastic in the Bologna injured the consumers. A search in the FSIS Consumer Complaint Monitoring System (CCMS) did not reveal any additional complaints against the establishment or associated with their Bologna products. The establishment provided photographs of two of the plastic pieces measured against a ruler, and the plastic pieces varied in length.

18 Scenario 1 Discussion

- By asking a series of questions, referring back to the statutes and regulations, the recall committee generates a decision tree.
- Use the decision tree to determine if a recall needs to be made in this scenario.
- Remember, FSIS always includes the regulatory and statutory basis for the decision made. The decision must be legally defensive, scientifically based, and procedurally correct.

19	Scenario 2
	The District Office has provided the PHV with a heads up electronic mail message regarding a potential recall situation associated with an allergen and sensitive ingredient. During a food safety assessment (FSA), an Enforcement, Investigations, and Analysis Officer (EIAO) discovered the Chorizo used as an ingredient in the establishment's finished product contained lactose and isolated soy protein as ingredients; however, these ingredients were not declared on the finished product label.
20	Scenario 2 Discussion
	Use the thought process to determine if a recall should be done or not.

	Why did you choose that?
21	Scenario 3
	An inspector notifies the PHV that during a labeling review task, the inspector observed that the establishment mislabeled a cheddar hot dog product with a plain hot dog product label.
22	Scenario 3 Discussion
	1. What information would you want to know?
	 What actions do you expect the inspector to take?

	3. As a supervisor, how could you acknowledge this employee's finding?					
Slides	RECALL CASE STUDY					
24	Case Study					
	You are a PHV trained in the EIAO methodology assigned at a large combination poultry slaughter/processing plant, P-42. The establishment produces fully cooked, breaded RTE chicken parts. It sells the product to distributors and to national supermarket chains.					
	On July 12, 2018, one of the establishment's customers, a national supermarket, notified P-42 that a consumer that is allergic to soy, notified the store that she had an allergic reaction to the breaded chicken. A preliminary investigation by P-42 indicated that a label not listing soy in the ingredients' statement may have been used on breaded cooked chicken, the breading of which contained soy protein.					
	The establishment notifies you of the finding immediately after they learn about it.					
25	Question 1					
	What action would you take next?					
	 Wait and observe how the establishment reacts to the situation, determine if it follows its HACCP plan Notify the DO Tell P-42 to notify the District Office (DO) Notify the DO and instruct P-42 to notify the DO as well 					

26	Question 2				
	From whom would you take direction regarding this situation?				
	 The DO-Recall Officer (RO) The establishment's Quality Assurance (QA) Manager The IIC at establishment P-42 Recall Management and Technical Analysis Staff (RMTAS) 				
27	Question 3				
	Briefly list the type of information you may be asked to collect.				
28	Question 4				
	To whom do you submit the information collected?				
	 RMTAS DO-Recall Officer (RO) Establishment IIC 				
	 Plant management to submit to DO-Recall Officer (RO) 				
29	Question 5				
	It is acceptable to share/verify the information with the establishment prior to submitting.				
	 True False 				

30	Question 6					
	Under FSIS, a recall is an establishment's voluntary action to remove product from commerce to protect the public from consuming adulterated or misbranded product.					
	 True False 					
31	Question 7					
	Which entity of FSIS is responsible for evaluating potential recall situations and when warranted, recommending that an establishment recalls product?					
	 Office of Public Health Science District Office 					
	 Recall Committee Office of Field Operations, Recall Management and Technical Analysis Staff 					
32	Question 8					
	If an establishment decides to recall product, what information (documents) does FSIS prepare and post on its website to inform the public?					
	 Only a Retail Consignee List A Recall Notification Report (RNR) or Recall (press) Release and Retail Consignee List depending on the class and depth of the recall None, it is the establishment's responsibility to notify the public Only a Recall (press) Release 					
32	Guestion 8 If an establishment decides to recall product, what information (documents) does I prepare and post on its website to inform the public? Only a Retail Consignee List A Recall Notification Report (RNR) or Recall (press) Release and Retail Consignee List depending on the class and depth of the recall None, it is the establishment's responsibility to notify the public Only a Recall (press) Release					

33	Question 9				
	Based on the scenario, if P-42 decided to recall product, briefly list the actions the establishment would be expected to take?				
34	Question 10				
	Who is the primary contact in FSIS for the establishment when conducting a recall?				
	 Recall Management and Technical Analysis Staff Office of Field Operations, Assistant Administrator Inspector-in-Charge DO-Recall Officer (RO) 				
35	Question 11				
	As an EIAO/PHV, which follow-up actions might you be expected to take? (Select all that apply.)				
	 Detaining product in commerce (when needed) Effectiveness checks Notify consignees that received product about the recall Verification of product disposition 				

36	Question 12				
	Which entity is responsible for contacting businesses on the consignee list when conducting recall effectiveness checks?				
	 Recall Management and Technical Analysis Staff Recalling establishment Office of Field Operations, FLAOs and Compliance Investigation Division (CID) 				
	 Onice of held Operations, EfActs and Compliance Investigation Division (CID) Investigators Compliance Investigation Division (CID) Investigators 				
37	Question 13				
	If directed to do effectiveness checks list some of the actions you would take.				
38	Question 14				
	To whom would you submit your report?				
	 Your Front Line Supervisor Descall Management and Tashnisel Analysis Staff 				
	 Recall Management and Technical Analysis Stall Your Inspector-in-Charge 				

39	Question 15				
	FSIS has reason to believe that adulterated or misbranded product is in commerce and requests that an establishment do a recall, but the establishment chooses not to do so. Which action would FSIS take?				
	 Immediately withdraw inspection from the establishment Withhold inspection Detain product in commerce Retain the product in commerce 				
40	Question 16				
	Establishments are required to have written recall procedures.				
	 True False 				
41	Question 17				
	How often do IPP verify if establishments have written recall procedures?				
	 When directed Each occurrence of a recall Once every 30 days Once per year 				
42	Question 18				
	Which PHIS task should be used when verifying if establishments have written recall procedures?				
	 SSOP SPS HACCP Other inspection requirements 				

Slides	SUMMARY
43	Review your score on the Summary screen and notes about this topic. Make note of any areas that you need to work on.
	Please note that this score does not count toward your overall class grade. Rather, it helps you identify which areas you may need to study more in preparation for your exams. Your overall class grade only consists of the daily quizzes, midterm exam, and final exam. Any scores you receive on Knowledge Check questions or course activities are <u>not</u> counted. They are for your use only.

Recalls

OBJECTIVES

At the end of this module, you will be able to:

- 1. Identify the regulations and statutes which are relevant to recalls.
- 2. Discuss recall class types and common examples.
- 3. Understand the PHV's role in the recall process

4. Walk through the critical thinking process and generate a decision tree used to determine if a recall is recommended.

RESOURCES

<u>FSIS Directive 5000.8 "Verifying Compliance with Requirements for Written Recall Procedures"</u> <u>FSIS Directive 8080.1 "Recall of Meat and Poultry Products"</u> <u>FSIS Directive 8091.1 "Procedures for the FSIS Health Hazard Evaluation Board"</u> <u>FSIS Directive 8410.1 "Detention and Seizure"</u> <u>How to Develop a Meat and Poultry Product Recall Plan guidebook</u>

PRE-CLASS ACTIVITY (optional)

Visit FSIS <u>Recalls and Public Health Alerts</u> Website Review <u>Federal Register 77 FR 26929</u> Review <u>FSIS Food Recalls Fact Sheet</u> Review <u>9 CFR 418.2 – 418.4</u> Review FSIS Directive 8080.1 "Recall of Meat and Poultry Products"

INTRODUCTION

A recall is a firm's voluntary removal of product from trade or consumer channels (e.g., by manufacturers, distributors, or importers) to protect the public from consuming adulterated (injurious to health or unfit for human consumption) or misbranded (false or misleading labeling and/or packaging) products. (**21 U.S.C. 601(m)**,(n); **21 U.S.C. 453(g)**,(h); **21 U.S.C. 1033 (a)**,(I))

If a company refuses to recall its product, then FSIS has the legal authority to detain and/or seize meat and poultry product(s) in commerce when there is a reason to believe they are hazardous to public health or if other consumer protection requirements are not met. Although recalls are voluntary, FSIS oversees all recall activities by official meat & poultry establishments, and coordinates any FSIS actions with the recall taken by the firm. For recalls conducted by state-inspected firms or retail establishments, the appropriate state agency oversees the recall in most cases. FSIS will provide the state agencies any needed assistance and information.

FSIS **Directive 8080.1** "Recall of Meat and Poultry Products" provides the FSIS program personnel with the terminology, responsibilities, and public notification procedures regarding the voluntary recall of FSIS-inspected meat and poultry products.

Federally inspected meat and poultry establishments are required to prepare and maintain written recall procedures. The written procedures must specify how the establishment will decide if they need to conduct a product recall and how they will implement a recall. The written procedures and all records associated with recalls must be available for FSIS review. (9 CFR 418)

TERMINOLOGY

The following are some of the common terms (pertinent to the discussion of this module) that Directive 8080.1 uses related to recalls:

Recall Classifications

FSIS assesses the public health concern or hazard presented by a product being recalled, or considered for recall, whether firm-initiated or requested by FSIS, and classifies the recall based on the relative health risk as follows:

- Class I: Reasonable probability of serious, adverse health problem or death
- Class II: Remote probability of adverse health problem
- Class III: No adverse health consequences

Each product recall's classification is unique. Let's look at each of these in more detail, with some common examples.

Class I. This is a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death. For example, the presence of pathogens in ready-to-eat product or the presence of *E. coli* O157:H7 in ground beef.

Class II. This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product. For example, the presence of undeclared allergens such as very small amounts of potential allergenic substances (milk or soy) or small sized non-sharp edged foreign materials (plastic).

Class III. This is a health hazard situation where the use of the product will not cause adverse health consequences. For example, the presence of undeclared generally recognized as safe non-allergenic substances, such as excess water.

Depth & Scope

Recalls are also classified by the level of product distribution to which the recall is to extend (Wholesale, Retail, HRI, Consumer). This is defined as the depth of the recall.

The scope of a recall is defined by the amount and type of product in question. Multiple factors are used in determining the scope, such as establishment sanitation procedures and process flow.

<u>OPHS</u>

This group addresses microbiological, epidemiological, and other scientific issues associated with the recall.

Health Hazard Evaluation Board (HHEB)

This group is convened on an ad hoc basis to address situations involving potential human health hazards when the Agency is uncertain about the nature or severity of the human health risk. If the hazard presented by a given product appears to be unique or in some way unusual, the Recall Committee may consult with the HHEB.

Recall Committee

A committee of representatives from various FSIS offices and staffs assembled to respond to potential or real health hazard incidents reported to the Recall Management and Technical Analysis Division. The primary members of the committee are representatives of the following program areas:

1. Recall Management and Technical Analysis Staff (RMTAD) OFO

RMTAD calls a committee meeting, distributes information about the recall to committee members, has the primary responsibilities for recall activities and is responsible for the following:

- Leads the Recall Committee meeting.
- Reviews and evaluates incoming data (Recall worksheets, charts, labels, etc).
- Formally recommends and closes out recalls.
- Acts as a liaison with other programs and Agencies.

They invite other program areas to assist as necessary. This includes:

- Office of Investigation, Enforcement and Audit (OIEA), Compliance and Investigations Division (CID) (conducts investigations of alleged criminal violations),
- Office of Public Health Science (OPHS),
- Office of Policy and Program Development (OPPD),
- Office of Public Affairs and Consumer Education (OPACE), Congressional and Public Affairs Staff (CPA),
- Office of Data Integration and Food Protection (ODIFP), and
- Other Federal or State agencies (such as FDA, Food and Nutrition Service, CDC, Office of General Counsel, State Departments of public health).
- 2. FSIS Recall Officer (RO), District Office, OFO

Each District designates an individual who acts as the FSIS Recall Officer, or RO. This is a designated FSIS person with jurisdiction in the district of the firm conducting the recall. This may be a Deputy District Manager (DDM), the District Case Specialist (DCS), or Enforcement, Investigations, and Analysis Officer (EIAO) in the district where the recalling firm is located. The RO is responsible for the following activities:

- Coordinates field recall activities if a recall should be recommended.
- Assigns designee (often an EIAO).
- Interacts with recalling firm, other districts, and RMTAD.
- Clarifies and explains to the Recall Committee the information collected during the preliminary inquiry.
- Develops effectiveness check strategy.
- Interprets results of the effectiveness checks and disposition of affected product.
- Submits a final recall effectiveness report to RMTAD.

3. Office of Policy and Program Development (OPPD)

Personnel in this Office provide the statutory basis for each recall; address other statutory issues, the regulations, and any regulatory policies that are relevant to the recall.

4. Office of Public Health Science (OPHS)

Personnel in this Office address microbiological, epidemiological, and other scientific issues associated with the recall

5. Congressional and Public Affairs Office (CPAO; Media Relations), Office of Public Affairs and Consumer Education (OPACE)

Personnel in this office father information and generate a Recall Release or a Recall Notification Report if there is a recall. When appropriate, they generate public notification, such as a Public Health Alert or Press Release, in situations where a recall action is not warranted.

ROLE OF THE PUBLIC HEALTH VETERINARIAN

The role of the PHV in a recall is to assist the RO and designee when requested in gathering information about the affected product. For example, you may be asked to provide information about whether the product represented by an FSIS or establishment sample that tested positive for *E. coli* O157:H7 has been held under the establishment's control, or whether it has left the establishment's control and has entered commerce. You might be asked to help the RO designee gather information about a consumer complaint concerning a product that was produced in the establishment that you cover in your assignment.

Establishment personnel may notify you that they learned or determined that adulterated or misbranded product entered commerce. If this happens, you need to contact the District Office, through supervisory channels, as soon as possible. You also need to notify establishment managers that they need to contact the District Office directly within 24 hours. (**9 CFR 418.2**)

If you are an EIAO-trained PHV, you may be asked to investigate a consumer complaint at your duty station or other nearby establishments. You may be asked to complete recall effectiveness checks if product subject to recall was produced or distributed in your local area.

Finally, as you go about your daily in-plant activities, if you suspect that there is a problem with product such that it may need to be recalled, discuss your concerns with your supervisor first. You may then be asked to report your concerns to the district RO.

Verifying Written Recall Plans

Part of your responsibilities is to verify that establishments have written recall procedures as required by 9 CFR 418.3. To do this, at least once a year, you or your designee will perform a directed Other Inspection Requirements task. Document your findings in PHIS.

RECALL PROCESS

Problem Identification

The process of recalling a product begins with problem identification. A problem with a product is identified through various sources such as the firm, the Agency, or sources outside of the Agency. The most common sources are:

- Information from in-plant inspectors and program investigators in the course of their routine duties.
- A positive result from FSIS sampling programs (microbiological, physical, chemical, misbranding).
- The company that manufactured or distributed the food product informs FSIS of the potential hazard (e.g., positive microbiological test results, consumer complaint, formulation records).

- Information from outbreak investigations, epidemiological or laboratory data submitted by State or local public health department, or other Federal Agencies.
- Consumer complaints reported to FSIS (reported in the FSIS Consumer Complaint Monitoring System see text box below).
- Information from other agencies such as the Department of Homeland Security, Customs and Border Protection, the Animal and Plant Health Inspection Service, or foreign inspection officials.

Preliminary Inquiry

When FSIS learns there is reason to believe that adulterated or misbranded product is in commerce, FSIS will conduct a preliminary inquiry. A recall officer (RO) contacts in-plant IPP and the establishment's Recall Coordinator (RC) to gather product information, contact information, and any additional relevant information. Information is collected on FSIS Recall Worksheets and provided to RMTAD. The establishment is responsible for providing this information, however as in-plant PHVs with working knowledge of establishment protocols and records, you may be asked to assist with information gathering. It is important that this information is gathered accurately and in a timely manner.

Recall Committee Meeting

Recall Committee members discuss the reason that a particular product may need to be removed from commerce and whether there is a statutory basis to recommend a recall. If the committee decides to recommend a recall, it is also The CCMS, or Consumer Complaint Monitoring System, is an electronic database used to record, triage, coordinate, and track all consumer complaints reported to the agency. Some examples of complaints associated with consumption of a meat, poultry or egg product are as follows:

- Product caused an illness or injury
- Product contained a foreign object/material
- Product caused an allergic reaction
- RTE product has been under processed
- Product is misbranded/economic adulteration
- Product is of inferior quality

A consumer may report a complaint either locally to a public health official, to FSIS OPHS, or to the Meat & Poultry Hotline. An EIAO can enter consumer information into the CCMS and OPHS triages the information. They may recommend case investigation.

When cases are investigated, the DDM of the complainant district is notified through the CCMS. An EIAO is assigned to the matter for further investigation and should immediately contact the consumer to verify information alleged in the complaint. The EIAO visits the consumer who made the complaint to verify that the information provided by the consumer and entered into the CCMS is accurate. The EIAO will collect the relevant information and evidence needed to identify and document the problem. Based on the findings of the investigation, FSIS may initiate recall proceedings, or take a regulatory or enforcement action.

The Office of Investigation, Enforcement, and Audit (OIEA) should be contacted if there are concerns regarding criminal activity. In addition, complaints concerning product tampering or potential food security threats should be referred to the USDA, Office of the Inspector General (OIG).

to determine the appropriate recall classification.

When determining whether to recommend a product recall, the Recall Committee is to seek the answers to the following questions:

- Does FSIS have reason to believe that the product in question is adulterated or misbranded under the FMIA or PPIA? For example, if the results of a laboratory analysis show that raw ground beef or beef manufacturing trimmings contains *E. coli* O157:H7, the product is clearly adulterated because it is likely to be injurious to health.
- What is the extent of the hazard to public health? This will assist in determining the recall classification.
- Does any of the product in question remain in commerce or remain available to consumers? If the committee finds that the establishment has recovered all products from commerce that would have been subject to recall, a recall is not recommended as no product is available to consumers.

To determine if product remains available to consumers, the committee seeks answers to questions such as:

• When was the product produced?

- To whom has the product been distributed?
- What type of product is involved?
- How much product is involved and how was this determined?
- What is the typical, useable shelf life of the product?

Recall Recommended

If a recall is recommended, RMTAD generates a memo which includes the reason for the recall and the recall classification (Class I, II, or III).

Notification and Action of Firm

FSIS outlines in "*Product Recall Guidelines for Firms*" the actions a firm can take to ensure that it recovers the maximum amount of product in the shortest amount of time. If the firm decides not to accept the Agency's recommendation and chooses not to conduct a recall, FSIS personnel may detain any product found in commerce that would have been subject to recall as set out in FSIS **Directive 8410.1**.

Public Notification

For every recall, FSIS notifies the public through a press release, entitled Recall Release (for Class I or Class II), and/or a Recall Notification Report (RNR; for Class III only). The press release will inform the consumer, industry, and other stakeholders of information related to the product in question. It is issued to media outlets in the areas where the product was distributed and to an e-mail listserv. All FSIS press releases concerning recalls can be found on the FSIS web site at the <u>Recalls and Public Health Alerts</u> page.

These press releases clearly describe the product recalled along with any identifying marks or codes, explain the reason for the recall, and describe the risk involved in consuming the product. They also provide instructions to the public on what to do with the product if people identify it and have it in their possession and the name and telephone number of a company contact for consumers to call with any questions. In addition, they provide general information about the product's destination, for example, "The beef burritos were distributed to an airline caterer and restaurants in the states of....." or "Frankfurters were sold to grocery stores, delis, and convenience stores in the states of" Press releases issued by FSIS will not identify the name and address of the recipients of product (e.g., specific grocery stores, restaurants, airlines, etc.). However, for Class I recalls, FSIS posts a retail distribution list, which identifies the retail establishments that may have received the recalled products.

There may be situations in which the Recall Committee determines that a specific product may present a risk to human health, but the committee cannot recommend a recall. In these circumstances, a Public Health Alert may be issued. Public Health Alerts include information on the product involved, identify whether the product presents any health risk, and instructs consumers on how to properly handle the product if they have it in their possession.

Effectiveness Checks

The RO or designee will follow up on the recalling firm's actions by verifying that the distribution information is collected and provide feedback to the RO. The RO directs FSIS personnel in the District Office (DO) where the recall originated to conduct recall effectiveness checks.

Effectiveness checks are a process by which FSIS program personnel verify that the recalling firm has been diligent and successful in notifying and advising the consignees of the need to retrieve and control recalled product, and that the consignees have responded accordingly. Subsequent consignees are then expected to notify their customers of the recall. FSIS will conduct these effectiveness checks throughout the distribution chain.

The RO or designee will perform effectiveness checks using the process outlined in Directive 8080.1. The effectiveness checks are conducted based on risk to public health. Risk is measured by combining the hazard, as defined by the class of recall and any available epidemiological data, and potential exposure to the product measured by the number of the consignees or exposure. Recall effectiveness checks allow FSIS program personnel to ensure that the firm makes all reasonable efforts to retrieve the recalled meat, poultry, or egg product. A sufficient number of effectiveness checks are made to verify that the recall is conducted in an effective manner, and that the firm locating, retrieving, controlling, and disposition of the product is acting according to regulatory requirements.

If the affected product has been distributed in other Districts, the RO notifies other DDMs that assistance in conducting recall effectiveness checks is needed. Other Districts conduct effectiveness checks and report results back to RO. If there is a Memorandum of Understanding (MOU) with a state (9 CFR 390.9), the RO or DDM notifies state authorities about the recall. When it is appropriate, the RO recommends closure of the recall to the RMTAD and RMTAD recommends closure of the recall to the Assistant Administrator of OFO.

Recall Closure

After FSIS has determined that the recalling firm has made all reasonable effort to retrieve and appropriately dispose of the recalled food product, the firm is officially notified by letter that the recall is completed and no further action is expected.



Decision Tree

RMTAD organizes and supports its thought process for determining if a recall is warranted by using a decision tree. As the committee asks questions, the answers form the tree.

The committee decision process is not standardized. It is unique to each recall and can vary greatly. In other words, there is no one "correct" version of a decision tree/process. The tree develops as more information about a recall and involved products is discovered.

WORKSHOP

Instructions: Work in small groups and as a class to generate decision trees to assess if a recall may be recommended.

Scenario 1: The District Office has provided you with an electronic mail message regarding a potential recall situation. A Federally inspected establishment received three complaints from customers regarding the presence of plastic pieces in their fully cooked, not shelf stable, ready-to-eat Bologna. The complaints did not indicate the plastic in the bologna injured the consumers. A search in the FSIS Consumer Complaint Monitoring System (CCMS) did not reveal any additional complaints against the establishment or associated with their bologna products. The establishment provided photographs of two of the plastic pieces measured against a ruler, and the plastic pieces varied in length.

Scenario 2: The District Office has provided you with an electronic mail message regarding a potential recall situation associated with an allergen and sensitive ingredient. During a food safety assessment (FSA), an Enforcement, Investigations, and Analysis Officer (EIAO) discovered the Chorizo used as an ingredient in the establishment's finished product contained lactose and isolated soy protein as ingredients; however, these ingredients were not declared on the finished product label.



RECALL WORKSHEET- FOR INTERNAL FSIS USE ONLY

(Include attachments, additional pages, label copies and flowcharts as necessary)

TODAY DATE:

ESTABLISHMENT NUMBERS:

ESTABLISHMENT NAME:

ADDRESS:

COMPANY RECALL COORDINATOR (name, title, telephone)

COMPANY MEDIA CONTACT (name, title, telephone)

COMPANY CONSUMER CONTACT (name, title, telephone)

REASON FOR RECALL:

IDENTIFY RECALLED PRODUCTS SEPARATELY BY:

BRAND NAME						
PRODUCT NAME						
PACKAGE (Type & Size)						
PACKAGE CODE (Use By/Sell By)						
PACKAGING DATE						
CASE CODE (Identifying)						
COUNT/CASE						
PRODUCTION DATE						
AMOUNT (lbs./cases) PRODUCED						
AMOUNT HELD AT ESTABLISHMENT						
AMOUNT (lbs./cases) DISTRIBUTED						
DISTRIBUTION LEVEL (institutional/retail/etc)						
DISTRIBUTION AREA						
EXPORTED TO (country)						
SCHOOL LUNCH (CN, AMS Contract)	(YES)	(NO)	(YES)	(NO)	(YES)	(NO)
DEPT. OF DEFENSE (DSCP, Commissary, etc.)	(YES)	(NO)	(YES)	(NO)	(YES)	(NO)
INTERNET OR CATALOG SALES	(YES)	(NO)	(YES)	(NO)	(YES)	(NO)
THE FOLLOWING	G TO BE COM	PLETED BY F	SIS HEADQUA	ARTERS STAF	`F:	
CASE	DATE		DEDEL		DOD	
NUMBER:	_INITIATED:	CLASS	: <u> </u>		_DO Rep.:	

RECALL WORKSHEET -FOR INTERNAL FSIS USE ONLY

(Listeria monocytogenes ATTACHMENT)

(READY-TO-EAT PRODUCT)

DESCRIBE THE PRODUCTION/PROCESSING OPERATION AND/OR ATTACH A PROCESS FLOW DIAGRAM:

WHAT WERE THE "CLEAN-UP TO CLEAN-UP" TIMES?

WAS CARRYOVER PRODUCT FROM PREVIOUS PRODUCTION PACKED WITH THIS PACKAGING CODE? (YES) (NO)

WAS THERE A COMPLETE LINE CLEANUP AFTER THE CARRYOVER WAS RUN? (YES) (NO)

WHAT DATE WAS THE CARRYOVER PRODUCT CARRIED OVER FROM?

WERE THERE ANY PROCESS DEVIATIONS DURING THE PRODUCTION OF THE CARRYOVER PRODUCT? (YES) (NO)

EXPLAIN:

WHAT WAS/WERE THE CORRECTIVE ACTION(S)?_____

WERE OTHER PRODUCTS PRODUCED ON THE SAME LINE OR USING SOME OF THE SAME EQUIPMENT DURING THE "CLEAN-UP TO CLEAN-UP" PERIOD? (YES) (NO) EXPLAIN:

WHAT INTERNAL COOK TEMPERATURE WAS REACHED?

DID THE PRODUCT REACH ANY SPECIFIED AW OR pH REQUIREMENT? (YES) (NO) SPECIFY:

DOES THE FIRM HAVE AN IN-PLANT ENVIRONMENTAL MONITORING PROGRAM FOR Listeria monocytogenes? (YES) (NO)

WAS THE SOURCE OF THE CONTAMINATION IDENTIFIED? (YES) (NO)

EXPLAIN:

IS THERE DATA THAT COULD LIMIT THE AMOUNT OF PRODUCT AFFECTED? (YES) (NO) EXPLAIN:

RECALL WORKSHEET- FOR INTERNAL FSIS USE ONLY

(E. coli O157:H7 ATTACHMENT)

DESCRIBE THE PRODUCTION/PROCESSING OPERATION AND/OR ATTACH A PROCESS FLOW DIAGRAM:
DOES THE ESTABLISHMENT CONDUCT DAILY <i>E. coli</i> 0157:H7 TESTING? (YES) (NO) WHAT FREQUENCY?
WHAT WERE THE "CLEAN-UP TO CLEAN-UP" TIMES?
POUNDS OF PRODUCED "CLEAN-UP TO CLEAN-UP":
WAS REWORK OR CARRYOVER FROM THIS PRODUCT USED IN FUTURE PRODUCTION? (YES) (NO)
ON WHAT DATES WERE THE REWORK OR CARRYOVER USED AND WAS THERE ANY REWORK OR CARRYOVER FROM THAT DAYS PRODUCTION USED IN FUTURE PRODUCTION?
WERE THERE ANY PROCESS DEVIATIONS DURING THE PRODUCTION OF THE REWORK/CARRYOVER? (YES) (NO) WHAT WAS/WERE THE CORRECTIVE ACTION(S)?
WERE OTHER PRODUCTS PRODUCED ON THE SAME LINE OR USING SOME OF THE SAME EQUIPMENT DURING THE "CLEAN-U TO CLEAN-UP" PERIOD? (YES) (NO) EXPLAIN:
WERE OTHER PRODUCED FROM THE SAME MATERIALS? (YES) (NO) EXPLAIN:
WAS ANY MICROBIOLOGICAL TESTING PREFORMED BY THE COMPANY? (YES) (NO) EXPLAIN, INCLUDE RESULTS:
IS THERE DATA THAT COULD LIMIT THE AMOUNT OF PRODUCT AFFECTED? (YES) (NO) EXPLAIN:

RECALL WORKSHEET -FOR INTERNAL FSIS USE ONLY

(Salmonella sp. ATTACHMENT)

(READY-TO-EAT PRODUCT)

DESCRIBE THE PRODUCTION/PROCESSING OPERATION AND/OR ATTACH A PROCESS FLOW DIAGRAM:

WHAT WERE THE "CLEAN-UP TO CLEAN-UP" TIMES?_____

WAS CARRYOVER PRODUCT FROM PREVIOUS PRODUCTION PACKED WITH THIS CODE? (YES) (NO)

WAS THERE A LINE CLEANUP AFTER THE CARRYOVER WAS RUN? (YES) (NO)

WHAT DATE WAS THE CARRYOVER PRODUCT CARRIED OVER FROM?___

WERE THERE ANY PROCESS DEVIATIONS DURING THE PRODUCTION OF THE CARRYOVER PRODUCT? (YES) (NO)

EXPLAIN:

WHAT WAS/WERE THE CORRECTIVE ACTION(S)?_____

WERE OTHER PRODUCTS PRODUCED ON THE SAME LINE OR USING SOME OF THE SAME EQUIPMENT DURING THE "CLEAN-UP TO CLEAN-UP" PERIOD? (YES) (NO) EXPLAIN:______

WHAT INTERNAL COOK TEMPERATURE WAS REACHED?

DID THE PRODUCT REACH ANY SPECIFIED AW OR pH REQUIREMENT? (YES) (NO) SPECIFY:

DOES THE ESTABLISHMENT HAVE POST-PROCESSING CONTROLS? (YES) (NO) SPECIFY (include records):

WAS ANY MICROBIOLOGICAL TESTING PERFORMED BY THE COMPANY? (YES) (NO) EXPLAIN, INCLUDE RESULTS:

IS THERE DATA THAT COULD LIMIT THE AMOUNT OF PRODUCT AFFECTED? (YES) (NO) EXPLAIN:

RECALL WORKSHEET- FOR INTERNAL FSIS USE ONLY

(Foreign Material or Non-Microbial Contamination Attachment)

DESCRIBE THE PRODUCTION/PROCESSING OPERATION AND/OR ATTACH A PROCESS FLOW DIAGRAM:
WHAT WERE THE "CLEAN-UP TO CLEAN-UP" TIMES (where applicable)?
HAVE YOU IDENTIFIED THE SOURCE OF THE CONTAMINATION? EXPLAIN:
IS THERE DATA THAT COULD LIMIT THE AMOUNT OF PRODUCT AFFECTED? (YES) (NO) EXPLAIN:
WERE THERE ANY DEVIATIONS REPORTED IN THE MEASURING AND/OR MIXING OF INGREDIENTS? (YES) (NO) EXPLAIN:
DOES THE ESTABLISHMENT ROUTINELY USE METAL DETECTORS OR OTHER VISUAL IMAGING DEVICES? (YES) (NO) EXPLAIN:
WERE OTHER PRODUCTS PRODUCED ON THE SAME LINE OR USING SOME OF THE SAME EQUIPMENT DURING THE "CLEAN-UI TO CLEAN-UP" PERIOD? (YES) (NO) EXPLAIN:
The Administrative Enforcement Report (AER) Process

OBJECTIVES

After successful completion of this module the trainee will be able to:

- 1. Explain and/or list the following concepts of critical thinking
 - a. What is critical thinking?
 - b. The importance of critical thinking to the AER process
- 2. Explain the role of the PHV in the AER process
 - a. In-plant team leader
 - b. Ensuring accurate supporting documentation
 - c. Ensuring proper lines of communication
 - d. Performing verification activities (verification plans)
- 3. Explain the role of the AER within the FSIS regulatory framework
 - a. Statutes and Rules of Practice as a framework of the AER case file
 - b. Ensuring that the establishments receive due process
- 4. List and describe the main supporting components of the AER
 - a. Noncompliance Records (NRs)
 - b. Memoranda
 - c. Memoranda of Interview (MOI)
 - d. Signed Statements
 - e. Other Agency Letters
- 5. Accurately document a Memorandum of Interview (MOI)
- 6. List two "other" sources of information pertinent to the AER process
 - a. Consumer Complaint Monitoring System (CCMS)
 - b. Recall System

INTRODUCTION

This module covers the agency's "**Administrative Enforcement Report**" (AER) format and thought processes.

This module will also cover:

- The use of critical thinking in developing an enforcement action.
- Different types of official documentation.
- The work methods and general process of building a case.
- The process behind recommending or taking an enforcement action.

- The basics of building a case and assembling an AER case file.
- How an establishment's response is verified by the agency.
- How to assess an establishment's corrective actions.

Overview of the AER Process

Background

Program Investigators prepare enforcement reports for serious violations of the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and Egg Products Inspection Act (EPIA). These reports typically include a Predication Statement, Synopsis of Facts, Narrative Summary, Chronology of Events, List of Witnesses, and Evidence Obtained but not Submitted. This format has proven to be useful and necessary for significant criminal and civil cases. However, this format can also be time consuming to complete. Under *9 CFR Part 500 - Rules of Practice*, FSIS is faced with the challenge of providing a report immediately which supports the basis of the action taken.

Administrative proceedings, including the documentation produced as a result of administrative actions, provide FSIS the authority to suspend inspection, with or without notice. They also provide FSIS the authority to stop a establishment's right to do business when serious inhumane practice or food safety concerns are raised. Administrative proceedings can immediately affect the establishment's right to conduct business and profit financially. FSIS needs this documentation immediately if an appeal by the establishment is received, if the establishment requests an expedited hearing, if FSIS requests a complaint to withdraw the grant of inspection, or if legal actions are taken such as hearings, injunctions, requests for seizure, etc.

Administrative enforcement actions can be appealed immediately and can result in an expedited hearing before an Administrative Law Judge, or other legal officials such as a District Court Judge. The AER and accompanying exhibits support that the agency has a basis for the action taken. <u>This section describes the role of the PHV in the AER</u> process to ensure that there is accurate supporting documentation when the agency proposes or imposes an enforcement action (e.g., Notice Of Intended Enforcement

(NOIE), withholding the marks of inspection, suspension). The documentation (e.g., NRs, memoranda, other Agency letters, etc.) must demonstrate the link between the enforcement action and the regulations. The regulations will be linked with specific provisions of the FMIA, PPIA, or EPIA later in the AER process. The AER process is used by FSIS to ensure that Agency personnel have analyzed all available information, applied critical thinking when making decisions, and have documented those decisions in a manner that will support the actions taken by the agency. The AER method of documentation demonstrates that FSIS has an effective and efficient means to document and maintain administrative actions taken under the Rules of Practice. The methodology helps to ensure uniformity and consistency.

The AER Report (FSIS Form 5400-9)

The Administrative Enforcement Report (AER), FSIS Form 5400-9, provides an effective and efficient means for FSIS to document and maintain enforcement actions taken under the *Rules of Practice (9 CFR Part 500)*. Some AER documentation is written with statutory and regulatory citations. It is important that both the regulatory and statutory support is properly cited for the instances that the AER case file is needed as an exhibit in court proceedings.

The Rules of Practice include:

- Regulatory control action
- Withholding action or suspension without prior notification
- Withholding action or suspension with prior notification
- Notification, appeals, and actions held in abeyance
- Withdrawal of the grant of inspection
- Refusal to grant inspection
- Procedures for rescinding or refusing approval of marks, labels, and containers

Statutory support includes the Acts:

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

The <u>AER process</u> entails using a critical systems thinking approach to analyzing available information and facts. Once all pertinent and available information has been properly documented and analyzed <u>and</u> the decision leads to a recommended enforcement action, the case file is assembled and maintained by specially trained personnel. After the establishment has responded to the intended or effective enforcement action, the adequacy of the response must be verified by agency personnel. <u>You as the PHV-IIC will play a critical role gathering and documenting facts</u>, as well as in these verification procedures.

The AER process is not necessarily linear. Many of the elements are performed concurrently, in a "back and forth," or circular/spiral manner. For example, if it is decided that more information is needed to make a solid recommendation, and then steps must be taken back to gather this necessary information and then the information must be reanalyzed. It may take several "rounds" of information gathering/documenting and analyses before a recommendation for an enforcement action can or should be made. Under many circumstances, the issue may be resolved by the establishment without the need for such a recommendation.

Critical Thinking

An Overview of Critical Thinking

This section is a brief introduction into "critical thinking." This is an integral part of the AER process and your job as a PHV-IIC and also later in your role as an EIAO. Every field PHV will receive training as an EIAO and will ultimately perform the same duties as "full time" EIAOs, albeit at a lower frequency.

Applying critical thinking and analysis will help ensure that any action taken or recommendation made by you as the PHV, whether it be to recommend or not to recommend enforcement, is <u>well thought out</u> and based on a <u>thorough review</u> of all pertinent information. It is important to realize that this process is meant to result in a legally defensible case file that will, if necessary, stand up in a court of law. If your analysis is correctly performed and your thought process is well documented, then chances are very good that any resulting enforcement decision will never be taken to court.

Applying critical thinking will help associate any actions taken with the applicable statute or regulation, and also ensure that a solid basis exists for taking further action when warranted. The best laid out thought process is worthless if actions taken are not supported by the statutes or regulations.

Critical Thinking and How It Fit into the AER Process

Richard Paul¹ defines critical thinking as: "The ability to think about one's thinking in such a way as to recognize its strengths and weaknesses and, as a result, to recast the thinking in an improved form."

Studies have also been performed that have looked at people identified as "critical thinkers" and the following common characteristics were identified². Not everyone that is a critical thinker will possess all of these characteristics, but this gives you an idea of some of the qualities that are beneficial to the process:

- People who hone critical thinking as a skill
- Inquisitive people
- People with a keenness of mind
- People with a hunger for reliable information
- People who actively use reason
- Open minded people
- People who are systematic
- Analytically minded people

Some examples of people who use critical thinking in their profession or life include scientists, doctors, trial lawyers, engineers, and good thinkers in general. Critical

¹ Dr. Richard Paul. (1993) Critical Thinking – What Every Person Needs to Survive in a Rapidly Changing World, edited by Jane Willsen and A.J.A. Binker, Foundation for Critical Thinking, Santa Rosa, CA

² Steven D. Schaefersman, 1997, Miami University and Peter A. Facione, 1998, Santa Clara University

thinking is a natural part of these professions, and by default your education in veterinary medicine has set you up for a career in "critical thinking."

Critical Thinking Frameworks

As scientists and veterinarians, you are already familiar with several types of critical thinking frameworks:

- The scientific method
- A medical diagnosis
- A systems analysis

You have used the "*scientific method*" in veterinary school and in practice. A medical diagnosis is basically a mixture of the scientific method and a systems analysis. When you make a veterinary diagnosis, you use the basic framework of the scientific_method, but also include a "*systems analysis*" approach when you assess the symptoms by organ system(s). You must have an understanding of the organ *systems* to rule out certain differential diagnoses. When performing an analysis of the effectiveness of an establishment's food safety *system*, you will use these same basic principles.

You may not be as familiar with the *legal or regulatory analysis* method as with the other methods mentioned. This method is used when assessing an establishment's compliance with regulatory requirements, as they relate to their food safety system and public health.

In reality, you will be using a mixture of the above methods to achieve your goal. You will be analyzing a variety of both scientific and regulatory information that is intertwined in an establishment's food safety system. It will be your job as a PHV-IIC to determine whether the mixture that the establishment has put together is effective and meets <u>basic</u> regulatory requirements. Later, after receiving specialized EIAO training, you will be assessing whether the mixture meets the intent of <u>all</u> of the statutory and regulatory requirements.

Critical Thinking and Public Health

So far, we have been focusing on critical thinking as a component of the AER thought process. Let's look at it from a public health point of view, since ensuring the public's health is the ultimate goal of FSIS. FSIS has long been a public health regulatory agency. The recent emergence of certain foodborne diseases, such as *E. coli O157:H7* has forced FSIS to take a new look at this mission and make changes to the long established system of meat, poultry, and egg inspection.

It is part of any regulatory public health agency's mission to seamlessly integrate scientific principles with a legal framework and public health values³. Critical thinking is important in achieving this seamless integration. It was used while making significant organizational and necessary changes at the agency level—it will be as important when you are making public health and related enforcement decisions at the local level.

The Scientific Method as an Example of Critical Thinking

Now that we have covered some of the basics of critical thinking, we will spend some time reviewing the "scientific method" as an example of a critical thinking method. This will help to better understand the connection of scientific critical thinking to the AER process. Later, we will look at the legal analysis methodology as an example of how to assess information from a regulatory aspect.

According to Steven Schafersman⁴, the scientific method requires three major prerequisites:

- 1. Use of empirical evidence
- 2. Use of logical reasoning
- 3. Possessing a skeptical attitude

The first prerequisite of the scientific method is the <u>use of empirical evidence</u>, which is using evidence that can be seen, heard, touched, tasted, etc. It is *tangible* evidence that can be experienced and is repeatable. In other words, it is using evidence that can be objectively verified.

³ Steven D. Schafersman, 1997, Miami University

⁴ Steven D. Schafersman, 1997, Miami University

The <u>use of logical reasoning</u>, the second prerequisite of the scientific method, is an *acquired* skill—it must be learned. Logical reasoning forces us to face the true facts and not give in to personal emotions or beliefs. Remember, *emotions* are not empirical evidence they are personal reactions to the facts. Likewise, feelings and subjective beliefs are not empirical facts. *Beliefs* are personal perceptions of the truth—they have a personal or subjective spin on them that is influenced by many things, such as culture, environment, etc. The use of logical reasoning forces us to face reality and be as objective as possible.

The third major prerequisite of the scientific method is the <u>possession of a skeptical</u> <u>attitude</u>. This does not mean that you should be skeptical beyond accepting the truth but it does mean that you should not accept something as the truth without question. Change and progress would not happen if we did not constantly question our beliefs, examine new evidence, reexamine old evidence, and combat self deception. Just because someone says it is so—does not make it true. A healthy questioning of the perceived "truth" can lead to new insights and change for the better.

One way of questioning the "truth" is by testing beliefs against objective reality. Remember beliefs are personal, subjective *perceptions* of reality. If the consequences and/or outcomes of an action can be consistently and objectively predicted, regardless of who is performing the action, we are much closer to the *real* truth.

The Steps of the Scientific Method:

Now that we have covered the prerequisites of performing the scientific method, we will review the individual steps to be performed in this methodology. Remember, this is not a new concept for you as a scientist and veterinarian, but it *will be used in an unfamiliar way* in your new position as a PHV.

In the purely scientific world, the steps to perform are as follows:

The first step is to identify the problem to study. This is done through an analysis
of existing information and facts, as well as through gathering new information
and facts. This is often performed through observation or qualitative studies.

- 2. The second step is to gather information and facts relevant to the identified problem. This will help further define the problem and assist in formulating a hypothesis to be scientifically tested.
- 3. The third step, once sufficient information has been gathered, is to formulate the hypothesis.
- 4. The fourth step is to scientifically test the hypothesis. This is generally performed through quantitative studies. The result of this test will be to either prove that your hypothesis is correct—or not.
- 5. The fifth step, if your hypothesis was not correct is to modify the hypothesis after further study and then test the revised hypothesis. This is repeated until the correct solution is found.
- 6. The final step is then to construct a theory from the evidence gathered and the proven hypothesis.

In your role as PHV-IIC, you will not be conducting pure scientific studies. You will, however, use the basic concepts of this logical thought process when analyzing the effectiveness of an establishment's food safety system. You will be tasked with identifying problems, such as regulatory noncompliance, gathering and documenting information pertinent to the identified problem, and proposing a regulatory solution if the establishment does not adequately remedy the problem on their own.

By using this type of thought process, you stand less of a chance of letting your emotions or feelings dictate your actions. Your actions will be supportable by the agency, both to the regulated industry and if necessary in a court of law.

Regulatory Analysis as an Example of Critical Thinking

As was mentioned before, you will also be performing a legal or regulatory analysis in your role as PHV-IIC. This section of the module will be an introduction into this thought process. You will receive more in-depth and detailed training on this type of methodology when you receive EIAO training in the near future.

When performing a regulatory (legal) analysis, you will follow a framework that is very similar to the scientific methodology you are acquainted with. There is, however, an important distinction between the two methods: The goal of the scientific method is to

scientifically prove a point, while the goal of the legal analysis is to *legally* prove a point. Another way of looking at it is that the scientific method follows the laws of science, while the legal analysis follows man-made laws, statutes, regulations, etc.

The steps to perform are as follows:

- 1. Gather the facts
- 2. Evaluate the evidence
- 3. Identify the regulatory (legal) elements
- 4. Develop the rationale
- 5. Draw the conclusion

The first step is basically the same as in the scientific methods—<u>gather the facts</u> or information needed to determine what the problem is. You will ask yourself such questions as:

- Who are the persons involved?
- What event has happened?
- What is the location that is involved?
- Why did the event happen?

It is important that the information gathered is pertinent and based on *objective facts* not subjective opinions. All of the gathered evidence should be properly documented.

After the facts have been gathered, then the <u>evidence must be evaluated</u>. In doing this, the significance of the gathered information is weighed and assessed to determine if there is an indication of a problem. In other words, does the evidence point to a potential statutory or regulatory noncompliance? If not, do we need more evidence? Or, does the evidence indicate that there is no problem at all?

If it is determined that there is evidence of a potential noncompliance, then the next step is to <u>identify the statutory and regulatory elements</u> involved. This, of course, *requires a basic understanding and good working knowledge* of the most commonly used statutes, regulations, and current policies (i.e. directives, notices). To identify the applicable elements, you can ask yourself:

- What are the applicable provisions of the statute?
- What are the applicable regulations?
- What are the applicable policies?

It is not expected of you that you will be an expert in *all* of the statutory and regulatory language. You may also need an interpretation of the most current policies, since these are frequently updated to meet changing conditions. If you need technical assistance with unfamiliar statutes, regulations, or current policies, then you can contact your supervisor, mentor, or the Technical Service Center.

After you have identified the regulatory elements, the next step is to <u>develop the</u> <u>rationale</u>. This is putting the pieces of the puzzle together to see the *big picture*.

- In doing so, you evaluate and explain the *relationship* of all of the pertinent events and actions. For example, you could create a "timeline" of the events by time, place, person, etc.
- Once you have identified the relationships of the events and actions, you will need to explain the *cause and effect* of the relationships. In other words, you need to be able to explain why the events took place in the manner that they did.
- Finally, you will explain the *consequences*, or outcomes, of the action or actions, given the relationships identified.

The final step of the regulatory analysis is using a process of deduction to <u>draw a</u> <u>conclusion</u>. When drawing your conclusion, it is once again vital that you limit yourself to the known *facts*. In legal language, the facts are stated in a "premise," which includes the reasons for the action, the pertinent facts, and the gathered evidence. Relying on certainty that is based on the logical connection of premises will result in an accurate and defensible conclusion that has been proven as true.

As you can see, the general principles are very similar to the scientific methods; the difference is that this method is more focused on whether a law, statute, or regulation has been violated rather than whether a scientific principle has been met.

In recommending actions, you will need an <u>explanation</u> of your conclusion. In doing so, you will state the results of your thought process—of your reasoning. You will then *justify* your reasoning and base this justification on the facts and credible evidence. Finally, you will present your explanation in the form of a compelling argument. Being able to accurately state results, justify procedures, and effectively present arguments, both orally and in writing, are essential skills in accomplishing this goal.

Examples of how a justification can be presented include:

- Constructing a chart that organizes the findings
- Citing the standards and contextual factors used to judge the quality or interpretation of a text
- Appealing an established criteria as a way of showing the reasonableness of a given judgment

As a PHV-IIC you will mainly be documenting your thought process on NRs and in *memoranda*. There are also other occasions that will require you to justify your reasoning, such as in responses to an establishment's appeals to actions, when answering inspector's grievances, and many others.

<u>Self regulation</u> is not as much an individual step in critical thinking as it is a common thread throughout the process. When performing any of the five steps mentioned above, you should *constantly* be evaluating and correcting your interpretation as more or better information becomes available. You should consequently examine and correct any inferences that have been drawn and that are affected by the change in interpretation. You should then review and reformulate any explanations you have completed that are based on the corrected inferences. This requires skills in self examination and self correction.

As an example, you may possibly need to change your conclusion in view of the realization that you have misjudged the importance of certain information. This realization could come about after you have received additional credible and pertinent evidence that was not immediately available during your first analysis of the information.

As a PHV-IIC, you will find this to often be the case, such as when an establishment appeals a decision made by yourself or a CSI. If the establishment can provide you with new, credible, and pertinent information, you may need to revise your conclusion and possibly sustain the appeal. It is important to be open to new information and not let your emotions or beliefs be your guide.

One of the inherent problems with any assessment of information is that there might be holes in the information. Another problem is that the information may be presented in such a way that the person assessing the information is missing something—even though all of the information is there. In other words, they are not seeing the forest for the trees.

Information Sources Used in the AER Process

The critical thinking process is all about looking at information - and there are many sources of information available. The following section is a brief overview of some the more common sources of information used in the AER process.

Sources of documented information from "within" the establishment include:

- Noncompliance Records (NRs)
- Memoranda of interview, discussions, meetings, agreements, and similar documents
- Other agency letters

These methods of documentation will be discussed in more detail later in the module. There are other sources of information that are located outside of the establishment. These include:

- The Consumer Complaint Monitoring System (CCMS)
- The Recall System

The following is only a very brief introduction to these systems. You will receive more indepth training in your EIAO training.

Other Administrative Activities

OFO personnel also carry out other administrative activities for which an FSIS Form 5000-9 is started, and all supporting documentation will be attached exhibits. Such administrative activities include:

- 1. Reviews of the sanitary conditions at custom exempt operations, and, when necessary, the preparation of written recommendations along with evidence to the Office of Program Evaluation, Enforcement, and Review (OPEER).
- 2. Detention of product as set out in FSIS Directive 8410.1
- Recall Effectiveness Checks as set out in FSIS Directive 8080.1, Recall of Meat and Poultry Products, and FSIS Directive 5100.2, Enforcement, Investigations, and Analysis Officers (EIAO) Responsibilities Related to Recalls and Consumer Complaints,
- 4. Investigations of prohibited activities as set out in the FMIA, section 10, the PPIA, section 9 and 10, and the EPIA section 8, such as adulterated product deliberately distributed into commerce,
- Investigating illness outbreaks such as illness outbreak related to recall NOTE: Illness outbreak investigations related to the Consumer Complaint Monitoring System are documented under the CCMS system, not the AER system.
- Non-routine incident investigations addressed in FSIS Directive 5500.2, Significant Incidence Response, and FSIS Directive 5500.3, Incident Investigation Team Reviews.

The <u>Consumer Complaint Monitoring System</u>, or CCMS, can be described as follows:

- FSIS receives, tracks, and uses consumer complaints to *help identify* unsafe meat, poultry, and egg products that are available to consumers in commerce
- It is important to remember that complaints are *alleged* by the consumer until they have been verified by the agency
- It is however not possible to verify all complaints

FSIS receives consumer complaints through a wide variety of sources:

• USDA Meat and Poultry Hotline

- Office of Field Operations (OFO) District Offices/Headquarters, FSIS
- Office of Program Enforcement Evaluation and Review (OPEER), FSIS
- Office of Public Health Science (OPHS), FSIS
- Labeling and Consumer Protection, FSIS
- State or Local Health Departments
- Other Federal Agencies

Once the complaint is received, it is entered into an electronic database that is used to record, triage, coordinate, and track all consumer complaints that are reported to the agency. Personnel in the District Office review the database daily for open and new cases and dispatch an EIAO when necessary to investigate.

Similarly, if FSIS becomes aware of a presumptive positive laboratory sample result for a foodborne public health hazard <u>and</u> the establishment has shipped the affected product, a <u>recall</u> of that product will be issued. In this instance, the District Office will once again dispatch an EIAO to investigate.

In both cases, you as the PHV-IIC at the affected establishment will be working closely with the EIAO in the investigation and, if necessary, in building the case for the AER.

Supporting Documentation in the AER Process

Proper and well thought out documentation is the key to supporting any conclusions or decisions made. Documentation is the rock foundation of the AER process. Like any foundation, if it is built of solid rock it can support a lot of weight. If, on the other hand, it is built of sand, it will not adequately support any structure.

In your role as a PHV-IIC, it will be your duty to ensure that all documentation generated by you and your inspection team is complete, accurate, well thought out, and well supported

The following section is a brief overview of some of the documentation that is used in the AER process. These documents are then attached to an AER as support.

The most common types of documentation encountered in the AER process include:

- Noncompliance Records (NRs)
- Memoranda
- Memoranda of Interview (MOIs)
- Signed Statements
- Decision Memos
- Other Agency Letters

Now let's take a closer look at some of these types of documents.

The Noncompliance Record (NR)

The Noncompliance Record, or NR, will be the format that you will use most frequently in the establishment environment. This is an electronic form used to document regulatory noncompliance and build a history through linking non-compliances with common causes. The NR is created in the Public Health Information System (PHIS) when a noncompliance is found during an inspection task.

As was discussed in the Inspection Methods portion of your PHV training, it is important to ensure that the *proper regulatory citation* is included on the form when documenting any noncompliance. If an improper regulation is cited, then the document will not stand up to the appeals process or in a court of law. If you are not sure about the regulatory citation, then ask your supervisor or contact the Policy Development Division for assistance.

The documentation on an NR should be *complete* and accurately depict the circumstances and relevant facts. The description should focus on the big picture—on the systems-level problem. If you concentrate on minor non-compliances then chances are you will miss larger systems problems. Again, you should <u>focus</u> on the forest, not the trees—the trees should help <u>describe</u> the forest.

<u>Memoranda</u>

Memoranda are important documents in establishing a history. These documents are created in PHIS in a standard format. Regardless of style, the memorandum should be *signed and dated*.

The content of a memorandum can include matters that are not regulatory noncompliance, but are pieces of information that "round out" or complete the picture. This includes information provided to the establishment, documentation of group discussions, or minutes of meetings. It is important to keep a copy of any memorandum provided to the establishment in the agency files.

Memoranda of Interview (MOI)

Memoranda of Interview (MOI) are a special form of memorandum that documents a formal or informal interview with agency personnel. An interview is conducted if the pertinent facts are unclear or if there is additional relevant information that is otherwise not documented. These are important pieces of documentation in establishing a history Such memoranda are to: 1) identify all participants present at the meeting; 2) explain all facts that provide the basis for the meeting; 3) fully describe the meeting and 3) be written in a concise and clear manner.

MOIs are used to document information pertaining to a specific set of facts and summarize key points of this information as it is gathered in an interview with a person with *direct*, not second-hand, knowledge of relevant information.

When documenting the information, it is important to accurately depict the relevant *facts* as they have been revealed in the interview. Do not document opinions or speculation. Like any other memorandum, the <u>interviewer</u> documents the information and is the one who signs and dates the document.

Signed Statement

A signed statement is very similar to an MOI, but is a more formal record of an interview taken by specially trained personnel. In this case, the person <u>interviewed</u> is asked to sign and date the document after they have reviewed for accuracy. You will not be taking signed statements until you receive further training.

Decision Memo

Decision memos are an integral part of the AER documentation process. In the discussion of critical thinking and cognitive skills, we illustrated the importance of explaining, or justifying, one's reasoning based on credible evidence. A decision memo does just that; it explains the reasoning behind a decision or recommendation for an enforcement action.

Decision memos are vital pieces of documentation in the AER case file. They *synthesize* the available information and supporting documents into a single document. They relay to the reader the *critical thought process* used in analyzing the information and how a conclusion was reached. The decision memo relates the information not only back to regulatory requirements, but also back to the statutory authority of the agency. This is an important aspect of the AER documentation process, since the AER case file is a legal document.

As a PHV-IIC, you may be documenting decision memos pertaining to the recommendation of enforcement action related to repeated noncompliances or inhumane handling.

Official Agency Letters

There are a number of official agency letters that are issued to establishments by the District Office. These letters officially inform an establishment, in writing, of an intended enforcement action or one in effect. These are *enforcement letters* and are <u>not</u> issued by PHV-IICs. They are listed here for informational purposes only.

- Notice of Intended Enforcement (NOIE)
- Notice of Deferral
- Notice of Suspension
- Notice of Suspension Held in Abeyance
- Letter of Information (LOI)
- Letter of Warning (LOW)

BUILDING A CASE

Up to now, we have focused on the building blocks of the AER process. These are:

- How to critically process information and reach a defensible and logical conclusion
- How to properly document the information and justify your conclusion

We are now going to look at how to put these building blocks together and build the case for enforcement.

The first step in building a case for enforcement is determining the "enforcement stage" that the establishment is currently in. The enforcement stages are based on the *Rules of Practice (ROP)*, which are found in *9 CFR Part 500*. The ROP were covered in the Inspection Methods portion of your training.

The enforcement stages include:

- Pre-Enforcement Stage
- Enforcement Stage
- Deferral or Abeyance Stage
- Legal Stage

These stages require different actions in your role as PHV-IIC, which will be covered later in this module. For now, let's take a brief look at each of the stages.

Pre-Enforcement Stage

In the Pre-Enforcement Stage, the establishment is not currently under any type of active enforcement action—either NOIE, suspension, or withdrawal.

Possible regulatory actions taken under the ROP in this stage are:

- Regulatory Control Action (RCA)
- Withholding the Marks of Inspection

This is the stage that <u>most establishments</u> operate under and is the stage where the professional judgment and critical thinking abilities of the in-plant inspection team are

extremely important and most frequently used. In this stage, you as the PHV-IIC will ensure proper documentation of regulatory non-compliances on NRs and appropriate association of recurring problems. You discussed how to do this in the Inspection Methods portion of your training. You will also ensure proper documentation of other issues and concerns on memoranda, as was discussed earlier in this module in the "Documentation" section. This is a vital part of the AER process for two reasons. First, you are building a history of any recurring problems while taking the establishment's entire food safety system into account. Second, you are ensuring that the establishment's due process rights are not violated by providing them with the feedback they need to comply with the regulatory and statutory requirements of the agency.

Under normal circumstances the establishment will not leave this stage. If, however, you determine through your critical thinking process that the establishment's <u>food safety</u> <u>system is not effective</u> and that there is a public health food safety concern, you are required to act. In doing so, you will follow the ROP:

- If there is an *immediate* concern, you will take immediate action and ensure that there is no threat to the public's health. You will then contact your supervisor for further guidance.
- If there is *no immediate* concern, you will recommend an enforcement action to your supervisor. At this point, an EIAO may or may not be dispatched to the establishment to perform a comprehensive food safety assessment. This will depend on the specifics of the case and whether the specific type of detailed information gathered through this type of methodology is necessary for the analysis or not.
- In both instances, your documentation of the information and the justification you
 provide regarding your conclusion is an integral part of the continuation of the
 process.

Enforcement Stage

The establishment is in the Enforcement Stage if it has been issued an NOIE or placed immediately under a suspension. According to the ROP, these constitute two types of suspensions:

Suspension of inspection personnel <u>with</u> prior notification: In this case, the establishment will receive an NOIE prior to the suspension going into effect. This gives the establishment an opportunity to respond to the agency's concerns before the suspension goes into effect and provides them due process.

Suspension of inspection personnel <u>without</u> prior notification: Here, the establishment is placed immediately under a suspension; the suspension is in effect, because of an immediate threat to the public's health.

At the point the establishment receives an NOIE, or when the suspension goes into effect without prior notification, is when the establishment is in the enforcement stage. As a PHV-IIC, you and your in-plant inspection team will be actively engaged in the evaluation process of the establishment's response to the suspension while the establishment is in this stage.

Deferral or Abeyance Stage

The Deferral or Abeyance Stages are technically a sub-set of the enforcement stage. An establishment is in this stage when:

- An <u>NOIE</u> has been issued and the establishment has <u>adequately responded</u> to FSIS. The suspension then <u>temporarily</u> does not go into effect, allowing the establishment to operate and demonstrate to FSIS the effectiveness of their response. You as the PHV-IIC, together with your in-plant inspection team, will verify this effectiveness through a verification plan. If your verification results lead to the conclusion that the response is not effective, the suspension then goes into effect. So the decision to place the suspension in effect is <u>deferred</u> while the effectiveness of the establishment's response is verified.
- An establishment has been placed <u>under a suspension</u> in effect and has <u>adequately responded</u> to FSIS' concerns. The suspension is then temporarily lifted, or <u>held in abeyance</u>, while the establishment demonstrates the effectiveness of their response. As above, you as the PHV-IIC and your in-plant inspection team will verify this effectiveness through a verification plan. If your verification results lead to the conclusion that the response is not effective the suspension is <u>reinstated</u>.

Legal Stage

The Legal Stage is a special type of enforcement stage. In this stage, the agency has filed a legal complaint for withdrawal of inspection. This means that the establishment's Grant of Inspection, which allows them to operate under federal inspection, is permanently revoked. The agency will petition the court for withdrawing inspection from an establishment if there are <u>acts of *criminal* intent</u> or if <u>multiple *enforcement* actions</u> against the establishment have been necessary.

If the establishment has been placed in the legal stage, then many layers of the agency will be involved in the case, including legal council. You, as the PHV-IIC may be requested to provide information or to testify under these circumstances. This only once again illustrates the importance of properly thinking through and documenting your decisions and conclusions.

Recommending or Taking an Enforcement Action

As you have seen, the decision to place an establishment under an enforcement action is a multi-layered process and should not be taken lightly. It must be well thought out and supported. The following is a synopsis of the elements involved in making a recommendation for an enforcement action or for taking one.

First, remember that recommending or taking enforcement actions is based on a conclusion reached through a critical analysis of the pertinent and credible information. Ultimately, portions of the analysis will be performed by various members of the District inspection team, such as EIAOs, FLSs, and DMs. But, under normal circumstances, the in-plant inspection team will be the driving force that initiates the process. This recommendation will or will not be supportable based on the strength of their documented case history and the objectivity and logic of the justification. It is your responsibility as a PHV-IIC to ensure that all "in-plant" pieces of the process are well thought out, properly documented, and supportable.

The action that you recommend will depend on several factors that you must take into account during your critical thinking process:

- The <u>enforcement stage</u> the establishment is in—as a PHV-IIC, you will most commonly be recommending an action revolving around a suspension.
- The <u>egregiousness</u> of the issue(s)—depending on the severity of the issue you will recommend a suspension either with or without prior notification, or under extreme situations, a complaint for withdrawal of inspection may be recommended. The Rules of Practice (9 CFR 500) are the regulations used for making these decisions.
- <u>Prior actions</u> taken—the regulatory and enforcement history of the establishment will play an important role in your recommendation. As such, an establishment that repeatedly cannot, or will not, comply with the regulatory and statutory requirements will be considered for regulatory enforcement based on the repetitive noncompliance. FSIS documentation of the establishment's failures is critical in this case.

It cannot be stressed enough that the recommended or implemented action must be adequately *supported and justified*. The documented history found in the relevant NRs, memoranda, and other agency letters, build the foundation for the critical thought process leading to the recommendation. The synopsis of the entire thought process and the justification for the recommendation is then documented in the decision memo and attached to the AER file. Once again, it is your responsibility as a PHV-IIC to ensure that all in-plant pieces of the AER process are well thought out, properly documented, and supportable.

Assembling an AER Case File

At the point that a recommendation is made to take an enforcement action against an establishment, an AER case file is initiated. This section is a short introduction into how such a case file is assembled. In your EIAO training, you will receive a more thorough introduction into the management of these AER case files.

The AER case file is commonly compared to a book that is comprised of multiple chapters. The entire case file is the "book" which is assembled in multiple sections that are the "chapters," called *Administrative Enforcement Reports* (AER). Each AER

corresponds to an enforcement action or stage—from beginning to end. The AER is a special FSIS form that is filled out by specially trained personnel, such as EIAO.

For example, a chapter would begin with the issuance of an NOIE and would end, either:

- When the case is closed after a deferral and the establishment's response was verified as effective, or
- When the suspension goes into effect due to an inadequate response.

All supporting documentation, including the decision memo, is then attached to the AER form for future reference. Each "chapter" (AER) is assembled in the same manner and receives a special AER number that is assigned to it by the DO. While each AER is an independent piece of the file, or "story," they build on one another to complete the "story" that is told by the "book."

There are special rules for assembling and maintaining the AER case files and you will receive specialized training for this purpose in your EIAO training. Until you have received this specialized training, you will not be expected to complete an AER form and/or assemble or maintain an AER case file. You will, however, still be a vital part of the AER *process*.

See chart at the end of this module on pages 34 & 35

Verifying an Establishment's Response to an Enforcement Action

Earlier in this module, we discussed verifying the adequacy or effectiveness of an establishment's response to an enforcement action. FSIS verifies this response through the development and implementation of a verification plan. You have already covered verification plans in the Inspection Methods portion of your training, so this section will serve as a short review. This is an extremely important part of the AER process.

The verification plan provides a systematic means for FSIS to ensure that an establishment is effectively carrying out its corrective actions regarding an NOIE or suspension. Its main purpose is to ensure that <u>all</u> aspects of the establishment's response are appropriately verified.

The verification plan is designed to:

- Verify that an establishment has *fully* implemented revisions to its Sanitation SOP and HACCP system
- Verify that an establishment has *fully* implemented all corrective actions
- Verify that the revisions and corrective actions are *effective* in assuring regulatory compliance

The verification plan also assists the establishment in understanding the nature and importance of FSIS' verification activities. This is an important factor in the establishment's due process rights.

A verification plan should be developed whenever:

- A decision is made to *defer enforcement* (suspension) following the issuance of a NOIE
- A decision is made to hold a *suspension in abeyance* following the suspension of the assignment of inspectors
- In both instances, the establishment will provide FSIS with a response to agency concerns. This response must then be verified.

Under normal circumstances, the assigned EIAO has the primary responsibility for preparing the written verification plan. If an EIAO was not involved in the development of the case, then this responsibility will be with the FLS and the in-plant inspection team. In any case, development of the plan should be based on input from the FLS, the assigned EIAO, and the in-plant inspection team, since these are the individuals with the best knowledge of the establishment and the conditions under which it operates.

As the plan is being developed, the FLS should correlate with the PHV-IIC and the EIAO to assure the verification plan:

- Covers pertinent issues
- Is comprehensive
- Accurately reflects verification activities to be carried out by the inspection team

It is important that the plan be correctly developed containing all critical details. This requires objective input from all agency parties involved. The establishment is <u>not</u> a part of this process.

The Role of the PHV in the AER Process

Now that you are familiar with all of the components of the AER process, we will recap your role as a PHV-IIC in the process. Your primary role as a PHV-IIC is to be the <u>in-plant team leader</u> in the development of enforcement actions. Once you receive EIAO training, you will also be called upon to perform AER functions specific to that methodology. This will include more detailed assessments of the design of an establishment's food safety system, writing decision memos, and more.

Pre-Enforcement Stage

Depending on the enforcement stage that the establishment is in, you as a PHV-IIC will perform varying functions related to the AER process. In the Pre-Enforcement Stage you will ensure that <u>NRs</u> are properly documented for regulatory non-compliances by the in-plant inspection team. Remember, NRs are not only a vital document for the AER case file, they also are an important vehicle in ensuring that the establishment's due process rights are not violated.

In the pre-enforcement stage, you will ensure that <u>timely information</u> on the conditions in the establishment is provided to your FLS, and when necessary, you will consult with your FLS for guidance on how to proceed, as well as your approach to an enforcement action or recommendation. You will also ensure <u>constant communication</u> with establishment management to provide and obtain relevant information related to pertinent issues. As the PHV-IIC, you will ensure that these discussions are documented in memoranda and placed in the agency's files for future reference.

Enforcement Stage

In the Enforcement Stage, you will ensure important information regarding any action to be taken is <u>communicated</u> to establishment management. You will further work with your FLS, any assigned EIAO, and your in-plant inspection team to provide accurate and

pertinent information and/or content to the DO for inclusion in the NOIE or suspension letter.

In the enforcement stage, you will remain in <u>communication</u> with your FLS to provide him or her with timely information and updates on the current and continuing conditions in the establishment. You will also continue your role as the <u>in-plant team leader</u> and provide your in-plant inspection team with leadership and support, and you will ensure that the team remains on track and is focused on the task at hand. Tempers can rise during an enforcement action. You will ensure that your in-plant team remains objective and professional, as well as ensure that they are not subjected to intimidation or harassment from the establishment's employees.

Deferral or Abeyance Stage

In the Deferral or Abeyance Stage, you will <u>provide information</u> to your FLS as it applies to the review of the establishment's proposed corrective actions. When necessary, you will communicate with establishment management to obtain additional clarifying information to facilitate the review. You will also work with your FLS and any assigned EIAO to ensure that the <u>verification plan</u> is complete and comprehensive. In doing so, you will <u>discuss</u> the verification plan with the FLS and the in-plant inspection personnel, prior to the establishment implementing its corrective actions. As the in-plant team leader, you will <u>provide guidance</u> to and coach your in-plant inspection team on the appropriate execution of the verification plan.

In the Deferral or Abeyance Stage, you will continue to conduct <u>weekly meetings</u> with the establishment with an emphasis on discussing issues that emerge during the deferral or abeyance period. You will conduct special <u>work unit meetings</u> with your inplant inspection team to correlate on verification activities and discuss any problems, questions, or concerns. When necessary, request clarification from your FLS, who is the overall team leader in this effort. You will provide information to and <u>collaborate with any</u> <u>EIAO</u> assigned to the case to summarize the verification activities. Finally, you will <u>provide timely information</u> to your FLS to recommend a decision on whether to close out, continue, or reinstate a suspension of inspection at the establishment.

Legal Stage

While it is a relatively rare occurrence, the District Office may recommend that the agency file a complaint for withdrawal of inspection from the establishment. As the PHV-IIC, you will also have a role in this Legal Stage of the AER process.

In the Legal Stage, you may be asked to:

- *Collaborate* with the FLS, assigned EIAO, and/or DDM to prepare the recommendation for withdrawal.
- Prepare or assist in the preparation of a *declaration* to be submitted to the court.
- *Testify* at a hearing regarding the conditions in the establishment.
- Provide *timely information* to the FLS, DO, and/or Office of General Council regarding current conditions in the establishment.

A Systematic Review of Enforcement Actions

Now that you have a basic understanding of the components of, and your role in, the AER process, let's look at the flow of the enforcement process from beginning to end. The following pages are flowcharts that depict the options of enforcement actions possible, as they are determined by the critical thought process.

The Pre-enforcement Stage



The <u>pre-enforcement stage</u> begins with a documented history of noncompliances and issues. Based on the in-plant inspection team's assessment of the information, which is led by the PHV-IIC, there are two courses of action:

- 1a) The available information does not support any action at this time.
- 1b) The available information <u>supports</u> further review.

If the consensus is that a <u>further review</u> is warranted (1b), depending on the types of noncompliance an EIAO may or may not become involved in the process at this point. There are three options at this point, depending on the conclusion of the review:

- 2a) The available information does not support any action at this time.
- 2b) There is insufficient information to draw a proper conclusion, or the available information is inadequately documented to support an action.
- 2c) There is sufficient information to start a formalized process. This is the most common option at this point if an EIAO is involved; this is in order to have complete records of their review.

If the option of a <u>formalized review</u> (2c) is chosen, then a decision memo is documented with a formal recommendation. There are three possible recommendations:

- 3a) No action is warranted.
- 3b) There is insufficient or inadequate information at this time to make a recommendation.
- 3c) There is sufficient evidence to recommend a suspension, either with or without prior notification.

It should be pointed out that there is *no specific, minimum, or maximum timeframe* attached to this process—the process should be timely and the ultimate timeframe will depend on the specific circumstances.

The Enforcement (NOIE) and Deferral Stage



The Enforcement Stage begins when an NOIE has been issued to the establishment. Based on the District inspection team's assessment of the response, which is led by the FLS, there are three courses of action:

- 4a) The establishment's response reveals that the <u>agency's conclusion is wrong</u> and a suspension is not warranted. The case is closed out with a Letter of Information—this should be an extremely rare occurrence if the assessment is properly performed and supported.
- 4b) The establishment's response is <u>adequate</u> and the suspension is placed in deferral. (Note: At this point, the establishment is in the *deferral stage*, which is also depicted on this slide.)
- 4c) The establishment's response is <u>inadequate</u> and the suspension is placed in effect.

If the <u>decision to suspend is deferred</u> (4b), then a verification plan is developed and implemented. Based on the results of the agency's verification, there are two options:

5a) The establishment has adequately and effectively demonstrated compliance and the case are closed with a Letter of Warning. This also closes out the AER and the case file. 5b) The establishment cannot adequately and effectively demonstrate compliance and the case the suspension is placed in effect.

If the <u>suspension is placed in effect</u> (4c or 5b), then the AER for this stage is closed and a new AER for the suspension stage is opened. The case file remains open.

It should be pointed out that, as above, there is also **no** specific timeframe attached to this process.



The Enforcement (Suspension) and Abeyance Stage

The <u>enforcement stage for a suspension</u> begins when a suspension goes into effect. Based on the District inspection team's assessment of the response, which is led by the FLS, there are three courses of action:

- 6a) The establishment's response is <u>adequate</u> and the suspension is held in abeyance. (Note: At this point in time the establishment is in the abeyance stage, which is also depicted on this slide.)
- 6b) The establishment's response is <u>inadequate</u> and the suspension remains in effect.
- 6c) Circumstances warrant that the agency file a <u>complaint for withdrawal</u> of inspection. This closes out this AER and opens a new AER for the legal stage. The case file remains open.

If the suspension is <u>held in abeyance</u> (6a), then a verification plan is developed and implemented. Based on the results of the agency's verification, there are two options:

- 7a) The establishment has adequately and effectively demonstrated compliance and the case are closed with a Letter of Warning. This also closes out the AER and the case file.
- 7b) The establishment cannot adequately and effectively demonstrate compliance and the suspension is reinstated. As above, there is *no specific timeframe* attached to this process.

SUMMARY

Using the AER process is an important part of your job as a PHV. The process entails using your critical thinking skills to assess information and take or recommend actions based on those assessments. The assessment will only be as good as the quality and completeness of the information that is analyzed. Likewise, the accuracy of the conclusion will be heavily dependent on the objectivity of your assessment.

As an in-plant PHV-IIC, another of your main functions in the AER process will be to ensure accurate, relevant, and complete documentation of all information related to a problem or concern. Your in-plant inspection team plays a vital role in identifying problems and collecting information. If this is not properly documented, then the information will not be available as support for a potential future case. Proper documentation also means that the appropriate regulation and/or statute is cited.

Remember, your team's documentation and assessments are the foundations of the AER case files. It is your responsibility as the in-plant team leader to ensure that that foundation is rock solid.

A numbering system has been devised to facilitate using the AER for multiple types of cases.

To number the AER:

- The <u>first number</u> is the DO number.
- The second number is the fiscal year.
- The <u>lettering</u> identifies the report type.
- The <u>last numbers</u> enable FSIS to determine how many reports of this nature have been completed in a given District.

For example, AER 15-05-N003, the:

- 15 is for the Denver DO.
- 05 is for the fiscal year 2005.
- N indicates an NOIE.
- 003 means the NOIE is the 3rd NOIE issued in Denver in the fiscal year.

The table on the following page contains all of the types of reports that may be completed under the AER system and the abbreviations for each type.

AER Report Type	Report Number Example
NOIE (N)	65-05- N 003
Suspension (S)	65-05- S 001
Reinstatement (R)	65-05- R 001
Appeal to DM (A)	65-05- A 010
Withholding of Labels (WL)	65-05- WL 001
Custom (C)(Request to withdraw the custom exemption)	65-05- C 001
Recall Effectiveness Check (REC) NOTE: When completed for recall effectiveness checks, insert in block 11 of the FSIS 5400-9, the FSIS Recall Number, (e.g., FSIS-REC-XXX-200X).	65-05- REC 001
Detention (D)	65-05- D 002
Prohibited Act (PA)	65-05- PA 001
Outbreak of Illnesses Investigation (OI)	65-05- 01 001
Non-routine incident report (NRI)	65-05- NR I001
Withdrawal of Inspection (W) NOTE: This would be specified under OTHER in block 11.	65-05- W 001
Complaint for Suspension (CS) NOTE: This would be specified under OTHER in block 11.	65-05- CS 001
Other (O)	65-05- 0 001

WORKSHOPS

Workshop I

- 1. The role of the PHV in the AER process is to:
 - a. Act as the in-plant team leader
 - b. Ensure accurate supporting documentation
 - c. Ensure proper lines of communication
 - d. Perform verification activities
 - e. All of the above
- 2. Which of the following are supporting components of the AER:
 - a. NRs
 - b. Memoranda
 - c. MOIs
 - d. NOIEs
 - e. All of the above
- 3. A Memorandum of Interview is signed by the person performing the interview.

TRUE FALSE

- 4. Which of the following are sources of information pertinent to the AER process?
 - a. Documented establishment history (NRs, memoranda, etc.)
 - b. Consumer Complaint Monitoring System (CCMS)
 - c. Recall System
 - d. All of the above
- 5. A recommendation for an enforcement action should be based on subjective opinions.

TRUE FALSE

6. A Memorandum of Interview can be the only documentation issued to an establishment by a PHV for a SPS regulatory noncompliance.

TRUE FALSE

- 7. When completing an NR, it is important that it be (choose the best answer):
 - a. Short and concise
 - b. Long and very descriptive
 - c. Accurate and complete
 - d. Written in technical terms
- 8. All noncompliance records should be accurate, well thought out, and properly supported by an appropriate regulatory citation.

TRUE FALSE

Workshop II

Assignment:

You are the PHV assigned to a large establishment that slaughters swine and processes miscellaneous pork cuts and cooked sausages. Over the last three months, you and inspection personnel have issued NRs for multiple and recurring noncompliances identified for failure of the Sanitation SOP to prevent direct product contamination and failure to maintain sanitary conditions as required in the SPS and linked them appropriately. You issue two more NRs this week for heavily beaded condensation found in multiple non-production areas. You review the following NRs:

- #1 The original NR was written on rodent activity.
- #2 A NR issued for condensation leading to direct product contamination.
- #3 A NR issued for condensation leading to direct product contamination.
- #4 A NR issued for holes in walls around pipes behind the smokehouse.
- #5 A NR issued for a door with gaps leading to the outside and a hole in the processing room wall leading to the outside.
- #6 A NR issued for rodent droppings in the boiler room.
- #7 A NR issued for insanitary conditions due to rodents and contamination of product by insanitary conditions.
- #8 A NR issued for condensation in a production area without direct product contamination.
- #9 A NR issued for condensation in a non-production area without direct product contamination.
- #10 A NR issued for condensation in a non-production area without direct product contamination.
- #11 A NR issued for condensation in a non-production area without direct product contamination

A) Is this a SPS or Sanitation SOP issue? What is the root cause(s) of the noncompliances?
The establishment responses indicate that corrective actions and preventive measures have been identified and implemented for each noncompliance. FSIS verification and documentation shows that these actions were either not implemented or not effective.

You have kept your Frontline Supervisor informed of the recurring nature of the situation. You have discussed this with establishment management during the weekly meetings, and documented these discussions in a memorandum of interview.

B) What is your recommendation, if any?

You first contact your Frontline Supervisor and make him aware of your recommendation. You then contact the District Office and provide data to support your recommendation.

C) From the NRs listed above which ones support your recommendation?

D) What would be your role during this deferral stage?

The District Manager will make a decision on the adequacy of the preventive action as soon as sufficient information becomes available. The DM will use the information to determine the adequacy of the establishment's proposed corrective action, and will notify the establishment in writing of the final decision.

Workshop III

Assignment:

- Pair up with your neighbor
- Interview you partner.
- You are interested in the specifics of his/her veterinary education and career
- Write a short Memorandum of Interview (MOI) documenting the facts you have learned

Be prepared to present your MOI to the class.

Food Microbiology: Part 1

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Slides	LEARNING OBJECTIVES
N/A	Scientific:
	1. List pathogens of concern in the Slaughter/Kill Floor context.
	Identify and give an example of observable pitfalls that could skew sampling results in the Slaughter/Kill Floor context.
	Explain how establishment sampling programs in the Slaughter/Kill Floor context are used to validate and support the establishment's food safety system.
	Regulatory/Administrative:
	[None for this topic in this context.]

Slideo	
Sildes	PATHOGENS OF CONCERN
2	In groups, review the references related to your assigned pathogen and present relevant findings about your pathogen. <i>Consider</i> . What do the directives say about your pathogen? What are the regulatory requirements? What types of products are high risk? What are appropriate controls? Take notes in the space provided below.

Slides	SAMPLING
3	Common Sampling Errors
	What are some common FSIS sampling errors that may lead to skewed sampling results? What are some examples of how these errors can happen?

4 Establishment Sampling Programs

How are establishment sampling programs used to validate and support the establishment's food safety system?

Slides	FOOD MICRO KNOWLEDGE CHECK
5-8	Knowledge Check 1
	Which of the following (on screen) are sources of Salmonella? (Choose all that apply.)
	Knowledge Check 2
	In the poultry slaughter process, which of the following (on screen) are common antimicrobial treatments to control for Campylobacter? (Choose all that apply.)
	Knowledge Check 3
	Which of the following (on screen) are characteristics of Escherichia coli O157:H7? (Choose all that apply.)
Slides	SUMMARY
9	Review your score on the Summary screen and notes about this topic. Make note of any areas that you need to work on.
	Please note that this score does not count toward your overall class grade. Rather, it helps you identify which areas you may need to study more in preparation for your exams. Your overall class grade only consists of the daily quizzes, midterm exam, and final exam. Any scores you receive on Knowledge Check questions or course activities are <u>not</u> counted. They are for your use only.

Food Microbiology: Part 2

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Slides	LEARNING OBJECTIVES
N/A	Scientific:
	 Given a scenario, analyze given microbiological data in the Processing context and interpret the data.
	2. List pathogens and allergens of concern in the Processing context.
	 In the Processing context, demonstrate correct techniques for collecting raw, intact N=60 sampling, RTE sampling, and Salmonella sampling of poultry.
	Explain and demonstrate how sampling programs are used to validate and support an establishment's food safety systems in the Processing context.
	 Given a scenario about an establishment's sampling practices in the Processing context, identify and explain observable pitfalls that could skew sampling results.
	Regulatory/Administrative:
	1. Identify FSIS sampling programs related to the Processing context.
	Identify the pathogen of focus for each of those programs and products eligible for sampling.
	Identify and locate the directives and notices related to those sampling programs.

Slidos	PROCESS CONTROL OVERVIEW
Sinces	PROCESS CONTROL OVERVIEW
3	Microbial Contamination
	In the Roadmap Connection below, identify the points in the process where you think the level of microbial contamination will increase and where you think the level of microbial contamination will decrease.

Λ	Process Control Regulations
-	
	9 CFR 381.65(g) Notes:
	So, how do we know if a process is in control or not?
5	Process Control Regulations (Continued)
	What directive pertains to verifying that poultry slaughter establishments have procedures to control visible fecal and enteric pathogen contamination throughout the slaughter and dressing operations?







8	Process Control Verification
	How will you verify whether the establishment is effectively implementing these procedures to control contamination throughout the poultry slaughter process? What questions would you ask? (Select all that apply.)
	If there have been issues, has the establishment taken corrective actions and were they effective?
	What do establishment records indicate about their implementation of these procedures? [Keep in mind that in poultry this would include their monitoring records, records of corrective actions taken, sampling records, and the process control charts themselves.]
	Is there any previous noncompliance documented in NRs?
	Is there a trend of noncompliance that has been discussed in meetings and documented in MOIs?
	Did the establishment pass the last two weeks of finished product standard tests?
	What is temperature of the scald vat water?
	What do FSIS IPP observations of implementation of these procedures indicate today? [Keep in mind that in poultry, establishment procedures to prevent contamination throughout slaughter and dressing include sampling and analysis for microbial organisms, so we should observe establishment sampling procedures.]
	Are there any associated NRs?
9	Potential Problems
	Potential problems in poultry slaughter operations that may increase contamination:

Transport crate that is not washed with sufficient frequency. There is a buildup • of fecal material and feathers that can contaminate subsequent flocks during transport. Excessive fecal material is present in the scalder. • Birds not held off feed may have full crops resulting in increased contamination at the cropping step. Viscera are stuck in machine and there is product build up on breast plates and • bars around wings and legs (yellow arrows). Organic material is present on an establishment employee's arm (yellow arrow). • Water is available for washing, but the employee is not washing with sufficient frequency to prevent cross-contamination during manual evisceration. Plastic sleeves are more sanitary and easier to wash than bare arms. Bird washes are out of adjustment providing incomplete coverage in rinsing the • bird. Only part of the carcass is receiving the spray. Rinses are not positioned to wash contamination off tail area. On the left, a contaminated carcass moves on the line toward two washes. On the right, the carcass has moved past the washes, and the contamination remains. In this situation, should the nozzles be moved up, it is likely that due to the high pressure and angle of the spray, contamination may not be washed off but instead may spread to surrounding areas of the carcass. Overspray spreads contamination to adjacent areas of the carcass. In the closeup on the right, the middle spray bar results in splashing of water from the thigh up over the back of the thigh and onto the abdomen area (under yellow arrow), where it will run down the breast area. The contaminated vent area visible on the left (inside the red box) will not be washed off when it goes through the middle spray bar. Instead it will spread contamination to adjacent areas. This is also true of the faint yellow contamination on the outside of the thigh and bird's side (black bar of the right image). Cut-up stations do not have water for cleaning knives. Knife sharpeners are available at each cut-up station and are used as needed. This set up and practice increases cross-contamination. Plastic tubs used to hold raw poultry parts are stacked on wooden pallets, which are moved to another area in the establishment for further processing. Establishment employees picked up the tubs and frequently touched the bottoms of the tubs when emptying them into the hopper. Then, without first sanitizing their gloves, employees pushed the parts into the hopper. This is an example of both cross contamination and not maintaining operational sanitation. Sanitary operation is not being maintained. There is significant buildup of fat and • other organic material on the belts. This presents an increased risk of cross contamination. Sanitary operation is not being maintained. There is a significant buildup of fat and other organic material on the conveyors, blades, and associated product contact surfaces. This presents an increased risk of cross contamination.

	What would you expect the pre-chill microbiological process control charts to show if the establishment is effectively implementing their procedures?
10	Verification Question What would you suspect if you saw evidence of the establishment regularly or systematically allowing frequent or recurring contamination of carcasses with feces or ingesta to occur, but the pre-chill microbial process control charts showed almost perfect process control?
11	Next Step for Verification According to our schematic, what's the next thing we would use to verify process control in official poultry slaughter establishments?

12	Written Procedures
	9 CFR 381.65(f) Notes:

	True or False: An official poultry slaughter establishment must have a CCP to prevent carcasses with visible fecal contamination from entering the chiller.
13-15	Process Control Questions
	Question 1: A trend of noncompliance with 9 CFR 381.65(f) would be likely to correlate with which of the following?
	Question 2: If a poultry slaughter establishment has an increase in carcasses contaminated with fecal material at pre-chill, it is likely due to a failure of what?
	Question 3: If an establishment has placed its procedures for controlling visible fecal contamination in its HACCP plan as a CCP and FSIS finds fecal contamination while performing a Poultry Zero Tolerance task, what regulation(s) should IPP cite?
	Question 4: If an establishment has placed its procedures for controlling visible fecal contamination in its Sanitation SOPs and FSIS finds fecal contamination while performing a Poultry Zero Tolerance task, what regulation(s) should IPP cite?
	Question 5: If an establishment has placed its procedures for controlling visible fecal contamination in a prerequisite program and FSIS finds fecal contamination while performing a Poultry Zero Tolerance task shat regulation(s) should IPP cite?



17	Antimicrobial Interventions
	Which of the following would indicate a problem with the establishment's antimicrobial interventions? (<i>Select all that apply.</i>)
	Intervention is unvalidated
	Critical operating parameters were not met
	Multiple zero tolerance failures occurred
	Interventions located in unsupportable position
	Antimicrobial not being applied as stated in written procedure
	Antimicrobial level is less than specified in written procedure
	Establishment monitoring of intervention conducted more frequently than specified in procedure
	Are there any associated NRs?
18	Poultry Slaughter Interventions
	What could possibly go wrong?

	 Incomplete coverage is because of inadequate reach of antimicrobial spray in both images. On the left, only part of the carcass is receiving the spray. On the right, no spray is applied to the underside of products. In addition, not all pieces on the conveyor belt are being treated because the arc of the spray (just inside the yellow lines) is too narrow to cover all product that could pass on the conveyor. Spray is also not being applied to all pieces due to product piling up and overlapping on the conveyor belt.
	 Note: Dipping (Immersion) is generally a better application method than spraying as it ensures full coverage of an intervention for a longer period of time.
	 Best practice: Boneless, skinless poultry parts receive an antimicrobial dip prior to being ground.
	What if the critical operating parameters of dwell time, temperature, and concentration of antimicrobial were not met?
19	Next Step for Verification
	According to our schematic, what's the next thing we would use to verify process control in official poultry slaughter establishments?

20 Sampling Regulations for Process Control

381.65(g)(1) Notes:

381.65(g)(1) states, "Establishments, except for very small establishments operating under Traditional Inspection or very low volume establishments operating under Traditional Inspection must collect and analyze samples for microbial organisms at the pre-chill and post-chill points in the process. Very small establishments operating under Traditional Inspection and very low volume establishments operating under Traditional Inspection must collect and analyze samples for microbial organisms at the post-chill point in the process. Very small establishments operating under Traditional Inspection and very low volume establishments operating under Traditional Inspection must collect and analyze samples for microbial organisms at the post-chill point in the process."

381.65(g)(2)(i) Notes:

381.65(g)(2)(i) states, "Establishments, except for very low volume establishments as defined in paragraph (g)(1)(ii) of this section, must, at a minimum, collect and analyze samples at a frequency proportional to the establishment's volume of production at the following rates:

- (A) Chickens. _____ per _____ carcasses, but a minimum of once during each week of operation.

S	PROCESS CONTROL CHARTS
	Chart Overview
	What are the key considerations regarding process control charts?

23	Maintaining Process Control
	 Who is required to document the test results monitoring the establishment's ability to maintain process control? The establishment is required to implement their procedure for sampling and analysis for microbial organisms and monitor their ability to maintain process control by 9 CFR 381.65(g) and are required to document the implementation and monitoring of the procedure by 9 CFR 381.65(h).
24	Process Control Charts: Your Role



Slides	PROCESS CONTROL CHARTS EXERCISE
26-31	Step 1
	Job Aid for Charting Generic E. coli Data – Statistical Process Control (SPC)
	 Job Ald for Charting Generic <i>E. coli</i> Data – Statistical Process Control (SPC) How to Calculate the Mean/Average (Steps 1-3) 1. Open an Excel Spreadsheel. Start by labeling the columns, for example, Column A – du/cm², Column B – Mean, Column C – UCL (2SD), and Column D – UCL (3SD). Always save the raw data. 2. Enter the <i>E</i>. coli data points in Column A (clu/cm²). The lowest value that can be entered is 0.08, which is the minimum detectable level for Generic <i>E. coli</i>. Essentially, a value of 0.08 equals 0. 3. Click in an empty cell below and to the right of your data. Type "Av" and a pop-up function box appears. Scroll down and double click Average. 4. Highlight all the data points in all the cells in column A by left clicking on the first data point and running down the column with your cursor to the end of the data points. The boxes that are highlighted will appear in the cell you selected '(A1/A13, for instance'). 4. Or then add a closing parenthesis mark "1' to make it into a formula. In the example above it would appear as a -AVERAGE(A1/A13) when you are done. 6. Click anywhere outside the cell under of an et done and the calculated average (mean) of column A data points appears in the cell. Label the cell as "Mean". 4. The "Number' tab appears as the default. 4. Under "Category" on the left aside, select "Mumber". 4. Rounding to two decimals is the default. 6. Click '0X' and the value will be rounded to two decimals in the cell. 4. Type "=S' in the box and a pop-up function box appears. 6. To calculate the Standard Deviation (SD) (Step 5) 7. To calculate the Standard Deviation (SD) of the data in column A, click in a second empty cell below and to the right dyour data. 7. Type "=S' in the box and a pop-up function box appears. 6. Dive for Kard TDEV PJ and "=STEDEV PJ (Parapears in the cell. 7. Wou then add a closing parent

How to Construct a P	rocess Control Chart (Steps 7-10)
7. To be able to co 4 above in colur	nstruct the SPC chart, enter the mean (average) of your data from column A calculated in Step nn B (labeled as Mean). Enter it into as many cells in Column B as you have data points in colu
A. (EX. If there (Hint: The e cells below ir	asiest way is to type it in the first box, then right click in the box and select "Copy". Highlight the nto which you want to enter the data, then right click and select "Paste".
Enter the Step 7 ab	numerical Upper Control Limit, calculated using either the mean + 2 or 3 Standard Deviations, pove, into the cells in Column C corresponding to the data in columns A and B. If the establishn
had calcu in Colum	lated an Upper Control Limit from the previous year's data, you would enter that value in the ce n C.
8. To make a proce "Insert" tab, in the	ess control chart from the data, highlight all the data in columns A, B, and C, then click on the ne Toolbar section at the very top.
9. To give addition of the chart.	al detail to the chart, click on the chart, then click on the + sign (Chart Elements) to the upper rig
Place a c Trend line	heck mark in the box next to the following: Axes, Axis Titles, Chart Title, Gridlines, Legend, and e for Series A (the data in column A).
 Click in b units in w "Font" fro 	ox on the <u>vertical axis</u> that says, "Axis Title". Delete that name and type "cfu/cm2'. These are hich generic <i>E. coli</i> is measured for sponging sampling. Then highlight the 2 and right click. See m the list of choices. Check the box to the left of "Superscript" under Choices and click OK.
 Click in the Each value Each value 	ie box on the <u>nonzontal axis</u> that says, "Axis Title". Delete that name and type "Sample Numb ie plotted on the graph corresponds to a value in Column A. Sample #1 = value in A:1. Sample A:2, ect.
If only even over the read of the rea	ery other sample number is displayed, extend the chart to make it longer by hovering your curso niddle dot on the end of the chart until a two way arrow (↔) appears, then left clicking on the do ging it to make the chart longer.
Click on Range co	Chart Title". Delete that name and type "Generic E. coli (Name of the Establishment) (Date overed by the chart)". Ex: Generic E. coli Open Beef 10/23-28/2017.
10. At the bottom of titles in the Lege from Column A, Column B, and	the chart you will see the titles of the lines that say, "Series 1, Series 2, Series 3, etc." These and and identify what the line graphing those data points represents. Series 1 represents the data Generic <i>E. coli</i> in cfu/cm ² , Series 2 represents the mean/average of the data, which is listed in Series 3 represents the Upper Control Limit, which is listed in Column C.
To chang	e the names of the titles, click on the area where the series are listed.
 A box are Click "Sel 	und the listed series will appear. Right click in that box. lect Data" from the drondown. The Select Data Source Box appears
Click on S	Series 1 to highlight it. Click "Edit", which is immediately above where the Series are listed. A
"Edit Ser	ies" box appears.
 Type "Ge 	neric E. coli" in the Series Name box.
Click on S Click #Ed	Series 2 to highlight it.
Click Ed	an and type "Mean" in the Series Name box. Series 3 to bioblight it
Click "Ed	it" and type "Upper Control Limit = (whatever value represents the UCL)"
Click "OK	
Examples of da chart with UCL	ita entered and process control charts (upper chart with UCL of mean + 2 SD and lower of mean + 3 SD are shown below.



Question 1

Is the mean for the last two weeks above or below the historical mean for Novosibar Poultry's Ebac?

Step 2

What is the standard deviation (SD) of the last two week's worth of data rounded to two decimal points? Answer: 152.40

Is it above or below Novisbar's historical SD of 231.31 which was used to calculate the Upper Control Limit? Answer: Below (152.40 vs. 231.31)

Step 3	
Check	Your Answers
How di	d you do?
Interp	etation
Now th	at you know how to enter and chart process control data, how do you interp
IL ?	
IL ?	
п <i>?</i>	
11.7	
IL ?	
IL ?	
II.?	
11.7	
11.7	
11.7	
11.7	
11.7	






	Conditions Notes:
35	Scenario 1: Part 2
	Notes:
36	Scenario 1: Part 3
	Notes:

	stions			
 Given wha weeks at N 	t you've observed and lovosibar Poultry, do	d what ha the chart	as been documented i s show what you'd ex	in the last two pect?
2. If not, what	are some possible e	xplanatio	ns?	
3. What would	d be your next steps?			
Scenario 1: Part	4			
Scenario 1: Part	4 e 2 - Indicator Organi	sm Medi	an Values for Chicke	ns
Scenario 1: Part	4 e 2 - Indicator Organi Generic E. coli	sm Medi M	an Values for Chicke ledian (CFU/mL) Enterobacteriaceae	ns Total Coliform
Scenario 1: Part Tabl	4 e 2 - Indicator Organi Generic <i>E. coli</i> ong 540	sm Medi M APC 28,000	an Values for Chicke ledian (CFU/mL) Enterobacteriaceae 1.600	ns Total Coliform 940

39	Scenario 1: Questions (Continued)
	1. Could this information be relevant to your analysis of the charts?
	 In verifying compliance with 9 CFR 381.65(f and g), what other information would you seek? (Hint: Verification of Procedures for Controlling Contamination Throughout Poultry Slaughter and Dressing Operations Observation and Record Review)

Verification of Procedures for Controlling Contamination Throughout Poultry Slaughter and Dressing Operations Observation and Record Review

What do observations and record review indicate about establishment procedures to control contamination during slaughter and dressing operations?

Written procedures?

Frequent or recurring contamination? Equipment properly adjusted? Employee hygiene and sanitation? Effective corrective actions if needed? Reconditioning, Reprocessing, Antimicrobial Interventions effective?

Does the establishment have written procedures to control contamination during slaughter and dressing operations in its HACCP plan, SSOP, or other prerequisite program?

Do FSIS observations of carcasses at various points on the slaughter line or establishment records indicate that the establishment's procedures regularly or systematically allow frequent or recurring contamination of carcasses with feces or ingesta to occur?

If so, where?

Do FSIS observations of the contact surfaces and operation of establishment equipment (e.g., venter, opener) show that the equipment appears to be adjusted correctly for the bird size or other factors and is not routinely contributing to fecal and or ingesta contamination of the carcasses?

Do FSIS observations of establishment employees show that they are consistently preventing contamination of carcasses during dressing tasks and that they respond appropriately to correct visible contamination when it does occur?

Do FSIS observations of establishment employees implementing the procedures for preventing contamination with enteric pathogens and feces, including any monitoring, recordkeeping, or sampling activities that the establishment uses to document control of contamination during the slaughter process show that they are implemented as written and are effective?

Do FSIS observations and establishment records show that the establishment uses reconditioning, reprocessing, or antimicrobial intervention treatments effectively to address any contamination that occurs during the slaughter process?

Slides	PROCESS CONTROL CHARTS CONTINUED
41	Skewed Samples
	How might samples be skewed?

Example 1: Potential Sample Skewing from Improper Sampling Technique Any number of things can affect or skew sample results for pathogens and indicator organisms. Below is a list of items that could potentially skew sample results. It is not an all-inclusive list.

- 1. Lack of aseptic sampling. This can potentially elevate counts.
- 2. Using outdated or turbid sterile sampling solutions such as Butterfield's phosphate diluent (BPD) or buffered peptone water (BPW).
- 3. Not storing sterile sampling solutions according to the manufacturer's recommendations.
- 4. Freezing samples will tend to decrease bacterial counts.
- 5. Applying additional interventions to products to be sampled or increasing concentrations of antimicrobial interventions beyond what is used in the normal process does not "randomly" sample product, as it is not indicative of the actual process.
- 6. Improper storage of samples. Samples should be held under refrigeration until shipped to the lab. Samples should be shipped to the lab cold with frozen gel packs in insulated containers.
- 7. Delayed time to ship samples to the lab. Samples should be held under refrigeration and shipped so as to arrive at the laboratory and be analyzed no later than the day after it is collected. If this is not possible, the carcass or product should be refrigerated until the process can be accomplished in the appropriate span of time.
- 8. Not allowing adequate drip time after microbial interventions are applied. Immediate sample collection will include a significant amount of residual antimicrobial, which can and will make it harder for the laboratory to detect live bacteria. FSIS generally recommends establishments wait at least 60 seconds after application of antimicrobial interventions before collecting a sample to reduce the amount of antimicrobial carryover. Allowing more than 60 seconds of drip time will further reduce antimicrobial carryover. Tipping over the carcass to allow drainage of chiller water that has accumulated in the body cavity should also result in greater accuracy of the test result.
- 9. The sample collection method can significantly affect the ability to detect bacteria on carcasses. For example, non-destructive collection methods (such as rinses and sponge samples) are less likely than destructive methods (such as collecting product) to collect bacteria that are in feather follicles, crevices, or skin folds as well as bacteria present in biofilms on the poultry skin.

	10. Samples should be carefully controlled to prevent temperature abuse, sample leakage, and other events that could affect sample integrity and lead to unreliable test results.
	11. Compositing pre-chill samples without adequate support that minimal variation exists within its pre-chill process.
	12. Compositing pre-chill and post-chill samples.
	13. If equipment is sampled, it should not be sanitized prior to sampling.
	Example 2: Potential Sample Skewing from Lab Analysis
	Any number of things can affect or skew sample results for pathogens and indicator organisms. Below is a list of items that could potentially skew sample results. It is not an all-inclusive list.
	 Labs not using FSIS equivalent methods. Sample size used is below what methodology specifies. Sample remains chilled for a longer period than normal during incubation. In-house lab is not segregated from manufacturing areas and access to the laboratory is not limited to qualified personnel. In-house lab personnel not under the supervision of a qualified microbiologist or equivalent. In-house lab technicians not properly trained or not following written protocols. Lab did not properly document any of the following: Date received; Condition of the sample upon receipt, including sample temperature, if applicable; Date the analysis was started and completed; and the Analytical result.
42	Next Step for Verification
	control in official poultry slaughter establishments?
1	



Slides	CASE STUDIES
45-46	Case Study 1: Part 1
	What would this indicate?
	Case Study 1: Part 2
	What do you conclude from your observations?
47	
47	According to our schematic, what's the payt thing we would use to verify process
	control in official poultry slaughter establishments?

48	Salmonella Sample
	Four of the last thirteen FSIS samples for Salmonella have had positive results. What do you conclude?

40	Casa Study 2
49	Case Study 2
	What do you conclude?
	Reminder: Poultry and livestock slaughter processes are similar, but there are some physical and regulatory differences.
Slides	LIVESTOCK OPERATIONS
51	Livestock Operations Regulations
	Which FSIS Directive gives guidance on beef sanitary dressing procedures and process control in cattle slaughter operations?
	FSIS Directive Notes:

-
-
-
-
-









Verification of Livestock Establishment Antimicrobial Interventions – Review and Observation and Record Review

What do observations and record review indicate about establishment antimicrobial interventions?

Antimicrobial interventions validated? Supportable critical operating parameters used in written procedures? Antimicrobial interventions implemented as written? Monitor ing conducted as written and at specified frequency? Deviations or deficiencies found? Corrective actions taken? Procedures still support decisions in Hazard Analysis?

Were the establishment's antimicrobial interventions validated?

Were the critical operating parameters in the establishment's supporting documents for the intervention incorporated into written procedures?

(Time or dwell time, temperature, concentration, pH, coverage, etc.)

Are the establishment's antimicrobial interventions being implemented as per their written procedures?

Were establishment monitoring procedures of the antimicrobial interventions performed according to their written procedures and at the frequency specified?

Were any deviations or deficiencies related to the application of antimicrobial interventions documented by establishment monitoring or FSIS verification?



Were corrective actions taken by the establishment when deviations or deficiencies related to the application of antimicrobial interventions were discovered?

Do the establishment's sanitary dressing procedures coupled with its antimicrobial intervention procedures still support the decisions in its Hazard Analysis?

Note: How well an establishment conducts its sanitary dressing procedures has a direct bearing on whether the decontamination and antimicrobial intervention treatments in place in livestock slaughter operations will have their intended effects. When contamination overwhelms the decontamination efforts and antimicrobial intervention treatments, the establishment may need to take additional steps to reduce pathogens. In order to assess whether an establishment's food safety system is having the effect that the hazard analysis anticipates, each establishment should monitor its overall processes very closely and maintain documentation that supports that its procedures to prevent contamination by fecal material and associated pathogens throughout the slaughter process, coupled with all intervention treatments at slaughter. are effective at addressing STEC on carcasses under the actual conditions that apply in its operation.

Wree there findings of contamination with fecal, ingesta, or milk by findings of fecal, ingesta or milk contamination part of a trend of noncompliance? Has the trend of noncompliance been discussed at weekly meetings and documented in MOIs? Did FSIS observations while performing the Livestock Zero Tolerance tasks find fecal, ingesta, or milk, then inform establishment management, and document ti? Is there a trend of noncompliance with 9 CFR 310.18(a) 17.2(c)(4)? Mote Tolerance tasks find fecal, ingesta, or milk, then inform establishment management, and document ti? Is there a trend of noncompliance with 9 CFR 310.18(a) 17.2(c)(4)? Mote Tolerance tasks find fecal, ingesta, or milk, then inform establishment management, and document ti? Is the end fiscussed with establishment management, and document ti? Mote Corrective actions for the affected product.) If so, is the NR documenting the current zero tolerance failure or sanitary dressing failure? How long ago was the last time FSIS found a zero tolerance failure or labelesthment tecords indicate that the establishment found zero tolerance failures during their CCP monitoring the currence? Wree the establishment's corrective actions effective at preventing recurrence? Mot 1 Mot 2 Mot 3 Mot 4 Mot 1 Mot 2 Mot 3 Mot 4 Establishment corrective actions of function task to the establishment corrective actions effective at the establishment corrective actions of t	Wret here findings of contamination with fecal, ingesta, or milk by findings of lecal, ingesta or milk contamination part of a trend of noncompliance? Has the trend of noncompliance been discussed at weaky meetings and document of MOIs? Discretions while performing the Livestock Zero Tolerance tasks find fecal, ingesta, or milk, then information part of a trend of noncompliance with 9 CFR 310.18(a). Rise is the NR documenting the current zero tolerance failure associated with a previous NR documenting active: Is there a trend of noncompliance with 9 CFR 310.18(a). Wording ago was the last time FSIS found a zero tolerance task? The satablishment records indicate that the establishment performing their zero tolerance task? Wording ago was the last time FSIS found a zero tolerance task? The satablishment records indicate that the establishment performing their ZCP monitoring is over the establishment corrective actions effective at zero tolerance task? Wording ago was the last time FSIS found a zero tolerance task? Destablishment records indicate that the establishment performing a Livestock Zero Tolerance task? Wirth establishment's corrective actions effective at zero tolerance task? More the establishment corrective actions effective at zero tolerance failure or and the requency specified task zero Tolerance task? Ming ago was the last time FSIS found a zero tolerance task? More the establishment corrective actions effective at zero tolerance task? Ming ago was the last time FSIS found a zero tolerance task? More tolerance failure or and the frequency specified tascoveretion active during their ZCP monitoring i	Were there findings of contamination with fecal, ingesta, or milk b FSIS or the establishment? Are there associated NRs? Are the findings of fecal, ingesta or milk contamination part of a trend of noncompliance? Has the trend of noncompliance been discussed weekly meetings and documented in MOIs? Did FSIS observations while performing the Livestock Zero Tolerance tasks find fecal, ingesta, or milk, then inform establishment management, and document it? (<i>Note:</i> Schedule a directed Slaughter HACCP Verification task to verify corrective actions for the affected product.) If so, is the NR documenting the current zero tolerance failure associated with a previous NR documenting a zero tolerance failure or sanitary dressing failure? How long ago was the last time FSIS found a zero tolerance failure while performing a Livestock Zero Tolerance task? Were the establishment's corrective actions effective at preventing recurrence?	by ed at Is there a trend of noncompliance with 9 CFR 310.18(a) 417.2(c)(4)? If so, has it been discussed with establishment man at one or more weekly meetings and documented in Is the establishment performing their zero tolerance procedure as written and at the frequency specified HACCP plan? Do establishment records indicate that the establishmer foond zero tolerance failures during their CCP monitoring if so, were the establishment corrective actions effective preventing recurrence?
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NR1 + NR2 + NR3 + NR4 + NR5 MOI1 MOI2 MOI3 MOI4	Image: NR1 + NR2 + NR3 + NR4 + NR5 MOI1 MOI2 MOI3 MOI4 Associated NRs + Discussions of trends of noncord documented in MOIs = Due Process and Support for Enforcement Action	NR1 + NR2 + NR3 + NR4 + NR5 K k k k	
		MOI 1 MOI 2 MOI 3 MOI 4	Associated NRs + Discussions of trends of noncon documented in MOIs = Due Process and Support f Enforcement Action

Verification of Process Control in Livestock Establishments using Process Control Charts

What do the establishment's process control charts indicate about trends in microbial contamination?



Good process control? Abrupt process failure? Excess Variability? Recurring transitory process failure? Graual loss of process control over time? Results skewed?

Do the establishment's process control charts indicate good process control?

In a well-controlled system, the majority of test results will be clustered around a central value. It is important to note that even in a well-controlled system; there is some frequency of isolated results above the acceptable level.

Do the establishment's process control charts indicate a lack of process control due to excess variability? This is reflected in both an increased number of results above the maximum acceptable level and an increase in the scatter of points below the maximum acceptable level.

Do the establishment's process control charts indicate a gradual loss of process control over time? This loss of control is usually apparent by the upward trend in the data points toward the maximum acceptable level. Do the establishment's process control charts indicate a loss of control due to abrupt process failure?

A pattern of multiple test results above the upper control limit in a short period of time would indicate a catastrophic loss of process control encountered such as in a situation where an abrupt failure of a key piece of equipment, such as an antimicrobial wash or steam pasteurization cabinet occurred.

Do the establishment's process control charts indicate a loss of control due to reoccurring transitory process failure?

- This is indicated by multiple intermittent results above the maximum acceptable level and shows that there is the existence of an intermittent but reoccurring problem within the process. An example of a situation where this pattern may be observed is when establishment personnel are periodically not following sanitary dressing procedures.
- Are the sampling results skewed? Improper sampling technique? Improper analysis?



2. What does the above chart indicate about sanitary dressing and process control in the de-hiding area? 3. Were there any days when there may have been problems with Open Beef's sanitary dressing procedures and process control? If so, what days were they? 4. What other things would you verify in evaluating sanitary dressing and process control?



3.	Do you see any correlations in data between the Generic <i>E. coli</i> chart and the Process Control Carcass Mapping Chart? If so, what correlation do you see?
4.	What does the <i>E. coli</i> chart indicate about sanitary dressing and process control?
5.	Does the Generic <i>E. coli</i> chart indicate that there are any days when there manale have been problems with Open Beef's sanitary dressing procedures and process control? If so, what days were they?

	6. What other things would you verify in evaluating sanitary dressing and process control?			
60-63	53 Scenario 2: Part 3			
	Scenario Notes:			



Discussion Questions

1. Were there any High Event Periods during the timeframe charted? If so, how many?



	 Name three ways these samples could be skewed through improper sampling techniques.
4	. Would sampling combos for STEC on days other than the day after slaughter influence the way the chart looks?
2	Would sampling combos for STEC on days other than the day after slaughter influence the way the chart looks?
4	. Would sampling combos for STEC on days other than the day after slaughter influence the way the chart looks?
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	Would sampling combos for STEC on days other than the day after slaughter influence the way the chart looks?
	 Would sampling combos for STEC on days other than the day after slaughter influence the way the chart looks?

5. What does the chart indicate about sanitary dressing and process control? 6. Were there any days when there may have been problems with Open Beef's sanitary dressing procedures and process control? If so, what days were they? 7. Do you see any correlations in data between the Generic E. coli chart and the Process Control Carcass Mapping Chart? If so, what correlation do you see?

	8. What other things would you verify control?	in evaluating sanitary dressing and process		
64	Scenario 2: Summary			
	Match the terms on the left with the definitions on the right.			
	1. N=60 Sampling	A. Post-lethality exposed product is aseptically collected in its final package and analyzed for <i>Listeria</i> <i>monocytogenes</i> and <i>Salmonella</i> .		
	2. RTE Sampling	B. Whole bird rinses or sponge samples are aseptically collected at the post-chill location.		
	3. Salmonella Sampling of Poultry	C. Thin slices of exterior surfaces of raw beef components are aseptically taken and analyzed for		

Slides	KNOWLEDGE CHECK			
66-69	39 Knowledge Check 1			
	Which of the following is not used by FSIS personnel to verify process control?			
	Knowledge Check 2			
	Process control procedures such as Sanitary Dressing Procedures and Process Control Chart data are not related.			
	Knowledge Check 3			
	What is the indicator of variation in Process Control Charts?			
	Knowledge Check 4			
	There are no regulatory requirement differences concerning process control between poultry and livestock slaughter operations.			
Slides	SUMMARY			
70	Review your score on the Summary screen and notes about this topic. Make note of any areas that you need to work on.			
	Please note that this score does not count toward your overall class grade. Rather, it helps you identify which areas you may need to study more in preparation for your exams. Your overall class grade only consists of the daily quizzes, midterm exam, and final exam. Any scores you receive on Knowledge Check questions or course activities are <u>not</u> counted. They are for your use only.			

Overview of Food Microbiology

OBJECTIVES

At the end of this module, you will be able to:

- 1. Explain the structural similarities and/or differences among Gram-positive and Gram-negative bacteria as well as their isolation and identification using serological, biochemical, and molecular techniques.
- 2. Identify the functions of the bacterial cell wall.
- 3. Identify the extrinsic and intrinsic parameters that affect bacterial growth.
- 4. List the primary sources of microorganisms in meat and poultry products as well as the establishment's environment.
- 5. Explain the rationale of how food become contaminated and how does it leads to food borne illnesses.
- 6. Identify the food borne pathogens of concern from the public health regulatory and food industry perspectives. Explain their physiology and pathogenicity.
- 7. Describe how a food borne outbreak occurs, the methods of detection, and the outcome in food legislation.
- 8. Define the terms epidemiology, epidemic, and endemic.
- 9. Identify the surveillance systems for tracking food borne disease.
- 10. List the types of food preservation that are currently practiced to control, reduce, or eliminate food borne pathogens.
- 11. List the microbiological testing programs conducted by FSIS and the meat and poultry establishments.

INTRODUCTION

Food microbiology encompasses the study of microorganisms, which have both beneficial and deleterious effects on the quality, and safety of raw and processed meat, poultry, and egg products. Food microbiology focuses on the general biology of the microorganisms that are found in foods including: their growth characteristics, identification, and pathogenesis. Specifically, areas of interest which concern food microbiology are food poisoning, food spoilage, food preservation, and food legislation. Pathogens in product, or harmful microorganisms, result in major public health problems in the United States as well as worldwide and are the leading causes of illnesses and death.

It is important for you as a Public Health Veterinarian (PHV) to understand some of these basics because they have an effect on the meat, poultry, and egg products that FSIS regulates. In this module, we will cover a brief overview of some of the basic principles of food microbiology and explain how they apply to meat, poultry, and egg products. In addition, we will review the FSIS microbiological sampling programs.

OVERVIEW OF BASIC MICROBIOLOGY

Let us review, in general, the microbiology basics that you learned in Veterinary School. As an FSIS PHV, it is important for you to understand the dynamics (identification, physiology, pathogenesis, survival, etc) of those pathogens of concern to the food industry and consumers.

As you know microbiology is defined as the science that deals with the study of microorganisms, including algae, bacteria, fungi, protozoa, and viruses. Specifically, bacteria are the most abundant of all organisms, they are unicellular, are relatively small ranging in size from 0.5- to 5.0 μ m, and for the most part they reproduce asexually. Although there are bacterial species capable of causing human illness (pathogens) and food spoilage, there are also beneficial species that are essential to good health and the environment (examples: synthesize vitamins, digest plant cellulose, fixing nitrogen in plant roots, etc.).

Every bacterial species have specific nutritional requirements, temperature, humidity, etc for energy generation and cellular biosynthesis. The bacterial cells divide at a constant rate depending upon the composition of the growth medium and the conditions of incubation and under favorable conditions, a growing bacterial population doubles at regular intervals ranging from about 15 minutes to 1 hour. This means that if we start with 1,000 cells with a generation time of 30 min. then after an hour we end with 4,000 cells. In the next section of this module, the parameters affecting bacterial growth will be discussed.

Bacteria are also known as prokaryotes because they do not possess nuclei; i.e., their chromosome is composed of a single closed double-stranded DNA circle. Structurally, a prokaryotic cell has three architectural regions: appendages (attachments to the cell surface) in the form of flagella and pili (or fimbriae); a cell envelope consisting of a capsule, cell wall and plasma or inner membrane; and a cytoplasmic region that contains the cell genome (DNA), ribosomes and various sorts of inclusions. Following is a brief discussion of some of these structural components.

- Cell envelope- is made of three layers: cytoplasmic membrane (inner layer), the cell wall (relatively rigid outer layer called peptidoglycan), and in some bacterial species- an outer capsule. The role of the bacterial capsule is to keep the bacterium from drying, can serve as a virulence factor and as an antigen for identification, mediate adherence of cells to surface (crucial in biofilm formation), and confer protection against engulfment and attack by antimicrobial agents of plants, animals, and the environment. Bacteria can be placed into two basic groups, Gram-positive or Gram-negative, based on the profiles of the bacterial cell wall (see below).
- Chromosome- where the bacterium's genetic information is contained. It is a crucial tool for genetic fingerprinting (will be discussed further in this module).
- Cytoplasm- is where the function for cell growth, metabolism, and replication are carried out. It is composed of water, enzymes, nutrients, metabolic wastes, and gases; it also contains the ribosomes, chromosomes, and plasmids. As mentioned before, the cell envelope encases the cytoplasm and all its components.

2

- Flagella- are hair-like structures that serve as propellers to help bacterium move toward nutrients and away from toxic chemicals. This structure can be found at either or both ends or all over the bacterium surface and serve as antigen (H-antigen) for serotyping. In addition, this organelle is a contributor for biofilm formation.
- Pili and fimbriae- many species of bacteria have these small hair-like projections emerging from the outside cell surface. Its function is to assist in attaching to other cells and surfaces. Specialized pili are used for passing nuclear material between bacterial cells (conjugation).
- Plasmid- short length of extra-chromosomal genetic structure (circles or loops) which are carried by many strains of bacteria. They are not involved in reproduction but replicate independently of the chromosome and are instrumental in the transmission of special properties, such as antibiotic drug resistance, resistance to heavy metals, and virulence factors necessary for infection of animal and human hosts. Plasmids are extremely useful tools in the area of genetic engineering.
- Ribosomes- these are organelles that translate the genetic code DNA to amino acids which are the building blocks of proteins. They are also an important tool in the fields of molecular biology and genetics.
- Spores- produced by some species and they are resistant to hostile conditions such as heat and drying. They serve as survival mechanisms when environmental conditions are not suitable for growth and replication.

The cell wall of bacteria is dynamic and extremely important for several reasons:

- 1. They are an essential structure for viability; protects the cell protoplast from mechanical damage and from osmotic rupture or lysis.
- 2. They are composed of unique components found nowhere else in nature.
- 3. They are one of the most important sites for attack by antibiotics.
- 4. They provide ligands for adherence and receptor sites for drugs or viruses.
- 5. They cause symptoms of disease in humans and animals.
- 6. They provide for immunological distinction and immunological variation among strains of bacteria.
- 7. They can be modified to protect the cell against harsh environmental conditions like heat, pH, antimicrobials, etc.

Cell wall composition varies widely amongst bacteria and is an important factor in bacterial species analyses and differentiation. The main functions are to give the cell its shape (rod, sphere, helix, or comma) and surround the cytoplasmic membrane, protecting it from the environment. As mentioned above, the profiles of the cell walls of bacteria, as seen with the electron microscope, make it possible to distinguish two basic types of bacteria as follows:

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- <u>Gram-positive bacteria</u> (those that retain the purple crystal violet dye when subjected to the Gram-staining procedure) the cell wall adjoining the inner or cytoplasmic membrane is thick (15-80 nanometers), consisting of several layers of peptidoglycan, also known as murein. Intertwine within the cell wall are polymers composed of glycerol, phosphates, and ribitol, which are known as teichoic acids. In general, Gram-positive bacteria produce extra cellular substances that typically account for most of the virulence factors and this is illustrated by *Staphylococcus aureus*.
- <u>Gram-negative bacteria</u> (which do not retain the crystal violet) the cell wall adjoining the inner membrane is relatively thin (10 nanometers) and is composed of a single layer of peptidoglycan surrounded by a membranous structure called the <u>outer membrane</u>. The outer membrane of Gram-negative bacteria invariably contains a unique component, <u>lipopolysaccharide</u> (LPS or endotoxin), which is toxic to animals. This outer membrane is usually thought of as part of the cell wall. The pathogenesis and virulence properties of Gram-negative bacteria are far more complex including outer membrane components as well as the production of extra cellular substances, which can be illustrated by *E. coli* O157:H7.

It may be advantageous for epidemiological purposes to identify a particular bacterial strain by serotyping, which is a useful tool to accomplish this goal. Previously we mentioned that there are components in the cell envelope that serves as antigens for serotyping, therefore, serotyping is based on the ability of the bacteria to agglutinate antibodies specific for those antigens. Following is a brief description regarding to the serotyping of those pathogens of public health concern.

Serotyping of Gram-negative bacteria (examples: E. coli and Salmonella spp.) consist of the immunoreactivity of three classes of antigens: the O-antigen (somatic), H-antigen (flagellar), and the K-antigen (capsular) surface profiles. The O-antigen is a polysaccharide which is a polymer of O-subunits, composed of 4-6 sugar residues, attached to the lipid A-core polysaccharide portion of the LPS molecule. Differences in the immunoreactivity of antibodies (O antiserum) with the O-antigen result from the variation in the sugar components and/or covalent linkages between the O-subunit. On the other hand, the H-antigen is the filamentous portion of the flagella, which is composed of protein subunits called flagellin. The antigenically variable portion of flagellin determines the H serotype as determined by H antiserum. Finally, the Kantigens are the somatic or surface antigens that occur as envelopes, sheaths, or capsules. They act as masking antigens for the O-antigen, inhibiting agglutination of living cell suspensions in O antiserum (for the purpose of the scope of this module this antigen will not be further discussed). A specific combination of O- and H-antigens defines what is known as the serotype and/or serogroups of a bacterial isolate. The serotype and serogroups in particular species provide identifiable chromosomal markers that correlate with specific bacterial virulent clones.

In *E. coli*, a total of 170 different O-antigens and 55 H-antigens, defining the isolate serotype, have been identified; a well-known example is *E. coli* O157:H7 serotype, which is part of the enterohemorrhagic (EHEC) serogroup. More than 2,500 *Salmonella* serotypes have been described and reported. Serotyping regarding to this species is complex due to the multiple composition of the O-antigen and these are divided into serogroups or O groups, designated by the primary O factor(s) that are associated with the group. In addition, *Salmonella* is unique among enteric bacteria in that it can

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express two different flagellin antigens, referred to as Phase 1 and Phase 2. Examples are *S*. Enteritidis and *S*. Newport, which belong to Serogroup D and B, respectively.

Likewise, the serotyping of Gram-positive bacteria (an example is *Listeria monocytogenes*) is based on the combination of somatic (O; teichoic acids) and flagellar (H) antigens. Although serological confirmation is not necessary for regulatory identification of *L. monocytogenes*, it is useful for determining the prevalence of specific serotypes in epidemiological studies and for environmental recontamination tracking. Strains of *L. monocytogenes* can be assigned to 13 different serotypes, based on their combination of O- and H-antigens. While all of them are considered to be potentially pathogenic, most (>95%) human clinical isolates belong to three serotypes 1/2a, 1/2b, and 4b.

It is evident that bacteria are a complex system with the capability to adapt and survive to adverse environmental conditions. This explains, in part, why some microorganisms are very difficult to eliminate (biofilm formation), why other becomes pathogenic, and why other develops resistance toward antibiotics or antimicrobial interventions. In slaughter as well as in the processing establishments there are bacterial species associated with particular meat and poultry products, including the environment.

PARAMETERS AFFECTING THE GROWTH OF MICROORGANISMS

There are two parameters affecting the growth of microorganisms in food products: extrinsic and intrinsic. Extrinsic parameters are those properties of the environment (processing and storage) that exist outside of the food product, which affect both the foods and their microorganisms. In the other hand, intrinsic parameters, are properties that exist as part of the food product itself, for example, tissues are an inherent part of the animal that, under a set of conditions, may promote microbiological growth.

Following is a list of these parameters that may result in multiplication or inhibition of microbial growth in meat, poultry, or egg product.

Examples of intrinsic parameters are:

<u>pH:</u> It has been well established that most microorganisms grow best at pH values around 7.0 (6.6 - 7.5), whereas few grow below a pH of 4.0. Bacteria tend to be more fastidious (complex nutritional or cultural requirements for growth) in their relationships to pH than molds and yeasts, with the pathogenic bacteria being the most fastidious. Most of the meats have a final pH of about 5.6 and above; this makes these products susceptible to bacteria as well as to mold and yeast spoilage.

<u>Moisture content (water activity [aw]):</u> One of the oldest methods of preserving foods is drying or desiccation. The preservation of foods by drying is a direct consequence of removal or binding of moisture, without which microorganisms do not grow. It is now generally accepted that the water requirements of microorganisms should be described in terms of water activity (aw) in the environment. Water molecules are loosely oriented in pure liquid water and can easily rearrange. When a solute is added (like salt) to water, the water molecules orient themselves on the surface of the solute, in this case the Na⁺

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and Cl⁻ ions, and the properties of the solution change dramatically. Therefore, the microbial cell must compete with solute molecules for free water molecules. The water activity of pure water is 1.00; the addition of solute decreases a_w to less than 1.00. Most food borne pathogenic bacteria require a_w greater than 0.9, however, *Staphylococcus aureus* may grow in a_w as low as 0.86.

<u>Oxidation-reduction potential:</u> Microorganisms display varying degrees of sensitivity to the oxidation-reduction potential (O/R or EH) of their growth medium or environment. Aerobic microorganisms require more oxidized environments (more oxygen) versus anaerobic organisms which require more reduced environments (lacking oxygen).

<u>Nutrient content:</u> In order to grow and function normally, the microorganisms of concern in the food industry require the following: water, source of energy, source of nitrogen, vitamins and related growth factors, and minerals.

<u>Antimicrobial constituents:</u> The stability of some foods against attack by microorganisms is due to the presence of certain naturally occurring substances that have been shown to have antimicrobial activity. Nisin and other bacteriocins are good examples.

<u>Biological structures:</u> The natural covering of some food sources provides excellent protection against the entry and subsequent damage by spoilage organisms. Examples of such protective structure are the hide, skin and feathers of animals.

Examples of extrinsic parameters are:

<u>Storage temperature:</u> Microorganisms, individually and as group, grow over a wide range of temperatures. It is important to know the temperature growth ranges for organisms of importance in foods as an aid in selecting the proper temperature for product storage. A helpful reference is the FDA's Food Code (<u>http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/default.ht</u> m); it contains some recommendations for storage temperatures of product that are widely accepted in the scientific community.

<u>Relative humidity:</u> The relative humidity of the storage environment is important from both the standpoint of water activity (aw) within foods and the growth of microorganisms at the surfaces. Humidity can also be an important factor to consider when producing some types of product.

<u>Presence/concentration of gases:</u> Carbon dioxide (CO₂) is the single most important atmospheric gas that is used to control microorganisms in foods. It has been shown to be effective against a variety of microorganisms. Because of its effectiveness, CO₂ is used as one of the methods for modified-atmosphere packaging (refer to FDA Food Code).

<u>Presence/activities of other microorganisms:</u> The inhibitory effect of some members of the food microbiota on other microorganisms is well established. Some food borne organisms produce substances that are either inhibitory or lethal to others. These include antibiotics, bacteriocins, hydrogen peroxide, and

organic acids (such as lactic acid). General microbial interference is a phenomenon that refers to general nonspecific inhibition or destruction of one microorganism by other members of the same habitat or environment; the mechanism for this interference is not very clear. Some of the possibilities are competition for nutrients; competition for attachment/adhesion sites; unfavorable alteration of the environment and/or combinations of these.

ISOLATION AND IDENTIFICATION OF PATHOGENS

You have learned during the FSRE Training that FSIS is responsible for aseptically collecting samples to determine the presence of pathogens (*E. coli* O157:H7 and *Listeria monocytogenes*) and *Salmonella* species according to the regulations.

Since January 2008 (Federal Register Docket No. FSIS-2008-0007; Sept 16, 2008) FSIS has implemented a revised laboratory methodology for the detection, isolation, and identification of *Escherichia coli* O157:H7 in the regulatory verification samples. The FSIS revised methodology for this pathogen can be found in the Microbiology Laboratory Guidebook (MLG), Chapter 5A and 5.04, which is available on the FSIS Web site (<u>http://www.fsis.usda.gov/Science/Microbiological_Lab_Guidebook/index.asp</u>). This revised methodology has affected the sampling procedures and testing methods for *E. coli* O156:H7 in raw beef products and environmental sponge samples. Furthermore, state programs, foreign government programs, and non-FSIS laboratory testing methods for this pathogen in raw beef products must be at least as sensitive as FSIS' procedures and testing methods or equivalent (concerning to foreign countries).

Once these samples are received by the Agency's laboratory, how are they processed?

When sample is received by any of the three field service laboratories (Athens, GA, St. Louis, MO, or Alameda, CA), it is first subject to a selective enrichment procedure to favor growth of the desired organism, followed by an initial screening test for presumptive positives. The BAX® system is used as one of the initial screening test for the detection of *Salmonella, Listeria monocytogenes* and *E. coli* O157:H7, and is based on the polymerase-chain reaction (PCR) technology which has proven to be rapid and highly sensitive. Thereafter, those found to be a screening positive are further confirmed using immunological, biochemical, and molecular methods.

Let us look at an example pertaining to the isolation and characterization of *E. coli* O157:H7 and/or O157:H7/NM from raw and ready-to-eat beef products based on the FSIS revised methodology. The first step is to enrich the samples using an enrichment broth suitable for this pathogen followed by the screening test using the BAX® system or lateral flow devices screening test. Those samples found to be positive (<u>potential</u> <u>positive</u>) are further processed by performing an immuno-magnetic separation using magnetic beads coated with O157-antibodies and plating an aliquot on a highly selective media (Rainbow agar); plates are then incubated for 18-24 hours at 35°C. One or more typical colonies are tested with O157 antiserum and colonies that show agglutination (<u>presumptive positives</u>) are processed for <u>confirmation</u> by performing serological, biochemical, Shiga toxin assays, and genetic analyses. The time frame for reporting potential positive or screen negative result is two days; presumptive positive is 3 days; and confirm positives is 5-7 days. Please note that the example discussed above as

well as the other two microorganisms (see below) does not include follow-up testing (e.g., NVSL serotyping, PFGE fingerprinting) and the days listed do not include delays (e.g., re-streak for purity).

The isolation and characterization of *L. monocytogenes* and *Salmonella* spp follows the same rationale as discussed in the previous example using the appropriate culture media and assays. The time frame for reporting the test results of these microorganisms is as follows:

- *L. monocytogenes:* for screen negative is 3 days; presumptive positive is 4-5 days (a sample from which one or more typical colonies produces beta-hemolysis on Horse Blood agar); and confirmed positive is 5-8 days (when a beta-hemolytic isolate is CAMP test positive, shows tumbling motility, and is characterized biochemically).
- Salmonella spp: for screen negative is 2 days; presumptive positive is 5 days (when a sample yields one or more isolates which show typical appearance on TSI and LIA slants, and agglutinate *Salmonella* somatic antisera); and confirmed positive is 7 days (*Salmonella* O group positive isolates are characterized biochemically as the genus).

These results are then posted on LEARN to be accessible for the FSIS inspection personnel. Remember that, in the case of *E. coli* O157:H7 and *L. monocytogenes* in ready-to-eat (RTE) products, presumptive positives reports are also posted so immediate action can be taken by the establishment concerning to the adulterated product.

PRIMARY SOURCES OF MICROORGANISMS IN FOOD

From the meat and poultry regulatory perspective, we will be addressing bacteria as a main source of food contamination. Keep in mind that there are other microorganisms like viruses, parasites, fungi, etc., that are able to contaminate food and cause food borne illnesses in animals and humans.

Bacteria can be found virtually everywhere including humans and can enter food products through different routes. The following list outlines some of the most common ways in which microorganisms enter food products.

<u>Soil, water, and establishment environment:</u> Many bacteria are carried in soil and water, which may contaminate food. In addition, the establishment environment is an important source of contamination because of the daily activities and pest infestation. *Listeria, Clostridium, Salmonella,* and *Escherichia* are good examples.

<u>Animal feeds:</u> This is a source of salmonellae to poultry and other farm animals. It is a known source of *Listeria monocytogenes* to dairy and meat animals when fed silage. The organisms in dry animal feed are spread throughout the animal environment and may be expected to occur on animal hides, hair, feathers, etc.

<u>Animal hides:</u> The hide is a source of bacterial contamination of the general environment, hands of establishment employees, and skinned carcasses. Studies have

shown that this may be a primary source for *E. coli* O157:H7, *Salmonella*, and *Listeria* in cattle.

<u>Gastrointestinal tract</u>: The intestinal biota consists of many organisms; notable among these are pathogens such as *Salmonella, Campylobacter, E. coli* O157:H7, and other microorganisms. Any or all of the Enterobacteriaceae may be expected in feces of livestock and poultry.

<u>Food handlers:</u> The microbiota on the hands and outer garments of handlers generally reflect the environment and habits of individuals (hygiene), and the organisms in question may be those from hides, gastrointestinal tracts, soil, water, dust, and other environmental sources.

<u>Food Utensils:</u> Saws, cutting boards, knives, grinders, mixers, etc. may become contaminated during slaughter and processing operations and ensure a constant level of contamination of meat-borne organisms.

<u>Air and dust:</u> A variety of bacteria may be found in air and dust in food-processing operations at any one time. *Listeria* is an example of a Gram-positive organism that survives in the environment.

<u>Vegetables (plant) and vegetable products:</u> May be a significant concern in the processing of meat, poultry and egg products. A good example is the processing of frozen entrees, salads, etc. containing meat and poultry components. Many or most soil and water organisms contaminate vegetables and fruits.

<u>Globalization of food supply:</u> This is a major factor of contamination resulting in transfer of pathogenic agents between countries (import/export) such as Bovine Spongiform Encephalopathy (BSE) infective agent and *Salmonella* Typhimurium DT104, among others. Also, with the increase in international travel this imposes a risk of introducing pathogens to this country like Foot and Mouth Disease.

<u>Terrorist attacks</u>: There are growing concern in the food industry that terrorist could use pathogens to contaminate food and water supplies in attempt to disrupt the economy, health, and lifestyle among others.

HOW DOES FOOD BECOME CONTAMINATED?

We live in a microbial world, and there are many opportunities for food to become contaminated as it is produced and prepared. Many food borne microbes are present in healthy animals (usually in their intestines, hides, feathers, etc) raised for food. Meat and poultry carcasses can become contaminated during slaughter by contact with small amounts of intestinal contents or poor dressing procedures. Also, it has been shown scientifically that some *Salmonella* serotypes can infect a hen's ovary in such a manner that the internal contents of a normal looking egg can be contaminated with *Salmonella* even before the shell is formed.

In food processing, food borne microbes can be introduced from infected humans who handle the food, or by cross contamination from some other raw agricultural product

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and/or the establishment environment. For example, the unwashed hands of food handlers who are themselves infected can introduce bacteria and viruses.

In the RTE processing environment exposed product that is fully cooked can become cross contaminated if it touches raw meat or poultry that contain pathogens or from food contact surfaces that are contaminated.

In the kitchen, microbes can be transferred from one food to another food by using the same knife, cutting board or other utensil to prepare both without washing the surface or utensil in between.

The way that food is handled after it is contaminated can also make a difference in whether or not an outbreak occurs. Many microorganisms need to multiply to a larger number before enough are present in food to cause disease. Given warm moist conditions and an ample supply of nutrients, one bacterium that reproduces by dividing itself every half hour can produce 17 million progeny in 12 hours. As a result, lightly contaminated food left out overnight can be highly infectious by the next day. If the food were refrigerated promptly, the bacteria would not multiply at all or at a very slow rate.

To inhibit bacterial growth in meat, poultry, or egg products or in food handled by the consumer, it is important to store foods at a reduced temperature. Refrigeration or freezing prevents virtually all bacteria from growing but freezing preserves them in a state of suspended animation.

FOODBORNE ILLNESS

Microorganisms can cause a variety of effects in food products including spoilage, which primarily affects product quality, and food poisoning, which is generally caused by pathogens. As regulators, we are most concerned with the effects that microorganisms have on food that leads to food borne illness, because this affects public health.

A food borne illness (or disease) is exactly what the term indicates - a disease or illness caused by the consumption of contaminated foods or beverages. It would seem rather obvious that a food borne microbial pathogen, or a preformed microbial toxic product, or another poison such as a poisonous chemical that has somehow contaminated the food and/or beverage, leads to one of the many different food borne illnesses.

There is no one "syndrome" that is representative of food borne illness/disease. Different diseases have many different symptoms. However, the microbe or toxin enters the body through the gastrointestinal tract, and often causes the first clinical signs such as nausea, vomiting, abdominal cramps and diarrhea, which are common symptoms in many food borne diseases.

More than 250 different food borne diseases have been described. Most of these diseases are infections, caused by a variety of bacteria, viruses, and parasites. Other diseases are poisonings, caused by harmful toxins or chemicals that have contaminated the food, for example, poisonous mushrooms or heavy metal contamination.

To cause illness, the pathogen must overcome several hurdles. A simple summary of these hurdles are as follows.

-Survive the acidic environment of the stomach.

-Attach to/colonize intestinal walls.

-Compete against the natural microbiota of the gut.

-Survive the host defense mechanisms.

-Once attached in the large intestine: elaborate toxins and virulence factors, and cross the epithelial barrier, which then results in the symptoms characteristic to the disease or illness.

FOODBORNE PATHOGENS

Following is a list of pathogens and infectious agents of public health concern. This list is not exhaustive; however, it contains most of the food borne pathogens that affect meat, poultry, and egg products.

1. Bacteria

Gram Positive:

-Listeria monocytogenes -Staphylococcus aureus -Bacillus cereus -B. anthracis -Clostridium botulinum -C. perfringens

Gram Negative:

-Salmonella spp -Campylobacter spp -Escherichia coli 0157:H7 -Yersinia enterocolitica -Brucella spp

- 2. <u>Viruses:</u> -Hepatitis -Rotaviruses
- 3. <u>Prions:</u> -new variant CJD
- 4. <u>Tapeworms:</u> -Taenia spp
- 5. <u>Roundworms:</u> -*Trichinella* spp
- 6. <u>Protozoa:</u> *-Toxoplasma* spp *-Sarcocystis* spp

The Centers for Disease Control (CDC) reports that the most commonly accounted food borne infections are those caused by viruses (59%), bacteria (39%), and parasites (2%) (2011, Emerging Infectious Diseases, Vol 17 (1), pages 7-20; <u>www.cdc.gov/eid</u>). Furthermore, this report showed that the pathogens that caused the most illnesses were noroviruses (58%), nontyphoidal *Salmonella* spp. (11%), *C. perfringens* (10%), and *Campylobacter* spp. (9%). Looking at the hospitalization and death estimates caused by contaminated food due to bacterial pathogens, the leading cause of hospitalization were nontyphoidal Salmonella (35%) and Campylobacter ssp. (15%); nontyphoidal *Salmonella* spp. (28%) and L. monocytogenes (19%) caused the most deaths.

We will be discussing these aforementioned microorganisms because they are of concern to the food industry, to FSIS as a public health regulatory agency, and the consumer.

Pathogens and Infectious Agents of Concern from the Public Health Regulatory Perspective

Salmonella spp

Salmonella is a rod-shaped, motile bacterium (non-motile exceptions are *S*. Gallinarum and *S*. Pullorum), non-spore forming and Gram negative. This microorganism grows at $6.5-47^{\circ}C$ (43.7-116°F), pH as low as 4.5, with or without air, and a_w of >0.95 (may vary, e.g., *S*. Newport = 0.941 and *S*. Typhimurium = 0.945). The optimum growth temperature is at the human body temperature but it grows very poorly at refrigerated temperatures. Even though freezing and frozen storage can have some deleterious effect on *Salmonella*, it is known that this microorganism remains viable for long periods of time in frozen foods. There are specific serotypes that are capable of producing food borne illness (salmonellosis) including *S*. Enteritidis (eggs and egg products), *S*. Newport (milk and dairy cows), and *S*. Typhimurium (cattle) among others.

Salmonella spp. have the ability to cross the mucosal barrier invading and replicating within the host causing chronic infections, long term carriage, and systemic disease. Pathogenic *Salmonella* possess a myriad of virulence factors including those that promote adhesion to host cells in the intestine, endotoxins, siderophores, invasins, and the production of cytotoxins and diarrheagenic enterotoxins, which act in concert in the pathogenesis of infection. It is believed that the enterotoxins are responsible in causing the acute symptoms of the disease.

As of 2007 there were 2,541 *Salmonella* serotypes identified and approximately 2,000 serotypes cause human disease. The CDC has estimated 1.4 million cases occur annually in the United States but approximately 2.14% (culture-confirmed) of those cases are reported to CDC. In addition, annual estimates of over 500 cases are fatal and 2% of the salmonellosis cases are complicated by chronic arthritis. Furthermore, salmonellosis is more common in the summer than winter. In 2006, a total of 40,666 isolates were reported from participating public health laboratories which represents 12.3% increase compared to 2005. The national rate of reported *Salmonella* isolates (2006) was 13.6/10,000 people. From that total, the four most frequently reported *Salmonella* serotypes from human sources (expressed in per cent) by CDC encompass S. Typhimurium (includes var. 5-)(16.9%), S. Enteritidis (16.6%), S. Newport (8.3%), and S. Heidelberg (3.7%). (PHLIS Surveillance Data, Salmonella at http://www.cdc.gov/ncidod/dbmd/phlisdata/salmonella.htm). The four most common

aforementioned serotypes in 2006 (have been in this order since 1995) represent 45% of all isolates.

The cumulative (year-to date: http://www.cdc.gov/mmwr/summary.html) of salmonellosis cases reported by CDC for the years 2009 and 20010 were 49,192 and 18,734 (cumulative - not final), respectively. All age groups are susceptible to salmonellosis, but symptoms are most severe in the elderly, infants (<5 yrs), and those individuals with impaired immune systems. AIDS patients suffer salmonellosis frequently (estimated 20fold more than general population) and suffer from recurrent episodes. This microorganism is usually transmitted to humans by ingestion of contaminated foods of animal origin, such as beef, poultry, milk, or eggs. As mention before, the organism penetrates and passes from the gut lumen into the epithelium of small intestine where inflammation occurs. The enterotoxins produced by Salmonella, perhaps within the enterocyte, cause acute symptoms such as nausea, vomiting, abdominal cramps, diarrhea, fever, and headache. The symptoms may last from 1 to 7 days or may be prolonged depending upon age, health of host, ingested dose, and the degree of pathogenicity (virulence) among the members of the genus. Chronic consequences can include arthritic symptoms, which may follow 3-4 weeks after onset of acute symptoms. The onset time of the disease typically ranges from 8-72 hours and the minimal infective dose (MID) to cause illness varies according to the individual and food material. Generally, around 10⁵ Salmonella per gram of food is enough (for different serovars) to cause illness but it can be as few as 15-20 cells (depends upon age and health of host, and strain differences among the members of the genus;

http://www.fda.gov/Food/FoodSafety/FoodbornellIness/FoodbornellInessFoodbornePath ogensNaturalToxins/BadBugBook/ucm069966.htm).

Data on *Salmonella* isolates obtained from non-human sources (animals, feed, and environment) can help identify possible sources of human illness. The three most common serotypes of *Salmonella* isolated in livestock and poultry in 2006 are *S*. Typhimurium (Serogroup C_2), *S*. Newport (Serogroup B), and *S*. Heidelberg (Serogroup C_2) which accounted for approximately 28% of the isolates reported to CDC.

The epidemiology of *Salmonella*, based on serotype characterization, has been changing; *S. enterica* serotype Typhimurium has decreased in incidence while the incidence of serotypes Newport has remained relatively stable since 2004. Following we are going to discuss in detail the five common serotypes that causes illness in humans based on the list of the 20 most frequently serotypes from human sources for 2006.

Salmonella Typhimurium, the most common serotype in humans, is identified from clinical samples (results from animal disease) mainly from bovine and porcine sources, and from non-clinical samples (results from animal surveillance and food products) from chicken sources. Some of the outbreaks of *S*. Typhimurium infections have been associated with the consumption of ground beef. Rates of antibiotic resistance among certain serotypes have been increasing; a substantial proportion of serotypes Typhimurium and Newport isolates are resistant to multiple drugs. A large portion of the isolates recovered from humans were resistant to multiple antimicrobial drugs including those with a five-drug resistant pattern characteristic of the *S*. Typhimurium phage type DT104 (26% in 2003). Davis *et al* (2007, Emerging Infectious Diseases, Vol. 13, 1583-1586; www.cdc.gov/eid) compared the antimicrobial-drug resistance profiles and PFGE profiles of human and bovine *S*. Typhimurium isolates (2002-2006; strains TYP035/TYP 187) originated from the Pacific Northwest. They concluded that these strains might

represent an emerging epidemic clonal strain in this region of the United States. The recall (July 2009) of approximately 466,000 pounds in Colorado linked to an outbreak, where an antibiotic resistant *S*. Typhimurium DT104 was confirmed by CDC, suggest that this strain is spreading.

Salmonella Enteritidis (SE), the second most common serotype in humans, are identified from clinical and non-clinical chicken sources. The present situation with SE is complicated by the presence of the organism inside the egg yolk. This and other information strongly suggest vertical transmission, i.e., deposition of the organism in the yolk by an infected layer hen prior to shell deposition. Specific control programs (e.g., farm-based egg-quality assurance programs) have led to the reduction of SE infections, which have been associated with the consumption of internally contaminated eggs. Foods other than eggs have also caused outbreaks of SE.

While the number of human infections caused by the previous top two serotypes had substantial decreases from 1994-2006, *Salmonella* Newport has emerged as a major multidrug-resistant pathogen (resistant to at least nine of 17 antimicrobial agents tested), becoming the third most common serotype in the United States. This serotype has been identified from clinical bovine sources. Between 2002 and 2004, CDC reported four outbreaks of antimicrobial resistant *Salmonella* infection that implicated FSIS regulated products, including three attributed to ground beef. Two of the three ground beef associated outbreaks were linked with *S*. Newport infection. In August 2009, approximately 826,000 pounds of ground beef products was recalled that might have been linked to an outbreak of salmonellosis in Colorado; an antibiotic resistant *S*. Newport was identified as the culprit.

Lastly, S. Heidelberg was the fourth most common serotype in humans in 2003, 2005, and 2006; it has been identified from clinical porcine sources as well as non-clinical chicken and turkey sources.

The prevalence of the pathogen *Salmonella* in beef, lamb, pork, and poultry carcasses varies greatly. The overall contamination of meat and poultry carcasses with these pathogens depends not only on the numbers of the pathogens on the hair, hide, feathers, skin, and in the intestinal tract of the animals, but is also significantly affected by the degree of cross-contamination occurring from these sources during slaughter and processing.

In addition, *Salmonella* has been isolated from milk and dairy products, fish, shrimp, frog legs, yeast, coconut, sauces and salad dressing, cake mixes, cream-filled desserts and toppings, dried gelatin, peanut butter, cocoa and chocolate, etc.

Environmental sources of the organism include water, soil, insects, factory surfaces, kitchen surfaces, and animal feces, to name only a few.

The establishments that slaughter and/or process meat and poultry products must adhere to pathogen reduction performance standards for *Salmonella*, as specified in 9 CFR 310.25 for livestock and in 9 CFR 381.94 for poultry. Between 2002 and 2005, USDA reported an increase in the percentage of chicken carcasses that tested positive for *Salmonella* (from 11.5 to 16.3 %.) including a significant increase in SE. On February 27, 2006 (Federal Register, Docket No. 04-026N), FSIS posted a new approach to *Salmonella* verification activities in meat and poultry establishments

including reporting each sampling test results (containing serotype data) to the establishment as they become available, classifying establishments in three process control categories according to their performance in completed sample sets relative to the regulatory performance standard or baseline guidance level for *Salmonella* percent positive in their product class, among others described activities.

FSIS has also developed guidelines and procedures for the comprehensive assessment of food safety systems in poultry establishments with less than consistent *Salmonella* process control. Furthermore, the Agency has accomplished a new risk-based approach allocating *Salmonella* sampling resources. Since April 2006, FSIS has been providing these results; this quarterly report can be access on FSIS Web site at http://www.fsis.usda.gov/Science/Q2_2006_Salmonella_Testing/index.asp.

In response to comments received by the Agency on the aforementioned Federal Register Notice of February 27, 2006, FSIS has announced new policies for the Agency's *Salmonella* Verification Sampling Program and related activities conducted in meat and poultry establishments (Federal Register Docket No. FSIS-2006-0034, January 28, 2008). These changes include:

- publication of completed FSIS verification sample set results for establishments that show inconsistency in their ability to meet *Salmonella performance standards,* beginning with those from young chicken slaughter establishments;
- a voluntary incentive-based program for meat and poultry establishments that should yield significant data on attribution of human illness to FSIS-regulated products; and
- increasing the Agency's use of targeted sampling approaches and collaborative serotype and subtype data.

In May 2010, FSIS published another Federal Register Notice (Docket No. FSIS – 2009-0034) announcing the implementation of new *Salmonella* and *Campylobacter* performance standards for young chicken (broiler) and turkey slaughter establishments. The new performance standards are based on the Agency's Nationwide Microbiological Baseline Data Collection Programs of 2007 – 2008. This notice detailed the baseline surveys and their use in developing the new performance standards.

In a follow-up Federal Register Notice (Docket No. FSIS-2010-0029, March 2011) FSIS announced the implementation of the new standards for July 2011. The Notice stated that the new *Salmonella* standards apply to sample sets from establishments included in the Agency's *Salmonella* Verification Program in the place of the performance standards for young chickens (as broilers) codified in 9 CFR 381.94 and the standards for turkeys announced in a Federal Register Notice of February 17, 2005. The Agency intends to issue a proposed rule that would formally rescind the codified standards that are no longer in effect.

FSIS recently published Notice 31-11 New Performance Standards for *Salmonella* and *Campylobacter* in Chilled Carcasses at Young Chicken and Turkey Slaughter Establishments. It instructs IPP to collect samples of young chickens and turkeys according to the sampling methodology described in the Notice. Samples will be analyzed for *Salmonella* and *Campylobacter*, serotyping and subtyping will be performed for all positive samples.

FSIS is taking these actions to advance its efforts to achieve the Agency's public health goal of significantly reducing human cases of salmonellosis.

Campylobacter species

Campylobacter species, including *C. jejuni, C. coli,* and *C. lari,* can be isolated from the intestinal tract of poultry and poultry products. The two most frequently occurring *Campylobacter* species of clinical significance for human consumption of food are *C. jejuni* and *C. coli,* but *C. jejuni* causes most of the human infections (www.cdc.gov). These species are the ones most often isolated in poultry products.

Campylobacter jejuni is a Gram-negative slender, curved, and motile rod. It is a microaerophilic organism, which means it has a requirement for reduced levels of oxygen and requires 3 to 5% oxygen and 2 to 10% carbon dioxide for optimal growth. The isolation of this pathogen requires special antibiotic-containing media and a special microaerophilic atmosphere (5% oxygen). *Campylobacter jejuni* is relatively fragile and sensitive to environmental stresses such as 21% oxygen, drying, heating, disinfectants, and acidic conditions. This microorganism can grow at temperatures between 25-42°C (77-107°F), pH range of 5.5-8, and $a_w > 0.95$.

This bacterium is now recognized as an important pathogen. The pathogenic mechanisms of *C. jejuni* are still not completely understood; however, research has demonstrated that a series of virulence factors come into play for the pathogen to be able to cause disease. These factors include motility, chemotaxis, invasins, and adhesins, among others. Some investigators have shown that *C. jejuni* firstly colonizes the jejunum and ileum, and then the colon producing a heat-labile toxin (*Campylobacter* invasion antigens or CIA proteins) that may cause diarrhea.

Campylobacteriosis is the name of the illness caused by the pathogen *C. jejuni* and it is often known as campylobacter enteritis or gastroenteritis. It is one of the most common bacterial causes of diarrheal illness (even more than *Shigella* spp and *Salmonella* spp combined) in the United States. Active surveillance through FoodNet indicates about 13 cases per 100,000 persons are diagnosed each year. Many more cases go undiagnosed or unreported, and it is estimated that this illness affect over 2.4 million persons every year and it is estimated that approximately 124 persons with *Campylobacter* infections may die. Campylobacteriosis occurs more frequent in the summer months than in the winter (www.cdc.gov).

Although anyone can become ill with campylobacteriosis, children under 5 years and young adults (15-29) are more frequently afflicted than other age groups. *Campylobacter jejuni* infection causes diarrhea, which may be watery or sticky and can contain blood (usually occult) and fecal leukocytes. Other symptoms often present are fever, nausea, cramping, abdominal pain, headache, and muscle pain within 2-5 days after exposure to the organism. A very small number of the pathogen (fewer than 500) can cause illness in humans. The illness generally lasts 7-10 days and in individuals with compromised immune systems, the pathogen occasionally spreads to the bloodstream and causes a serious life-threatening infection.

Since *C. jejuni* is an invasive organism long-term effects of this illness can lead to Guillain-Barré syndrome, a rare disease that affects the nerves of the body beginning several weeks after the diarrheal illness. This disease occurs when a person's immune

system is triggered to attack the body's own nerves, and can lead to paralysis that last several weeks and usually require intensive care. It is estimated that approximately one in every 1000 reported Campylobacteriosis cases leads to Guillain-Barré syndrome (40% of the syndrome cases).

Many chicken flocks are asymptomatically infected with *Campylobacter*, i.e., the chickens are infected with the organism but show no sign of infection and can be easily spread from bird to bird through a common water source or contact with infected feces. When infected chickens are slaughtered, the organism can be transferred from the intestines to the meat. More than half of the raw chicken in the United States market has *Campylobacter* on it. *Campylobacter* is also present in the giblets, especially the liver.

Raw milk, raw beef and pork are also sources of infection. The bacteria are often carried by healthy cattle, birds, and by flies on farms. Non-chlorinated water may also be a source of infections.

In 1982, CDC began a national surveillance program and a more detailed active surveillance was instituted in 1996; this will provide more information on how often the disease occurs and what risk factors are for getting it. The U.S. Department of Agriculture is conducting research on how to prevent the infection in chickens. Moreover, since 2006 FSIS started nationwide young chicken and turkey microbiological baseline data collection programs to acquire information concerning the prevalence and quantitative levels of selected food borne pathogens including Campylobacter. The outcome of this data has enabled the Agency to develop new performance standards for Campylobacter in young chicken and turkey slaughter (Federal Register, Docket No. FSIS-2009-0034, May 2010). One of the changes that is reflected in the Federal Register publication is that the Agency responses to *Campylobacter* sample set results will follow current Salmonella procedures for immediate follow-up testing for both organisms and for Food Safety Assessments when necessary. In the future FSIS will consider setting establishment categories 1/2/3 for Campylobacter under the new performance standard. Furthermore, on May 2010, the Agency published a Compliance Guideline for Controlling Salmonella and Campylobacter in Poultry, which include recommendations for controlling both pathogens at pre-harvest and during slaughter and processing.

Escherichia coli O157:H7

A minority of *E. coli* serotypes are capable of causing human illness (colibacillosis) by different mechanisms. *Escherichia coli* are normal inhabitant of the intestine of all animals, including humans; serves a useful function in the body by suppressing the growth of harmful bacterial species and by synthesizing appreciable amounts of vitamins.

Based on disease syndromes and other characteristics, there are six classes of diarrheagenic *E. coli* recognized: enteroaggregative (EAggEC), enteroinvasive (EIEC), enteropathogenic (EPEC), enterotoxigenic (ETEC), enterohemorrhagic (EHEC), and diffusely adherent (DAEC). EHEC is the class that is of concern to industry, FSIS, and public health; the more significant serotype is *E. coli* O157:H7.

Escherichia coli serotype O157:H7 is one of the rare serotype of this genus and, as mentioned above, belongs to the EHEC family that causes severe disease. This pathogen is a rod-shaped, generally motile, non-spore forming and Gram-negative. It generally grows at 2.5-45°C (36.5-113°F), pH between 4.6-9.5, with or without air, and a_w of >0.935. There are strains of *E. coli* O157:H7 that possess an unusual tolerance to environmental stress such as temperature, pH, dryness, and can survive in water; recent research have shown that some strains are capable of forming biofilms.

This pathogen produces several virulence factors that cause severe damage to the lining of the intestine, acute renal failure (children and elderly), hemolysis, thrombocytopenia, and neurological problems (the last three occur mainly in adults). All EHEC, including *E. coli* O157:H7, produce Shiga toxins (Stx 1 and 2; also known as Vero toxins and Shiga-like toxins) which are closely related to or identical to the toxin produced by *Shigella dysenteriae* type 1; these toxins targets the human kidney, particularly the cortical region which is rich in Gb₃ receptors for the toxin. These toxins are encoded on a bacteriophage that was transferred from *Shigella* to *E. coli* O55:H7 (parent strain of serotype O157:H7). Other virulence factors are the pO157 plasmid (90-kb size) which encodes the EHEC hemolysins and serine proteases; LEE pathogenic island which enclose the genes accountable for the A/E histopathology including a type III secretion system responsible for the epithelial cell signal transduction events leading to the attaching/effacing (A/E) lesion, and a bacterial adhesion proteins called intimin and Tir (Translocated intimin receptor); as well as other virulence factors.

Data collected by CDC through the National Notifiable Diseases Surveillance System (NNDSS) in collaboration with the Council of State and Territorial Epidemiologists (CSTE) have shown that during 1996-2004, the estimated cases of infections with *E. coli* O157:H7 had a substantial decline (2005, MMWR 54(14):352-356). *Escherichia coli* O157:H7 has been nationally notified since 1994. Surveillance categories for EHEC infection include EHEC O157:H7, serogroup non-O157, and EHEC not serogroup. During 2005, cases of EHEC infection were reported from 50 states, the District of Columbia, and Puerto Rico. Of these, 74% were classified as EHEC O157:H7; 14% as EHEC, serogroup non-O157; and 12% as EHEC, not serogroup. The majority of cases were reported during July-October.

During the period of 2003-2005, the Shiga-toxin positive cases associated to non-O157 EHEC serogroup have been on the rise with a total of 252, 316, and 501, respectively. Since 2006, Morbidity and Mortality Weekly Report (MMWR, CDC) has been reporting the data as Shiga-toxin-producing *E. coli* (STEC) (4,432 reported cases), which includes O157:H7, serogroup non-O157, and Shiga-toxin positive not serogroup making it difficult to assess the predominance of each individual STEC. Since then (2007-2008), incidence of human STEC infections has increased: 4,847 cases in 2007 and 5,309 cases in 2008. Worth mentioning, in 2009 the STEC reported cases decline to 4,643.

The 2007-2008 trend prompted FSIS, in conjunction with other Federal Agencies, to hold a public meeting (Federal Register Docket FSIS-2007-0041, Oct 9, 2007) to consider the public health significance of STEC non-O157. The scientific community believes that STECs that are pathogenic not only contain the Shiga toxin but also additional virulence determinants that, together with the toxin, causes illness similar to those caused by *E. coli* O157:H7. It is widely accepted that the prevalence of STEC non-O157 is underrepresented due to the limitations of the protocols for the isolation of non-O157 enteric pathogens in clinical laboratories. In a CDC publication, comprehensive and

detailed recommendations are provided for STEC testing by clinical laboratories, including the simultaneous culture for *E. coli* O157:H7 with a simultaneous testing with an assay that detects Shiga toxins to also identify non-O157 STEC (MMWR, Vol. 58, No. RR-12; October 16, 2009). The O-antigen that has been identified in a large number of the non-O157:H7 isolates include O26, O111, O103, O121, O45 and O145. In 2010, FSIS became aware of an E. coli O26 cluster of illnesses in the states of Maine and New York. The Agency determined that there was an association between the cluster of illnesses and beef products from an establishment in Pennsylvania. FSIS recalled approximately 8,500 pounds of ground beef products due to contamination with *E. coli* O26. The source material used to produce product associated with the *E. coli* O26 illness was traced to a foreign establishment supplier.

This microorganism causes three distinctive clinical manifestation including hemorrhagic colitis (HC), hemolytic uremic syndrome (HUS), and thrombotic thrombocytopenic purpura (TTP). All people are believed to be susceptible to hemorrhagic colitis, but young children and the elderly appear to progress to more serious symptoms more frequently (HUS and TTP, respectively).

HC is characterized by severe cramping (abdominal pain) and diarrhea, which is initially watery but becomes grossly bloody. Occasionally vomiting occurs and some individuals can exhibit watery diarrhea only. Fever is either low-grade or absent. The infectious dose is as few as 10 bacterial cells with an incubation period of approximately 4 days (median) and clinical manifestations can develop within 24-48 hours with duration of 8 days (average).

A week after the onset of gastrointestinal symptoms with this pathogen some victims (particularly the very young under the age of 10) have developed HUS, characterized by the triad of hemolytic anemia, thrombocytopenia, and renal failure. Permanent loss of kidney function may result and the mortality rate in children is 3-5%. Since 2005, the majority of reported cases occurred among children aged <5 yrs. In addition, the total HUS (post diarrheal) cases reported from the previous years has also shown an increase: 288 cases in 2006, 292 cases in 2007, and 330 case in 2008. As of 2009 the HUS reported cases declined to 242, which suggests that the trends reflected during the period of 2006-2009 with the HUS cases follows a similar pattern as the aforementioned STEC cases reported by CDC.

In the adults and elderly, a complication associated with this microorganism is TTP characterized by central nervous system deterioration, seizures, and strokes. This illness can have a mortality rate in the elderly as high as 50%.

Escherichia coli O157:H7 is a bacterial pathogen that has a reservoir mainly in cattle; other reservoirs have been identified including pigs, sheep, flies, deer and other wild animals. In published scientific studies, it has been shown that feedlot steers and heifers appear to carry the organism at higher levels than once thought, even higher than dairy cattle and calves. Also, it has been shown that *E. coli* O157:H7 is seasonal (April through September) peaking during summer.

Undercooked or raw hamburger (ground beef) has been implicated in many of the documented outbreaks. Because of its public health significance, the vast scientific evidence showing the high incidence in cattle, the severity of the illness, and outbreaks due to this pathogen, FSIS (1994) declared *E. coli* O157:H7 to be an adulterant in

ground beef products. By the year 2002, the Agency required all establishments producing raw beef to reassess their HACCP plans to determine if *E. coli* O157:H7 was a food safety hazard reasonably likely to occur in their production process (Fed Reg. Vol.67, No.194:62325-62334, October 7, 2002/Rules and Regulations). In 2005 FSIS published a notice (Fed Reg. Vol. 70, No. 101:30331-30334, May 26, 2005/Rules and Regulations) informing the establishments that produce mechanically tenderized beef products, including those that are injected with marinade, to reassess their HACCP plan by the year 2006. This reassessment was triggered by the fact that there have been three *E. coli* O157:H7 outbreaks associated with consumption of mechanically tenderized beef.

In June 2007, FSIS noticed an increased number of positive Agency E. coli O157:H7 results that occurred within a short period. As a result, FSIS decided to increase the number of scheduled raw ground beef product samples for testing during the month of July 2007 (FSIS Notice 41-07). However, in September 2007, there was a recall of 21.7 million pounds of frozen hamburger, the second largest recalls in US history, linked to 40 reported illnesses from a multi-state outbreak with 21 known hospitalizations. DNA fingerprint patterns were traced back from beef trim supplied by a foreign country firm. Thereafter, another recall of approximately 1.9 million pounds took place during the period of October-November 2007. In addition, on November 2007, 3.3 million pounds of frozen meat pizza products were recalled; the problem was discovered following an investigation carried out by the Tennessee Department of Health in coordination with CDC into a multi-state cluster of 21 E. coli O157:H7 illnesses that may be linked to this product. Therefore, in 2007 there were 18 recalls, in which 9 recalls were linked to illnesses, totaling approximately 29 million pounds of ground beef. During the 2009, there were 16 recalls (approximately 545,000 pounds), which two have been linked to multi state outbreaks. There was a significant increase in the amount of recalled beef products during 2010 (accounting for 11 recall cases) including approximately 6 million pounds of ground beef and 135,500 pounds of beef trim. Up-to-date recall cases for 2011 have involved 10, 633 pounds of ground beef (involving 4 recalls) and 23,000 pounds of Lebanon bologna.

Additionally, *E. coli* O157:H7 outbreaks have also implicated alfalfa sprouts, unpasteurized fruit juices, dry-cured salami, spinach, lettuce, game meat, cheese curds, among others.

FSIS announced new, ongoing and upcoming actions to protect public health against the risk of *E. coli* O157:H7. Among the measurements to target *E. coli* contamination and adulteration of ground beef products, FSIS has issued a series of directives and notices providing IPP the instructions necessary to fully implement risk-based verification activities including:

- Reissuance of <u>FSIS Directive 10,010.1</u> to incorporate in one document the instructions that the Agency has issued in multiple notices regarding *E. coli* 0157:H7.
- In response to the recent finding of *E. coli* O26 contamination associated with human illness from ground beef and the subsequent recall, FSIS has issued a notice (FSIS Notice 70-10) to IPP and import inspection personnel to provide instructions for collecting product samples from establishments that produced product associated with the illness.

Recently, there has been an outbreak in Germany where an unusual large proportion of HUS cases (in adults and two thirds are women) has been reported as compared with bloody diarrhea cases including 818 cases of HUS and 36 patients have died (Euro Surveill. 2011; 16(24):19890). Extensive investigations implicated organic sprouts as the likely vehicle of infection. Analysis of the clinical isolates revealed that the epidemic agent was an STEC strain of a rare serotype O104:H4 which produces the Shiga toxin 2, lacks the A/E pathogenicity island of virulent STEC strains, and presents a multi-drug resistant pattern. Using genotyping methods, the results indicated the the STEC strain causing the outbreak is a rare hybrid phenotype that harbours the phage-mediated Shiga toxin determinant with an enteroaggregative E. coli (EAggEC; enteroaggregative adherence phenotype) background in conjunction with other virulence factors, and it was described as an enteroaggregative, Shiga toxin producing *E. coli* (EAggEC STEC). It is widely accepted that EaggEC have a human reservoir. In the United States (cdcinfo@cdc.gov) four confirmed cases (travel to Germany; 3 HUS cases matches the outbreak strain) and one suspect case of STEC 104:H4 infections were identified. One Shiga toxin-positive diarrheal illness did not travel to Germany but was in close contact with one of the HUS case (person-to-person transmission). These emerging cases in the United States are an example of transfer of pathogenic agents between countries by humans.

Other vehicles of infection with *E. coli* O157:H7 include person-to person transmission (child day care facilities), water (recreational, well, and municipal water systems), animal contact (farms and petting zoos), and diagnostic laboratory related.

Listeria monocytogenes

Listeria species (spp) is a rod-shaped, non-spore forming Gram-positive bacterium. Within the *Listeria* genus six species has been identified consisting of *L. monocytogenes, L. innocua, L. ivanovii, L. welshimeri, L. seeligeri,* and *L. grayi.* Specifically, *L. monocytogenes* is recognized as a human pathogen that causes listeriosis. This pathogen is motile and can grow in cool (temperature range of 0-45°C [32-113°F]) and damp environments, at a pH range of 4.4-9.4, and $a_w > 0.92$. Some characteristics that make some strains of *L. monocytogenes* hearty include growth and/or survival in acidic environment (pH < 5.0), ability to withstand heat treatments, and growth and/or survival in concentrated salt solutions. The pathogenicity of this microorganism is associated with the virulence factors such as internalin A (allow the pathogen to induce its own uptake by specific host cells), Act A (a surface protein required for intracellular movement and cell-to-cell spread through bacterially induced acting polymerization), listeriolysin O (a toxin that acts as a hemolysin), among others. Only three *L. monocytogenes* serotypes (4b, 1/2a, and 1/2b) are pathogenic and account for the majority of human infections in the United States.

One outstanding characteristic of *L. monocytogenes* is its ability to form biofilm, which serve as a protection shell. This pathogen, as well as other biofilm microorganisms, elicits specific mechanisms for initial attachment (by the production of extra polymeric substance and the bacterial cell surface structures such as flagella, fimbriae, and other proteins) to a surface, development of a community structure and ecosystem (biofilm), and detachment. Biofilm is a heterogeneous structure of microbial cells (can be a mix culture) encased in an extracellular polymeric substance matrix (primarily polysaccharide material) which can entrap non cellular material such as mineral crystals, corrosion particles, blood components, food particles, etc. Active flow occurs in this niche allowing

diffusion of nutrients, water, oxygen, and even antimicrobial agents; there is also exchange of waste metabolic material. Since this ecosystem is dynamic, the community structure changes from a compact to a looser structure over time allowing the dispersion of planktonic cells to other sites, which starts the cycle of biofilm formation at that new site. Biofilm can form as little as a few hours to days depending of the number of bacterial cells, nutrient availability, surface characteristics, temperature, etc. Once formed, they can persist for a long time (years) and they are very difficult to remove, as the biofilm confers protection from the chemicals used to clean and sanitize surfaces.

The occurrence of listeriosis in the United States from previous years is as follows: 884 cases in 2006, 808 cases in 2007 and 759 case in 2008. As of 2009, 851 cases was reported by CDC. The numbers show that the incidence of listeriosis has been relatively steady during the aforementioned period.

Generally, listeriosis occurs among the elderly, pregnant women (resulting in fetal abortion, stillbirth, or neonatal sepsis), diabetics, those on kidney dialysis, and the immunocompromised (bone marrow transplant patients, corticosteroids and graft suppression, cancer patients- leukemic patients particularly, individuals with AIDS, etc.). Some reports suggest that normal, healthy people are at risk, although antacids or cimetidine may predispose.

Two forms of the illness, an invasive form and noninvasive form, characterize listeriosis in adults. The noninvasive form is characterized by febrile gastroenteritis and it has been documented in several outbreaks. The onset time may be greater than 12 hours. In the invasive form, the manifestation of listeriosis include septicemia (mortality rate as high as 50%), meningitis (mortality rate as high as 70%), encephalitis, and intrauterine or cervical infections in pregnant women (mortality rate from perinatal /neonatal infections greater than 80%). The onset of listeriosis is usually preceded by influenza-like symptoms including persistent fever. The onset time is unknown but is probably greater than 18-20 hours for noninvasive gastrointestinal symptoms and may range from a few days to three weeks for invasive listeriosis.

The infective dose of *L. monocytogenes* is thought to vary with the strain and susceptibility of the individual. From cases contracted through raw or pasteurized milk, fewer than 1000 total organisms may cause disease in susceptible persons. As an example, a listeriosis outbreak in Switzerland involving cheese suggested that healthy uncompromised individuals could develop the disease, particularly if the foodstuff was heavily contaminated with the organism. Summarizing, the risk of developing the disease will depend on the susceptibility of the individual, the bacterial strain (infectivity), ingested dose, and whether the food consumed is a high- or low-risk foods. Most healthy persons probably show no symptoms by consuming contaminated foods and some studies suggest that 1-10% of humans may be intestinal carriers of *L. monocytogenes*.

There are particular meat and poultry high-risk foods that are associated with listeriosis because of the potential for contamination, they support the growth (temperatures as low as 3° C [37.4°F]) of *L. monocytogenes*, and the common denominator is that they are ready-to-eat (RTE). RTE products usually require refrigeration and are stored for an extended period. Examples of high-risk foods are hot dogs, deli meats, pâté and meat spreads.

Other foods that are associated with contamination by *L. monocytogenes* include raw milk, supposedly pasteurized fluid milk, cheeses (particularly soft-ripened varieties), ice cream, raw vegetables, fermented raw meat sausages, raw poultry and meat (all types), and raw and smoked fish. As mentioned previously, the ability of this pathogen to grow at low temperatures permits the multiplication in refrigerated foods.

This pathogen has also been found in the gastrointestinal tract of 37 mammalian species, both domestic and feral, as well as at least 17 species of birds and possibly some species of fish and shellfish. *Listeria* is ubiquitous in nature; it can be isolated from soil, silage, water, vegetation, and other environmental sources.

The pathogen *L. monocytogenes* is also ubiquitous in the establishment environment (equipment, utensils, humans, water, airflow, etc). It's presence in the RTE environment can pose a serious problem, especially in RTE finished product and on food contact surfaces. Product flow must be designed to segregate finished from raw products as well as restrictions of personnel who handle RTE products to prevent cross-contamination. The main concern in the RTE environment is the ability of *L. monocytogenes* to form biofilm, which allows the microorganism to survive under adverse conditions such as freezing, drying, high salinity, antimicrobials, and heat. Thus, good sanitation including microbial analysis must be part of the establishment's quality control practice to avoid cross-contamination of the product and food contact surfaces.

Under the FMIA and PPIA, RTE product is adulterated if it contains *L. monocytogenes* or if the product comes into direct contact with a food contact surface that is contaminated with the microorganism. Government agencies (USDA, FDA) and the food industries have taken steps to reduce contamination of food by the *Listeria* bacterium. In 2003, USDA issued new regulations aimed at further reducing *L. monocytogenes* contamination of RTE meat and poultry products (USDA/FSIS: "Control of *Listeria monocytogenes* in ready-to-eat meat and poultry products"; Federal Register Docket No. 97-013F). FSIS requires the establishments producing RTE meat and poultry products to address control measures in their HACCP plans or to prevent contamination through their Sanitation SOP and/or pre-requisite programs. When a processed food is found to be contaminated, food monitoring and establishment inspection are intensified, and if necessary, the implicated food is recalled.

Bovine Spongiform Encephalopathy (BSE)

Bovine Spongiform Encephalopathy (BSE) or "mad cow disease" is a progressive neurological disorder of cattle that results from infection by an agent known as a **pro**teinaceous **in**fectious particle or **prion** protein. This agent exists in two forms, namely, the normal (PrP^c) and its pathological isoform (PrP^{res}). The PrP^{res} isoform is an abnormal shaped protein (β -pleated sheet) which lacks nucleic acids, resists protease digestion, and survives dry heat at 600°C for 15 min. The normal isoform (α -helix) is expressed most abundantly in the central nervous system (CNS) tissue and brain. The nature of the transmissible agent is not well understood. BSE possibly originated because of feeding of scrapie-containing sheep meat-and-bone meal to cattle.

In humans, the illness suspected of being food borne is variant Creutzfeldt-Jakob disease (vCJD). The human vCJD and cattle BSE appear to be caused by the same

agent. The neurodegenerative phase (build-up of PrP^{res} isoform) of vCJD typically involves the formation of "daisy-shaped" areas of damage in the CNS, and there is vacuolization (formation of holes) in the brain tissue that gives a spongy appearance when examined under a microscope. Cases of vCJD present with psychiatric problems, such as depression. As the disease progresses, neurological signs appears including unpleasant sensations in the limbs/face, problems with walking and muscle coordination, forgetfulness, among others. Late in the course of the disease, patients are hospitalized until death.

The most reliable means for diagnosis of the human disease vCJD is the microscopic examination (a post-mortem procedure). Preliminary diagnosis of vCJD is based on patient history, clinical symptoms, electroencephalograms, and magnetic resonance imaging of the brain. This disease is rapidly progressive and fatal. CDC has used several mechanisms to conduct surveillance for vCJD and, during 1996-97, established the National Prion Disease Pathology Surveillance Center (NPDPSC) at Case Western Reserve University, Cleveland, Ohio. NPDPSC provides advanced neuropathologic and biochemical diagnostic services free of charge to physicians and state and local health departments.

The methods of diagnosis in cattle include immunohistochemistry (using antibody/antigen staining of post-mortem biopsy tissue), SAF-Immunoblot of brain, and Western Blots techniques, to name a few.

The major concern for consumer is the potential contamination of meat product by BSE contaminated tissues or the inclusion of BSE contaminated tissues in foods, including dietary supplements. High-risk tissues for BSE contamination include the cattle's skull, brain, spinal cord, dorsal root ganglia, and the distal ileum of the small intestine. The direct or indirect intake of high-risk tissues may have been the source of human illness.

The U.S. experience of the BSE confirmed positive from a dairy cow in Washington State (December 2003) triggered a series of actions by the Secretary of Agriculture. In response to this event, in January 2004, FSIS issued three interim regulations and a notice in the Federal Register. The purpose of these policy issuances is to minimize human exposure to the BSE agent. For more information on FSIS policies and issuances, and the APHIS surveillance program refer to the module titled "Bovine Spongiform Encephalopathy (BSE): Key Points for the Public Health Veterinarian" in the PHV Training materials.

Emerging Food borne Pathogens of Concern from the Food Industry Perspective

Staphylococcus aureus

Staphylococcus aureus is a Gram-positive bacterium (coccus) which on microscopic examination appears in clusters resembling grapes. It is a non-motile, non-spore forming facultative anaerobe that grows by aerobic respiration or by fermentation yielding lactic acid. This microorganism can grow at a temperatures between 7-45°C (35.9-113°F; optimum 37°C [98.3°F), pH range of 4.2-9.3 (depend on the type of acid present), at NaCl concentrations as high as 25%, and it is resistant to drying capable of producing enterotoxins in foods with a_w as low as 0.85.

Staphylococcus aureus should be considered a potential pathogen. Its pathogenesis is multifactorial since it can expresses many potential virulence factors like surface proteins (laminin, fibronectin, clumping factor, and an adhesion), that promote colonization in host tissue; invasins (leukocidin, kinases, and hyaluronidase) that promote bacterial spread in tissues; surface factors (capsule and Protein A) which inhibit phagocytic engulfment; carotenoids and catalase production that enhance their survivor; and membrane damaging toxins (α -hemolysin, leukotoxin, leukocidin) that lyses eukaryotic cell membranes. There are other virulence factors including the exotoxins (enterotoxins of antigenic type SE A-G, Toxic Shock Syndrome Toxin-1, and Exfoliating Toxin) that damage host tissues or provoke symptoms of disease. The heat-stable enterotoxin A (SE A) is the most toxic and is responsible for causing diarrhea and vomiting when ingested and for staphylococcal food poisoning (staphyloenterotoxicosis or staphyloenterotoxemia).

One of the biggest concerns of this pathogen is the increase incidence of Methicillin resistant *S. aureus* (MRSA) and other strains that are resistant to a variety of different antibiotics. Furthermore, *S. aureus* strains can exhibit resistance, as a survival mechanism in the hospital environment, to antiseptic and disinfectants including quaternary ammonium compounds.

All people are believed to be susceptible to this type of bacterial intoxication; however, intensity of symptoms may vary. Death from staphylococcal food poisoning is very rare, although such cases have occurred among the elderly, infants, and severely debilitated persons. The onset of symptoms in staphylococcal food poisoning is usually rapid (30 min-8 hrs) and in many cases acute, depending on individual susceptibility to the toxin, the amount of contaminated food eaten, the amount of toxin in the food ingested, and the general health of the victim. The most common symptoms are nausea, vomiting, retching, abdominal cramping, and prostration. Some individuals may not always demonstrate all the symptoms associated with the illness. In more severe cases, headache, muscle cramping, and transient changes in blood pressure and pulse rate may occur. An enterotoxin A dose of less than 1.0 microgram in contaminated food will produce symptoms of staphylococcal intoxication and this toxin level is reached when *S. aureus* populations exceed 100,000 cells per gram. Recovery generally takes two days; however, it is not unusual for complete recovery to take three days and sometimes longer in severe cases.

The true incidence of staphylococcal food poisoning is unknown for a number of reasons, including poor responses from victims during interviews with health officials; misdiagnosis of the illness, which may be symptomatically similar to other types of food poisoning (such as vomiting caused by *Bacillus cereus* toxin); inadequate collection of samples for laboratory analyses; and improper laboratory examination. Thus, in the diagnosis of staphylococcal food borne illness, proper interviews with the victims and gathering and analyzing epidemiologic data are essential. Incriminated foods should be collected and examined for staphylococci. The presence of relatively large numbers of enterotoxigenic staphylococci is good circumstantial evidence that the food contains toxin. The most conclusive test is the linking of an illness with a specific food or in cases where multiple vehicles exist, the detection of the toxin in the food sample(s).

Foods that are frequently incriminated in staphylococcal food poisoning include meat and meat products; poultry and egg products; salads such as egg, tuna, chicken, potato, and macaroni; bakery products such as cream-filled pastries, cream pies, and

chocolate éclairs; sandwich fillings; and milk and dairy products. Foods that require considerable handling during preparation and that are kept at slightly elevated temperatures after preparation are frequently involved in staphylococcal food poisoning. Human intoxication is caused by ingesting enterotoxins produced in food by some strains of *S. aureus*, usually because the food has not been kept hot enough (60°C [140°F] or above) or cold enough (7.2°C [45°F] or below).

Staphylococci exist in air, dust, sewage, water, milk, and food or on food equipment, environmental surfaces, humans, and animals. Humans and animals are the primary reservoirs. Animals and poultry carry *S. aureus* on parts of their body, which can lead to infections. Cow's udder and teats, tonsils and skin of pigs, and skin of chickens and turkeys are known sources. Staphylococci are present in the nasal passages and throats and on the hair and skin of 50 percent or more of healthy individuals. This incidence is even higher for those who associate with or who are exposed to sick individuals and hospital environments. Although food handlers are usually the main source of food contamination in food poisoning outbreaks, equipment and environmental surfaces can also be sources of contamination with *S. aureus*.

Staphylococcus aureus is highly vulnerable to destruction by heat treatment and nearly all sanitizing agents when correctly applied. While heat processing (pasteurization) and normal cooking temperatures are effective to kill the pathogen, food establishments have to be alert that the enterotoxins are heat-stable (extremely resistant to heat) and are not inactivated by heat. There are guidelines for the industry to ensure that the processing steps they are using are adequate to meet their particular food safety objectives. Heat resistance is increased in dry, high-fat and high-salt foods, and survives frozen storage. Thus, the presence of this bacterium or its enterotoxins in processed foods or on food processing equipment (in areas that are difficult to clean) is generally an indication of poor sanitation and processing practices. Foods that present the greatest risk are those in which a heat treatment has been applied (e.g. cooking) or application of an inhibitory agent or treatment (e.g. cured, salted meats). Foods are examined for the presence of S. aureus and/or its enterotoxins to confirm that S. aureus is the causative agent of food borne illness, to determine whether a food is a potential source of staphylococcal food poisoning, and to demonstrate post-processing contamination, which is generally due to human contact or contaminated food-contact surfaces. The presence of a large number of S. aureus organisms in a food may indicate poor handling or sanitation; however, it is not sufficient evidence to incriminate a food as the cause of food poisoning. The isolated S. aureus must be shown to produce enterotoxins.

As mentioned previously, this pathogen can cause severe food poisoning and it has been identified as the causative agent in many outbreaks by eating foods in which enterotoxin has been produced because of time and temperature abuse, poor sanitation during processing, or other factors. *Staphylococcus aureus* is probably responsible for even more cases in individuals and family groups than the records show. This pathogen has been implicated in four Class I (high health risk) recalls. The first one took place in Washington State (November 22, 2005) where the firm recalled various sized vacuum-packed packages of fully cooked honey cured ham and smoked beef strips (approximately 340 pounds overall) that may had contained *S. aureus* enterotoxin. The problem was discovered by FSIS and no illnesses were reported. The second recall took place in New Jersey on June 13, 2006 where the importing firm voluntarily recalled approximately 664 pounds of boneless Prosciutto ham that also may had contained *S. aureus* enterotoxin. The problem was discovered through testing done by the Canadian Food Inspection Agency. FSIS did not receive any reports of illness associated with the

consumption of this product. The third recall took place in 2007, when a firm in Minnesota recalled approximately 330 pounds of ready-to-eat sausage products associated with this pathogen. The problem was discovered by FSIS but there was no report of illness. Lastly, a recent recall (March 2011) took place in New York where approximately 2,997 pounds of bologna products were implied. After the establishment discovering a malfunction with its smokehouse, the establishment recooked the bologna products and shipped them to the distribution center. During routine inspection activities, FSIS discovered that the time delay in recooking the product created an environment allowing potential production of *Staphylococcus aureus* enterotoxin.

This pathogen can be found in the farm/slaughter environment affecting food safety. In a study done in the Netherlands (2007), a new MRSA clone related to swine and cattle farming were detected and this clone was also isolated in meat products. Contamination of food products can be traced back to slaughter establishments and to poor sanitary conditions. This is another example of a major factor of contamination resulting in transfer of pathogenic agents between countries (import/export). Research done in Canada has revealed that MRSA has been found in pork products (in less than 10% of sampled pork chops and ground pork) bought in retail sores throughout that country. Furthermore, in January 2008, the Department of Epidemiology of the University of Iowa began testing swine for MRSA in the United States and found MRSA in 49% of the swine tested (299 pigs from 10 farms in Iowa and Illinois). In addition, they found that 45% of the workers carried the same MRSA strains as the pigs (2009, Plos ONE 4(1):e4258.doi:10.1371/journal.poe.0004258).

Norwalk and Norwalk-like viruses

Viruses are inert particles that can pass from host to host. Since these particles are completely inert, they cannot multiply in foods or outside the host, cannot carry out any metabolic activity, nor respond to stresses encountered in the environment. Nevertheless, viruses have emerged as causes of food borne disease.

Norwalk virus is the prototype strain of genetically and antigenically diverse single stranded ribonucleic acid (RNA) viruses, which is classified in the genus Norwalk-like in the family *Caliciviridae*. The family consist of several serological distinct groups of viruses that have been named after the places where the outbreaks occurred (i.e., in the U.S. the Norwalk virus was the first gastroenteritis virus in Norwalk County). Norwalk-like viruses (NLVs) have the ability to survive in relatively high levels of chlorine and varying temperatures (i.e., from freezing to 60°C [140°F]).

Common names of the illness caused by Norwalk and NLVs are viral gastroenteritis, acute nonbacterial gastroenteritis, food poisoning, and food infection. The virus has an incubation period of 12-48 hrs after consumption of contaminated food or water and lasts for 1-2¹/₂ days. The illness is self-limiting, mild, and characterized by acute onset of nausea, vomiting, abdominal cramps, and diarrhea. Vomiting is more prevalent in children whereas diarrhea is common to adults. The infectious dose is unknown but presumed to be low (less than 100 viral particles).

Theoretically, any food item can potentially be infected with NVL through fecal contamination; certain foods are implicated more than others in outbreaks of NLV gastroenteritis, like shellfish. Also, food contamination by infectious food handlers is another frequent cause of outbreaks (RTE foods like salads and deli sandwiches).

Other vehicles of transmission include water (from municipal supplies, wells, etc.) and person-to-person spread (nursing homes and day care centers).

Because of the antigenic and genetic diversity of NLVs various diagnostic methods have been developed to identify NLVs in clinical specimens. The most common ones include electron microscopy, immune electron microscopy, enzyme Immunoassays (ELISA), nucleic acid hybridization, and reverse transcription-polymerase chain reaction; the last two methods are assays to detect NLV genome in clinical and environmental specimens.

FOODBORNE DISEASE OUTBREAKS

An outbreak of food borne illness occurs when a group of people consumes the same contaminated food and two or more of the individuals develop the same symptoms or illness. For example, it may be a group who ate a meal together, or it may be a group of people who do not know each other at all, but who all happened to buy and eat the same contaminated item from a grocery store or restaurant.

For an outbreak to occur, an event or combination of events must happen to contaminate a batch of food eaten by a group of people. For example, contaminated food may be left out at room temperature for many hours, allowing the bacteria to multiply to high numbers, and then not properly cooked to kill the bacteria.

Many outbreaks are local in nature. For examples, a catered meal at a reception, a potluck supper, or eating a meal at an understaffed restaurant on a particularly busy day. These outbreaks are recognized when a group of people realizes that they all became ill after a common meal, and someone calls the local health department.

However, outbreaks are increasingly being recognized that are more widespread, that affect persons in many different places, and that are spread out over several weeks. As an illustration, in 2002, a five-state salmonellosis outbreak was traced to persons who consumed ground beef. Forty-seven cases were identified where 17 people were hospitalized and one died. The outbreak was recognized because it was caused by a multidrug-resistant *Salmonella* Newport and fingerprinting pattern of 94% of the isolates were indistinguishable indicating that the outbreak was originated by the same bacterial strain.

The vast majority of reported cases of food borne illnesses is not part of recognized outbreaks, but occurs as individual or "sporadic" cases. It may be that many of these cases are actually part of unrecognized widespread or diffuse outbreaks.

The initial clue that an outbreak is occurring can come in various ways:

- It may be when a person realizes that several other people who were all together at an event have become ill and he or she calls the local health department.
- It may be when a physician realizes she has seen more than the usual number of patients with the same illness.
- It may be when a county health department gets an unusually large number of reports of illness.

Once an outbreak is detected, an investigation begins. The outbreak is systematically described by time, place, and person by interviewing people, gathering epidemiological information, testing implicated food vehicle, and other associated information. If the causative microbe is not known, samples of stool or blood are collected from ill people and sent to the public health laboratory to make the diagnosis.

Detecting and investigating such widespread outbreaks is a major challenge to our public health system. This is the reason that new and more sophisticated laboratory methods are being developed and used by CDC and in state public health department laboratories.

EPIDEMIOLOGY

One of the public health strategies for dealing with food borne illness outbreaks is the use of epidemiology. Epidemiology is the study of factors determining and influencing the frequencies and distribution of a disease, injury, and other health-related events and their causes in a defined human population. The purpose is to establish programs to prevent and control their development and spread. Let us review a few very basic principles.

- The term "epidemic" is used when there is an occurrence of more cases of disease than expected in a given area or among a specific group of people over a particular period.
- The term "endemic" refers to the usual prevalence of a given disease or agent in a population or geographic area at all times.

FSIS employs a group of epidemiologists to assist in investigating food borne disease outbreaks related to meat, poultry, and egg products.

Surveillance systems for tracking food borne diseases

The hardest outbreaks to detect are those that are spread over a large geographic area, with only a few cases in each state. These outbreaks can be detected by combining surveillance reports at the regional or national level and looking for increases in infections of a specific type.

CDC is part of the U. S. Public Health Service, with a mission to use the best scientific information to monitor, investigate, control and prevent public health problems. CDC works closely with state health departments to monitor the frequency of specific diseases and conducts national surveillance for them. CDC provides expert epidemiologic and microbiologic consultation to health departments and other federal agencies on a variety of public health issues, including food borne disease. CDC can also send a team into the field to conduct emergency field investigations of large or unusual outbreaks, in collaboration with state public health officials.

CDC researchers develop new methods for identifying, characterizing and fingerprinting the microbes that cause disease. It translates laboratory research into practical field methods that can be used by public health authorities in States and counties.

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CDC is not a regulatory agency. The Food and Drug Administration, the Food Safety and Inspection Service (USDA), the National Marine Fisheries Service, and other regulatory agencies carry out government regulation of food safety. CDC maintains regular contact with the regulatory agencies. Although it does not regulate the safety of food, the CDC assesses the effectiveness of current prevention efforts. It provides independent scientific assessment of what the problems are, how they can be controlled, and of where there are gaps in our knowledge.

FoodNet (Food borne Disease Active Surveillance Network)

FoodNet consists of active surveillance for food borne diseases and related epidemiologic studies designed to help public health officials better understand the epidemiology of food borne diseases in the United States. It is the principal food borne disease component of CDC's Emerging Infections Program (EIP). It is a collaborative project of the CDC, ten EIP sites (California, Colorado, Connecticut, Georgia, New York, Maryland, Minnesota, Oregon, Tennessee and New Mexico), the USDA, and the Food and Drug Administration.

FoodNet provides a network for responding to new and emerging food borne diseases of national importance, monitoring the burden of food borne diseases, and identifying the sources of specific food borne diseases.

The FoodNet methods by this surveillance network consist of establishing laboratoryconfirmed cases of infection from each site. A case report is completed which includes information on demographics, clinical outcomes, and the pathogen.

PulseNet (The Molecular Subtyping Network for Food borne Bacterial Disease Surveillance)

PulseNet is the national molecular subtyping network for food borne disease surveillance and allows state laboratories and CDC to compare strains of pathogenic bacteria from all across the United States to detect widespread outbreaks. This CDC network of public health laboratories perform a DNA "fingerprinting" method called pulsed-field gel electrophoresis (PFGE) on food borne bacteria. PulseNet is a national network of public health laboratories that provides an early warning system for outbreaks of food borne disease.

PFGE is a molecular method where bacterial chromosomal DNA is digested with specific restriction enzymes (at least two); the digested fragments are then inserted into an agarose gel and separated in an electrical field (electrophoresis). The electrophoretic patterns are visualized following staining with a specific dye and the image is captured using commercially available digital systems. The data analysis can be performed by using software programs, and the PFGE typing criteria employed to determine the genetic relatedness among strains of particular bacterial specie is correlated with the similarities in the DNA banding pattern.

The network identifies and labels each "fingerprint" pattern and permits rapid comparison of these patterns through an electronic database at the CDC to identify related strains. At present, PulseNet tracks four food borne disease-causing bacteria: *E. coli* O157:H7, nontyphoidal *Salmonella*, *Shigella*, and *Listeria monocytogenes* at the DNA level.

The spectrum of food borne diseases is constantly changing. A century ago, typhoid fever, tuberculosis and cholera were common food borne diseases. Improvements in food safety, such as pasteurization of milk, safe canning, and disinfection of water supplies have conquered those diseases.

Newly recognized microbes emerge as public health problems for several reasons: microbes can easily spread around the world, new microbes can evolve, the environment and ecology are changing, food production practices and consumption habits change, and because better laboratory tests can now identify microbes that were previously unrecognized.

In the last 15 years, several important diseases of unknown cause have turned out to be complications of food borne infections. For example, we now know that the Guillain-Barré syndrome can be caused by *Campylobacter* infection, and that the most common cause of acute kidney failure in children, hemolytic uremic syndrome, is caused by infection with *E. coli* O157:H7 and related EHEC pathogens. In the future, other diseases whose origins are currently unknown may turn out be related to food borne infections.

FOOD PROCESSING ESSENTIALS

This section is not intended to cover each type of food preservation method in detail. It is intended to remind you of the types of food preservation that are currently practiced and to point out methods of preservation that you may be exposed to as the IIC in a facility. You will remember some of this from the section of your training on the Regulated Industries. Proper processing of food helps to ensure that the growth of harmful microorganisms is controlled, reduced, or eliminated.

Preservation of foods

The basic principle of all forms of food preservation is either to slow down the activity of disease causing bacteria, or to kill the bacteria altogether so that they do not cause illness in the consumer of the product.

Following is a list of food preservation techniques commonly used. Not all of these are present in a FSIS inspected slaughter/processing facility. However, as a PHV you will most likely be exposed to the use of refrigeration, freezing, heat, and chemical preservation in the slaughterhouse and processing environment, at a minimum. Irradiation is just starting to be more accepted by the public, there are a few irradiation facilities in the United States.

Types of food preservation:

- Refrigeration and freezing
- Canning
- Irradiation
- Chemical preservation
- Pasteurizing (heat)
- Pickling
- Salting

- Dehydration
- Fermentation
- Carbonation
- Cheese-making
- Freeze-drying

When you first report to your duty station it will be important to review the HACCP and Sanitation SOP plans and take a tour of the facility to familiarize yourself with the processes of the establishment. If you have questions about the processes, you can ask the establishment, or you may contact the Policy Development Division (PDD; formerly known as Technical Service Center) for technical guidance.

OVERVIEW OF FSIS MICROBIOLOGICAL TESTING PROGRAMS

This section will provide a brief overview of FSIS microbiological testing programs. You will either perform or be involved with these testing programs in the establishment. This is a very brief overview. You covered all of these in detail when you attended the FSRE training. Remember that the establishment may have its own microbiological testing program. You are to regularly review the records associated with the establishment's testing program when the testing program has relevance to the establishment's food safety systems.

FSIS conducts microbiological testing for *Salmonella, E. coli* O157:H7, and *Listeria monocytogenes*. FSIS also has performance standards for *Salmonella*, and a pathogen reduction regulation that requires some establishments to conduct *E. coli* generic testing.

Salmonella Performance Standards

First, let us review the performance standards for *Salmonella*. The requirements for livestock and poultry establishments are covered in 9 CFR 310.25(b) and 381.94(b), respectively. FSIS Directive 10,011.1 Attachment 1 contains instructions for the Salmonella performance standards. Attachment 1 also provides background information and answers to questions regarding FSIS Directive 10,011.1. FSIS Directive 10,230.5 is the self-Instruction guide for collecting raw meat and poultry product samples for Salmonella analysis for establishments.

Generic E. coli testing by establishments

The pathogen reduction regulation also covered a requirement for some establishments to conduct generic *E. coli* testing and is done by the establishment [9 CFR 310.25(a) and 381.94 (a)]. Generic *E. coli* is an indicator organism that gives an indication if the establishment's sanitary dressing procedures are working effectively. The samples can be collected using one of several methods (sponge, whole bird rinse, excision) depending on the type of carcass. FSIS has provided resources to assist establishments including "Guidelines of *Escherichia coli* Testing for Process Control Verification in Cattle and Swine Slaughter Establishments," and "Guidelines of *Escherichia coli* Testing for Process Control Verification in Poultry Slaughter Establishments". These resources can be found in the FSIS Website.

E. coli O157:H7

Escherichia coli O157:H7 is one of the pathogens included in the FSIS testing program. While *E. coli* infections do not cause the largest numbers of illnesses, the illness due to this pathogen is very severe and can result in death. The CDC now estimates that food borne transmission of the pathogen annually causes 73,000 illnesses, resulting in more than 2,000 hospitalizations and 60 deaths. This represents an economic burden where the annual cost (2003) of illness due to this pathogen was approximately \$405 million dollars. FSIS issued a final rule requiring establishments to conduct a reassessment of their HACCP plans for E. coli O157:H7. Here are some recent agency policy issuances on *E. coli* O157:H7 and can be access through the Web: "http://www.fsis.usda.gov/Regulations & Policies/Index.asp".

- FSIS Directive 10,010.1 Microbiological Testing Program for Escherichia coli O157:H7 in Raw Ground Beef Products and Raw Ground Beef Components and Beef Patty Components
- Federal Register Docket No. 04-042N (May 26, 2005/Rules and Regulations) HACCP Plan Reassessment for Mechanically Tenderized Beef Products.
- <u>Federal Register Docket No. FSIS-2008-0035 (October 10, 2008/Notices)</u> Sampling and Testing for *E. coli* O157:H7 in Beef Manufacturing Trimmings.

<u>Federal Register Docket No. FSIS 2010-0008 (March 8, 2010/Notices)</u> – Improving Tracing Procedures for *E. coli* O157:H7 Positive Raw Beef Products. *Listeria monocytogenes*

During the 1980's, *L. monocytogenes* (Lm) began to emerge as a problem in processed meat and poultry products. In the 1990's there were outbreaks of food borne illness in which hotdogs, and possibly deli (luncheon) meats, were implicated.

Since 1999-2003, FSIS published Federal Register Notices and FSIS Notices, held public meetings, and developed *Listeria* Guidelines for the industry. The FSIS risk assessment, in conjunction with a previously released FDA/FSIS risk ranking and public comment gathered on the topic, provided important data enabling FSIS to design a final *L. monocytogenes* rule. This rule was published on June 6, 2003 and became effective on October 6, 2003.

9 CFR 430 states that Lm can contaminate RTE products that are exposed to the environment after a lethality treatment (destroy/kill). Lm is a hazard that an establishment must control through its HACCP plan, or prevent in the environment through a Sanitation SOP or other prerequisite program if it produces RTE product that is exposed post-lethality. RTE product is adulterated if it contains Lm or if it contacts surfaces contaminated with *Lm*. In order to maintain sanitary conditions necessary to meet this requirement, an establishment producing post-lethality exposed RTE product must comply with one of three alternatives outlined in the regulation.

Following is a very brief summary of how establishments must meet the requirements of regulation 430. If an establishment chooses Alternative 1, they must use a post-lethality treatment that reduces or eliminates microorganisms on product and an antimicrobial

agent or process that suppresses or limits the growth of *Lm*. If an establishment chooses alternative 2 they can use either the post-lethality treatment of product or antimicrobial agent or process that suppresses or limits growth; however if an establishment chooses the antimicrobial agent or process they must also have a sanitation program that addresses the testing of food contact surfaces. For Alternative 3, it employ sanitation measurements only and there is a higher potential risk of post lethality contamination of the product with *Lm*, therefore FSIS will most likely sample at a higher frequency than for Alternative 2 or 1. The risk of contamination with Alternative 1 should produce the safest product, and therefore, this product will be subject to the lowest frequency of verification testing by FSIS.

The final rule contains a great deal of background information on *Listeria* contamination of RTE product. Directive 10,240.4 contains instructions for inspectors who will be verifying compliance with the 9 CFR §430 regulations, as well as procedures for collecting product samples. The Directive that is accessible through the FSIS website contains three attachments. In addition, FSIS has posted related documents for Directive 10,240.4, including updated questions and answers for the interim final rule, a compliance guideline (May 2006), as well as other resource materials. Altogether, there are probably several hundred pages of information regarding how the regulation is implemented, to whom it applies, and information companies should consider when addressing Lm in their food safety systems.

This information can be accessed through the FSIS website at http://www.fsis.usda.gov/Regulations_&_Policies/RD_10240_4/index.asp. Agency policies are updated as information develops about the prevalence of pathogens, food borne illness outbreaks, and industry practices. It is your responsibility to maintain a current knowledge of Agency policies and how they affect your job duties. This basic understanding of food microbiological principles will also help you as you perform your regulatory responsibilities.

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"Bad Bug Book": <u>http://vm.cfsan.fda.gov/~mow/intro.html</u> "Bacteriological Analytical Manual *Online*": "http://www.cfsan.fda.gov/~ebam/bam.html"

CDC Websites:

Other Websites:

"http://www.haccpalliance.org/alliance/foodsafety.com

Small Business Regulatory Enforcement Fairness Act (SBREFA)

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Slides	LEARNING OBJECTIVES
N/A	Scientific:
	[None for this topic in this context.]
	Regulatory/Administrative:
	1. Explain the PHV's role in meeting the agency's SBREFA requirements.
	 Identify effective techniques and agency resources that PHV's can use and provide when communicating with establishment management about assistance with plant compliance.


SBRE	FA Overview
Why i	s SBREFA important to the Agency?
What	qualifies an establishment to be a small business?
Your	Role
•	Help establishment owners gain access to information that the Agency supp to assist them
•	Identify materials/resources that are available
•	Work with the FLS to get answers to the establishment owner
•	Improve communication between the industry and FSIS
•	

Resources What techniques/resources should you use and provide when communicating with establishment management about assistance with plant compliance? What additional resources are available to small and very small establishments?

Slides	SBREFA KNOWLEDGE CHECK
8-9	Knowledge Check 1 What are the two key areas of emphasis FSIS has for the Small Business Regulatory Enforcement Fairness Act?
	Knowledge Check 2 Which of the following (on screen) is an example of how a PHV might help FSIS meet its SBREFA requirements?
Slides	SUMMARY
10	Review your score on the Summary screen and notes about this topic. Make note of any areas that you need to work on. Please note that this score does not count toward your overall class grade. Rather, it helps you identify which areas you may need to study more in preparation for your exame. Your overall class grade only consists of the daily guizzos, midtorm exam, and
	final exam. Any scores you receive on Knowledge Check questions or course activities are <u>not</u> counted. They are for your use only.

Wellness

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Knowledge Check 4	8
Knowledge Check 5	8
SUMMARY	8

Slides	LEARNING OBJECTIVES				
N/A	Scientific:				
	 Recognize the causes and symptoms of job stress and isolation, and remedies such as networking to create a supportive work environment. 				
	Recognize the causes and symptoms of the most common, repetitive stress injuries and ways to prevent or minimize such injuries.				
	Regulatory/Administrative:				
	 Identify and locate agency resources available to help personnel, including supervisors, cope with stresses related to the in-plant environment that may lead to misconduct or workplace violence. 				

Slides	INTRODUCTION				
2	Defining Wellness				
	Discussion Question 1: What does wellness mean to you?				
	Discussion Question 2: How does wellness fit into the workplace?				
	Discussion Quantian 2: What are notantial common aphae/paine/injuries that may be				
	experienced on the line?				
3	Wellness Video				
	Video Notes:				

4

Wellness Video Debrief
What would cause a back injury to develop?
What are some steps you can take to prevent back injury?
What are some common types of Cumulative Trauma Disorders (CTDs)?

5

Slides	WELLNESS: STRESS MANAGEMENT
6 - 7	Defining Stress
	A stressful situation is always defined as a negative response of the body to any demand.
	Which of the following is NOT a factor to how stress may impact people in the same situation differently?
	Stress can promote curiosity and exploration.

1	. Physical
2	. Psychological
3	. Psychosocial

7

8 **Personal Stress**

Take a few minutes to complete the Holmes and Rahe Stress Scale. Then compare your score to the score interpretation.

Directions: Fill out the number of times that the stressor has happened to you within the past year. Then calculate your total score.

Life Event (Stressor)	Value	Number of time it happened in the past year	Total
Death of a spouse	100		
Divorce	73		
Marital separation	65		
Jail term	63		
Death of close family member	63		
Major personal injury or illness	53		
Marriage	50		
Fired from work	47		
Marital reconciliation	45		
Retirement	45		
Major change in health of family	44		
member			
Pregnancy	40		
Sex difficulties	39		
Gain of new family member	39		
Major business readjustment	39		
Major change in financial state	38		
Death of close friend	37		
Change to different line of work	36		
Major change in number of arguments	35		
with spouse			
Mortgage over \$100,000	31		

Foreclosure of mortgage or loan	30	
Major change in responsibilities at	29	
work		
Son or daughter leaving home	29	
Trouble with in-laws	29	
Outstanding personal achievement	28	
Spouse begins or stops work	26	
Begin or end school	26	
Major change in living conditions	25	
Revision of personal habits	24	
Trouble with boss	23	
Major change in work hours or	20	
conditions		
Change in residence or schools	20	
Major change in recreation	19	
Major change in church activities	19	
Major change in social activities	18	
Mortgage or loan less than \$10,000	17	
Major change in sleeping habits	16	
Major change in number of family get-	15	
togethers		
Major change in eating habits	15	
Vacations, Christmas	13	
Minor violations of the law	11	
	1	Your Total =

	Score Interpretation:				
	Score	Comment			
	11-150	You have only a low to moderate chance of becoming ill in the near future.			
	150-299	You have a moderate to high chance of becoming ill in the near future.			
	300+	You have a high or very high risk of becoming ill in the near future.			
9	Commor	n Stressors			
	What are	e some common PHV-related stressors?			

Slides	WELLNESS SCENARIOS
11	Scenario 1: Establishment Management
	Scenario Notes:
	Question 1: What would you do in this scenario?

	Question 2: What resources should you use in this scenario?
12	Scenario 2: Isolation at Work Scenario Notes:
	Question 1: What would you do in this scenario?

G	uestion 2: What resources should you use in this scenario?

13	Scenario 3: Supervisor Responsibilities			
	Scenario Notes:			
	Question 1: What would you do in this scenario?			

	Question 2: What resources should you use in this scenario?
14	More Wellness Scenarios
	Think of a scenario that could or has happened to you, or you have heard about, to demonstrate causes and symptoms of negative job stress and isolation. This could be in the slaughter/kill floor, processing, or office environment.
	How would you handle this scenario?

Clister						
Sildes		ENSURING WELLNESS IN THE WORKPLACE				
16	Metho	ods of Stress Relief				
	What can you do to relieve stress? How can this benefit both your work life and your personal life?					
	-					
	-					
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	-					

Review the resources that you have access to for your wellness.			
Resources Notes:			
iy. cts the n a			
s wrong g the Jim is and d of			

	Knowledge Check 3			
	Match the following words with their characteristics.			
	Cumulative Trauma Disorders:			
	Physical Stress:			
	Psychological Stress:			
	Psychosocial Stress:			
	Wellness:			
	Knowledge Check 4			
	The Agency has benefits and services to support your wellness.			
	Knowledge Check 5			
	Who can you reach out to for wellness and stress management resources?			
Slides	SUMMARY			
24	Review your score on the Summary screen and notes about this topic. Make note of any areas that you need to work on.			
	Please note that this score does not count toward your overall class grade. Rather, it helps you identify which areas you may need to study more in preparation for your exams. Your overall class grade only consists of the daily quizzes, midterm exam, and final exam. Any scores you receive on Knowledge Check questions or course activities are <u>not</u> counted. They are for your use only.			

WELLNESS

OBJECTIVES

To demonstrate mastery of Module Subject the trainee will:

- 1. Define different types of stress.
- 2. Generate a list of coping techniques for stressors.
- 3. Identify personal resources for dealing with stress.

RESOURCES

Definitions of Stress

Stress researcher Hans Selye was one of the first to identify stress and its effects on the body. He defined stress as a nonspecific response of the body to any demand. The pioneers of stress research categorized all stress as negative or bad. Today, we understand that stress is anything in the environment that causes us to adapt, and that a "stressful" situation can be either happy/positive (like the birth of a baby) or sad/negative (like the death of a loved one).

We also understand that stress isn't limited to what goes on in our thoughts. We know that stress is a nonspecific automatic biological response to demands made upon an individual. Scientifically speaking, stress is any challenge to homeostasis, or the body's internal sense of balance. Stress is a biological and biochemical process that begins in the brain and that spreads through the autonomic nervous system, causing hormone release and eventually exerting an effect on the immune system. Simply stated, the stress response starts in two major systems: (1) the nervous system, which reacts almost simultaneously, and (2) the endocrine (or hormone) system, which takes longer to react but which persists much longer. Stress sets off a complex domino effect in the body, involving an entire series of body systems and a whole range of powerful hormones.

We know that stress does not do the same thing to all people. One of the factors that is involved in this difference is how the impact of stress in situations is altered by how it is perceived by individuals who are affected by the situation. For example, while traveling in the Middle East, Dr. Robert Eliot saw two individuals, both driving Mercedes, crash into each other. The two men, uninjured, jumped out of their cars and began hugging and laughing instead of yelling at each other, as Eliot would have expected. Curious about their odd exchange, Eliot asked his interpreter what the two men were saying. The interpreter explained that the two men were thanking Allah for the chance to meet this way.

Plenty of evidence confirms that the way you perceive stress has a lot to do with how stress affects you. American Institute of Stress president Paul J. Rosch likens stress to a

ride on a roller coaster. "There are those at the front of the car, hands over head, clapping, who can't wait to get on again," he points out, "and those at the back cringing, wondering how they got into this and how soon it's going to be over." Or, to put it another way, one roller coaster passenger "has his back stiffened, his knuckles are white, his eyes shut, jaws clenched, just waiting for it to be over. The wide-eyed thrill-seeker relishes every plunge, can't wait to do it again."

Another difference depends on the timing of the stress. We are all more vulnerable to the effects of stress at certain times - especially when we're already weakened by some circumstance in our lives. Most researchers agree that the time to make major changes in life is *not* the period following an already stressful event. For example, it's probably not the best idea to move to a new town and begin a new job just after going through a divorce. And since everyone is vulnerable to different stresses at different times, it's wise to reduce unnecessary challenges when you're particularly vulnerable, say the researchers.

Rosch points out that differences in perception can cause some stress to be good stress (*eustress*) rather than bad stress (*distress*), and he uses as an example symphony conductors. "They work long hours, travel frequently, deal with prima donnas and sensitive artists, yet they live long and productive lives. They've got positive vibes going. They enjoy what they're doing, have pride of accomplishment, the approbation of their peers, and the applause of the audience, all positive stresses." In essence, some things that are stressful also promote curiosity and exploration. They are challenging, stimulating, and rewarding. Competitive sports are an excellent example. It's extremely stressful, both physically and emotionally, to gear up for a football game, worry about winning, and then pound across the field for three hours in an attempt to do it. But many believe the rewards and the thrill are well worth the stress, and millions of fans couldn't agree more. On the other hand, boredom and understimulation can also be distressful.

Types of Stress

Basically, there are three types of stress: physical, psychological, and psychosocial. *Physical stress* involves stressors in the environment - factors such as extremes in temperature, environmental pollution, constant noise, or electric shock. Researchers also categorize physiological factors as physical stress. Examples include injury, surgery, hypoglycemia, prolonged exercise, or an inadequate supply of oxygen. *Psychological stress* stems from the way we feel, the attitudes we have, and the way we react toward anything that is threatening us, whether the threat is real or imagined. As in the example of the roller coaster, one person may react calmly, while another may become extremely stressed.

Psychosocial stress involves stressors from interpersonal relationships, arguments or conflicts with family members, neighbors, employers, friends, or other people around us. Psychosocial stress may result from intense social interactions, but it can also occur when there is isolation as a result of inadequate social interactions.

Outcomes of Stress

Stress is costly. Obviously, no one can put a precise price tag on the various health costs of stress, but figures from a variety of sources give us a fairly good idea of its devastating impact. For example, researchers at the American Institute of Stress estimate that 75 to 90 percent of all visits to health-care providers result from stress-related disorders. The American Heart Association says that more than half of all Americans who die succumb to heart disease and that more than 50 million work days a year, adding up to a whopping \$8 billion, are lost annually to heart-related diseases. Just among the nation's executives, an estimated \$10 to \$20 billion is lost each year through absence, hospitalization, and early death, much of it as a result of stress. The National Council on Compensation Insurance says that stress-related claims account for almost one fifth of all occupational disease. Fully one-fourth of all Workman's Compensation claims are for stress-related injuries, and researchers estimate that 60 to 80 percent of all industrial accidents are related to stress.

Stress-related symptoms and illnesses are costing industry a conservatively estimated \$150 billion a year in absenteeism, company medical expenses, and lost productivity. The results of a study at New Mexico State University suggest a strong relationship between stress and absenteeism. Other studies show that stress accounts for more than 20 percent of the costs associated with high job turnover, strikes, work stoppages, absenteeism, and decline in productivity.

Left unchecked, unremitting stress can also shorten your life. In one long-term study that gives a particularly good measure of the effects of stress, researchers studied more than 600 people over twelve years. Researchers tested each study subject at the beginning of the period, asking if they suffered from distress; at the end of the twelve years, they discovered that the existence of distress at the study's outset was a good predictor of who would die during the period of the study. Even when researchers tried to "juggle" the results - by controlling for factors such as smoking, cholesterol levels, obesity, or high blood pressure, or by excluding people with chronic heart disease - the figures remained the same.

The good news is that stress doesn't have to knock you out. Research shows that some people manage to be resilient to stress; others exhibit what scientists call "hardiness," an ability to resist the ill-effects of stress. Research has also indicated that there are things that help you cope better with stressors. To figure out where you stand, it's important to know the factors that lead to stress, the physiological reactions of the body when under stress, and the way that stress can compromise the immune system and lead to illness.

Factors Leading to Stress

While researchers recognized the presence of stress decades earlier and had specifically linked it to disease several years earlier, it was not until early in the 1950s that anyone was able to identify a list of specific events that contributed to stress. During the early 1950s, University of Washington psychiatrist Thomas Holmes noted that tuberculosis had occurred among patients after a cluster of disruptive events, such as a death in the family, a new job, or a marriage. Based partly on that observation and partly on his extensive research, Holmes pronounced that the single common denominator for stress is "... significant change in the life pattern of an individual." Holmes emphasized that stress did not *cause* the tuberculosis - tuberculosis bacteria had to be present - but that stress somehow weakened the body or made it more vulnerable to the disease.

Branching out in his research, Holmes began to search for specific links between disease and what he called *life events*, those things in life that call for the greatest adjustment. He found that the more life events a person was subjected to within a brief period of time, the more likely he or she was to become ill. Holmes developed a social-readjustment rating scale along with his colleague Richard Rahe; commonly known as the Holmes-Rahe Scale, it assigns a numerical score to the almost four dozen stressors, or life changes, that increase the risk of disease. Subsequent research by hosts of independent scientists has verified the accuracy of the Holmes-Rahe scale.

How to Protect Yourself from the Negative Effects of Stress

If everyone is a "victim" of stress, are there ways we can protect ourselves from the effects of stress? Absolutely! One of the first ways, says Baylor College of Medicine psychologist Michael Cox, is to face the stress head-on. Recognize it, and get ready to deal with it. "Avoiding and denying that stress exists won't make it go away," he says. "Look at different ways you can change the situation to lessen the stress, make your decision, and face the stress head on. Action is the fastest way to reduce the level of stress."

Following are some ideas from cardiologist Robert S. Eliot and others as to how you can reduce the effects of stress:

- Develop what Eliot calls a game plan for your personal aspirations, both short-term and long-term ones.
- Take a personal inventory and reestablish important priorities. You need to balance your talents and goals, similar to the way in which you'd balance your financial portfolio.
- Work to get things back into balance, and figure out where your long-term goals may be losing out to short-term pressures, Eliot says.
- Be nice to yourself. Do something nice for yourself every day. Take the time to read something you love, soak in a warm bath, take a brisk walk, or call an old friend.
- Develop a system of time management that will help you plan your day without becoming a stressor itself. When you're scheduling your time, remember to leave time for play, time for hobbies and friends, and time for simple relaxation. If you have to, schedule in time for breaks.
- Just as you need to develop a game plan for your personal aspirations, Eliot advises developing a game plan for your career or work. Especially important in today's economy is the ability to adapt, continually assess where you are, look ahead, and prepare for change.
- If you commute to work, make sure you plan enough time to arrive without feeling stressed. If you can, turn your commute into something pleasant: Ride the bus instead of driving, and take the chance to catch up on some favorite books or magazines. If you have to drive, try out some entertaining tapes instead of the usual radio fare.
- Once at work, try the following strategies: Instead of letting the telephone control you, control the telephone. For example, take initiative to make calls, and block out several periods during the day in which to return calls. Do what you can to reduce environmental stresses at work (noise, temperature extremes, and so on). And, at least once a day, concentrate on doing at least one task no matter how small that brings you satisfaction.
- Be realistic in your expectations of your other people in your life. According to Eliot, it's crucial to accept people for who they are and let them express their own ideas.

Pay attention to your physical health. Have regular checkups, and take care of health problems promptly. If you notice unusual symptoms, have a doctor check them out as soon as possible. Above all, believe that you are well.

- Get plenty of sleep. British researchers concluded that flexibility, spontaneity, and originality of thought can be seriously undermined by as little as one sleepless night.
- Eat a balanced diet; avoid alcohol, tobacco, and caffeine. During periods of particular stress, go for a small, high-protein meal.
- Get plenty of exercise.
- Stay socially connected. According to Eliot, "Friends are not just nice, they are a necessity." If you have problems, talk them out with a trusted friend; if you're facing something difficult, rehearse it with a friend first. Share your feelings often. Develop at least one confidant, someone with whom you can share your deepest thoughts and feelings. And write your thoughts down on a regular basis. Keeping a journal is good, but so is jotting your thoughts on scraps of paper.
- Get a pet!
- Learn to laugh at yourself, and fill your life with humor.
- When things get tough, find some way to relax. And, above all, stay flexible. There may be more ways to cope with any situation than at first are apparent.

Understanding the Importance of Optimum Stress Levels

The level of stress under which you operate is important: if you are not under enough stress, then you may find that your performance suffers because you are bored and unmotivated. If you are under too much stress, then you will find that your results suffer as stress related problems interfere with your performance.

It is important that you recognize that you are responsible for your own stress. Very often it is a product of the way that you think. Learn to monitor your stress levels, and adjust them up if you need to be more alert, or down if you are feeling too tense. By managing your stress effectively you can significantly improve the quality of your life. There is a linkage between stress and performance. Following are some tips on how you can ensure that you perform at your best by optimizing stress levels.

The approach to optimizing stress depends on the sort of stress being experienced:

- Short term stress such as difficult meetings, sporting or other performances, or confrontational situations. Here the emphasis is on short term management of adrenaline to maximize performance.
- Long term stress, where fatigue and high adrenaline levels over a long period can lead to degraded performances. Here optimizing stress concentrates on management of fatigue, health, energy and morale.

Naturally there is some element of overlap between these.

Short term stress

The graph below shows the relationship between stress and the quality of performance when you are in situations that impose short term stress:



The Relationship Between Stress and Performance

(Please note that this graph will be a slightly different shape for different people in different circumstances)

Where stress is low, you may find that your performance is low because you become bored, lack concentration and motivation.

Where stress is too high, your performance can suffer from all the symptoms of short-term stress.

In the middle, at a moderate level of stress, there is a **zone of best performance**. If you can keep yourself within this zone, then you will be sufficiently aroused to perform well while not being over-stressed and unhappy.

This graph and this zone of optimum performance are different shapes for different people. Some people may operate most effectively at a level of stress that would leave other people either bored or in pieces. It is possible that someone who functions superbly at a low level might experience difficulties at a high level. Alternatively someone who performs only moderately at low level might perform exceptionally under extreme pressure.

Long term stress

The problems of long term, sustained stress are more associated with fatigue, morale, and health than with short term adrenaline management.

The graph below shows the way in which performance can suffer when you are under excessive long term stress:

The Effect of Long Term Sustained Stress on Performance



The graph shows four major stages that you may go through in response to sustained levels of excessive stress:

- 1. During the first phase you will face challenges with plenty of energy. Your response will probably be positive and effective.
- 2. After a period of time you may begin to feel seriously tired. You may start to feel anxious, frustrated and upset. The quality of your work may begin to suffer.
- 3. As high stress continues you may begin to feel a sense of failure and may be ill more frequently. You may also begin to feel exploited by your organization. At this stage you may start to distance yourself from your employer, perhaps starting to look for a new job.
- 4. If high levels of stress continue without relief you may ultimately experience depression, burnout, nervous breakdown, or some other form of serious stress related illness.

Different people may move between these stages with different speeds under different stress conditions.

At a simple level it may appear that a measure of 'toughness' is how well you keep on going under extreme stress. This is simplistic. It is certainly possible to be self-indulgent and use stress as an excuse for not pushing yourself hard enough. It is, however, also far too easy to let yourself be pushed to a level where your work, and physical and mental health start to suffer. The strongest and most flexible position is to actively manage your levels of stress and fatigue so that you are able to produce high quality work over a long period, reliably.

High performance in your job may require continued hard work in the face of high levels of sustained stress. If this is the case, it is essential that you learn to pay attention to your feelings. This ensures that you know when to relax, slacken off for a short period, get more sleep, or implement stress management strategies. If you do not take feelings of tiredness, upset or discontent seriously, then you may face failure, burn-out or breakdown.

As well as paying attention to your own stress levels, it may be worth paying attention to the stress under which people around you operate. If you are a manager seeking to improve productivity, then failing to monitor stress may mean that you drive employees into depression or burn-out. If this is a danger, then reduce stress for long enough for them to recover, and then reconsider the pace you are setting.

REFERENCES

http://www.geocities.com/beyond_stretched/holmes.htm.

http://www.musc.edu/psychiatry/slater/stress1.htm.

WORHSHOP

- 1. Because stressors are rarely found in the home, an ergonomic program can focus exclusively on job-related stress:
 - True
 - False
- 2. Good posture is the way we ______or _____which causes the least amount of physical stress to the body:
 - a. sit, run
 - b. stand, walk
 - c. sit, stand
 - d. run, walk
- 3. Back injuries_____occur as a result of one injury or accident:
 - a. always
 - b. usually
 - c. sometimes
 - d. rarely
- 4. Two factors which can increase the risk of back injury are _____:
 - a. stress, walking
 - b. sitting, eating
 - c. high body fat, stress
 - d. standing, stretching
- 5. _____ are not typically a result of accidents or sudden mishaps. Rather, this type of injury develops gradually over time:
 - a. pulled/strained muscles
 - b. cumulative trauma disorders
 - c. broken bones
- 6. Keeping the muscles strong around the joints and tendons will not help prevent cumulative trauma disorders:
 - True False
- 7. While stress cannot be eliminated from our lives, it is best handled by being:
 - a. avoided
 - b. ignored
 - c. managed
- 8. Stress is any change (positive or negative) to which you must adjust: True

False

9. While stress is commonly reported by American workers, most FSIS inspectors experience a very low level of stress:

True False 10. The relaxation response lowers the heart rate, breathing rate, and blood pressure:

True False

- 11. Creating a sense of control in your life is a technique for managing stress: True False
- 12. People need extra sleep when they are stressed:

True False

- 13. What you eat does not have much impact upon your ability to cope with stress: True False
- 14. Strong lifestyle choices can help only minimally to neutralize the effects of stressful life events:

True False

15. Even small amounts of exercise result in the release of pleasure-inducing hormones (called endorphins) that can help you cope better with stress: True False

HOLMES AND RAHE STR ESS SCALE

multiply event by the number of times you have experienc	ed it in the last year
LIFE EVENT (STRESSOR)	VALUE #/YR TOTAL
1 DEATH OF SPOUSE1	$\mathbf{OOX} =$
2 DIVORCE	73 X =
3 MARITAL SEPARATION	65 X =
4 JAIL TERM	63 X =
	63 X =
6 MAJOR PERSONAL INJURY OR ILLNESS	53 X —
	50 × =
	47 X Ξ
	45 X =
12 PREGNANCY	40 X -
13 SEX DIFFICULTIES	
14 GAIN OF NEW FAMILY MEMBER	39 X =
15 MAJOR BUSINESS READJUSTMENT —————————	
16 MAJOR CHANGE IN FINANCIAL STATE	38 X
17 DEATH OF CLOSE FRIEND	37 X =
18 CHANGE TO DIFFERENT LINE OF WORK	36 X
19 MAJOR CHANGE IN NUMBER OF ARGUMENTS WITH SPOUSE	35 X $=$
MORDGAGE OVER \$100,000	31 X =
21 FORCLOSURE OF MORTAGE OR LOAN	30 X =
22 MAJOR CHANGE IN RESPONSIBILITIES AT WORK — — — — — —	29 X =
23 SON OR DAUGHTER LEAVING HOME	29 X =
	29 X =
25 OUTSTANDING PERSONAL ACHTEVENTENT	20 A =
28 MAIOR CHANGE IN LIVING CONDITIONS	25 X
29 REVISION OF PERSONAL HABITS	24 X =
	23 X
31 MAJOR CHANGE IN WORK HOURS OR CONDITIONS	$20 \times =$
32 CHANGE IN RESIDENCE OR SCHOOLS	20 X $=$
33 MAJOR CHANGE IN RECREATION	19 X $=$
SMAJOR CHANGE IN CHURCH ACTIVITIES	— 19X =
35 MAJOR CHANGE IN SOCIAL ACTIVITIES	-—— 18 X =
36 MORTGAGE OR LOAN LESS THAN \$10,000	17 X $=$
37 MAJOR CHANGE IN SLEEPING HABITS	16 X =
38 MAJOR CHANGE IN NUMBER OF FAMILY GET-TOGETHERS — — — —	
39 MAJOR CHANGE IN !EATING HABITS	15 X =
40 VACATIONS, CHRISTMAS	13 X =
41 MINOR VIOLATIONS OF THE LAW	$\frac{11 \text{ X}}{1000 \text{ FOTAL}} = 11 \text{ X}$
	TOUR IUTAL



OPINIONS AND FEELINGS ARE FREQUENTLY A PERSONAL TRIUMPH OVER GOOD THINKING YOU DEFINE REALITY BY WHAT YOU KNOW, WHAT YOU BELIEVE, AND WHAT YOU DO ABOUT IT.

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Resources and Networking

OBJECTIVE

To identify resources including professional organizations, web sites, and information useful in performing the job duties as an FSIS Public Health Veterinarian.

RESOURCE MATERIALS

The following resources will be useful to you in providing information that will help you be more effective in performing your job duties as an FSIS Public Health Veterinarian.

- 1. Agricultural Research Service, <u>http://www.ars.usda.gov</u>. This web site contains current research topics including food safety and animal diseases.
- 2. American Association of Public Health Veterinarians, <u>http://www.aaphv.org/</u> This website promotes the science, art, and practice of public health, epidemiology, and preventive medicine.
- 3. American Meat Institute, <u>http://www.meatami.org/</u>. This web site contains news about the meat industry and guidelines for humane handling recommended by the industry.
- 4. American Meat Science Association, <u>http://www.meatscience.org/</u>. This web site contains current news and research about meat.
- Centers for Disease Control and Prevention, <u>http://www.cdc.gov</u>. This web site contains important public health information including the MMWR (Morbidity and Mortality Weekly Report), travel advisories, FoodNet and PulseNet current updates.
- 6. CDC Morbidity and Mortality Weekly Report, <u>http://www.cdc.gov/mmwr/</u>. This web site contains weekly disease statistics, including foodborne illnesses.
- Center for Food Security and Public Health, <u>http://www.cfsph.iastate.edu/About/index.php</u> This website promotes preparedness for accidental or intentional introduction of diseases that threaten food production or public health.
- Code of Federal Regulations Online, <u>http://www.access.gpo.gov/nara/cfr/waisidx_08/9cfrv2_08.html#301</u>. This web site contains the regulations. For example, you can use it to access a copy of the HACCP regulations which are contained in 9 CFR 417.
- Environmental Protection Agency, <u>htpp://www.epa.gov</u>. This web site contains regulatory information about water, waste management (including concentrated animal feeding operations) and pesticides. EPA establishes the tolerance levels FSIS uses when testing regulated products.

- Federation of American Scientists: Working Group on Biological and Toxin Weapons, <u>http://www.fas.org/programs/ssp/bio/index.html</u>. This web site contains biosecurity news as well as general information at the main website on a broad range of scientific issues.
- 11. Food and Drug Administration, <u>htpp://www.fda.gov</u>. This web site contains all of the contacts and information about each office, news releases and current issues, such as animal feed regulations for preventing BSE and animal drug approvals- both found in the Center for Veterinary Medicine's webpage.
- 12. Food Safety and Inspection Service, <u>htpp://www.fsis.usda.gov</u>. This web site contains information about FSIS. For example, you can find the following information: vacancy announcements, job application information, emergency contact information for all District Offices, Directives, Federal Register Notices, a listing of upcoming public meetings, program area information, The Beacon, recent speeches by Agency officials. Get training information and order training CDs by searching under Browse, FSIS Employees, Workforce Training.
- 13. Food Safety Training and Education Alliance, <u>http://www.fstea.org/</u>. This web site contains current educational information.
- 14. International Veterinary Information Service, <u>http://www.ivis.org/home.asp</u>. This web site contains international training programs and curricula.
- National Agricultural Library Agricola Search Engine, <u>http://agricola.nal.usda.gov/</u>. This web site contains everything you'll need to search for publications and books.
- 16. National Cattlemen's Beef Association, <u>http://www.beef.org/</u>. This web site contains news and articles of interest to the cattle industry.
- National Library of Medicine Pubmed Search Engine, <u>http://www.ncbi.nlm.nih.gov/pubmed/</u>. This web site contains access to millions of scientific articles on public health.
- 18. North American Meat Association, <u>http://meatassociation.com</u>. This web site contains news and current issues.
- 19. National Pork Board, <u>http://www.pork.org/.</u> This web site contains animal health, welfare, environmental and meat news.
- 20. Office of International Epizootics (OIE), <u>http://www.oie.int/eng/en_index.htm.</u> This web site contains international standards for animal health.
- 21. One Health Initiative, <u>http://www.onehealthinitiative.com/</u> This website contains information on collaborations and communications in all aspects of health care for humans, animals and the environment.

- 22. ProMED-mail, <u>http://www.promedmail.org/</u> This website contains reporting system dedicated to rapid global dissemination of information on outbreaks of infectious diseases and acute exposures to toxins that affect human health.
- 23. Stanford University Highwire Medline Search, <u>http://highwire.stanford.edu/.</u> This web site contains ways to obtain more scientific articles.
- 24. Temple Grandin's Website on Humane Handling, <u>http://www.grandin.com</u>. This website contains guidelines for humane handling, and slaughter of livestock and poultry as well as published articles.
- 25. United States Animal Health Association, <u>http://www.usaha.org/.</u> This web site contains information on membership, meetings and news regarding all animal health, food safety and other scientific and regulatory issues important to USDA, FDA, EPA and all State Veterinarians.
- 26. USDA, APHIS Veterinary Services, <u>http://www.aphis.usda.gov/animal_health/.</u> This web site contains access to all APHIS information and special sites on BSE and current animal disease outbreaks.
- 27. USDA, APHIS Veterinary Services Foreign Animal Disease Training, <u>http://www.aphis.usda.gov/emergency_response/NAHEM_training/index_nahem.</u> <u>shtml</u>. This web site contains information on special courses conducted at Plum Island. Sometimes FSIS veterinarians are selected to attend through an APHIS invitation.
- 28. U.S. Poultry and Egg Association, <u>http://www.poultryegg.org/.</u> This web site contains information about egg safety and quality assurance programs to reduce Salmonella.
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Slides	LEARNING OBJECTIVES		
N/A	Scientific:		
	[None for this topic in this context.]		
	Regulatory/Administrative:		
	1. Use FSIS Directive 4430.3 Revision 4 to conduct IPPS and STAR assessments.		
	 Given scenarios, distinguish between on-target and off-target performance and other employee responsibilities that a PHV oversees such as NRs, MOIs, HACCP verification, etc. during IPPS assessments. 		
	 Create a follow-up plan to address an identified deficiency in employee knowledge or performance. 		



Slides	ACTIVITY 1		
3	Activity 1 Instructions		
	You will be split up into four groups.		
	 Each group will be responsible for reviewing materials and completing a Help Tool. 		
	 Each group will choose a leader who will distribute the workload among group members. 		
	 Each member will analyze their assigned part and document the essential learning points in the Help Tool sheet. 		
	• Within the group, each member will discuss their documented learning points.		
	 Each group will present their findings and gained knowledge to the rest of the class. 		
4	Group Materials		
	Based on your group, review the materials you need to successfully complete your task.		
	Group 1		
	Watch video 1Analyze Directive 4430.3		
	Group 2 • Watch video 2 •		
	 Group 3 Watch video 3 Analyze Department Regulation 4040-430 		
	 Group 4 Watch videos 1 and 2 Analyze Directives 4430.3 Focus on the comparison of IPPS and STAR 		

	Group /	Activity Notes:
	-	
	-	
	-	
	-	
5	Presen	tations
	-	
	-	
	-	
	•	

6	Takeav	vavs
-		
	What a	re come key tekeeweye abeut eupervieere, performence management IDDS
	what a	re some key takeaways about supervisors, performance management, IPPS,
	and ST	AR?

Slides	IPPS & S	TAR PART 1 KNOWLEDG	SE CHECK
7-12	Knowledge Check 1		
7-12	Milowiedge Check I		
	What is an In-Plant	What is a Supervisory Tool	What is performance
	Performance System	for Assessment Results	management?
	(IPPS)?	(STAR)?	
	Knowledge Check 2		
	What are the three methods of assassing parformance?		

	Knowledge Check 3		
	A Supervisory Public Health Veterinarian would be required to perform a STAR assessment on which position?		
	Knowledge Check 4		
	According to Departmental Regulation (DR) 4040-430, the appraisal period or performance year is comprised of the period from:		
	Knowledge Check 5		
	Following IPPS and STAR assessment, a completed IPPS or STAR assessment sheet should be mailed to the employee within two months.		
Slides	SUMMARY		
13	Review your score on the Summary screen and notes about this topic. Make note of any areas that you need to work on.		
	Please note that this score does not count toward your overall class grade. Rather, it helps you identify which areas you may need to study more in preparation for your exams. Your overall class grade only consists of the daily quizzes, midterm exam, and final exam. Any scores you receive on Knowledge Check questions or course activities are <u>not</u> counted. They are for your use only.		

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Knowledge Check 2	8
Knowledge Check 3	8
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Slides	LEARNING OBJECTIVES			
N/A	Scientific:			
	[None for this topic in this context.]			
	Regulatory/Administrative:			
	 Use FSIS Directive 4430.3 Revision 4 to conduct IPPS and STAR assessments. 			
	 Given scenarios, distinguish between on-target and off-target performance and other employee responsibilities that a PHV oversees such as NRs, MOIs, HACCP verification, etc. during IPPS assessments. 			
	 Create a follow-up plan to address an identified deficiency in employee knowledge or performance. 			

Slides	NONCOMPLIANCE RECORDS (NRS)		
2 Slides	Why are NRs reviewed during IPPS and STAR?		
Slides	ΔΟΤΙΛΙΤΑ 3		
Ondes			
3	Activity 2 Instructions		
	You will be split up into four groups.		
	 Each group will be responsible for reviewing materials and completing a Help Tool. 		
	 Each group will choose a leader who will distribute the workload among group members. 		
	 Each member will analyze their assigned part and document the essential learning points in the Help Tool sheet. 		
	• Within the group, each member will discuss their documented learning points.		
	 Each group will present their findings and gained knowledge to the rest of the class. 		

4 Group Materials

Review the NRs. There are 10 NRs that have been written by the same CSI in the past 8 weeks. Below are the group assignments.

Group 1

• Present information from NR #1, 2, and 3

Group 2

• Present information from NR # 4, 5, and 6

Group 3

• Present information from NR # 7 and 8

Group 4

• Present information from NR #9 and 10

Group Activity Notes:

5	Preser	ntations

6	Takeaways			
	What are some key takeaways about NRs and their role in IPPS and STAR?			

Slides	IPPS & STAR PART 2 KNOWLEDGE CHECK
7-11	Knowledge Check 1
	An example of a data source that you can review before an IPPS visit is a Noncompliance Record (NR) to determine whether the NRs are being written in accordance with FSIS Directive 5000.1?
	Knowledge Check 2
	Which of the following is NOT something you can evaluate a CSI on when reviewing NRs?
	Knowledge Check 3
	When conducting IPPS assessments, you should observe plant conditions and compare them to inspection results and NRs on file.
	Knowledge Check 4
	Which of the following is NOT one of the W's addressed in a NR?
<u></u>	
Slides	SUMMARY
12	Review your score on the Summary screen and notes about this topic. Make note of any areas that you need to work on.
	Please note that this score does not count toward your overall class grade. Rather, it helps you identify which areas you may need to study more in preparation for your exams. Your overall class grade only consists of the daily quizzes, midterm exam, and final exam. Any scores you receive on Knowledge Check questions or course activities are <u>not</u> counted. They are for your use only.

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Slides	LEARNING OBJECTIVES
N/A	Scientific:
	[None for this topic in this context.]
	Regulatory/Administrative:
	1. Use FSIS Directive 4430.3 Revision 4 to conduct IPPS and STAR assessments.
	 Given scenarios, distinguish between on-target and off-target performance and other employee responsibilities that a PHV oversees such as NRs, MOIs, HACCP verification, etc. during IPPS assessments.
	 Create a follow-up plan to address an identified deficiency in employee knowledge or performance.

Slides	INTRODUCTION
2	Observation
	When you observe the inspector on the job, as part of IPPS and STAR, what are you looking for?
	· · · · · · · · · · · · · · · · · · ·
3	Observation (Continued)
	Does the inspector:
	Perform procedures consistent with Agency policy?
	Make sound supportable decisions?
	Review and understand the plant's HACCP, SSOP, prerequisite programs?
	Use aseptic procedures when collecting a sample for microbial testing?

	If noncompliance is found during the assessment, what should the inspector do?
Slides	ACTIVITY 3
4	Activity 3 Instructions
	You will be split up into four groups.
	 Each group will be provided with a scenario of inspectors performing several inspection activities.
	 Each group will choose a leader who will distribute the workload among group members.
	 Each member will analyze their assigned scenario and document the essential learning points in the Help Tool sheet.
	 Within the group, each member will discuss the scenario together, and the leader will summarize the information on the Summary sheet.
	 Each group will present their summary and gained knowledge to the rest of the class.
5	Group Materials
	Review the materials you need to successfully complete your task.
	Groups 1 and 2 – Scenario 1
	Groups 3 and 4 – Scenario 2
	Group Activity Notes:

-		
6	Preser	ntations



Slides	IPPS & STAR PART 3 KNOWLEDGE CHECK
8-12	Knowledge Check 1
	Which of these positions is not convered under IPPS?
	Knowledge Check 2
	Onsite observation of employees conducting inspection and verification procedures in federally inspected establishments is <u>not</u> required during an IPPS assessment.
	Knowledge Check 3
	Supervisors should not observe plant conditions during IPPS assessments since the focus of IPPS assessments are on employee actions that warrant disciplinary action.
	Knowledge Check 4
	When observing an inspector for the IPPS assessment, which of the following should you be looking for?
Slides	
Silues	SUMMART
13	Review your score on the Summary screen and notes about this topic. Make note of any areas that you need to work on.
	Please note that this score does not count toward your overall class grade. Rather, it helps you identify which areas you may need to study more in preparation for your exams. Your overall class grade only consists of the daily quizzes, midterm exam, and final exam. Any scores you receive on Knowledge Check questions or course activities are <u>not</u> counted. They are for your use only.

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Slides	LEARNING OBJECTIVES
N/A	Scientific:
	[None for this topic in this context.]
	Regulatory/Administrative:
	 Use FSIS Directive 4430.3 Revision 4 to conduct IPPS and STAR assessments.
	 Given scenarios, distinguish between on-target and off-target performance and other employee responsibilities that a PHV oversees such as NRs, MOIs, HACCP verification, etc. during IPPS assessments.
	 Create a follow-up plan to address an identified deficiency in employee knowledge or performance.

Slides	INTRODUCTION
2	IPPS and STAR Follow-Up
	What should you do if you noted any deficiencies during the assessment?
Slides	ACTIVITY 4
3	Activity 4: Phase 1 Instructions
	 Download the Activity 4 Help Tool and the questions to ask when conducting an IPPS review sheet.
	 Complete the Help Tool to use while you are conducting the IPPS/STAR review. The tool should include 4 sections:
	1. How you will prepare for an IPPS/STAR review?
	2. What is the method you will use to conduct the review?
	3. What are the questions that you will discuss with the IPP?
	4. What will be included in the follow-up plan?
	Activity Notes:

Questions to Ask When Conducting an IPPS Review

Here are sample questions to use to ensure IPP are carrying out mission critical work activities - performance elements and activities assessed, mission support, communications, individual contributions to the team.

Food Inspector: Poultry

- What are some valid reasons to stop the line?
- What actions would you take if you see trends/patterns of bruising and fractures?
- How would you communicate increased incidence of cadaver birds
- How would you record birds that you suspect are DOA?
- What are some indications of a bird that hung on the line as a DOA?
- What are some characteristics of a cadaver bird, one that was alive in the scald vat?
- You could name various conditions and ask what the regulatory disposition would be?
- Discuss localized VS generalized.
- What is a systemic disturbance?
- Why do we consider sep/tox and fecal contamination to be of public health significance
- Explain the differences between chronic and acute
- Why is it important that the establishment record birds as plant rejects when they use the US condemn barrel?
- What action would you take when you see excessive grease or contamination on several carcasses?
- Discuss the difference in poultry between GCP vs HH in livestock
- When would it be appropriate to hang a carcass back for PHV disposition?
- What action should you take if the presenter or trimmer fails to clean hands or equipment between carcasses?
- What is the purpose of AM inspection?
- Where are the typical fat deposits in a bird and what can they tell us about overall health status?
- What is the purpose of PM inspection?
- How can you maintain positive control of a condemned product?
- What are some causes for liver condemnation?
- When IPP indicate a bird needs to go to airsacculitis salvage, what must be removed?
- How should you report an unsafe working condition?
- How should you respond to increased incidence of birds presented with no viscera? (non NPIS)
- What are considered the three critical organs when making a disposition? (non NPIS)

•	How do you address improper presentation?
Food	Inspector: Livestock
•	What are some reasons to stop the line?
•	What actions would you take if you saw evidence of multiple knocks in the skull?
•	What are some reasons you might retain a carcass? Head lesions? Carcass lesions? Visceral lesions?
•	You could name various conditions and ask what the regulatory disposition would be?
•	Please explain the differences between abscesses and pyemia?
•	What is the purpose of AM inspection?
•	What is the purpose of PM inspection?
•	What is the purpose of PPE and when should they be worn?
•	Please explain the HMSA?
•	Please give some causes for liver condemnations?
•	Please discuss the significance of SRMs and their removal.
•	How would you respond to inadequate procedures at the rail out loop? e.g.
	How would you communicate inadequate sanitary dressing or process control
•	issues?
•	Depends on species: What lymph nodes do you incise on the swine head? Cattle head. Cattle pluck/lungs. What do you palpate on PM viscera?
•	Explain the importance if incising bile ducts in cattle? What are you looking for?
•	Please explain the public health significance of fecal contamination in livestock?
•	How do you address visible fecal contamination at your inspector station?
•	How do you address improper presentation?
•	What are some reasons that the line speed may be reduced?
•	Can you name any zoonotic (transmissible to humans) diseases in livestock?
•	Please give some reasons for head condemnation in livestock
•	Please give some reasons for liver and or heart condemnations in livestock.
•	What are some signs of a generalized condition?
•	What are some signs of a septicemic carcass?
•	What are some of the signs of malignant lymphoma?
•	What are some of the AM and PM signs in cattle epithelioma?
CSI:	Any establishment (can use any of above if in a slaughter establishment)
•	What are some of the HATS tasks?
•	What are the corrective action requirements for SSOP?, HACCP?
•	How would an establishment bring themselves back in compliance with an SPS
	insanitary condition?
•	Please explain the purpose of the HAV task
•	Please explain how to conduct a HACCP verification task (insert that type slaughter etc.)
•	Please explain the importance of lock out tag out.

 How would you perform and record a poultry GCP task?
 When would you document an MOI vs document NR for GCPs (poultry)
 What action would you take if you saw egregious inhumane treatment of livestock?
 Please explain the relevance of holding weekly meetings and define due
 process? Please explain what aseptic sampling technique is?
 Why is it important to check for lab capacity before shipping a sample?
 What types of regulatory control actions can be taken and when? Either give suggestions or have CSL give examples
 Does the post management control program pood to be written?
 How would you respond if the establishment is unwilling to share records related
to the food safety system?
Exports: How would you perform reinspection
Where would you look up or access country requirements
 What are some reasons that may require supervisory communication with regards to exports?
 What are the frequency and significance of conducting Food Defense tasks?
 How would you react to establishment testing or micro sampling data that show results that reflect little to no process control?
 How would you respond to a positive FSIS sample result when it is an FSIS
recognized adulterant?

5	Activity 4: Phase 2 Instructions
	Video Example Notes:
	Role-Playing Activity:
	Divide the class into pairs.
	 Choose a Help Tool and a form from the list below: IPPS FI Form IPPS CSI Form STAR Form
	• Each pair will role play conducting and documenting an IPPS/STAR review.
	Don't forget to generate a follow-up plan.
	• Once the first student has gone, reverse roles and repeat the scenario.
	Activty Notes:





Slides	IPPS & STAR PART 4 KNOWLEDGE CHECK
8-12	Knowledge Check 1
	Following an IPPS and STAR assessment, a completed IPPS or STAR assessment should be e-mailed or printed and given to the employee within two weeks.
	Knowledge Check 2
	If any deficiencies were noted during the assessment, which of the following is NOT a way to follow-up?
	Knowledge Check 3
	After performing an IPPS assessment, the supervisor should monitor which of the following?
	Knowledge Check 4
	Which of the following is NOT a way to assess performance for the IPPS or STAR assessments?
Slides	SUMMARY
Chaco	
13	Review your score on the Summary screen and notes about this topic. Make note of any areas that you need to work on.
	Please note that this score does not count toward your overall class grade. Rather, it helps you identify which areas you may need to study more in preparation for your exams. Your overall class grade only consists of the daily quizzes, midterm exam, and final exam. Any scores you receive on Knowledge Check questions or course activities are <u>not</u> counted. They are for your use only.
In-Plant Performance System (IPPS) & Supervisory Tool for Assessment Results (STAR)

Objectives

After completing this module, you will be able to:

- 1. Define IPPS and STAR.
- 2. Identify the positions covered under IPPS and STAR.
- 3. Identify the relationship between IPPS, STAR, and OFO's management control system.
- 4. Identify the number of IPPS and STAR assessments that must be performed per rating cycle.
- 5. Identify the relationship between IPPS assessments, STAR assessments, progress reviews, and performance appraisals.
- 6. List the steps for preparing for IPPS and STAR assessments.
- 7. Identify the methods of assessing performance.
- 8. Recognize the importance of feedback.

Resources

United State Department of Agriculture Regulation 4040-430 Performance Management

FSIS Directive 4430.3 In-Plant Performance System (IPPS)

In-Plant Performance System (IPPS)

Introduction

The In-Plant Performance System (IPPS) is a tool that supervisors use to assess the performance of non-supervisory in-plant inspection program personnel. IPPS covers all non-supervisory in-plant inspection program personnel including Food Inspectors, Consumer Safety Inspectors, and Public Health Veterinarians. An IPPS review is conducted by Office of Field Operations (OFO) supervisors including Frontline Supervisors, Multi-IPPS Supervisors, Supervisory Public Health Veterinarians and Supervisory Consumer Safety Officers, who rate the performance of non-supervisory in-plant program personnel. In addition, IPPS provides the opportunity for first -hand, onsite observation of how well an employee conducts FSIS inspection and verification procedures in federally inspected establishments.

FSIS' mission of protecting the health and welfare of consumers is set forth in the FMIA, PPIA, and EPIA. In-plant supervisors are responsible for ensuring that the employees under their supervision know how to adequately perform their jobs and are aware of the impact that off-target performance might have on the health and welfare of consumers.

IPPS was first implemented on October 1, 2002. FSIS Directive 4430.3 explains the IPPS procedure. In 2006, FSIS launched AssuranceNet which is used to capture IPPS assessment findings. Some of these findings feed into organizational performance measures in AssuranceNet for management control purposes.

IPPS and the Management Control System

Performance Management is a mandatory and statutory requirement for federal agencies. Every Federal agency is required to have a performance management system that identifies and sets performance expectations for all of its employees, monitors their performance via progress reviews, and rates this performance by assigning a summary level rating. Summary level ratings are expressed as Fully Successful or Unacceptable.

OFO uses IPPS as a tool to assist supervisors in assessing the employee's knowledge of their job requirements. It is designed to provide supervisors with a structured process for examining the elements of a job to identify, address, and correct areas where there is a need for performance improvement, it also allows supervisors to provide feedback to the employees. Information is also extracted from the IPPS assessment sheets for use within the OFO's management control system. Despite the fact that IPPS measures individual performance while management control is focused on organizational performance, there is a link between the two. If individuals are not properly executing mission critical functions, an organization is less likely to successfully accomplish its mission as whole.

At least two IPPS assessments should be conducted for each covered employee during the rating cycle (October 1 – September 30). The first IPPS assessment should be conducted approximately 45 – 60 days after setting the performance standards, and again between the midpoint progress review and the final rating. IPPS assessments are used in addition to progress reviews and the annual performance rating. Supervisors may conduct more

than two IPPS assessments during the rating cycle; they should do so if they cannot thoroughly assess all of the IPPS performance elements within two assessments, or if they need to follow-up on issues that were identified within previous IPPS assessments. A performance rating is not assigned or discussed during IPPS assessments.

Non-supervisory IPP performance elements include:

- 1. Mission Support (Critical);
- 2. Communications (Critical); and
- 3. Individual Contributions to the Team.

OFO managers and supervisors review IPPS assessment results and provide appropriate feedback as follows:

- The SPHV reviews 25 percent of IPPS assessments conducted by the SCSI with at least two of these reviews accomplished by direct observation.
- The FLS reviews 10 percent of IPPS assessments conducted by the SPHV and SCSI with 1 percent of these reviews accomplished by direct observation.
- The District Manager (DM) team reviews 10 percent of IPPS assessments conducted by the FLS, SPHV, or SCSI with at least 1 percent of these reviews accomplished by direct observation.
- The Executive Associate for Regulatory Operations (EARO) reviews 2 percent of IPPS assessments that have been reviewed by the DM team.

Preparing for IPPS Assessment

Preparation is an essential aspect of any IPPS assessment. Make sure that you are familiar with the processes and the FSIS verification activities that are conducted at the establishment.

- Print out two IPPS forms, so that you and the employee can both take notes during the assessment.
- Select a number of applicable elements/sub-elements to cover during the assessment and decide how much time you want to spend on the assignment and arrange for staffing, if necessary.
- Determine how employees are maintaining electronic information as required by their positions.
- Review and assess Public Health Information System (PHIS) data and reports, where applicable, to identify potential problem areas to focus on during the IPPS assessment.
- Use Directive 4430.3 Attachment-3 which addresses data Sources for IPPS preparation to prepare for the IPPS visit.

- Review all data sources to determine whether IPP responsible for maintaining the PHIS system at the plant level are keeping the establishment profile current, completing routine inspection tasks, properly entering data concerning scheduled procedures performed or not performed, and entering unscheduled procedures performed.
- Use the standard reports to determine whether trends are developing, which indicate whether the inspectors are on or off target in performing their verification duties.

Examples of data sources you can review before an IPPS visits include:

- Noncompliance records to determine whether the NRs are being written in accordance with FSIS Directive 5000.1.
- Electronic Animal Disposition Report from PHIS to determine whether the inspector or the PHV is keeping the data current and is performing the appropriate humane handling procedures. The supervisor is to review the data to see if humane handling procedures performed are covering all humane handling activities over time, and that proper times are recorded for each activity.
- Food safety assessments and enforcement actions at the establishment where the assessed employee participated in a recent food safety assessment or enforcement action. The IPPS visit can be used to determine the inspection personnel's effectiveness in carrying out the verification plan and reporting on issues identified. Review the verification plan and the inspection personnel's verification reports and provide feedback to the employee.
- Previous IPPS assessments to determine whether there are follow-up issues to cover during the visit, and to ensure that the employee has completed any remedial assigned activities prescribed at the time of the prior IPPS assessment.
- New Agency directives and notices that are relevant to the employee's assignment and position.
- Training reports to ensure that employees have successfully completed required training.

Conducting an IPPS Assessment

There are 3 methods of assessing the performance of inspection program personnel: observation, records review, and discussion. You may use one method or a combination of these. You can observe the inspection program personnel and ask questions as they conduct verification procedures, perform the procedures after the inspector to see if you get the same results, or ask questions and discuss inspection procedures. Review the documentation, reports, and correspondence in the government files. Also, be sure to discuss inspection methods, the decision-making process, documentation, and enforcement protocol with the inspection program personnel. Observe the conditions in the establishment and compare them to the noncompliance reports that were written by the employee being assessed. How you choose to gather information during the assessment is up to you. However, you should be consistent in applying standards during your visits in order to come away with a true assessment of what the employees know and how they apply that knowledge.

When conducting an IPPS assessment, verify that the employee is:

- Applying the appropriate inspection methodology, such as observing establishment employees conducting procedures, reviewing establishment records, and performing tasks;
- Utilizing effective decision-making to determine whether there is noncompliance;
- Documenting their findings appropriately, if required;
- Implementing enforcement actions properly (e.g., verification plans for suspensions and Notices of Intended Enforcement (NOIEs)), when authorized to do so; and
- Implementing regulatory control actions.

NOTE: You don't have to conduct IPPS visits at all establishments on an employee's assignment. However, you should ensure that the employee can demonstrate an understanding of the methodology relevant to the whole assignment and an ability to execute it.

Feedback: After completing an assessment, give the employee verbal feedback based on what you observed during the assessment. This should be a constructive feedback session.

Documenting an IPPS Assessment

- Complete the IPPS Assessment Form, and state whether the employee understanding of and ability to execute regulatory requirements was satisfactory (using Yes or No).
- Document positive performance briefly in the narrative boxes.
- Document any deficiency in the employee's performance in a particular element or sub element indicating that the overall employee knowledge of the job requirement is deficient.
- Include recommended actions that the employee is to take to improve her/his knowledge and execution of inspection methods (e.g., review relevant directives, review Inspection Methods training module). Monitor the follow-up items to ensure that they are accomplished.
- Provide a copy of the assessment to the employee within 2 weeks of the assessment, by either printing a hard copy for the employee or e-mailing a PDF copy.

- Keep the completed IPPS assessment forms for one year following the termination of the previous rating cycle.
- Retain electronic copies of these in an electronic folder in your work files.
- At the appropriate time, discard or delete any electronic versions of the assessment sheets from your computer.

IPPS Assessment Forms are not filed in the HRFO's Official Personnel Folder or the Employee's Performance File. You will find that your IPPS assessment files provide useful information at the end of the appraisal year. They will refresh your memory, help you to make rating decisions, and serve as a history of consistently executed assessments of employee performance. Use good judgment when combining data from the IPPS Assessment Sheets with any other information regarding employee's performance

Any issues of misconduct that are identified during an IPPS visit should be addressed with your District Office. Once the IPPS Assessment form has been completed, an electronic, read-only version or a hardcopy needs to be given to the employee within two work weeks of the assessment.

Note: If an employee's performance is unacceptable in one or more critical elements at any time during the performance appraisal cycle, follow the directions outlined in Departmental Regulation 4040-430 Performance Management.

Supervisory Tool for Assessment Results (STAR)

Introduction

The Supervisory Tool for Assessment Results (STAR) is a tool that supervisors can use to assess the knowledge and proficiency of field level supervisory personnel. It requires supervisory personnel to determine whether in-plant, subordinate supervisors carry out both program activities and supervisory responsibilities, in accordance with applicable regulatory requirements and FSIS directives and notices. STAR does not replace the Performance Management System. The positions covered by STAR include the following:

- Supervisory Public Health Veterinarians (SPHVs),
- Supervisory Consumer Safety Inspectors (SCSI), and
- Supervisory personnel stationed at HACCP- based Inspection Models Project (HIMP) establishments.

OFO executives, managers, and field-level supervisory personnel must conduct an oversight review of the STAR assessments and provide feedback on them. The minimum expectations for the review are as follows:

- The front line supervisors (FLSs) review 50 percent of the STAR assessments conducted by the SPHV.
- The district management team reviews at least one assessment per circuit performed by the FLS.
- The executive associates for regulatory operations (EAROs) review 5 percent of the district management team reviews.

Preparing for STAR Assessment

Reviewve FSIS Form 4430-11A; and Supervisory Tool for Assessment Results (STAR) Guideline for the SPHV, SPHV (HIMP), SCSI. Print FSIS Form 4430-11 to use as a worksheet during your assessment. Use the same preparation methodology you use for IPPS assessment.

Conducting STAR Assessment

OFO field-level supervisory personnel must conduct at least one, in-person assessment for each covered employee during the rating cycle. Supervisors have flexibility in deciding when to conduct the assessment and whether to assess all the elements and sub-elements during a single visit or through multiple visits over the course of the rating cycle. Some elements, such as communication can be assessed separately from the on-site visit.

Supervisors can use the record review method, the discussion method, and the observation method, either singularly or in combination, while conducting the STAR assessment.

Conduct any appropriate follow-up (for example, if an employee lacks essential knowledge of certain elements or sub-elements) and discuss the actions necessary for performance

improvements, such as training.

If an employee's performance is unacceptable in one or more critical elements at any time during the performance appraisal cycle, follow the directions outlined in Departmental Regulation 4040-430 Performance Management. Any misconduct issues identified during the STAR visit should be addressed with the district office.

Documenting STAR Assessment

Give verbal feedback to the employee upon completing the assessment. Document your assessment in AssuranceNet. Provide the employee with a read- only electronic copy, or a hardcopy of the document within two work weeks of the assessment.

Workshop 1

1. IPPS is a tool that ______use to assess the performance of ______in-plant inspection program personnel.

2. A minimum of how many IPPS assessments must be performed per rating cycle?

3. A minimum of how many STAR assessments must be performed per rating cycle?

4. What are the three methods of assessing performance?

5. IPPS and STAR assessments will replace progress reviews and performance appraisals

- a. True
- b. False

6. Which of these positions is not covered under IPPS?

- a. Food Inspectors
- b. Public Health Veterinarians
- c. Consumer Safety Inspectors
- d. Supervisory Public Health Veterinarians

7. Following an IPPS and STAR assessment, a completed IPPS or STAR assessment sheet should be mailed to the employee within two months.

- a. True
- b. False

Workshop 2

Use the information below to complete the IPPS Assessment Sheet for Inspector Lynda Smith

Date: December 1, 2014 District Name: AtlantaBoulder District Code: 0011 Circuit Name: Anywhere Circuit Code: 01 Name of Supervisor: Dr. Thomas Williams

You are a new SPHV performing your first IPPS assessment of Food Inspector Lynda Smith. You have already set the performance standards by discussing the pre-selected performance elements in early July. You review the IPPS Assessment Sheet for Food Inspectors and select the performance elements and sub-elements that will be covered during the assessment. You select the sub-elements under Mission Support and Communications, and you decide to spend four hours at Lynda's assignment.

After reviewing the IPPS tools, you identify questions to discuss and activities to conduct from the Food Inspector Supervisory Guide. You develop a draft plan and an outline for the visit which will include observation and discussion. You arrange staffing for the IPPS Assessment.

You observe Lynda performing postmortem inspection procedures at her inspection station. She uses appropriate inspection procedures for the Streamlined Inspection System (SIS). She instructs the inspector helper (trimmer) to remove carcasses with improper presentation from the line and to retain them, but fails to notify the off-line inspection program personnel when improper presentation occurs with unacceptable regularity. She retains a carcass and viscera with a large mass in the abdominal cavity on the designated shackle for veterinary disposition. When you ask her why she retained the carcass, she states that she retained it because the carcass also appeared to be emaciated.

You ask Lynda the three disposition options during postmortem inspection. She responds appropriately. You evaluate Lynda's decision-making process by asking her questions regarding pathology and postmortem dispositions. While you are observing Lynda, you also notice that she is not identifying and condemning any cadavers. She is allowing her helper to identify cadavers and to make the dispositions. You ask her why she is allowing her helper to identify and condemn cadavers. She explains that, since she has difficulty identifying cadavers, she allows her helper to make that call. You discuss the disposition criteria for cadavers with her. Also, you discuss the differences between Lynda's role and the inspector helper's role during postmortem inspection.

Next, you decide to perform a correlation with her on the carcasses in her condemn can. As you examine the condemned carcasses and parts, you ask questions that help you to evaluate her thoughts and decision making process. Out of the twenty carcasses in her can, there are six without cause for condemnation. When you question her about why these were condemned, Lynda states that she condemned these carcasses for septicemia/toxemia because they appeared to be very thin. You review the condemnation criteria for septicemia/toxemia with her.

It is now time for Lynda to take a company break. Since off-line inspection personnel are not in the evisceration department, Lynda ensures that the denaturant is placed on the carcasses in her condemn can before leaving her station.

Following company break, Lynda returns to her inspection station. As part of her on-line postmortem inspection duties, she verifies the removal of the contaminated carcasses and those parts with visible fecal contamination. Although she handles the contaminated carcasses and parts correctly, she fails to notify the off-line inspection personnel when contamination occurs with unacceptable regularity.

You and Lynda go to the USDA office to discuss the assessment. You tell her that you are pleased with her knowledge of the inspection procedures of the SIS inspection system. Although you are pleased overall with her postmortem dispositions as well, you add that you are concerned about her ability to identify cadavers and carcasses with septicemia/toxemia. You tell her that she should retain carcasses for you when she is uncertain about the disposition, and that she should never allow her helper to make dispositions for her. You also discuss the relationship between her role and the helper's.

You point out the importance of notifying off-line inspection personnel when trends are detected such as multiple carcasses and parts with fecal contamination or presentation issues. You ask her to give you some examples of situations in which she needs to communicate information immediately to the off-line inspectors or to her supervisor. She answers correctly. To assess Lynda's knowledge of poultry good commercial practice, you ask her to give you some examples of bird mistreatment and the actions that should be taken in response to each, she again answers correctly.

You commit to performing weekly pathology correlations with her for the next month. During your discussion, you discover that she has not attended the Poultry Slaughter Inspection Training course. You contact the district office and make arrangements to enroll her in the next session of it. You tell Lynda that she will receive her completed IPPS assessment within two work weeks.

September Finish conducting IPPS reviews.	October Meet with employee to discuss performance rating and sign form	November Beginning November through March conduct at least one IPPS review for each of your employees *	December Continue conducting at least one IPPS review for each of your employees. *
using IPPS data and other data/information related to performance. Send tentative ratings to reviewer for signature.	Discuss performance plan for new rating cycle, set performance standards, and sign form.	your employees.	
January Continue conducting at least one IPPS review for each of your employees and any follow up IPPS reviews you have determined are necessary. *	February Continue conducting at least one IPPS review for each of your employees and any follow up IPPS reviews you have determined are necessary. *	March Beginning March 1 and continuting through March 31, conduct performance appraisal progress review to give feedback on performance. Do not assign a numerical or summary level rating.	April Beginning April through September conduct at least one more IPPS review for each of your employees. *
May Continue conducting at least one more IPPS review for each of your employees.	June Continue conducting at least one more IPPS review for each of your employees and perform any follow up IPPS reviews you have determined are necessary. *	July Continue conducting at least one more IPPS review for each of your employees and perform any follow up IPPS reviews you have determined are necessary. *	August Continue conducting at least one more IPPS review for each of your employees and perform any follow up IPPS reviews you have determined are necessary. *

*A minimum of 2 IPPS reviews per employee is required within the one year rating cycle. This schedule suggests that one be scheduled between the beginning of the rating cycle and the mid-cycle progress review, and that the second be scheduled between the mid-cycle progress review and the final appraisal.

						NFORMATION		
UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE			Name c	f Emplo	yee		Assessment Number	
		RE	Assess	ment Da	ate			<u> </u>
IPPS			District			District Code		
Food Inspector – S	Slaughte	r	Circuit				Circuit Code	
			Name c	f Super	visor			
II. REVIEW								
Method of Assessment: R – Records	Review, D – Di	iscussi	on, O -	Obser	vation			
		M As	Method of ssessment		Follow		Findings	
Element Assess	Assessed	R	D O	Up		Findings		
Mission Support								
 Performs AM Inspection a. Id and holds suspects PHV disposition 								
 Performs PM Inspection a. Identifies abnormal conditions 								
b. Rejects, condemns or hold suspects for examination by PHV								

3. Identifies and/or tag carcasses requiring further action by plant personnel			
4. Assures condemned products are disposed of in accordance with regulations			

5. Monitors operational sanitation to ensure sanitary handling and dressing procedures are in accordance with regulations				
6. Monitors slaughter activities in conformance with humane handling regulations and procedures and/or good commercial practices.				

Communications

1. Keeps supervisor informed of critical issues in accordance with established protocols			
2. Communicates with responsible program personnel and on line activities, plant employee actions, or facilities/equipment conditions			
3. Communicates with plant employees regarding line activities, Agency policy and procedures			
4. Completes administrative reports and maintains records and files as required			

IV. ADDITIONAL COMMENTS

V. REVIEWER 1 INFORMATION

Reviewer 1

Have you reviewed this IPPS Assessment?

Have you reviewed this IPPS Assessment by Observation?

VI. REVIEWER 2 INFORMATION

Reviewer 2

Have you reviewed this IPPS Assessment?

Have you reviewed this IPPS Assessment by Observation?

VII. REVIEWER 3 INFORMATION

Reviewer 3

Have you reviewed this IPPS Assessment?

Have you reviewed this IPPS Assessment by Observation?

VIII. REVIEWER 4 INFORMATION

Reviewer 4

Have you reviewed this IPPS Assessment?

Have you reviewed this IPPS Assessment by Observation?

IX. FEEDBACK REVIEW INFORMATION

Feedback

UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON. DC

FSIS DIRECTIVE

4430.3 Revision 4

1/6/16

IN-PLANT PERFORMANCE SYSTEM (IPPS)

I. PURPOSE

This directive provides revised procedures for supervisors in the Office of Field Operations (OFO) who conduct, document, and report on IPPS assessments. FSIS has revised this directive in its entirety.

KEY POINTS

- Introduces a revised IPPS Assessment Form
- Introduces new guidance on conducting an IPPS
- Merges content from the IPPS Supervisory Guide •

II. CANCELLATION

FSIS Directive 4430.3, Revision 3, In-Plant Performance System (IPPS), 9/11/12

III. BACKGROUND

A. IPPS provides a firsthand, onsite observation of how well employees conduct FSIS inspection and verification procedures in federally-inspected establishments. In addition, IPPS assesses employees' demonstrated knowledge of job requirements, appropriate regulatory decision-making, and ability to execute inspection and verification procedures.

B. This directive is to be followed by OFO supervisors who rate the performance of non-supervisory inplant inspection program personnel (IPP). In-plant inspection positions that are subject to IPPS assessments are identified in Attachment 1. The supervisory positions that are required to conduct IPPS assessments include:

- 1. Front-line Supervisors (FLS)
- 2. Multi-IPPS Supervisors
- 3. Supervisory Public Health Veterinarians (SPHV)
- 4. Supervisory Consumer Safety Inspectors (SCSI)

DISTRIBUTION: Electronic; All Field Employees

OPI: OPPD

C. IPPS is a tool that supervisors use to assess the work of non-supervisory in-plant inspection program personnel (IPP). IPPS includes the following benefits:

- 1. Encourages effective communication between supervisors and their subordinates;
- 2. Identifies and addresses the need to improve employees' knowledge of their job requirements;
- 3. Encourages correlation with employees to ensure consistency in inspection methods and applications;
- 4. Recognizes on-target or noteworthy employee performance;
- 5. Assists in measuring organizational performance through OFO's performance standards; and
- 6. Links IPPS assessment results and work unit meeting topics to address common or group needs that are discovered during IPPS visits (**example**: matters on which supervisors find misunderstandings or lack of program execution among multiple inspection personnel).

IV. GENERAL SUPERVISORY RESPONSIBILITIES

A. Supervisors are to conduct at least two IPPS assessments for employees covered by IPPS during the performance rating cycle. Typically, the first IPPS assessment is conducted between setting performance standards and the midyear progress review. The second IPPS assessment is usually conducted between the midyear progress review and the completion of the annual performance rating.

EXCEPTION: If an employee is supervised for part of the year, it may not be feasible for a supervisor to conduct two assessments before the close of the rating cycle.

B. Supervisors can conduct more than two IPPS assessments during the rating year and are to do so if they cannot thoroughly assess all of the elements and sub-elements over two assessments, or if they have a need to follow up on issues identified in previous IPPS assessments.

C. Supervisors are to ensure that IPP are reporting inspection results in accordance with Agency regulatory requirements, policies, and procedures.

V. OVERSIGHT AND MANAGEMENT CONTROLS

A. OFO has established a management control system that provides multi-layered, in-depth management oversight of the public health and management activities carried out by IPP. The management control system also provides OFO with the capability to demonstrate and verify its effectiveness in protecting the public health by achieving and maintaining specific levels of performance in its daily food safety, food defense, and management and supervisory operations.

B. To carry out this oversight, OFO managers and supervisors review IPPS assessment results and provide appropriate feedback as follows:

- 1. The SPHV reviews 25 percent of IPPS assessments conducted by the SCSI with at least two of these reviews accomplished by direct observation.
- 2. The FLS reviews 10 percent of IPPS assessments conducted by the SPHV and SCSI with 1 percent of these reviews accomplished by direct observation.

- The District Manager (DM) team reviews 10 percent of IPPS assessments conducted by the FLS, SPHV, or SCSI with at least 1 percent of these reviews accomplished by direct observation.
- 4. The Executive Associate for Regulatory Operations (EARO) reviews 2 percent of IPPS assessments that have been reviewed by the DM team.

VI. IPPS AND THE PERFORMANCE MANAGEMENT SYSTEM

A. IPPS does not replace the Agency's performance management system. OFO uses IPPS, which applies to non-supervisory in-plant occupations, to assess employees' knowledge of their job requirements. IPPS:

- 1. Is designed to provide supervisors with a structured process to look at specific elements of the job;
- 2. Is used to provide feedback to employees to identify, address, and correct areas where there is a need for improvement in performance; and
- 3. Does not provide or assign a performance rating. Therefore, IPPS data can be used, along with other data and information about an employee's performance, to determine the performance rating.

B. Performance management is mandated by 5 U.S.C. Chapter 43 and is a statutory requirement for Federal agencies. Every Federal agency is required to have a performance management system under which supervisors identify and set performance expectations and monitor performance. FSIS monitors performance by way of a midyear progress review and rates performance annually by assigning a summary level rating. Summary level ratings are expressed as Fully Successful or Unacceptable.

C. Supervisors are to use their judgment when combining data from IPPS assessments that are completed during the rating period and other information regarding an employee's performance. The performance rating is to reflect the employee's performance for the entire rating cycle.

D. The IPPS Assessment Form does not replace any existing performance appraisal processes or FSIS forms. Supervisors are to continue to use AD-435E and the PRT to set performance expectations, conduct progress reviews, and rate employees annually on their performance.

VII. TIMEFRAMES FOR CONDUCTING REQUIRED IPPS ASSESSMENTS

A. Supervisors, at their discretion, may conduct more than two IPPS assessments during the rating year. Supervisors are encouraged to do so if they cannot thoroughly assess all the performance elements over two assessments, or if they need to follow up on issues identified in previous IPPS assessments.

- B. For guidance purposes, the following are the general timeframes:
 - 1. October 1 through October 30. Issue new performance standards for the beginning of the rating cycle, sign and date Blocks 12 and 13 of FSIS Form 4430-10.
 - 2. **November 1 through February 28**. Conduct the first IPPS assessment and document results on the IPPS Assessment Form (See section IX. for the form's availability).
 - 3. March 1 through March 31. Conduct the midyear progress review, sign and date Block 15 on FSIS Form 4430-10.

- 4. **April 1 through September 30**. Conduct the second IPPS assessment and document results on the IPPS Assessment Form.
- 5. October 1 through October 30. Complete the annual performance rating at the end of the appraisal cycle and sign Blocks 19 and 20 on FSIS Form 4430-10.

VIII. IPPS ASSESSMENT PROCESS

A. When conducting IPPS assessments, supervisors are engaged in fulfilling their critical **Supervision** performance element. In addition, supervisors are to fulfill requirements related to the critical **Mission Support** performance element, as IPPS is a means by which supervisors ensure inspection personnel are carrying out their critical mission-related work activities. To receive a Fully Successful rating in these critical elements, supervisors are to successfully fulfill their responsibilities related to the IPPS.

B. The supervisor plays a key role in ensuring that:

- 1. Decisions made by IPP are uniform, consistent, and in accordance with applicable statutes, regulations, issuances, and other Agency policies; and
- 2. Duties performed by IPP are in accordance with prescribed inspection methods and procedures.

C. Supervisors also are to ensure that IPP are applying the appropriate inspection methods, using effective regulatory decision-making, documenting findings appropriately, and implementing regulatory enforcement actions properly.

IX. ASSESSMENT CRITERIA

A. OFO supervisory personnel are to use the following steps to assess non-supervisory IPP knowledge of their job requirements.

B. **Assess the Performance Elements**. The performance elements and activities are tailored to non-supervisory in-plant inspection program occupations. The performance elements include:

- 1. Mission Support (Critical);
- 2. Communications (Critical); and
- 3. Individual Contributions to the Team.

C. **Plan and Prepare for IPPS Assessment**. Preparation is an important aspect of any IPPS assessment. Before conducting the IPPS assessment, the supervisor is to:

1. Select a sufficient number of elements (and their sub-elements) on the IPPS Form to cover during the IPPS assessment to ensure that all applicable elements are covered for the positions before the end of the annual rating period.

NOTE: Make sure the mandatory critical mission support and other critical elements are covered first.

2. Determine how employees are maintaining electronic information as required by their positions.

- 3. Review and assess Public Health Information System (PHIS) data and reports, where applicable, to identify potential problem areas to focus on during the IPPS assessment. Attachment 3 outlines PHIS reports and other data sources supervisors can use to prepare for an IPPS visit. Supervisors are to also review these data sources to determine whether IPP responsible for maintaining the PHIS system at the plant level are keeping the establishment profile current, completing routine inspection tasks, properly entering data concerning scheduled procedures performed or not performed, and entering unscheduled procedures performed. This data review will give the supervisor insight into the decisions that the inspector makes regarding which procedures to perform and at what frequency. The supervisor can use the standard reports to determine whether trends are developing, which indicate whether the inspectors are on or off target in performing their verification duties. Examples of data sources supervisors are to review before an IPPS visits include:
 - a. Review noncompliance records to determine whether the NRs are being written in accordance with FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System*.
 - b. Use the electronic Animal Disposition Report from PHIS to determine whether the inspector or the PHV is keeping the data current and is performing the appropriate humane handling procedures. The supervisor is to review the data to see if humane handling procedures performed are covering all humane handling activities over time, and that proper times are recorded for each activity.
 - c. Review food safety assessments and enforcement actions at the establishment where the assessed employee participated in a recent food safety assessment or enforcement action. The IPPS visit can be used to determine the inspection personnel's effectiveness in carrying out the verification plan and reporting on issues identified. The supervisor is to also review the verification plan and the inspection personnel's verification reports and provide feedback to the employee.
- 4. Review feedback from previous IPPS assessments to determine whether there are follow-up issues to cover during the visit. When a follow-up is required, supervisors are to make sure that the employee has completed the remedial assigned activities prescribed at the time of the prior IPPS assessment. Supervisors are to also reassess the elements and sub-elements on which follow-up was indicated.
- 5. Identify new Agency directives and notices that are relevant to the employee's assignment and position. In addition, supervisors are to use the IPPS assessment as an opportunity to ensure that the employee has followed the instructions in the new directive or notice, as required, including ensuring that any required Memoranda of Interview are in place for required awareness meetings with establishment management, and that there is adherence to any verification procedures or other instructions provided in the issuance.
- 6. Ensure that employees have successfully completed required training (**examples**: on-thejob training or formal training courses). Training reports are available through AgLearn at <u>http://www.aglearn.usda.gov/</u>. District office personnel can provide supervisors with training reports and information upon request.

D. When completing the IPPS Assessment Form, a supervisor is to document very briefly how she/he prepared for the IPPS visit, including information on the data sources that he/she used.

X. METHODS FOR CONDUCTING AN IPPS ASSESSMENT

A. In general, supervisors are to use the following methods singularly or in combination when conducting IPPS assessments:

- 1. Observe the employee performing verification tasks;
- 2. Review documentation, reports, and correspondence in the government files;
- 3. Observe plant conditions and compare them to inspection results and noncompliance records on file; and
- 4. Ask questions about inspection methods, regulatory decisionmaking, documentation, and enforcement procedures (e.g., types of regulatory control actions that can be taken and when; due process) to the Agency employee as he/she performs inspection verification activities. Provide hypothetical situations or scenarios to get the employee to describe what she/he would do in response to the situation.

B. Supervisors are to properly plan, prepare, and execute the plan to document an effective IPPS assessment.

NOTE: A supervisor does not have to conduct IPPS visits at all establishments on an employee's assignment. However, the supervisor is to ensure that the employee can demonstrate an understanding of the methodology relevant to the whole assignment and an ability to execute it.

C. When conducting an IPPS assessment, a supervisor is to verify that the employee is:

- 1. Applying the appropriate inspection methodology, such as observing establishment employees conducting procedures, reviewing establishment records, and performing tasks;
- 2. Utilizing effective decisionmaking to determine whether there is noncompliance;
- 3. Documenting their findings appropriately, if required;
- 4. Implementing enforcement actions properly (e.g., verification plans for suspensions and Notices of Intended Enforcement (NOIEs)), when authorized to do so; and
- 5. Implementing regulatory control actions.

D. The supervisors is to meet with the employee at the end of the assessment and provide verbal feedback on performance.

E. The supervisors is to complete the IPPS Assessment Form. The supervisor is to state whether the employee's understanding and ability to execute regulatory requirements was satisfactory using Yes or No. A supervisor can document positive performance briefly in the narrative boxes. If the supervisor finds that performance of a sub-element is unsatisfactory, he/she is to clearly describe the deficiencies observed and discussed in documentation that is within the character limit allotted for the narrative boxes (2000 characters).

F. The supervisor is to provide a copy of the assessment to the employee within 2 weeks of the assessment, by either printing a hard copy for the employee or emailing a PDF copy.

G. When applicable, a supervisor's findings are to also include recommended actions that the employee is to take to improve her/his knowledge and execution of inspection methods (e.g., review relevant directives, review Inspection Methods training module) and a timeframe

for completing the action.

H. The supervisor is to follow the directions outlined in <u>DR-4040-430</u>, *Performance Management*, when an employee's performance is unacceptable in one or more critical elements at any time during the performance appraisal cycle.

I. The supervisor is to contact the appropriate district office for further guidance if misconduct issues are identified during the IPPS visit.

J. The supervisor is to monitor follow-up items to ensure that they are accomplished.

K. The supervisor is to follow up on any sub-elements for which performance was found to be unsatisfactory during the next IPPS assessment.

XI. IPPS ASSESSMENT FORM AND MAINTENANCE

A. A supervisor can download the fillable PDF IPPS Assessment Form or the Word format IPPS Assessment Form (see example in Attachment 2) via InsideFSIS at: <u>OFO Resources</u> (Level 2 eAuthentication is needed to access this page).

B. This Directive will be revised and reissued with new instructions once new storing and tracking methods for the IPPS are implemented.

NOTE: IPPS Assessment Forms are not filed in the Human Resource Operation's official personnel folder or the employee's performance file.

XII. QUESTIONS

Refer questions on conducting IPPS assessments to the appropriate District Office.

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Assistant Administrator Office of Policy and Program Development

POSITIONS COVERED BY IPPS – ATTACHMENT 1

Food Inspector Consumer Safety Inspector Supervisory Consumer Safety Inspector Public Health Veterinarian (VMO)

NOTE: Depending whether or not the position has supervision as a part of the assignment, the position may be subject to IPPS or responsible for conducting IPPS assessments.

IPPS ASSESSMENT FORM – ATTACHMENT 2

IPPS ASSESSMENT FORM

Name of Employee		Name of Supervisor			
Position Title	Assessment Nur	nber	Assessment Date		
District		Circuit			
How did you prepare for this IPPS?	•				
	MISSION	SUPPORT			
SPS/SSOP		Satisfactory? (Yes/No/NA)	Comments:		
Assess understanding of metho	odology:				
1. Employee is verifying compli	iance with SPS				
and SSOP regulatory requir	ements in				
accordance with 9 CFR 416	.1 – 416.17,				
Directive 5000.1., 5300.1, F	SIS Directive				
5030.1 and FSIS Directive 5	030.2.				
Assess execution of inspection	methodology:				
1. Employee is familiar with the	ne				
establishment's written SSC	OPs.				
a. Verifies establishm	ent is				
implementing and	maintaining				
SSOPs	6				
b Based on findings i	is able to				
determine if establ	ishment is				
implementing proc	oduros in				
proventing incenits	euures III				
	Igs III PHIS.				
c. If noncompliance is	s tound, takes				
appropriate regula	tory control				
action and docume	ents				
noncompliance in F	PHIS.				
2. Employee is familiar with th	ne				
establishment's pest contro	ol procedures.				
a. Verifies establishm	ent is				
implementing proc	edures to				
control pest and ro	dents in				
meeting the require	ements of 9				
CFR 416.2(a).					
b. Based on findings, i	is able to				
determine if the es	tablishment is				
preventing pest and	d rodents.				
c. If noncompliance is	s found, takes				
appropriate regulat	tory control		31		

action and documents		
noncompliance in PHIS.		
3. The employee is familiar with other SPS		
equipment utensils senitary operations		
and employee bygiene		
a ls able to determine insanitary		
conditions under the SPS		
regulations		
b. Based on findings, is able to		
determine if establishment is		
preventing insanitary conditions.		
c. If noncompliance is found, takes		
appropriate regulatory control		
action and documents		
noncompliance in PHIS.		
4. Employee maintains establishment profile		
to ensure proper SPS/SSOP tasks assigned.		
НАССР	Satisfactory? (Yes/No/NA)	Comments:
Assess understanding of methodology:		
1. Employee verifies compliance with HACCP		
regulations in accordance with Directive		
5000.1., 5300.1 and 9 CFR 417.1 – 417.8.		
Assess employee is executing the inspection		
methodology (FSIS Directive 5000.1):		
1. Is familiar with establishment's hazard		
analysis and any prerequisite programs.		
a. Verifies establishment is		
implementing all elements of		
HACCP system.		
I. Hazaru analysis		
iii. Monitoring of critical		
control points		
iv Record keeping		
v Corrective actions		
vi. Verification		
vii. Validation		
b. Based on findings, is able to		
determine compliance and		
consider broader implications of		
findings to the establishment's		
food safety system.		
c. If noncompliance is found, takes		
appropriate regulatory control		
action and documents		
noncompliance in PHIS.		
2. Is maintaining establishment profile to		
ensure proper HACCP tasks are assigned.		
		010

Food Defense	Satisfactory? (Yes/No/NA)	Comments:
Assess understanding of methodology:		
1. The employee is knowledgeable of		
applicable directives and notices.		
Assess employee is executing the inspection		
methodology (FSIS Directive 5420.1):		
1. Is verifying the establishment has a		
functional food defense plan in		
accordance with Directive 5420.1.		
2. Is documenting indings in Phis.	Satisfactory2	Commonto
Samping	(Yes/No/NA)	comments.
Assess understanding of sampling		
methodology:		
1. Is knowledgeable of applicable sampling		
projects in establishment.		
2. Understands sampling methodology for		
applicable projects as outlined in FSIS		
Directives and Notices.		
Assess employee is executing sampling		
1 Is performing sampling collection methods		
in accordance with directives applicable to		
assignment		
2 Appropriately reacts to positive sampling		
results		
3. Documenting all sampling in PHIS.		
including scheduling.		
4. Prepares and maintains reports (egg		
products).		
5. Is maintaining establishment profile to		
ensure proper sampling projects are		
assigned.		
AM/PM Duties	Satisfactory?	Comments:
	(Yes/NO/NA)	
Assess understanding of methodology:		
1. Employee understands applicable statutes,		
Access employee is executing Ante mortem		
inspection methodology (Directives 6100.1.8)		
6100 3)·		
1 Performs ante-mortem inspection		
appropriate for species.		
a. Based on findings, makes		
appropriate regulatory		
determinations. If applicable, is		
documenting ante-mortem		
findings in PHIS.		
b. Takes appropriate regulatory		
control of suspects and condemns.		319

	1	
c. If noncompliance is found,		
Assess employee is executing Post-mortem		
Inspection methodology (FSIS Directive		
6100.2, FSIS DIrective 6100.3, & FSIS Directive		
5300.1):		
1. Performs post-mortem inspection		
appropriate for species.		
a. Based on findings, makes		
appropriate regulatory		
determinations. If applicable, is		
documenting post-mortem		
findings in PHIS.		
b. Takes appropriate regulatory		
control action of carcasses		
needing vet dispositions.		
c. Takes appropriate regulatory		
control action of condemned		
carcasses.		
d. If noncompliance is found,		
documents in PHIS.		
2. Maintains establishment profile to ensure		
proper documentation within PHIS/ADR.		
Humane Handling	Satisfactory?	Comments:
	(Yes/No/NA)	
Assess understanding of methodology:		
1. Employee is knowledgeable of applicable		
statutes, regulations, directives and		
notices.		
Assess employee is executing inspection		
methodology (FSIS Directive 6900.2):		
1. Ensures establishment slaughter activities		
conform to humane handling regulations		
and procedures and/or GCPs.		
a. Takes appropriate regulatory		
control action when applicable.		
b. Documents noncompliances and		
humane handling activities in PHIS		
Egg Products	Satisfactory?	Comments:
	(Yes/No/NA)	
Assess understanding of methodology:		
1. Employee is knowledgeable of applicable		
statutes, regulations, directives and		
notices.		
Assess employee is executing inspection		
methodology (FSIS Directive 5030.1, FSIS		
Directive 5040. D:		
1 Conducts egg product inspection to assure		
1. Conducts egg product inspection to assure		
1. Conducts egg product inspection to assure products are in full compliance with regulations (other than SPS).		320

 Monitors the shipping and receiving of tanker egg products. 		
Economic Adulteration and Labeling Verification	Satisfactory? (Yes/No/NA)	Comments:
Assess understanding of methodology: 1. Employee is knowledgeable of applicable statutes, regulations, directives and notices.		
 Assess employee is executing inspection methodology (FSIS Directives 7000.1, 7230.1, 7221.1, 9900.5): 1. Ensures establishment or inspected lot (for imports) is meeting regulatory labeling requirements and product standards. a. Based on findings, is able to determine if establishment or inspected lot is in compliance. 2. In situations of noncompliance, takes 		
appropriate regulatory control action and documents in PHIS.	Satisfactory	Commontei
export	(Yes/No/NA)	comments:
 Assess understanding of methodology: Employee is knowledgeable of applicable statutes, regulations, directives and notices. Assess execution of Export Certification methodology (FSIS Directive 9000.1): Employee performs product re-inspection. Checks for recordkeeping and documentation for eligible country requirements, completion of certificates, labels and any other applicable forms 		
Import Inspection	Satisfactory? (Yes/No/NA)	Comments:
 Assess understanding of methodology: 1. Employee is knowledgeable of applicable statutes, regulations, directives and notices. 		
Assess employee is executing Import Inspection methodology (Directive 9900.1): 1. Performs product re-inspection. a. Monitors incoming shipment to ensure presentation of the lot. b. Appropriately controls Failure to Present (FTP) lots. c. Verifies required forms on presented lots.		
d. Makes appropriate determinations		321

	 whether the lot is passed or rejected. e. Appropriately marks inspected lots "inspected and passed" or "refused entry." f. Appropriately controls lots marked "refused entry." g. Appropriately performs TOI and documents verification results in PHIS. 		
	СОММИ	NICATION	
		Satisfactory? (Yes/No)	Comments:
1.	Employee affords industry due process in		
	accordance with 9 CFR 500.		
2.	Keeps supervisor informed in a timely		
	manner and in accordance with protocols.		
3.	Meets Agency standards for		
	professionalism.		
4.	Works cooperatively with other agency		
_	teams and organizations.		
5.	Makes regulatory decisions in a non-		
6	discriminatory and impartial manner.		
6.	Employee reinspecting imported lots		
	communicate with plant management as		
7	Holds weekly meetings with establishment		
/.	management to discuss pertinent topics in		
	accordance with Directive 5010.1.		

DATA SOURCES FOR IPPS PREPARATION – ATTACHMENT 3

Below is a chart outlining the reports and other data sources, organized by subelements, you can use to prepare for an IPPS visit.

Sub-Element	PHIS Reports	Data in PHIS
SPS/SSOP	Noncompliance Records for an Establishment	Establishment Profile Inspection
	Task Summary and List for an Establishment	Verification Results
	Tasks Regulation Verified and Noncompliant Summary for an Establishment	
	PHR Noncompliances for an Establishment	
НАССР	HACCP Sets for an Establishment	Establishment Profile
	Noncompliance Records for an Establishment	Inspection Verification Results
	Task Summary and List for an Establishment	
	Tasks Regulation Verified and Noncompliant Summary for an Establishment	
	PHR Noncompliances for an Establishment	
Food Defense	Task Summary and List of an Establishment	Inspection Verification Results
Sampling	In-Plant Residue Sampling Results for an Establishment	Establishment Profile
	Task Summary and List for an	Verification Results

	Establishment	
	Sample Collection Status for an Establishment	
	Sampling Form Results for an Establishment	
	Sampling Results for an Establishment	
	Sampling Schedule History for an Establishment	
	Sampling Schedule History with Results for an Establishment	
	Positive Sampling Results: HACCP	
AM/PM Duties	Pending Dispositions for an Establishment	Establishment Profile
	Noncompliance Records for an Establishment	Animal Disposition Reporting
	Missing Poultry Weights for an Establishment	Disposition Records
	Slaughter Daily Totals Worksheet for an Establishment	
	Slaughter Zero Head Count for an Establishment	
Humane Handling	HATS Detail and Summary for an Establishment	Inspection Verification Results
	Noncompliance Records for an Establishment	
	Task Summary and List for an Establishment	
	MOIs for Good Commercial Practice and Humane Handling for a District	
--	--	------------------------------------
	Good Commercial Practice Validation for an Establishment	
	HATS Validation Report for an Establishment	
Export	MOIs for an Establishment	
Economic Adulteration and Labeling Verification	Noncompliance Records for an Establishment Task Summary and List for an Establishment Tasks Regulation Verified and Noncompliant Summary for an Establishment PHR Noncompliances for an Establishment	Inspection Verification Results

SUPERVISORY TOOL FOR ASSESSMENT RESULTS (STAR) GUIDANCE

Responsibilities

Office of Field Operations (OFO) field-level supervisory personnel play a key role in assuring that the decisions made and the duties carried out by in-plant field-level supervisory personnel are uniform, consistent, and in accordance with applicable statutes, regulations, issuances, and other Agency policy. This guidance outlines OFO field-level supervisors' role regarding the STAR assessment and provides instructions for carrying out the assessment.

When conducting an STAR assessment, OFO field-level supervisory personnel are engaged in fulfilling the critical **Supervision** performance element. In addition, OFO field-level supervisory personnel are also fulfilling requirements related to the critical **Mission Support** performance element in the STAR, by ensuring that in-plant field-level supervisory personnel are carrying out their critical mission-related work activities. For in-plant field-level supervisory personnel to be successful in these critical elements, they must successfully fulfill their responsibilities related to the STAR.

Performance Elements

The following performance elements outline requirements that OFO field-level supervisory personnel use to assess the in-plant field-level supervisors' knowledge of job requirements and their competency in the program and supervisory activities. When conducting the STAR assessment, the supervisor must address each performance element and sub-element during the rating cycle.

Each in-plant field-level supervisory personnel's performance standards consist of a performance element, standard (description of the Fully Successful level), and the performance goals and measures that OFO field-level supervisory personnel must consider when performing a STAR assessment.

OFO field-level supervisory personnel must:

- Consider existing circumstances and situations and use judgment in selecting appropriate elements and sub-elements when assessing the supervisory employee's competency. If an activity described herein is not one required to be performed by the subordinate supervisor, do not use the guidance associated with it to plan and conduct the STAR assessment. Only use the elements and sub-elements that apply.
- Use the FSIS Form 4430-11A, Supervisory Tool for Assessment Results (STAR) Guideline for the SPHV, SPHV (HIMP), SCSI as a worksheet to record notes.
- Review in-plant records, electronic data, samples of written responses, e-mail instructions, and information requests to ensure accuracy, thoroughness, consistency, and timeliness.
- Ask questions and discuss observations of in-plant field-level supervisors' competence emphasizing strengths, weaknesses, and the need for improvement. **NOTE**: OFO field-level supervisory personnel may ask the in-plant, subordinate supervisor to demonstrate knowledge of job requirement by performing a specific activity while the supervisor observes.
- Provide feedback and note any on-target, off-target, and noteworthy performance on the FSIS Form 4430-11, Supervisory Tool For Assessment Results (STAR) Form For SPHV, SPHV (HIMP), SCSI. OFO field-level supervisory personnel comments must be clear, concise, and describe what was reviewed, discussed, or observed.
- Identify and reach an agreement on what in-plant field supervisory personnel should work on and address all areas that require improvement in work performance.

FSIS Form 4430-11A consists of providing a checklist to help OFO field-level supervisors pinpoint specific areas to cover and a section to record notes and observations during the assessment. Although the checklist is not all inclusive, the information provided is intended to stimulate questions, observations, and discussions with the subordinate supervisors about their knowledge of the job requirements, and provide assistance in conducting and completing the assessment. The notes taken by the supervisor during the assessment are summarized and transferred to FSIS Form 4430-11.

FSIS Form 4430-11A is available in the electronic public folder and can be accessed at Outlook Public Folders/All Public Folders/Agency Issuances/Forms/FSIS 4,000 Series.

Conducting a STAR assessment

OFO field-level supervisory personnel must conduct at least one, in-person assessment for each covered employee during the rating cycle. All elements and subelements must be assessed during the rating cycle. Supervisors have flexibility in determining when to conduct the assessment and whether to assess all elements and sub-elements during one visit or multiple visits over the course of the rating cycle. (**NOTE**: Some elements are assessed separate from the onsite visit. The majority of mission support elements must be reviewed during the onsite visit.) Supervisors must use the following methods singularly, in combination, or all together when conducting STAR assessments:

- **Records Review**. Review in-plant, subordinate supervisory personnel work products such as information in electronic records and office files to ensure accuracy, thoroughness, consistency, timeliness, and conformity with established policies and procedures.
- **Discussion**. Discuss program policies and procedures to assess supervisor's knowledge of inspection methods, regulatory decision-making abilities, and enforcement of policies and procedures. For further guidance on how to effectively assess knowledge and execution of these activities, see the Guide for Conducting In-Plant Performance System (IPPS) Assessments. (**NOTE**: The work methods outlined for assessing activities under the Mission Support element are applicable for assessing the same activities for the in-plant supervisory personnel, if they perform or supervise performance of those activities.)
- **Observation**. Observe and assess in-plant, subordinate supervisory personnel conducting their mission support, supervisory, or communication activities. (**EXAMPLES**: Observing the supervisor conducting a verification procedure, conducting ante mortem or post mortem inspection activities, observing the in-plant supervisor conducting a work unit meeting, conducting an IPPS assessment, or interacting with plant officials.)

Documenting results

When documenting STAR assessment results, OFO field-level supervisory personnel should:

- Share verbal feedback with the employee upon completing the assessment.
- Complete FSIS Form 4430-11, by summarizing the notes from FSIS Form 4430-11A and checking the block to identify the method(s) of assessment used (**examples**: records review, discussion, or observation).

• Document the narrative by summarizing the notes from FSIS Form 4430-11A to FSIS Form 4430-11. The summation should provide a description of observations and findings for each element and sub-element, and when applicable, any remedial action needed to improve performance (**example**: require the completion of a training course, review FSIS Directive 5,000.1, Verifying an Establishment Food Safety System).

Follow-up on results

OFO supervisors and field-level supervisory personnel, at the end of the STAR assessment, should be prepared to discuss follow-up items with in-plant, subordinate supervisory personnel. OFO supervisors must:

- Reassess agreements on work performance issues that in-plant supervisory personnel were required to work on between the current assessment and the agreed upon follow-up date.
- Indicate the follow-up training or additional visits needed, and ensure the completion of these activities.
- Follow procedures if an employee's performance is unacceptable in one or more critical elements at any time during the performance appraisal cycle.
- Report any identified misconduct issues during the STAR assessment by contacting the district office for further guidance.
- Monitor follow-up items to ensure completion.
- Provide in-plant supervisory personnel with a copy of the completed assessment sheet within 2 weeks after the STAR assessment.

Assessment Form Use and Maintenance

FSIS Form 4430-11, STAR Assessment Results Form, is an electronic form used to document the assessment process. After completing the assessment visit, the supervisor should:

- Summarize the information from FSIS Form 4430-11A to FSIS Form 4430-11.
- Share verbal feedback with the employee and send the employee a completed FSIS Form 4430-11, in read-only format by e-mail, no later than 2 weeks after the assessment.

- Retain an electronic copy in the electronic folder in the supervisor's work files. FSIS Directive 4293.1, Personnel Records, requires retention of the electronic file for 1 year from the date of the completion of the last rating on record. (**NOTE**: FSIS Form 4430-11A and FSIS Form 4430-11 are not filed in the employee's official personnel folder or the employee's performance file in Human Resource Policy (HRP).)
- Upload the completed assessment to the AssuranceNet application.
- Use judgment when determining how to factor in results documented during the STAR assessment into determinations made on the annual performance rating. The performance rating should reflect the employee's performance for the entire rating cycle. (**NOTE**: The STAR results should not serve as the sole basis for performance appraisal determinations, but can be used to inform the ratings on various performance elements.) The Performance Management public folder in Outlook provides valuable information for making decisions on annual performance ratings. Access the Performance Management public folder by clicking on Outlook/Public Folders/All Public Folders/Personnel/Performance Management/Perf Mgmt Tools.

FSIS Form 4430-11 **does not** replace any existing performance appraisal processes or FSIS forms. FSIS Directive 4430-1, Performance Plan provides guidance and instructions for setting performance expectations, conducting progress reviews, and rating employees annually on performance. The STAR guide and form are available in the Agency Issuances Public Folder and can be assessed via Outlook by clicking on Outlook/Public Folders/All Public Folders/Agency Issuances/Forms/FSIS-4000 Series.

Non-Food Safety Consumer Protection – Part 1

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Slides		LEARNING OBJECTIVES
N/A	Scien	tific:
	[None	o for this topic in this context.]
	Regu	latory/Administrative:
	1.	Given a scenario involving a presentation check at a line inspector station, apply
		NFS criteria to evaluate the establishment's method of presentation.
	2.	Given a scenario in the poultry slaughter context, apply prescribed NFSCP
		criteria to score poultry pre-chill and post-chill to verify the establishment's
		process control.
	3.	Using reference material or guidance material provided, apply post chill criteria
		to a 10 bird sample in the field/establishment setting.
	4.	Explain the establishment's responsibility when pre-chill or post-chill tests
		exceed established limits.
	5.	Given a scenario depicting a salvage program, identify factors that could result
		in the suspension of the salvage program.

Slides	Finished Product Standards
3	Finished Product Standards
	Finished Product Standards (FPS) are criteria applied to processed birds before and after chilling to ensure that the product being produced is consistently wholesome and unadulterated.
	Why use FPS?
	Relevant policy?
4	Responsibilities FPS
	Establishment
	FSIS

5	Presentation of Carcasses and Parts
	 The establishment must ensure that the carcasses are presented for inspection. They must also be hung on the line in a specified manner and spaced appropriately. The organs must be displayed in a specified order so that the inspector does not have to spend time locating them before he or she performs inspection procedures. Proper presentation helps to ensure consistent and accurate inspection. There are variations in the ways in which an establishment will present carcasses and parts for inspection.
6	Presentation Scenario
	Using the scenario below complete the Blank FSIS form provided.
	You are PHV at a Meyn Maestro evisceration system establishment. During breaks you hear the two USDA FIs chatting about the high number of birds that are being presented without viscera.
	When the line restarts, you head down to view the floor. You see carcasses presented without viscera. You perform a directed presentation check for each of the two food inspectors and see the following abnormalities:
	Notes for inspector 1:

Notes for inspector 2:

Is the establishment in control of their process?

Would this answer be different if only one carcass with viscera missing was seen?

What, if any, actions should you take?

Slides **Poultry Finished Product Standards** 8 **Poultry Finished Product Standards** Tasks covers finished product standards, rework/reprocess/salvage products, poultry carcasses, poultry products and other articles entering or at official establishments, examination and other requirements, returned products, and good commercial practices for poultry slaughter. Review common terms: • Unit – A unit is a single poultry carcass Subgroup – A subgroup is a 10-unit sample collected at the same time (10 birds) for one test) Rework – Rework is reprocessing product to correct nonconformances that • caused the product to be identified as unacceptable. • Cumulative sum (CUSUM) – Cumulative sum (CUSUM) is a statistical concept used by the establishment and monitored by FSIS. CUSUM represents the accumulated number of weighted nonconformances that exceed the tolerance in a series of consecutive subgroups. Action Number – The action number is a standardized value. When CUSUM reaches the action number, it indicates the process being tested might be out of control (questionable control). Product action is required when CUSUM reaches the action number. Start Number – The start number is a value halfway between zero and the action number. Under certain conditions it can be used to determine the CUSUM for the next shift and to reset the CUSUM after the action number is reached. Notes:

Poultry FPS Chart 9 Pre-chill • Pre-chill tests are conducted on carcasses after they pass the final wash and before they enter the chiller. • Each evisceration line must be tested. Each line's results are independent of the others. • The time allowed to conduct a pre-chill test (both processing and trim tests) is 8 - 10 minutes. • The frequency for pre-chill testing is two times per line per shift. • Lighting requirements at the pre-chill station are 200 foot-candles of shadow free light with a minimum color rendering index of 85. Notes:

Processing Test

- Processing tests determine if the dressing/evisceration process is in control. Processing nonconformances are items which should have been removed by machinery or establishment personnel to make the carcass acceptable as a ready-to-cook product. These items include:
 - o Extraneous material
 - Oil glands
 - o Lungs
 - o Intestines
 - \circ Cloacas
 - Bursa of fabricius (rosebud)
 - Esophagus
 - Crops
 - o Tracheas
 - o Hair
 - Feathers and pinfeathers
 - Long shanks
- FSIS Form 6500-1

Trim Test

- Trim tests determine if the trim process, which involves removal of unwholesome lesions and conditions, is in control. Trim nonconformances which should have been removed by establishment personnel include:
 - o Breast blisters
 - o Bruises
 - o Trimmable, localized tumors
 - o Carcasses marked for synovitis, airsacculitis, etc.
 - Compound fractures
 - o Short hocks
 - o Sores, scabs, IP
 - o External mutilation
- FSIS Form 6500-1

Post-Chill

- The post-chill finished product procedure monitors extraneous material that carcasses pick up during the chilling process. Birds are collected after they leave the chiller but before they are divided into separate processes (e.g., cut-up, packing, freezing).
- Each system's results are independent of the others.
- The time allowed to complete a post-chill test is 5 7 minutes.
- Lighting requirements at the post-chill station are 200 foot-candles with a color rendering index of 85.
- The test results are recorded on a post-chill fps form and CUSUM is calculated.

10 **Pre-Chill Scenario**

Use blank form 6500-1, form 6500-2, and nonconformance criteria charts in this Folder to complete the following scenario.

Prechill Trim Nonconformances Chart			
Line-Category	Factor	# of defects to equal Incident	Maximum Incidents/Carcass
1-Breast blister-untrimmed	2	Each finding is one incident.	1
2-Breast blister-partially trimmed	1	Each finding is one incident.	1
3-Bruise 1/2" to 1"	1	Each finding is one incident.	5
4-Bruise > 1"	2	Each finding is one incident.	3
5-Bruise black/green ¼" to 1"	2	Each finding is one incident.	3
6-Bruise black/green >1*	5	Each finding is one incident.	2
7-Trimmable lesion/Trimmable condition	5	Each finding is one incident. Note: Must have been marked to identify the removal lesions or condition.	1
8-Failure to complete task as indicated by marking system	5	Each finding is one incident. Note: Also record as a Line 7 nonconformance. Total factor of Lines 7 & 8 = 10.	1
9-Compound fracture	2	Each finding is one incident. Note: If bruising is associated with a compound fracture, do not record under bruising.*	3
10-Wingtip compound fracture	1	Each finding is one incident. Note: If bruising is associated with a compound fracture, do not record under bruising.*	2
11-Untrimmed short hock	2	Each finding is one incident.	2
12-Sores, scabs, IP, etc., ≤ 1/2"	2	Each finding is one incident.	2
13-Sores, scabs, IP, etc., > 1/2"	5	A finding is one incident.	1
14-External mutilation	1	Each finding is one incident.	3

*Bruises not associated with Compound fractures or Wingtip compound fractures should be recorded in the appropriate lines (Lines 3, 4, 5, or 6).

At an establishment under New Turkey Inspection System at the prechill location, you select ten random birds and perform a finished product standard verification task. While performing a pre chill you observe the following defects:

- Green bruise >1"
- trachea >1"
- Feather >1"
- Untrimmed breast blister

1. Are these processing or trim nonconformances?

2. What is the scoring? The plant's CUSUM was 5 in processing and 1 in trim.

3. Is the establishment in compliance?

4. What would happen if the subgroup total had exceeded the absolute limit?

11 Young Chicken Scenario

Complete the blank FSIS form 6500-1 and 6500-2 in this folder using the nonconformance criteria charts and the information from the scenario below.

You are the QC technician examining 10 birds for pre-chill processing nonconformances and trim nonconformances. Click here to view the table representing your observations:

Bird 1: 1 gall stain > 1" 1 feather > 1"	Bird 2: 1 external mutilation 1 lung fragment 13 hairs	Bird 3: 1 bruise > 1" 2 whole lungs	Bird 4: 2 specks of ingesta > 1/16" 1 oil gland remnant	Bird 5: 2 pieces of lung > ¼ ⁿ 1 partial crop with mucosa
Bird 6: 1 whole lung 1 bursa of fabricius	Bird 7: 3 pinfeathers ¼" 1 bruise > 1" 1 breast blister	Bird 8: 1 speck of grease < 1/16" 2 scabs < ½"	Bird 9: 1 trachea < 1" 1 untrimmed short hock 1 black/green bruise ½"	Bird 10: 1 trachea > 1 1 lung fragment > 1/4" 1 compound wingtip fracture
Notes:				

12 **Post-Chill Scenario**

Complete the blank FSIS 6500-3 using the nonconformance criteria chart and the information from the scenario below.

You are examining 10 birds for post-chill nonconformances. Click here to view the table representing your observations:

Bird 1:	Bird 2:	Bird 3:	Bird 4:	Bird 5:
3 specks of ingesta < 1/16"	None	None	2 specks of ingesta > 1/16"	5 specks of ingesta < 1/16"
Bird 6:	Bird 7:	Bird 8:	Bird 9:	Bird 10:
1 speck of grease > 1/16"	1 speck of ingesta < 1/16"	1 speck of grease < 1/16"	None	None

Notes:

Slides **Livestock Finished Product Standards** 14 **Livestock Finished Product Standards** Pertains to the requirements concerning procedure, ingredients, and other articles used in preparation of products. Examples of products: Boneless meat • Meat carcasses • Pork skins for popping • Video Notes:

Slides	Salvage
16	Salvage
	The term salvage refers to the actions the establishment takes to trim away any unwholesome or diseased portion of a carcass that is localized. There can be many types of salvage depending on the establishment, and products produced. Conditions for Salvage: Procedure for each type Sanitary conditions Adequate facilities and personnel Continuous product flow Product available for FSIS reinspection Notes:
17	 Salvage Can Be Suspended if: The establishment fails to follow their salvage procedures. They fail to make birds available for FSIS reinspection. They are unable to maintain adequate product flow. Voluntarily they may elect in some instances, most commonly when birds are affected with airsacculitis in high numbers. They must notify FSIS IPP of their decision. Notes:

18 Salvage Scenario: Osteomyelitis

Last week you verified turkey osteomyelitis (OM) salvage on an OM positive flock. At that time, you observed an employee trim a carcass with OM in the proximal tibia. That employee removed the tibia at the stifle and attempted to put the carcass back into production. You showed the issue to a supervisor and discussed and documented this issue in the weekly meeting. Today you observe this happen again.

1. What is the issue?

2. What should you do?

3. Is the establishment at risk of losing the ability to perform OM salvage?

Slides	SUMMARY
19	Review your score on the Summary screen and notes about this topic. Make note of any areas that you need to work on.
	Please note that this score does not count toward your overall class grade. Rather, it helps you identify which areas you may need to study more in preparation for your exams. Your overall class grade only consists of the daily quizzes, midterm exam, and final exam. Any scores you receive on Knowledge Check questions or course activities are <u>not</u> counted. They are for your use only.

Non-Food Safety Consumer Protection – Part 2

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Slides	LEARNING OBJECTIVES
N/A	Scientific:
	[None for this topic in this context.]
	Regulatory/Administrative:
	1. Review Verification Methodology for Non-Food Safety Tasks and discuss in a
	group which tasks may be relevant at your duty station.
	2. Given a scenario involving verification tasks in the Processing context, apply
	labeling regulations, FSIS Directive 7000.1, the NIST Handbook, and the
	Calculation Aid to verify NFSCP compliance.
	3. Given a scenario in the Processing context, provide appropriate feedback and
	guidance to an IPP when he or she incorrectly performs a non-food safety
	consumer protection task.
	4. Given a scenario in the Processing context, identify the NFSCP noncompliance
	and the task to document the NR in, whether a recall is likely, and select the
	appropriate action regarding the product involved.

Slides	NFSCP: Big Picture Summary
3	Non-Food Safety Consumer Protection (NFSCP): Big Picture
	Using the resource in the folder, discuss the following questions:
	What are some key regulations in regards to the labeling of meat products?
	What does it mean when a meat product is misbranded?
	 If, while performing a NFSCP task, IPP observe food safety concerns, how should they proceed?
	 What steps of enforcement are to be made when a product is found to be noncompliant with NFSCP regulations?

Sonus Question: What is a generically approved label?	\ \/ ====	e como kou regulationo in regenda to the lobalizer of months with 0
Bonus Question: What is a generically approved label?	what a	e some key regulations in regards to the labeling of meat products?
Bonus Question: What is a generically approved label?	-	
Bonus Question: What is a generically approved label?	-	
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5 NFSCP: Big Picture Summary

What does it mean when a meat product is misbranded?

	1.	. Has labeling which is false or misleading	7. Has a label that purports that it was produced in a manner that follows a standard of identity, but the product does not conform to those standards
	2 a	. Is offered for sale under the name of nother food	8. The amount of product in the container falls below the fill standard
	3	. Is an imitation of another food	9. Contains ingredients that are not represented on the label by common names of the food
	4	. Has a container that is misleading	10. Makes special dietary claims but does not list the corresponding dietary properties and information required on the label
	5. P Q	. Has a label that fails to show the name and lace of business that produced the product, r fails to contain an accurate statement of the uantity of the contents of the meat product	11. Contains artificial flavoring, coloring, or chemical preservatives that are not listed on the label
	6 ir	. Contains a label that is missing required formation	12. Requires some type of handling for a wholesome condition to be maintained but the label fails to contain that information
	Notes:		
6	NFSCI	P: Big Picture Summary	
	lf, whil procee	e performing a NFSCP task, IPP obsect?	erve food safety concerns, how should they

7	NFSCP: Big Picture Summary
	What steps of enforcement are to be made when a product is found to be noncompliant with NFSCP regulations?
Slides	Verification Methodology for Non-Food Safety Tasks
9	Verification Methodology Tasks
	Generally, how do IPP perform the NFSCP verification tasks?

	If, following a preliminary assessment, you have reason to believe that non-compliant product is being or has been produced, perform a directed verification procedure and a thorough evaluation. What are the NFSCP tasks that can be performed?
10	Percent Yield/Shrink/Gain Verify the requirements associated with percent yield/shrink/gain. Example products: bacon, BBQ meats, roasts beef, corned beef, cured beef tongue, country ham, etc. Video Notes:

11	X% Solution Labeled Products
	 Verify the requirements associated with X percent solution for labeled products Task is verifying that the percent of a solution added to a product does not exceed the regulatory requirements Examples of products: cured pork products, ham patties, chopped ham, ready-to-cook poultry products, turkey ham, corned beef, beef brisket, etc.
	Video Notes:
12	MSP/MSKP/PDBFT/PDPFT/AMR Products
	 Mechanically Separated Pork (MSP), Mechanically Separated Kind of Poultry (MSKP), Partially Defatted Beef Fatty Tissue (PDBFT), Partially Defatted Pork Fatty Tissue (PDPFT), and Advanced Meat Recover (AMR) products To verify compliance: Check product identification, condition ,temperature, holding time/temperature; Examine bones (for example, two intact portions of bones) before and after the meat recovery systems in order to observe condition and conformation; Review establishment laboratory results and compare findings with the appropriate regulatory standard, and Collect samples as directed.

13	Batter/Breading • Verify requirements associated with batter and breading • Examples of products: breaded products, breaded patties, breaded meat cuts, fritters Video Notes:
14	Labeling - Product Standards • Verify requirements for product standards • Examples of products: miscellaneous beef products, sausage, frankfurters, luncheon meats, chili con carne, meat stews, tamales and others • Finished Product Testing Job Aid Video Notes:

15	 Child Nutrition (CN)/Grade Labeling/Declared Count/Vignette Verify the requirements related to false or misleading labeling or practices, including specific prohibitions and requirements for labels and containers, and wording on labels of immediate containers Examples of products: All types of products Video Notes:
16	Net Weights • Verify the requirements related to net weights whether the containers are catch weight or bear a stated net content • Examples of products: All types of products that carry a net weight statement Video Notes:
17	General Labeling
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	 Task applies to all products that bear a label It includes verifying the requirements related to standards of identity Examples of products: All products
	Video Notes:
Slides	Scenarios
19	Scenario A: Part 1
	Video Notes:
	Describe how the CSI should perform this task?

	Identify specific resources the CSI could review for this task (e.g., regulations, CDs, directives, and notices).
20	Scenario A: Part 2 Video Notes:



Bases on the review of the product formulation and the labeling applied to the immediate containers and shipping containers, has the establishment produced adulterated product? Is there a food safety hazard associated with the production of the product?

What a	action should the CSI take?

21	Scenario A: Part 3
	Video Notes:
	Which corrective action regulations would apply in this situation?
	How should the CSI document the finding of the task? What regulations would he cite?

Processing: NFSCP – Part 2

What	action should the CSI take next?
Could	I what you and the CSI observed indicated an inadequate food safety system

	What action should you take next?		
22	Scenario B		

How do	bes the CSI determine the sample size?
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What is	the sample size of the containers that CSI should examine?
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How do	bes the CSI determine the tare sample size?
What is	the initial tare sample size?
How is	Maximum Average Variation (MAV) defined?
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What w	vould constitute a failure of the MAV criteria for the containers of the chick
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thigh h	bes the CSI calculate the individual package errors?
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thigh h	bes the CSI calculate the individual package errors?

	How does the CSI determine if the inspection lot passes or fails the net weight inspection?
	What action should the CSI take for this inspection lot?
23	Scenario C
	Video Notes:
	What action should you take next?

31-22



Slides	Knowledge Checks
24	Knowledge Check 1
	True or False: MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS are new industry technologies and have no FSIS regulations or standards associated with them.
25	Knowledge Check 2
	True or False: Anytime an individual unit in the lot of sampled breaded product exceeds 30% breading, there is noncompliance.
26	Knowledge Check 3
	True or False: Ingredients used in products' formulations are to be listed on labels' ingredients statements in the descending order of predominance.
Slides	SUMMARY
Ondes	
27	Review your score on the Summary screen and notes about this topic. Make note of any areas that you need to work on.
	Please note that this score does not count toward your overall class grade. Rather, it helps you identify which areas you may need to study more in preparation for your exams. Your overall class grade only consists of the daily quizzes, midterm exam, and final exam. Any scores you receive on Knowledge Check questions or course activities are <u>not</u> counted. They are for your use only.

Non-Food Safety Consumer Protection Regulatory Requirements – FSIS Directive 7000.1

OBJECTIVES

After completing this module, you will be able:

- 1. Identify the statutes and regulations that relate to non-food safety consumer protection responsibilities.
- 2. Describe how to conduct the PHIS Economic/Wholesomeness tasks.
- 3. Explain what to do when noncompliance is observed.
- 4. Describe what to do when there are multiple noncompliances.

RESOURCE MATERIALS

- Federal Meat Inspection Act (FMIA)
- Poultry Product Inspection Act (PPIA)
- 9 CFR Parts 301, 313, 316, 317, 318, 319, 327, 381 Subpart P, 412, 424, 441, and 500
- FSIS Directive 5000.1 "Verifying an Establishment's Food Safety System"
- FSIS Directive 5400.5, Attachment 5, "Inspection System Activities"
- FSIS Directive 6100.3 Ante-Mortem and Post-Mortem Poultry Inspection
- FSIS Directive 6120.1, "Finished Product Standards Program for the New Line Speed Inspection System and the Streamlined Inspection System"
- FSIS Directive 6700.1, "Retained Water in Raw Meat and Poultry Products"
- FSIS Directive 6810.1, "Grademark Labeling on Meat and Poultry Product"
- FSIS Directive 6900.2, "Humane Handling and Slaughter of Livestock"
- FSIS Directive 7000.1 "Verification of Non-Food Safety Consumer Protection Regulatory Requirements"
- FSIS Directive 7000.2, "Experimental and Sample Product Policy"
- FSIS Directive 7120.1 "Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products"
- FSIS Directive 7124.1, "Standards of Identity or Composition—Use of Cooked or Cured Product"
- FSIS Directive 7160.1, "Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery Systems"
- FSIS Directive 7160.2, "'Meat" Prepared Using Advanced Mechanical Meat/Bone Separation Machinery and Meat Recovery Systems"
- FSIS Directive 7160.3, "Advanced Meat Recovery Using Beef Vertebral Raw Materials"
- FSIS Directive 7220.1, "Food Labeling Division Policy Memoranda"
- FSIS Directive 7221.1, "Prior Labeling Approval"
- FSIS Directive 7235.1, "Mandatory Safe Handling Statements on Labeling of Raw and Partially Cooked Meat and Poultry Products"
- FSIS Directive 7237.1 Amendment 1, "Labeling of Ingredients"
- Directive 7230.1 Ongoing Verification of Product Formulation and Labeling Targeting

Entry Training for PHV

the eight most common (big 8) Food Allergens

- FSIS Directive 7270.1, "Sampling and Testing Procedures for Raw Poultry Products Labeled "Fresh"
- FSIS Directive 7355.1, "Use of Seals for Program Samples and Other Applications"
- FSIS Directive 7620.3, "Processing Inspector's Calculation Handbook"
- FSIS Directive 8080.1, Rev. 7, "Recall of Meat and Poultry Products";
- FSIS Directive 10,210.1 " Unified Sampling Form"
- Part 3, Section 3, "Import Inspection Manual of Procedures for the Species Verification Testing Program"
- Policy Memos 42, 44A, 57A, 66C, and 84A (<u>http://www.fsis.usda.gov/OPPDE/larc/Policies/Policy_Memos_082005.pdf</u>)
- Food Standards and Labeling Policy Book (<u>http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf</u>)
- NBS Handbook 133
- <u>NIST Handbook 44</u> (http://museum.nist.gov/object.asp?ObjID=55)

Additional Resources

- Start-All Programs-FSIS Applications-Tools-Calculation Aids
- FSIS <u>Topics</u> / <u>Regulatory Compliance</u> / <u>Labeling/Label Approval</u> / <u>Labeling Policies</u>
- FSIS Compliance Guidance for Label Approval (Nov 2015; PDF Only)
- <u>A Guide to Federal Food Labeling Requirements For Meat and Poultry Products (PDF</u> Only)
- Compliance Guide on the Determination of Processing Aids (Apr 8, 2008; PDF Only)
- <u>Guidance on Meaning of "Prohibited Substances" in FSIS Actions on the Use of</u> <u>Ingredients in Meat and Poultry Products (Apr 8, 2008; PDF Only)</u>
- <u>Labeling Compliance Policy Guide on Poultry Food Product Dating</u> (Aug 23, 2010; PDF Only)
- <u>Labeling Policy Guidance Uncooked, Breaded, Boneless Poultry Products (Updated</u> Jan 17, 2007; PDF only)
- Letter to Industry Regarding Frozen Uncooked Poultry (Mar 20, 2006; PDF only)
- <u>Supplemental Q and A's to Address Products Affected by FSIS Notice 75-06</u> Verification Instructions for Changes in Label Requirements for Uncooked and Raw, Frozen Breaded, Boneless Poultry Products
- Information on Validation of Labeled Cooking Instructions for Products Containing Raw
 or Partially Cooked Poultry | PDF

INTRODUCTION

In this module, we'll be covering your responsibilities related to the statutes, regulations, and directives that cover the regulatory requirements for what is called the Non-Food Safety Consumer Protection, or NFSCP. These requirements relate to economic adulteration and misbranding of products other than food safety. Additional information may be obtained from the Training CD developed by FSIS Center for Learning.

FSIS' highest priorities are protecting public health and food safety. The Agency is ensuring that inspection program personnel (IPP) focus on food safety first followed by food security (when specific heightened security threat condition is declared), and yet still Entry Training for PHV 2

verify compliance with requirements that provide non-food safety protection to consumers extended by the FMIA and PPIA. The NFSCP duties are the ones that are covered by Public Health Inspection System Economic/Wholesomeness Tasks. These tasks are performed to verify that the establishments are complying with regulatory requirements designed to protect the consumer in ways other than ensuring food safety.

The Agency is making changes in the verification procedures that relates to these other protections to ensure that they align with FSIS' responsibilities and priorities.

STATUTES

Federal Meat Inspection Act (FMIA)

Let's start by reviewing the statutes related to NFSCP requirements. The term "misbranded" is defined in 21 U.S.C. 601(n) of the FMIA. There are twelve parts to this definition. Misbranded is defined in the FMIA as a meat product that:

- Part (1), has labeling which is false or misleading.
- Part (2), is offered for sale under the name of another food.
- Part (3), is an imitation of another food.
- Part (4), has a container that is misleading.
- Part (5), has a label that fails to show the name and place of business that produced the product, or fails to contain an accurate statement of the quantity of the contents of the meat product.
- Part (6), contains a label that is missing required information.
- Part (7), has a label that purports that it was produced in a manner that follows a standard of identity, but the product does not conform to those standards.
- Part (8), the amount of product in the container falls below the fill standard.
- Part (9), contains ingredients that are not represented on the label by common names of the food.
- Part (10), makes special dietary claims but does not list the corresponding dietary properties and information required on the label.
- Part (11), contains artificial flavoring, coloring, or chemical preservatives that are not listed on the label.
- Part (12), requires some type of handling for a wholesome condition to be maintained but the label fails to contain that information.

The terms "label" and "labeling" are also defined in the FMIA as follows.

- FMIA 601(o) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article.
- FMIA 601(p) The term "labeling" means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article.

Section 607 of the FMIA covers labeling, marking, and container requirements. Section 607(b) states: labels must be "in distinctly legible form." Section 607(c) states that misleading or false labeling is to be avoided. It also indicates articles that are subject to

standards of identity must be consistent with those standards when they apply to the article. Section 607(d) states, "No article subject to this subchapter shall be sold or offered for sale by any person, firm, or corporation, in commerce, under any name or other marking or labeling which is false or misleading, or in any container of a misleading form or size, but established trade names and other marking and labeling and containers which are not false or misleading and which are approved by the Secretary are permitted". Section 607(e) states that when there is reason to believe the marking or labeling or container is false or misleading, FSIS has the authority to withhold its use until it is modified so that it is no longer false or misleading.

Poultry Products Inspection Act (PPIA)

There are similar provisions related to the definition of the term "misbranding" in the PPIA. Here's an overview.

- PPIA 453(h) Definition of "misbranded" with 12 provisions.
- PPIA 457 Labeling and container standards. There are four parts to this section:
 - (a) Must bear legible labels
 - (b) Must comply with definitions and standards of identity; and fill of container
 - (c) Must not be sold under false labeling or misleading size
 - (d) Label may be withheld until modified so that it is not misleading or false.

REGULATIONS

The regulations related to the NFSCP requirements are extensive and detailed. We will review the highlights of some of the key NFSCP regulations for meat and poultry products. You will need to review the regulations on your own to become familiar with them in more detail, as we will not cover all aspects that you need to know during this training program.

General requirements for meat products

Let's start with some of the key regulations related to meat products. 9 CFR 317 outline all of the regulatory requirements including labeling, marking devices, and containers. Currently, there are forty two regulations related to NFSCP requirements for meat products, and some of these regulations have a number of subparts.

9 CFR 317.1 states that labels are required for containers of meat products. There are a few exceptions which are outlined in the regulation.

9 CFR 317.2 outlines the required features of labels for meat products. Here are some of the basic requirements. The label must list the name of the product and ingredients used in the production of the product. The name and place of business of the manufacturer must be shown on the label. It must also contain an accurate statement of the net quantity of the contents of the product. Just as was stated in the statutes, the label must not be false or misleading. It must list any handling of the product that is required in order to maintain the product in a wholesome condition. There are also some very specific requirements for safe handling instructions for meat and meat products.

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9 CFR 412.1 contains the requirements related to labeling approval. One of the key statements is that no final labeling shall be used on any product unless the sketch labeling of such final labeling has been submitted for approval to FSIS except for generically approved labels authorized for use in 9 CFR 412.2. Currently, the organizational unit responsible for handling the approval of labels is the Labeling and Program Delivery Staff (LPDS), Office of Policy and Program Development. A sketch label is a printers proof or the equivalent which clearly shows all labeling features, including the size, and location. The LPDS may grant a temporary approval that extends up to 180 calendar days. If the label is to be applied directly to a meat carcass, make sure that the type of ink the establishment uses complies with 9 CFR 312 and 316, which states they must be legible and of harmless material. FSIS requires the submission of labeling applications for the following:

- Labels for temporary approval (9 CFR 412.1(c)(4)),
- Labels for products produced under religious exemption (9 CFR 412.1(c)(1)),
- Labels for products for export with labeling deviations (9 CFR 412.1(c)(2)), and
- Labels with special statements and claims (9 CFR 412.1(c)(3))

9 CFR 412.2 covers generically approved labels. IPP do not generically approve labels. Establishments do not generically approve labels. Generically approved labels are approved by FSIS if the label meets the criteria listed in 9 CFR 412.2(b). Therefore, a label that meets one of the conditions of being generically <u>approved</u> does not have to be submitted to FSIS for further approval. Some generically approved labels Include labeling for:

- Products that have a standard specified, such as a standard of identity (identifies the kind and amount of meat required in that product; e.g., hot dogs).
- A product, such as steak, that has a single ingredient. There can be no special claims on these generically approved labels.
- Containers of products sold under government contract specifications, such as those sold for the school lunch program.
- Consumer test products which are not intended for sale.
- Any label that was previously approved as a sketch by FSIS qualifies to be used without any further approval.

As mentioned earlier, there are many more details regarding the regulatory requirements for labeling meat products. For example, there are extensive requirements related to nutritional labeling. These are found in 9CFR 317.300-317.400. Nutritional labeling is currently required for all meat products intended for human consumption except for those that are single ingredient, raw products, such as steaks. However, nutritional labeling may be provided for these products on a voluntary basis. We will not review these requirements in general, but you should take time to review the regulations and become familiar with them, as from time to time, you will need to verify that the establishment is complying with these requirements.

Later in this module we will review some of the basic requirements for labeling related to products that have standards of identity. But first, let's review some of the basic regulatory requirements of general labeling for poultry products.

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General requirements for poultry products

Just as there are a number of regulatory requirements related to the labeling of meat products, there are also a number related to poultry products. They are found in 9 CFR Subpart N of regulation 381, from 381.115 through 381.144. Let's review a few of the key parts. As we walk through these, you'll see that they are very similar to the regulations that we reviewed for meat products. They also match the same principles contained in the statutes that we reviewed. Here are some highlights.

9 CFR 381.115 – Require the containers of poultry products to be labeled.

9 CFR 381.118 – Covers the requirement for ingredients statements for poultry products.

9 CFR 381.119 – States that artificial flavoring or coloring must be declared on labels of poultry products.

9 CFR 381.120 – States that antioxidants, chemical preservatives, and other additives must be declared on the labels of poultry products.

9 CFR 381.121 – Requires that the label shows the quantity of the contents of the product.

9 CFR 381.122 – Requires that the label identifies the product manufacturer, packer or distributor.

9 CFR381.124 – States that dietary food claims must be matched with appropriate details on the label.

9 CFR 381.125 – Requires that if poultry products require special handling to maintain a wholesome condition, these handling requirements must be listed on the label.

9 CFR 381.130 – States that false or misleading label are not permitted for poultry products.

9 CFR 381.132 – Describes the labeling approval process. This process is the same as the one for meat products.

9 CFR 381.133 – Covers the requirements related to generically approve labeling. Just as was true for meat products, those products for which a standard of identity exists are eligible for generically approved labels.

Standards of identity

Now, let's review some of the regulatory requirements for products that are subject to standards of identity. Remember those products can use generic labels. The "Definitions and Standards of Identity or Composition" regulations for meat and poultry products are found in 9 CFR 319 and 9 CFR 381 Subpart P, respectively. We won't cover each of the products outlined in the regulations in detail but you need to review these regulations and become familiar with the requirements associated with each product that is produced in the establishment where you are assigned.

The requirements in 9 CFR 319.1 cover the general labeling and preparation of standardized meat products. This regulation states that products for which standards of identity exist must have a label showing the products name and ingredients statement and other information as appropriate. The 9 CFR 319.15-319.881 (Subparts B through U) cover the specific requirements for various meat products – from raw products that have very few, if any ingredients or preparation, to products such as cooked sausage that may have a number of ingredients and may go through a variety of steps in preparation. Remember that we covered some of the processing steps when we introduced you to the regulated industry. For example, Subpart B (-Raw Meat Products) covers the following products: chopped and ground beef, hamburger, beef patties, fabricated steak, and partially defatted beef and pork fatty tissue. In Subpart D (-Cured Meats, Unsmoked and Smoked) some products such as cured pork products, the regulations relate to the list of ingredients on the label, such as binders, and the percent of water added. Also, for some products, there are protein fat free (PFF) percentage regulatory requirements; in other products Mechanically Separated (Species) Product may be used in accordance with \$319.6. The regulations also specify that smoking must be done with approved nonresinous materials (§319.160). Furthermore, there are definitions in the regulations of each of these types of products. For example, in Subpart L (-Meat Specialties, Puddings and Nonspecific Loaves), there is a very specific definition of the meat product bockwurst that includes details of the formulation of the product. Subpart M (-Canned, Frozen, or Dehydrated Meat Food Products) contains a very specific definition for "hash".

Remember that in this section of the training we are covering the labeling requirements related to these products. There are food safety requirements for these products as well. You will learn about the food safety requirements when you attend the Food Safety Regulatory Essentials (FSRE) training.

Here's an outline of all the regulations covering the definitions and standards of identity or composition (Part 319) for meat products:

Subpart B – Raw meat products Subpart C – Cooked meats Subpart D – Cured meat, unsmoked and smoked Subpart E – Sausage generally: fresh sausage Subpart F – Uncooked, smoked sausage Subpart G – Cooked sausage Subpart K – Luncheon meat, loaves, jellied products Subpart L – Meat specialties, puddings, nonspecific loaves Subpart M – Canned, frozen, dehydrated meat food products Subpart N – Meat food entrée products, pies, and turnovers Subpart O – Meat snacks, hors d'Oeuvres, pizza, and specialty items Subpart Q – Meat soups, soup mixes, broths, stocks, extracts Subpart R – Meat salads and meat spreads Subpart U – Miscellaneous (breaded and liver meat products)

9 CFR 381 Subpart P covers the labeling requirements for poultry products that have standards of identity. Again, if the establishment you are assigned produces any of these types of products, you must familiarize yourself with the specific regulations, as from time

Subpart A – General

to time you will be performing procedures to verify that these products comply with the labeling requirements. Let's walk through a few of these requirements briefly. 9 CFR 381.156 covers the requirements for using terms such as light or dark meat on a label containing poultry products. Similar to the regulations related to meat products, these regulations covering poultry products cover percent of poultry light/dark meat required for the product to meet the standard, and in some cases the type of ingredients required/allowed, such as binders or extenders.

Here are the 9 CFR §381 Subpart P regulations covering the standards of identity for poultry products:

- 381.155 General
- 381.156 Poultry meat content standards for certain poultry products
- 381.157 Canned boned poultry and baby or geriatric food
- 381.158 Poultry dinners (frozen) and pies
- 381.159 Poultry rolls
- 381.160 (Kind) burgers; (Kind) patties
- 381.161 "(Kind) A La Kiev"
- 381.162 "(Kind) steak or fillet"
- 381.163 "(Kind) baked" or "(Kind) roasted"
- 381.164 "(Kind) barbecued"
- 381.165 "(Kind) barbecued prepared with moist heat
- 381.166 Breaded products
- 381.167 Other poultry dishes and specialty items
- 381.168 Maximum percent of skin in certain poultry products
- 381.169 Ready-to-cook poultry products to which solutions are added
- 381.170 Standards for kind and classes, and for cuts of raw poultry
- 381.171 Definitions and standards for "Turkey Ham"
- 381.173 Mechanically Separated (Kind of Poultry)
- 381.174 Limitations with respect to use of Mechanically Separated (Kind of Poultry)

VERIFICATION METHODOLOGY FOR NON-FOOD SAFETY TASKS

If you are assigned to a large establishment, the inspection tasks for verifying that the establishment complies with the NFSCP requirements will be performed by a Consumer Safety Inspector (CSI) that you supervise. You may perform the economic wholesomeness and sampling tasks when you are acting in a relief capacity for the CSI. If you are assigned to work in establishments that are small or very small, you may perform these duties yourself. In either case, you need to know the details of how to perform the procedures. So, we will cover how to perform the procedures as if you were doing them yourself.

FSIS Directive 7000.1 provides instructions for how you are to perform verification procedures related to NFSCP requirements. While performing NFSCP tasks, it is possible that you may uncover concerns related to an establishment's food safety systems, such as the Sanitation SOP or HACCP plan. When this occurs, you should perform the food safety task as a directed procedure and take any necessary enforcement actions. For example, if you are performing a routine labeling verification task and discover that the establishment has issued an ingredient of public health Entry Training for PHV

concern without properly declaring the ingredient, you should pursue the food safety aspects of the findings and performed any warranted, directed food safety task as instructed in FSIS Directive 5000.1.

Inspection program personnel are not to perform directed NFSCP verification tasks unless, during the performance of food safety verification activities, they observe conditions or activities that cause them to suspect that the establishment is not meeting non-food safety regulatory requirements. If, following a preliminary assessment of such information, you have reason to believe that non-compliant product is being or has been produced perform a directed verification task and a thorough evaluation. Whenever an directed verification task added to the task calendar, a pop-up dialogue screen will appear in the Public Health Information System (PHIS). Use the dialogue screen to provide a brief explanation of why you believe a directed task is warranted.

Performing the Economic/Wholesomeness tasks

When you move a non-food safety consumer protection task from the task list to the task calendar, you are to perform the appropriate verification tasks by:

- observing establishment product formulation, verifying the accuracy of labeling;
- observing preparation or processing procedures;
- reviewing establishment records;
- examining product;
- checking product identification, condition and temperature;
- performing a variety of other in-plant measurements, testing and calculations;
- observing slaughter practices

Inspection personnel need only examine product when they have reason to believe that product does not meet regulatory requirements. However, there are no designated sampling plans or sample sizes that IPP are to use when examining products to assure that the products meet non-food safety regulatory requirements, nor are IPP to examine all products. They examine product to determine whether the product complies with regulatory requirements, such as product standards, net weight standards, regulatory maximum or minimum limits of ingredients or components, or product defects. Inspection program personnel are to determine whether product complies with the regulation based on production lots or process controls rather than on individual units of product. For example, if one package of product exceeds its net weight, IPP are to investigate whether there have been problems in the process that will cause all packages to exceed the net weight requirements.

When you verify the condition of inspected and passed product, verify product identification, and evaluate the product condition. That includes the product temperature and storage. After such an assessment, you should be able to determine the extent of the verification tasks that you may need to perform. Where effective establishment processing controls are evident, only limited verification activity may be necessary. You should, in these cases, direct the inspection to those parts of the processing operation that are not covered by an establishment's control procedures. You do not need to count individual defects to make a judgment on a finished production lot. The condition of product should be clearly evident and sufficient to allow inspection personnel to render a judgment that the product is not adulterated.

Verification activities under Formulation and Labeling

Verify that the establishment is producing product in compliance with the appropriate 9 CFR reference (see Attachment 1 of Directive 7000.1) and determine whether the product complies with the regulations by comparing the product to the relevant regulatory requirements.

So, what should you be looking for when you observe product formulation?

- Verify that the product meets requirements that are specified in the applicable standards of identity.
- Verify that all ingredients have been added in amounts that come within the maximum or minimum level specified in the applicable standard.
- Verify all ingredients used in formulating the product are accurately declared on the label in descending order of predominance and any proteinaceous substances used in the formulation are declared in the ingredient statement.
- Verify that the product defects level are consistent with applicable standards.
- Observe establishment activities.
- Review establishment records.

Proteinaceous substances can trigger food sensitivities or allergies in certain individuals and therefore, such substances are of a food safety concern if they are not clearly declared in the ingredients statement. The eight most common food allergens that have become a serious issue for the food industry include milk, eggs, fish, crustacean shellfish (e.g., shrimp), peanuts, tree nuts (almonds, walnuts, etc.), soybeans, and wheat. The U.S. Department of Agriculture considers the above mentioned undeclared allergens, with the exception of wheat, as the basis for Class I or II recalls which have potential for severe health consequences. The Recall Committee is responsible in making the decision for which recall classification the undeclared allergen will fall under based on their assessment of the product in question. Following are a few examples of products with undeclared ingredients that triggered a recall. Recently, there were two products that were retrieved from market under Class I classification. One of them was deli franks which may have contained dry milk, and the other product was soup with meatballs and chicken which contained cheese as the undeclared ingredient. Under Class II classification, the product "Steak for Country Frying-Fully Cooked Cubed Steaks" was recalled from the market due to undeclared "buttermilk blend" in the ingredient statement on the carton.

What should you do when verifying the NFSCP requirements related to labeling?

- Review the establishment's labeling records including any supporting documentation such as letters from FSIS, temporary approvals, etc.
- Determine whether labeling is approved in accordance with appropriate regulations, i.e., either approved as a sketch by the FSIS LPDS, or generically approved in accordance 9 CFR §412.2.
- Verify that the required features are present on the labels.
- Verify that the net weight of the product is accurately reflected on its label.
- Verify that the labels are not false or misleading.
- Verify that the correct labels are applied to products.

Verification activities under Livestock Product Examination

When performing Livestock Product Examination, IPP are to verify that the establishment complies with 9 CFR 318.2, 318.5, and 318.6. The IPP are no longer to perform activities known as livestock carcass re-inspection, boneless meat re-inspection, and other product re-inspection duties to verify compliance with the relevant regulations. Instead, IPP only are to examine product that may have undergone a significant change after it was inspected and passed (e.g., chilled in the cooler or boned). In other words, the IPP should be able to determine the extent of the tasks needed based on conditions observed in the establishment. Where effective establishment processing controls are evident (i.e., the establishment has procedures in place to examine incoming product for acceptability, uses control programs to monitor product processing, and such controls and procedures are documented), the IPP will limit non-food safety verification activities. In these cases the IPP will direct their inspection to those parts of the processing operation that the establishment does not cover by control procedures. The IPP need not count individual defects to make a judgment on a finished production lot but need to base determinations of product compliance by making determinations regarding product usability. The products should not pass inspection if defects are severe or numerous enough to affect the usability of the product. The condition of the product should be clearly evident and sufficient to allow inspection personnel to determine that the product is in compliance. As mentioned earlier, determinations of acceptability should be based on production lots and process controls rather than on individual units of product.

The purpose of the product examination is to determine whether standards are being met and the product meets the conditions as set out in the Act: "...any valuable constituent has been in whole or part omitted or abstracted there from; or any substance has been substituted, wholly or in part thereof, or if damage or inferiority has been concealed in any manner; or if any substance has been added to the product 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" (21 U.S.C. 601(m) (8)).

In addition, IPP may also observe establishment's quality control programs and review associated records to verify whether the establishment meets regulatory requirements.

Inspection program personnel should consult with their Frontline Supervisor (FLS) for assistance, when necessary, in determining noncompliance. The Policy Development Division (PDS) will provide additional guidance to assist with policy questions.

Examples of noncompliance situations:

• IPPS find that a carcass in the cooler has a large and heavy blood clot that would increase the weight of the carcass in such a way to reduce its quality, and the establishment has failed to address the situation.

Note: The blood clot is an example of an "inferiority that has been concealed" because it could not be seen until the carcass was chilled.

• IPP find that after the boning process the boneless product does not represent "boneless meat" because the number of bone fragments, and the establishment has failed to address the situation.

Verification activities under Poultry Product Examination

The Poultry Product Examination task is used to verify that the establishment complies with the relevant regulations for poultry finished product standards (FPS), Giblet Acceptable Quality Levels, rework product standards, inspection of received products and returned products for slaughter. Inspection program personnel inspect raw or unprocessed poultry products under the Poultry Product Examination.

Inspection program personnel verifying compliance with FPS are to use criteria as listed in the regulations. They should verify compliance by performing pre-chill FPS testing, post-chill FPS testing, reinspection of carcasses and giblets, inspection of returned products, inspection of rework products, and condition inspection of products in the establishment. Also, they are to perform the activities at the frequencies prescribed in 9 CFR 381.76. Each time inspection program personnel perform the FPS activities they are to record the activities in PHIS as either routine or directed.

Sample collection for NFSCP verification

When sampling task is placed on the task calendar, conduct sampling activities as appropriate. Inspection program personnel may perform inspector generated non-food safety sampling activities when, during the performance of food safety verification activities, they observe conditions or activities that cause them to suspect that the establishment is not meeting non-food safety regulatory requirements and testing is the only means available to determine noncompliance. For example, finished product in which IPP cannot verify formulation and composition without laboratory testing.

Whenever you believe an inspector generated sample is warranted, notify the FLS by email explaining why you believe an inspector generated sample is warranted and receive his or her approval before proceeding.

When inspection program personnel perform any sampling they are to inform the establishment management when they are taking a sample and the reason why FSIS is analyzing the sample. This notification will afford establishment management the option to hold all product represented by the sample, pending the sample results.

Sampling tasks are documented in the Lab Sampling part of PHIS when n a non-food safety sample is collected. However, if the sample result indicates that the product does not comply with the regulations, the IPP document a Noncompliance Record (NR) under the appropriate HACCP verification task.

Note: The Office of Public Health and Science (OPHS) directs food safety sampling. When directed by OPHS to perform food safety sampling, IPP should document the collection of the samples as a directed procedure in PHIS.

Please note that IPP will no longer receive the Species Identification Field Test (SIFT) kits to conduct in-plant tests to determine whether product contains a species that is not accurately declared on the product label. When IPP have concerns about the species in a product, they are to collect the sample as follow.

 When IPP collect samples for species testing, they are to collect at least one pound of product and put in a plastic bag supplied by the laboratory. If the product is in a Entry Training for PHV natural casing, IPP are to collect a sample of the emulsion. Thereafter, IPP are to complete FSIS form 10,000-2 (form may be requested from Field Supply Center in Beltsville, MD) as follows:

- Block 7 -- establishment number
- Block 13 -- date sampled
- Block 14 -- date mailed
- Block 21 -- check 'species identification' box
- Block 24 -- provide production lot sample and declared species
- Block 25 -- inspector name (type or print)
- Block 26 -- badge number
- IPP are to attach product label showing an ingredient statement to the 10,000-2 Form. Also, they are to:
 - follow FSIS Directive 7355.1, Revision 2, "Use of Sample Seals for Laboratory Samples and Other Applications";
 - ship the samples to the Eastern Laboratory in an insulated shipping container;
 - use sufficient frozen gel packs to keep the sample cold, and
 - ship via overnight contact carrier, Monday thru Friday. For samples shipped on Fridays, be sure to mark Saturday delivery on package and include a Saturday delivery sticker on the box.
- The results will be on the LEARN intranet site (see FSIS Directive 10,200.1) for receipt information and sample results. The laboratory will test the product against a panel of species anti-sera, report species results that correlate with the ingredient statement as "Acceptable", and report species result that indicate a species **not** declared on the ingredient statement is present, or one of the species on the ingredient statement is **not** present as "Not Acceptable".

Enforcement

Product compliance determinations are made based on NFSCP regulatory requirements (see Attachment 1 in Directive 7000.1), including product standards, net weight standards, regulatory minimum or maximum limits of ingredients or components, or product defects. If product is found to exceed any of the maximum limits, falls below the minimum requirements, or fails to meet any of the other NFSCP regulatory requirements, there is regulatory noncompliance. As mentioned before, determinations of noncompliance should be based on production lots or process controls rather than on individual units of product. Use professional judgment and consult with your FLS for assistance when necessary.

Issue an NR when product is not in compliance with NFSCP regulatory requirement, and orally notify the establishment management of the finding. Consider any relevant factors when determining the amount of noncompliant product involved. Factors to be considered include factual information such as the establishment's lot identification procedures, receiving records, and production records, as well as those facts that can be reasonably ascertained based on the average amount of product produced per shift or per production line. When necessary, consult with the FLS for assistance in determining the extent of product involvement.

When noncompliance is found, take the appropriate regulatory control actions, such as retention of product, rejection of equipment or facilities, stopping lines, or refusing to allow the processing of specifically identified product (9 CFR 500.1(a)), if it is determined that misbranded or economically adulterated product (e.g., under-weight product, the product does not meet requirements that are specified in the applicable standard of identity for the product, etc.), would otherwise enter commerce (be shipped from the establishment). Additionally, 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 per 9 CFR 500.8.

Inspection program personnel are to issue NRs when they determine the process are out of control, resulting in economically adulterated or misbranded product. Inspection program personnel should link the NRs when noncompliances are from the same cause, as described in FSIS Directive 5000.1and are to notify the District Office (DO) through supervisory channels when establishment management is unwilling to meet regulatory requirements.

The DO may notify the establishment in writing that the repeat noncompliances may lead to a regulatory control action (9 CFR 500.1-3) that would affect the entire production of the product in question because product may be economically adulterated or misbranded. Whenever a regulatory control action is taken, such action will remain in place until the DO receives written assurances from the establishment indicating what procedures the establishment has instituted to regain and maintain process control to meet regulatory requirements. The DO will make a determination whether those procedures appear to correct the problem. Additionally, to determine the effectiveness

of the actions, IPP will verify that the establishment's corrective actions are adequate and are operating as described in the establishment's response.

The DO should notify the Regional Manager of the Compliance and Investigations Division whenever there is a reason to believe that non-food safety noncompliances involve the shipment of economically adulterated or misbranded product or criminal intent to defraud the consumer.

SPECIFIC NFSCP PROCEDURES

Now, let's walk through each of the NFSCP procedures.

% Yield/Shrink/Gain

When performing this task, you'll verify the requirements associated with percent yield/shrink/gain.

Examples of products: bacon, BBQ meats, roasts beef, corned beef, cured beef tongue, country ham, etc.

Regulations: 319.80; 319.81; 319.100; 319.101; 319.102; 319.103; 319.106; 319.107; 424.21 (c)

Directive: 7620.3

Entry Training for PHV

When performing the task, select an appropriate product and verify compliance with regulatory requirements by reviewing establishment records and labels, calculating the % yield or shrink, and comparing the result with the appropriate regulatory requirement. You may also verify compliance by weighing a sample of product before and after the appropriate step in the process (i.e., pumping, cooking, chilling, curing, drying, etc.), calculating the % yield, shrink or gain, and comparing the result with the appropriate regulatory requirement.

X% Solution Labeled Products (applies only to X% labeled products)

You will verify the requirements associated with X percent solution for labeled products. This task relates to the regulations regarding false or misleading labeling or practices, because you are verifying that the percent of a solution added to a product does not exceed the regulatory requirements.

Examples of products: cured pork products, ham patties, chopped ham, ready-to-cook poultry products, turkey ham, corned beef, beef brisket, etc.

Regulations: 317.2 (c); 317.8; 381.129, 381.169 319.104, and 319.105 (in these regulations, the sections that apply are those covering X% label products)

Directive: 7620.3 FSIS

Issuances:

Policy Memos 57A, "Labeling Turkey Ham Products Containing Added Substances" Policy Memos 42, "Labeling of Raw Bone-in Poultry Products Containing Solutions" Policy Memos 44A, "Labeling of Raw Boneless Poultry Products Containing Solutions" Policy Memos 66C, "Uncooked Red Meat Products Containing Added Substances" Policy Memos 84A, "Cooked Red Meat Products Containing Added Substances"

When performing this task, select an appropriate product and verify compliance with X% labeling requirements by reviewing establishment records and labels, calculating the % added solution and comparing the results with the X% labeling declaration. You may also verify compliance by weighing a sample of product before and after the appropriate step in the process (i.e., pumping, curing, drying, etc.), calculating the % added solution, and comparing the result with the X% labeling declaration.

MSP/MSKP/PDBFT/PDPFT/AMR products

You will verify one of the requirements depending on the type of product that is being produced: Mechanically Separated Pork (MSP), Mechanically Separated Kind of Poultry (MSKP), Partially Defatted Beef Fatty Tissue (PDBFT), and Partially Defatted Pork Fatty Tissue (PDPFT), and Advanced Meat Recovery (AMR) products.

Regulations: 319.5; 319.15; 319.29; 318.24; 381.173

Directives: 7160.1; 7160.2; 7160.3,

When performing this task, select an appropriate product and verify compliance by reviewing establishment records and labels, or by observing the preparation of products, and comparing the findings to the standards listed in the regulations. Also, take samples as directed.

To verify compliance:

- check product identification, condition, temperature, holding time/temperature;
- examine bones (for example, two intact portions of bones) before and after the meat recovery systems in order to observe condition and conformation;
- review establishment laboratory results and compare findings with the appropriate regulatory standard, and collect samples as directed.

Batter/Breading

You will verify the requirements associated with batter and breading.

Examples of products: breaded products, breaded patties, breaded meat cuts, fritters

Regulations: 319.880; 381.166

Directives: 7220.1; 7620.3

Resources and Examples: CD Center's for Learning "OCP Directive 7000.1; Calculation Aid "Tool" in FSIS Applications

Here's what you should do when performing this task. Select an appropriate product and verify compliance with the batter and breading regulatory requirements by reviewing

establishment records to calculate final % batter/breading and comparing the findings to the standards listed in the regulations. You may also verify compliance by performing batter and breading pickup tests on one or more subgroups (according to the establishment's QC programs) or batches of the product.

Product Standards

You will verify the requirements for product standards.

Examples of products: miscellaneous beef products, sausage, frankfurters, luncheon meats, chili con carne, meat stews, tamales, and others (see Directive 7000.1)

Regulations: 319.15; 319.140-145; 319.160; 319.180-182; 319.260-261; 319.280-281; 319.300-313; 319.500; 319.700-703; 319.720-721; 319.760-762; 319.881; 381.156-168; 381.170-171.

Directives: 7220.1, Rev. 3; 7620.3

When performing this task select an appropriate product and verify compliance by reviewing establishment records and labels, or observing the preparation of products and comparing the findings to the appropriate regulatory standards. To verify some regulatory requirements, calculations will need to be performed to determine specified components, such as % fat, or % water.

Grade Labeling/Declared Count/Vignette

You will verify the requirements related to false or misleading labeling or practices, including specific prohibitions and requirements for labels and containers, and wording on labels of immediate containers.

Examples of products: All types of products Regulations:

317.2; 317.8; 381.116

Directives: 6810.1;

Resources and Example Task Verification: CD Center's Learning

When performing this task, select product and verify that the labeling is used on appropriate product and that there is a label approval on file. Remember that products for which there is a standard of identity can use generically approved labels.

Net weights

You will verify the requirements related to net weights whether the containers are catch weight or bear a stated net content.

Examples of products: All types of products that carry a net weight statement.

Regulations: 317.18-22; 381.121 (a-e)

References: NBS Handbook 133 NIST Handbook 44

<u>Note:</u> FSIS has determined that both handbooks mentioned above should be used as the definitive references for determinations of net weight compliance.

When performing this task, select an appropriate retail-sized packaged product and verify net weight regulatory requirements by reviewing establishment records and conducting net weight/drained weight checks, scale calibration checks (certification and accuracy), and calculating average tare weights. For QC inspection verification, follow the QC program requirements after first evaluating the program to ensure that following the program results in compliance with net weight regulatory requirements.

General labeling

This task applies to all products that bear a label. For example, it includes verifying the requirements related to standards of identity.

Example of products: All products

Regulations: 316; 317; 318; 319; 327.10(d); 327.26; 381; 412; 424.21; 441.10

Directives: 6700.1; 7120.1; 7235.1; 7270.1; 7620.3 Entry Training for PHV When performing this task, select an appropriate product and verify that the label contains all required information. This includes the ingredients statement is accurate (i.e., that all ingredients are listed in descending order of predominance and any proteinaceous substances used in the formulation are declared in the ingredients statement), restricted ingredients are used as per regulatory requirements, the label is used on appropriate product, and that there is a label approval on file. When verifying restricted ingredient requirements or ingredients statement compliance, observe the establishment formulating product and compare to the approved label.

NOTE: Proteinaceous substances can cause adverse reactions (i.e., allergic and nonallergic) in certain individuals, and therefore, such substances are of a food safety concern if not clearly declared in the ingredients statement.

When verifying imported products verify that the establishment meets the regulatory requirements for pre-stamping.

Livestock Product Examination

The Livestock Product Examination task applies to carcasses, boneless meat, returned products, product reconditioning, reinspection, retention, and disposal of meat products at official establishments; and to requirements concerning procedures, ingredients, and other articles used in preparation of products.

Examples of products: boneless meat, meat carcasses, pork skins for popping

Regulations: 318.2; 318.5; 318.6

When performing this task, select an appropriate product/procedure and verify these regulatory requirements by reviewing establishment records and/or observe establishment performance of activities. You may perform direct examination of the product, if warranted, to verify that the product is not economically adulterated or misbranded (318.2b).

Poultry Product Examination

This task covers finished product standards, rework/reprocess/salvage products, poultry carcasses, poultry products and other articles entering or at official establishments, examination and other requirements, returned products, and good commercial practices for poultry slaughter.

Regulations: 381.1; 381.76; 381.78; 381.84; 381.86; 381.91(b); 381.145; 381.65 (b)

When performing this task, verify compliance by performing:

- pre-chill FPS tests;
- post-chill FPS tests:
- reinspection of carcasses and giblet;
- inspection of returned products;
- inspection of rework products; and
- condition of products in the establishment.
- observation of slaughter practices

Misbranding/Economic Adulteration Sampling, Directed and Inspector GeneratedSampling

This task covers misbranding and economic adulteration sampling. It can be directed or inspector generated.

Examples of products: cooked sausage, Italian sausage, ground beef, hamburger, ground pork, pH controlled product, lard, and others

Regulations: 301.2; 318.9; 318.22; 318.24; 319; 319.5; 381.1; 381 Subpart P; 381.146; 381.173; 500.3

When performing this task, randomly select an appropriate product for verification. Verify compliance by collecting, processing and mailing samples to the designated laboratory as directed in PHIS, or when there is a reason to believe that product does not comply with regulatory requirements. Request permission to sample suspect product from the FLS and notify the establishment of the sampling.

FSIS Directive 7000.1 -Verification of NFSCP Regulatory Requirements – Workshop

- A. Choose the best answer:
 - 1. Which of the following represents the definition of the term "misbranded" in the Statutes?
 - a. A product with labeling that is false or misleading.
 - b. A product with a label that does not show the name and place of business that produced the product.
 - c. A product that is subject to standards of identity but was not produced to follow those standards.
 - d. All of the above.
 - 2. Which of the following is **NOT** true about labeling approval?
 - a. Sketch labels must show the size, location, and final color of the label.
 - b. Temporary approval of labels may be granted.
 - c. A single ingredient product with no special claims must have label approval.
 - d. Some labels have generic approval.
 - 3. If when performing an NFSCP procedure you uncover concerns related to an establishment's Sanitation SOP or HACCP plan, you should:
 - a. Perform a directed economic wholesomeness/labeling task.
 - b. Perform a directed food safety task.
 - c. Perform an inspector generated sampling task.
 - d. Contact the Policy Development Staff.
 - 4. NFSCP duties cover which one of the following?
 - a. HACCP verification
 - b. economic adulteration
 - c. Sanitation SOP verification
 - d. food safety sampling
 - 5. Which of the following represents what you should do when performing the economic wholesomeness tasks?
 - a. Observe establishment product formulation, labeling, packaging, preparation, and processing procedures.
 - b. Examine product and review establishment records.
 - c. Check product identification, condition and temperature.
 - d. Perform a variety of in-plant measurements, testing and calculations.
 - e. All of the above.

- 6. When observing product formulation, you should do all of the following except:
 - a. Verify product formulation and compliance with permitted amounts of restricted ingredients.
 - b. Verify all ingredients used in formulating the product are listed on the label in ascending order of predominance and any proteinaceous substances used in the formulation are declared in the ingredient statement.
 - c. Verify compliance with standards of identity and composition regulatory requirements.
 - d. Observe establishment activities and review establishment records.
- 7. Is the following statement TRUE or FALSE?

When verifying NFSCP requirements for labeling, you should determine whether labeling is approved in accordance with appropriate regulations, i.e., either approved as a sketch by the FSIS LPDS, or generically approved in accordance with 9 CFR 412.2.

- a. TRUE
- b. FALSE
- 8. Which one of the following should you do when establishment processing controls appear to be effective?
 - a. Count defects.
 - b. Direct your attention to establishment records.
 - c. Direct your attention to areas in the process not covered by establishment controls.
 - d. Review product formulation.
- 9. Is the following statement TRUE or FALSE?

It is appropriate to perform unscheduled NFSCP verification procedures when you suspect regulatory requirements are not being met?

- a. TRUE
- b. FALSE
- 10. Is the following statement TRUE or FALSE?

It is not appropriate to perform inspector generated sampling unless you suspect regulatory requirements are not being met.

- a. TRUE
- b. FALSE

- 11. Which of the following must be done first if you believe collecting an inspector generated sample is warranted?
 - a. Notify the FLS by e-mail explaining why the sample is warranted.
 - b. Inform the DO before you take the sample.
 - c. Inform establishment management before you take the sample.
 - d. Inform establishment management of the type of analysis that will be done on the sample.
 - e. All of the above.
- 12. Is the following statement TRUE or FALSE?

Make determinations of noncompliance on individual units of product.

- a. TRUE
- b. FALSE
- 13. What should you do when noncompliance with an NFSCP requirement is found?
 - a. Issue an NR.
 - b. Notify the establishment orally of the finding.
 - c. Determine the amount of noncompliant product involved.
 - d. Take appropriate regulatory control actions if without such action a misbranded or economically adulterated product would be shipped from the establishment.
 - e. All of the above.
- 14. When noncompliance is found which of the following must be considered in determining the amount of noncompliant product involved in the noncompliance?
 - a. The establishment's number of employees.
 - b. Sampling records.
 - c. Production records.
 - d. None of the above.
- 15. All of the following are appropriate regulatory control actions to take if it appears that a product that is economically adulterated or misbranded will be shipped from the establishment except:
 - a. Retention of product.
 - b. Rejection of equipment or facilities.
 - c. Stopping lines.
 - d. Refusing to allow the processing of specifically identified product.
 - e. Refusing to allow the establishment manager to leave the establishment.
- 16. What should you do when there are repeated violations involving the same process and product and the establishment seems unable or unwilling to maintain regulatory compliance?
 - a. Associate the NRs.
 - b. Notify the DO through supervisory channels.
 - c. If a regulatory control action is taken, maintain that action in place until the DO receives written assurances from the establishment indicating what procedures the establishment has instituted to regain and maintain process control to meet regulatory requirements.
 - d. Conduct any follow up verification activities as directed by the DO to ensure compliance.
 - e. All of the above.
- 17. When performing the %Yield/Shrink/Gain task to verify compliance with regulatory requirements, you should do all of the following except:
 - a. Select an employee to accompany you.
 - b. Select an appropriate product.
 - c. Review establishment records and labels.
 - d. Calculate % yield, gain, or shrink and compare result with regulatory compliance.
 - e. Be familiar with the regulatory requirements.
- 18. Is the following statement TRUE or FALSE?

For %Yield/Shrink/Gain you may also verify compliance by weighing a sample of product before and after the appropriate step in the process (pumping, cooking, chilling, curing, drying, etc.), calculating the % yield, gain, or shrink, and comparing the result with the appropriate regulatory requirement.

- a. TRUE
- b. FALSE
- 19. What should you do when performing the X% Solution Labeled Products tak to verify compliance with regulatory requirements?
 - a. Select an appropriate product for verification.
 - b. Review establishment records and labels, calculating the % added solution and comparing the results with the X% labeling declaration.
 - c. Weigh a sample of product before and after the appropriate step in the process (pumping, curing, drying, etc.), calculating the % added solution, and comparing the result with the X% labeling declaration.
 - d. All of the above.

- 20. What should you do when performing the MSP/MSKP/PDBFT/PDPFT/AMR task to verify compliance with regulatory requirements?
 - a. Call the DO prior to performing verification.
 - b. Review establishment safety records.
 - c. Observe the preparation of products and, compare the findings to the standards listed in the regulations.
 - d. None of the above.
- 21. When directed to take samples while performing the MSP/MSKP/PDBFT/PDPFT/AMR task, you should do all of the following except:
 - a. check product identification, condition, temperature, holding time/temperature
 - b. compare your finding with the closest establishment
 - c. review establishment laboratory results and compare findings with the appropriate regulatory standard
 - d. examine bones (for example two intact portions of bones) before and after the meat recovery system to observe condition and conformation
- 22. Is the following statement TRUE or FALSE?

When performing the Batter/Breading task to verify compliance with regulatory requirements, it is not appropriate to perform batter and breading.

- a. TRUE
- b. FALSE
- 23. What should you do when performing the Product Standards task to verify compliance with regulatory requirements?
 - a. Select an appropriate product for verification.
 - b. Review establishment records and labels, or observe the preparation of products and compare the findings to the appropriate regulatory standards.
 - c. For some regulatory requirements, perform calculations to determine specified components, such as % fat, or % water.
 - d. All of the above.
- 24. What should you do when performing the Grade Labeling task to verify compliance with regulatory requirements?
 - a. Verify that labeling is used on appropriate product
 - b. Contact your supervisor prior to performing verification
 - c. Verify that there is a label approval on file at the PDS
 - d. Review all NRs

- 25. What should you do when performing the Net Weights task to verify compliance with regulatory requirements
 - a. Select an appropriate wholesale-sized product for verification.
 - b. Review establishment records and conduct net weight/drained weight checks, scale certification and accuracy, or calculate average tare weight checks.
 - c. For QC inspection verification, follow HACCP requirements.
 - d. None of the above.
- 26. When performing the General Labeling task to verify compliance with regulatory requirements, you should do all of the following except:
 - a. Verify that the label contains all required information.
 - b. Verify that restricted ingredients are used as per regulatory requirements by observing the establishment formulating product and comparing it to the approved label.
 - c. Verify that there is a label approval on file.
 - d. Verify that the label has been used at least twice
- 27. What should you do when performing the Livestock Product Examination task to verify compliance with regulatory requirements?
 - a. Select an appropriate product for verification.
 - b. Review establishment records and/or observe establishment performance of activities.
 - c. You may perform direct examination of the product.
 - d. All of the above.
- 28. What should you do when performing the Poultry Products Examination task to verify compliance with regulatory requirements
 - a. only perform pre-chill and post-chill FPS testing
 - b. perform reinspection of carcasses, giblets, and spleens
 - c. return reworked product
 - d. observes poultry slaughter practices.

UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE

WASHINGTON, DC

FSIS DIRECTIVE

7000.1

12/11/06

NOTE: DO NOT IMPLEMENT THIS DIRECTIVE UNTIL FEBRUARY 20, 2007

VERIFICATION OF NON-FOOD SAFETY CONSUMER PROTECTION REGULATORY REQUIREMENTS

I. PURPOSE

This directive instructs inspection program personnel on how to verify that plants comply with regulatory requirements designed to protect the consumer in ways other than ensuring food safety. It also issues new Inspection System Procedures (ISP) descriptions for all 04 and 05B procedures, except 04C02, Humane Handling. FSIS is retiring procedure code 04C01, and therefore, inspection program personnel are not to use it. Inspection program personnel are to follow FSIS Directive 6900.1, Revision 1 and 6900.2, Revision 1 when verifying humane handling requirements.

Key Points Covered

Verification activities performed by inspection program personnel are to be predominantly food safety focused, but it is also necessary to verify compliance with requirements that provide non-food safety protections to consumers.

Methodology and documentation for verifying that there is compliance with these non-food safety requirements.

II. CANCELLATIONS

FSIS Directive 5400.5, Attachment 6, "Inspection System Procedure Guide," pages 4-1 through 4-10, 5-3 and 5-4

FSIS Directive 7110.2, Revision 1, "Update of Protein Fat Free (PFF) Instructions" FSIS Directive 7130.3, "Inspection Procedure for Fat and Added Water in Cooked Sausage"

FSIS Directive 7140.2, "Determining Added Water in Cooked Sausage"

FSIS Directive 7140.3, "Determining Added Water in Fresh Sausage"

FSIS Directive 7236.2, "Nutrition Labeling of Meat and Poultry Products"

FSIS Directive 7240.1, "Compliance Testing for Net Weight Labeling of Meat and Poultry Products"

FSIS Directive 7310.6, "Bacon Yield Determinations"

DISTRIBUTION: Inspection Offices; T/A Inspectors; TSC; Import Offices

OPI: OPPED

FSIS Directive 7330.1, "Sampling Frequencies for Cooked Sausage Produced Under a Quality Control Program"

FSIS Directive 10,230.1, "Species Identification Sampling for Cooked Products" MPI Manual Part 11-D and Part 18

MPI Bulletins 75-56, 78-111, 79-42, 80-4, and 83-54

Any Regional Notices, MPI Bulletins or other written instructions related to reinspection of livestock product for reasons other than public health and food safety.

III. [RESERVED]

IV. REFERENCES

Federal Meat Inspection Act (FMIA)

Poultry Products Inspection Act (PPIA)

9 CFR Parts 301, 313, 316, 317, 318, 319, 327, 381 Subpart P, 424, 441, and 500 FSIS Directive 5000.1, Revision 3, "Verifying An Establishment's Food Safety System" FSIS Directive 5400.5, Attachment 5, "Inspection System Activities" FSIS Directive 6120.1, "Finished Product Standards Program for the New Line Speed Inspection System and the Streamlined Inspection System" FSIS Directive 6700.1, "Retained Water in Raw Meat and Poultry Products" FSIS Directive 6810.1, "Grademark Labeling on Meat and Poultry Products" FSIS Directive 6900.1, Revision 1, "Humane Handling of Disabled Livestock" FSIS Directive 6900.2, Revision 1, "Humane Handling and Slaughter of Livestock" FSIS Directive 7000.2, "Experimental and Sample Products Policy" FSIS Directive 7120.1, "Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products" FSIS Directive 7124.1, "Standards of Identity or Composition—Use of Cooked or Cured Product" FSIS Directive 7140.1, "Questions and Answers Relating to Ingredients That May Be Designated as Flavors, Flavorings, Natural Flavors or Natural Flavorings in the Ingredients Statements on the Labels of Meat and Poultry Products" FSIS Directive 7160.1, "Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery Systems" FSIS Directive 7160.2, "Meat' Prepared Using Advanced Mechanical Meat/Bone Separation Machinery and Meat Recovery Systems" FSIS Directive 7160.3, Revision 1, "Advanced Meat Recovery Using Beef Vertebral Raw Materials" FSIS Directive 7220.1, "Policy Memoranda" FSIS Directive 7221.1, Amendment 1, "Prior Labeling Approval" FSIS Directive 7222.1, "Inspection Requirements for Food and Nutrition Service In-plant Control Programs" FSIS Directive 7235.1, "Mandatory Safe Handling Statements on Labeling of Raw and Partially Cooked Meat and Poultry Products" FSIS Directive 7237.1, Revision 1, Amendment 1, "Labeling of Ingredients" FSIS Directive 7270.1, Revision 1, "Sampling and Testing Procedures for Raw Poultry Products Labeled 'Fresh'" FSIS Directive 7355.1, Revision 2, "Use of Sample Seals for Laboratory Samples and Other Applications" FSIS Directive 7620.3, "Processing Inspectors' Calculations Handbook"

FSIS Directive 8080.1, Revision 4, Amendment 1, "Recall of Meat and Poultry Products"
FSIS Directive 10,200.1, "Accessing Laboratory Sample Information via LEARN"
FSIS Directive 10,210.1, "Unified Sampling Form"
FSIS Directive 10,520.1, Revision 1, "Pumped Bacon Sampling Program – Nitrosamine Analysis"
Part 3, Section 3, "Import Inspection Manual of Procedures for the Species Verification Testing Program"
Policy Memos 42, 44A, 57A, 66C, and 84A
NBS Handbook 133
NIST Handbook 44

V. BACKGROUND

FSIS' highest priorities are protecting public health and food safety. By making the procedural changes announced in this directive, the Agency is ensuring that inspection program personnel focus on food safety, yet still verify other protections extended by the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA). The Agency is making changes in the verification procedures that relate to these other protections to ensure that they align with FSIS' responsibilities and priorities.

VI. VERIFICATION METHODOLOGY FOR NON-FOOD SAFETY ISP CODES (ALL 04A AND 04B CODES AND 04C03 and 04C04 CODES)

A. When the Performance Based Inspection System (PBIS) schedules one of these non-food safety procedures per one of the above codes, inspection program personnel are to perform the appropriate verification procedure. This includes observing establishment product formulation, verifying the accuracy of labeling, observing preparation or processing procedures; reviewing establishment records; examining product; checking product identification, condition and temperature; or performing a variety of other in-plant measurements, testing, and calculations.

B. Inspection program personnel are not to perform unscheduled non-food safety consumer protection verification procedures unless, during the performance of food safety verification activities, they observe conditions or activities that cause them to suspect that the establishment is not meeting non-food safety regulatory requirements. Conversely, if while performing a scheduled non-food safety consumer protection verification procedure inspection program personnel identify food safety concerns, they should perform the food safety procedure as an unscheduled procedure and take any necessary enforcement actions. For example, if an inspector is performing a routine labeling verification procedure and discovers that the establishment has used an ingredient of public health concern without properly declaring the ingredient, the inspector should pursue the food safety aspects of the findings and perform the appropriate unscheduled food safety procedures as instructed in FSIS Directive 5000.1, Revision 3.

C. Attachment 1 to this directive reissues and replaces all of the 04 and 05B codes from FSIS Directive 5400.5, Attachment 5. When verifying compliance with a non-food safety requirement, inspection program personnel are to use attachment 1 to find:

1.	Procedure code	(column 1)
2.	Examples of products	(column 2)
3.	Regulatory references	(column 3)
4.	FSIS issuance references	(column 4)

5. Verification instructions (column 5)

NOTE: Lists of example products, regulatory references, FSIS issuances, and verification instructions provide guidance. They are not "all inclusive" lists.

D. Inspection personnel need only examine product when they have reason to believe that product does not meet regulatory requirements. However, there are no designated sampling plans or sample sizes that inspection program personnel are to use when examining products to assure that the products meet non-food safety regulatory requirements, nor are inspection program personnel to examine all products. Inspection program personnel examine product to determine whether the product complies with regulatory requirements (see Attachment 1), such as product standards, net weight standards, regulatory minimum or maximum limits of ingredients or components, or product defects. If inspection program personnel find that product exceeds any of the maximum limits, falls below the minimum requirements, or fails to meet any of the other non-food safety regulatory requirements, there is regulatory noncompliance. Inspection program personnel are to determine whether product complies with the regulations based on production lots or process controls rather than on individual units of product. For example, if one package of product exceeds its net weight, inspection program personnel are to investigate whether there have been problems in the process that will cause all packages to exceed the net weight requirements.

E. Verification Activities Under 04A and 04B (Formulation and Labeling)

1. Inspection program personnel are to verify that the establishment is producing product in compliance with the appropriate Title 9 Code of Federal Regulations (CFR) reference (see Attachment 1).

2. Inspection program personnel are to determine whether the product complies with the regulations by comparing the product to the relevant regulatory requirements and determining whether:

a. the product meets requirements that are specified in the applicable standards of identity;

b. the net weight of the product is accurately reflected on its label;

c. all ingredients have been added in amounts that come within the maximum or minimum level specified in the applicable standard;

d. ingredients are accurately declared on the product label in descending order of predominance; and

e. the product defect levels are consistent with applicable standards.

NOTE: When import inspectors perform inspections at official import inspection establishments, the establishment may place the official inspection legend on containers of imported product before inspectors complete their inspections. (9 CFR 327.10 (d)).

F. Verification Activities Under 04C03 (Livestock Product Examination)

1. Under 04C03, inspection program personnel are to verify that the establishment complies with 9 CFR 318.2, 318.5, and 318.6. Inspection program personnel are no longer to perform activities known as livestock carcass re-inspection, boneless meat re-inspection, and other product re-inspection duties to verify compliance with the relevant regulations. Instead, inspection program personnel should be able to determine the extent of the procedures needed based on conditions observed in the establishment. Where effective establishment processing controls are evident, (i.e., the establishment has procedures in place to examine incoming product for acceptability, uses control programs to monitor product processing, and such controls and procedures are documented), inspection program personnel will limit non-food safety verification activities. Inspection program personnel will, in these cases, direct their inspection to those parts of the processing operation that the establishment does not cover by control procedures. Inspection program personnel need not count individual defects to make a judgment on a finished production lot. Inspection program personnel need to base determinations of product compliance by making determinations regarding product usability. The products should not pass inspection if defects are severe or numerous enough to affect the usability of the product. The condition of product should be clearly evident and sufficient to allow inspection personnel to determine that the product is in compliance. The purpose of product examination that inspection program personnel are to perform is to determine whether standards are being met. Determinations of acceptability should be based on production lots and process controls rather than on individual units of product. Inspection program personnel should consult with their Frontline Supervisor for assistance when necessary.

Examples of noncompliance situations include:

a. inspection program personnel find that a carcass in the cooler has a large and heavy blood clot that would increase the weight of carcass in such a way to reduce its quality, and the establishment has failed to address the situation.

NOTE: The blood clot is an example of an "inferiority that has been concealed" because it could not be seen until the carcass chilled.

b. inspection program personnel find that after the boning process, the boneless product does not represent "boneless meat" because of the number of bone fragments, and the establishment has failed to address the situation.

2. Inspection program personnel may also observe establishment's quality control programs and review associated records to verify whether the establishment meets regulatory requirements.

3. When necessary, inspection program personnel are to consult with their Frontline Supervisor for assistance in determining noncompliance. The Technical Service Center (TSC) will provide additional guidance to assist with determining noncompliance.

G. Verification Activities Under 04C04 (Poultry Product Examination)

1. Under the 04C04 procedure, inspection program personnel are to verify that the establishment complies with the relevant regulations for poultry finished product standards, Giblet Acceptable Quality Levels, and rework product standards. Inspection program personnel inspect raw or unprocessed poultry products and return of questionable poultry products under the 04C04 procedure.

2. In addition, the 04C04 procedure is used to verify conformance with good commercial practices for poultry slaughter that comply with 9 CFR 381.65 (b), (i.e., thorough bleeding of the carcasses, ensuring that breathing has stopped prior to scalding, and that blood from the killing operation is confined to a relatively small area).

3. Inspection program personnel verifying compliance with finished product standards (FPS) are to use the criteria as listed in the regulations (see Attachment 1). Inspection program personnel should verify compliance by performing pre-chill FPS testing, post-chill FPS testing, reinspection of carcasses and giblets, inspection of returned products, inspection of rework products, and condition inspection of products in the establishment. Inspection program personnel are to perform the activities at the frequencies prescribed in 9 CFR 381.76. Each time inspection program personnel perform the finished product standard activities they are to record the activities in PBIS as unscheduled.

VII. SAMPLE COLLECTION FOR NON-FOOD SAFETY CONSUMER PROTECTION VERIFICATION (05B01)

A. PBIS will schedule non-food safety sampling under ISP code 05B01 (see Attachment 1). Inspection program personnel may perform unscheduled non-food safety sampling activities when, during the performance of food safety or non-food safety verification activities, they observe conditions or activities that cause them to suspect that the establishment is not meeting non-food safety regulatory requirements and testing is the only means available to determine noncompliance, e.g., finished product in which inspection program personnel cannot verify formulation and composition without laboratory testing.

NOTE: Inspection program personnel will no longer receive the Species Identification Field Test (SIFT) kits to conduct in-plant tests to determine whether a product contains a species that is not accurately declared on the product label. When inspection program personnel have concerns about the species in a product, they are to collect the sample as described in Attachment 2. Import inspection personnel should follow the instructions provided in the Import Inspection Manual of Procedures for the Species Verification Testing Program.

B. When inspection program personnel perform any sampling, they are to inform the establishment management when they are taking a sample and the reason why FSIS is analyzing the sample. This notification will afford establishment management the option to hold all product represented by the sample pending the sample results.

C. Code 05B01 is the procedure code inspection program personnel should enter on the schedule when they collect a non-food safety sample. However, if the sample result indicates that the product does not comply with the regulations, inspection program personnel document a Noncompliance Record (NR) (FSIS Form 5400-4) under the appropriate ISP code, not 05B01.

NOTE: The Office of Public Health Science (OPHS) directs food safety sampling. When directed by OPHS to perform food safety sampling, inspection program personnel should document the collection of the samples as an unscheduled procedure under code 05B02.

VIII. ENFORCEMENT

A. Inspection program personnel are to issue an NR when a product does not comply with a non-food safety regulatory requirement and are to notify the establishment orally of the finding. Inspection program personnel are to consider all relevant factors when determining the amount of noncompliant product that is involved. Factors inspection program personnel should consider include facts such as the establishment's lot identification procedures, receiving records, and production records, as well as those facts that can reasonably be ascertained based on the average amount of product produced per shift or per production line. When necessary, inspection program personnel will consult with their Frontline Supervisor for assistance in determining the extent of product involvement.

B. Inspection program personnel are to take the appropriate regulatory control actions, such as retention of product, rejection of equipment or facilities, stopping lines, or refusing to allow the processing of specifically identified product (9 CFR 500.1(a)), if they determine that misbranded or economically adulterated product, e.g., under-weight product, the product does not meet requirements that are specified in the applicable standard of identity for the product, etc., would otherwise enter commerce (be shipped from the establishment). Additionally, 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 per 9 CFR 500.8.

C. Inspection program personnel are to issue NRs when they determine the processes are out of control, resulting in economically adulterated or misbranded product. Inspection program personnel should link the NRs when noncompliances are from the same cause, as described in FSIS Directive 5000.1, Revision 3 and are to notify the District Office (DO) through supervisory channels when plant management is unwilling or unable to take necessary steps to re-establish control of its process necessary to meet regulatory requirements.

D. The DO is to notify the establishment, in writing, that repeated noncompliances may lead to a regulatory control action (9 CFR 500.1-3) that would affect the entire production of the product in question because product may be economically adulterated or misbranded. Whenever inspection program personnel take such regulatory control action, the action will remain in place until the DO receives written assurances from the establishment as to what procedures the establishment has instituted to regain and maintain the control of its process necessary to meet regulatory requirements. The DO will make a determination whether those procedures appear to correct the problem. Additionally, to determine the effectiveness of the actions, inspection program personnel will verify that the establishment's corrective and preventive actions are adequate and are operating as described in the establishment's response.

E. The DO should notify the Regional Manager of the Compliance and Investigations Division whenever there is reason to believe that non-food safety noncompliances involve the shipment of economically adulterated or misbranded product or criminal intent to defraud the consumer.

Questions are to be directed to the Technical Service Center at 1-800-233-3935.

Pling Salafle-

Assistant Administrator Office of Policy, Program, and Employee Development

Attachments

Attachment 1

Procedure	Example	9 CFR	FSIS Issuance	Inspection Personnel
Code	Products	References	References	Responsibilities
04A01		Parts	Directive 7620.3	Inspection program personnel are
% Yield/Shrink/Gain	Bacon	319.107	"Processing	to select an appropriate product
	Barbecued meats	319.80	Inspectors' Calculations Handbook"	and verify compliance with regulatory requirements by reviewing establishment records
	Roast beef parboiled and steam roasted	319.81	Chapters 11, 12, & 13; % gain, % shrink & % yield	and labels, calculating the % yield or shrink, and comparing the result
	Corned beef	319.100	/oshinik & /oyield	requirement. In addition, inspection program personnel are
	Corned beef brisket	319.101		to verify compliance by weighing a sample of product before and after
	Corned beef round and other corned beef cuts	319.102		the appropriate step in the process (i.e., pumping, cooking, chilling, curing, drying, etc.), calculating
	Cured beef tongue	319.103		the % yield or shrink, and comparing the result with the
	Country ham, Country style ham, Dry cured ham, Country style pork shoulder, and Dry cured pork shoulder	319.106		requirement.
	Tenderizing agents	424.21 (c)		

Procedure	Example	9 CFR	FSIS Issuance	Inspection Personnel
Code	Products	References	References	Responsibilities
04A02		Parts		Inspection program personnel
X% Solution	Cured pork products	319.104*		are to select an appropriate
Labeled			Directive 7620.3,	product and verify compliance
Products*	Ham patties,	319.105*	"Processing Inspectors"	with X% labeling requirements
	chopped ham,		Calculations Handbook"	by reviewing establishment
*NOTE	pressed ham,	*NOTE:	Chapter 10, "Products	records and labels, calculating
*NOIE:	spiced ham and	Applies only	"X% of Weight Is Added	comparing the results with the
Applies only	sinna products	to sections of	Ingredients"	X% labeling declaration In
to X%		319.104 and 310 105	mgreatents	addition inspection program
Labeled		517.105 covering X%		personnel are to verify
Products		labeled	Policy Memos:	compliance by weighing a
		products	57A, "Labeling Turkey	sample of product before and
		1	Ham Products	after the appropriate step in the
			Containing Added	process (i.e., pumping, curing,
			Substances"	drying, etc.), calculating the %
			12 "Laboling of Down	added solution, and comparing
			42, Labeling of Raw	the result with the X% labeling
	Ready-to-cook poultry		Containing Solutions"	declaration.
	products to which		Containing Solutions	
	solutions are added		44A, "Labeling of Raw	
			Boneless Poultry	
	Turkey ham products		Products Containing	
	containing added water		Solutions"	
	Corned beef, beef brisket,	381 120	66C, "Uncooked Red	
	corned beef round and	301.127	Meat Products	
	tongue and other beef cuts		Containing Added	
	to which solutions are		Substances"	
	added	381.169		
			84A, "Cooked Red Meat	
	False or misleading		Added Substances"	
	containers		Audeu Substances	
	containers	317.2 (c)		
	Ready-to-cook poultry			
	products to which	317.8		
	solutions are added	517.0		
	Labels, definition;			
	required features			
	Faise and misleading			
	apporally			
	generally			

Procedure	Example	9 CFR	FSIS Issuance	Inspection Personnel
Code	Products	References	References	Responsibilities
04A03 – MSP/MSKP/ PDBFT/ PDPFT/AMRS	Mechanically separated pork Mechanically separated kind of poultry	Parts 319.5 381.173	Directive 7160.1, "Meat Produced by Advanced Meat/Bone Separation	Inspection program personnel are to select an appropriate product and verify compliance by reviewing establishment records and labels, or by observing the preparation of products, and comparing the
	Partially defatted beef fatty tissue	319.15	Meat Recovery Systems"	the regulations. In addition, inspection program personnel are to take samples as directed
	Partially defatted pork fatty tissue	319.29	Directive 7160.2 "'Meat' Prepared	To verify compliance, inspection
	Advanced meat recovery products	318.24	Using Advanced Mechanical Meat/Bone Separation Machinery and Meat Recovery Systems" Directive 7160.3, Revision 1 "Advanced Meat Recovery Using Beef Vertebral Raw Materials"	program personnel should: -check product identification, condition, temperature, and holding time/temperature. -examine bones (for example, two intact portions of bones) before and after the meat recovery systems in order to observe condition and conformation. -review establishment laboratory results and compare findings with the appropriate regulatory standard. -take samples as directed

Procedure	Example	9 CFR	FSIS Issuance	Inspection Personnel
Code	Products	References	References	Responsibilities
Code 04A04 – Batter/Breading	Products Breaded patties Breaded meat cuts Breaded poultry cuts Fritters	References Parts 319.880 381.166	References Directive 7620.3, "Processing Inspectors' Calculations Handbook", Chapter 14, "Miscellaneous Calculations" Directive 7220.1 Policy Memo 089 "Use of the Term "Breaded" on Labels for "Fritters"	Responsibilities Inspection program personnel are to select an appropriate product, verify compliance with the batter and breading regulatory requirements by reviewing establishment records to calculate final % batter/breading, and comparing the findings to the standards listed in the regulations. In addition, inspection program personnel are to verify compliance by performing batter and breading pickup tests on one or more subgroups (according to the plant's QC programs) or batches of the product.

Procedure	Example	9 CFR	FSIS Issuance	Inspection Personnel
Code	Products	References	References	Responsibilities
04B01		Parts		Inspection program
Product	Miscellaneous beef products	319.15		personnel are to select an
Standards			Directive 7620.3,	appropriate product and
	Sausage	319.140	"Processing	verify compliance by
	Fresh pork sausage	319.141	Inspectors'	reviewing establishment
	Fresh beef sausage	319.142	Calculations	records and labels, or
	Breakfast sausage	319.143	Handbook"	observing the preparation of
	Whole hog sausage	319.144		products and comparing the
	Italian sausage	319.145	Directive 7220.1,	findings to the appropriate
	Smoked pork sausage	319.160	"Policy	regulatory standards.
	Frankfurters and similar products	319.180	Memoranda"	
	Cheesefurters and similar products	319.181		To verify some regulatory
	Braunschweiger, Liver sausage, or			requirements, inspectors will
	Liverwurst	319.182		need to perform calculations
	Luncheon meat			to determine specified
	Meat loaf	319.260		components, such as % fat, or
	Scrapple	319.261		% water.
	Brockwurst	319.280		
	Chili con carne	319.281		
	Chili con carne w/beans	319.300		
	Hash	319.301		
	Corned beef hash	319.302		
	Meat stews	319.303		
	Tamales	319.304		
	Spaghetti with meat balls and	319.305		
	sauce, spaghetti with meat and	319.306		
	sauce, and similar products			
	Spaghetti sauce with meat			
	Tripe with milk	319.307		
	Beans with frankfurters in	319.308		
	sauce, sauerkraut with wieners	319.309		
	and juice and similar products			
	Lima beans with ham in sauce, beans			
	with ham in sauce, beans with bacon	319.310		
	in sauce, and similar products			
	, r			

Procedure	Example	9 CFR	FSIS Issuance	Inspection Personnel
Code	Products	References	References	Responsibilities
04B01		Parts		Inspection program personnel
(Continued)	Chow mein vegetables with	319.311		are to select an appropriate
	meat and chop suey		Directive 7620.3,	product and verify compliance
	vegetables with meat		"Processing	by reviewing establishment
	Pork with barbecue sauce and	319.312	Inspectors'	records and labels, and/or
	beef with barbecue sauce		Calculations	observing the preparation of
	Beef with gravy and gravy	319.313	Handbook"	products and, comparing the
	with beef			findings to the appropriate
	Meat pies	319.500	Directive 7220.1,	regulatory standards.
	Margarine or Oleomargarine	319.700	"Policy	
	Mixed fat shortening	319.701	Memoranda"	To verify some regulatory
	Lard, leaf lard	319.702		requirements, inspection
	Rendered animal fat or	319.703		program personnel will need to
	mixture thereof			calculate specified components,
	Meat extract	319.720		such as % fat, or % water.
	Fluid extract of meat	319.721		
	Deviled ham, deviled tongue	319.760		
	and similar products			
	Potted meat food product and	319.761		
	deviled meat food product			
	Ham spread, tongue spread and	319.762		
	similar products			
	Liver meat food products	319.881		
	Poultry meat content standards for	381.156		
	certain poultry products			
	Canned boned poultry and	381.157		
	baby or geriatric food			
	Poultry dinners and pies	381.158		
	Poultry rolls	381.159		
	(Kind) burgers; (Kind) patties	381.160		
	(Kind) A La Kiev	381.161		
	(Kind) steak or fillet	381.162		
	(Kind) baked or (Kind)	381.163		
	roasted			
	(Kind) barbecued	381.164		
	(Kind) barbecued prepared	381.165		
	with moist heat			

Procedure	Example	9 CFR	FSIS Issuance	Inspection Personnel
Code	Products	References	References	Responsibilities
04B01 (Continued)	Other poultry	Parts 381.167		Inspection program personnel are to select an appropriate product and
	dishes and		Directive 7620.3,	verify compliance by reviewing
	specialty items		"Processing Inspectors'	establishment records and labels, and/or observing the preparation of
	Maximum % of	381.168	Calculations	products, and comparing the
	skin in certain		Handbook"	findings to the appropriate
	poultry products		Directive 7220 1	regulatory standards.
	Standards for	381 170	"Policy	To verify some regulatory
	kinds and classes,	501.170	Memoranda"	requirements, inspectors will need
	and for cuts of			to perform some calculations to
	raw poultry			determine specified components, such as % fat, or % water.
	Definition and	381.171		
	standard for			
	turkey ham			

Procedure	Example	9 CFR	FSIS Issuance	Inspection Personnel
Code	Products	References	References	Responsibilities
Code 04B02 CN/Grade Labeling/Declared Count/Vignette	Products False or misleading labeling or practices generally: specific prohibitions and requirements for labels and containers Wording on labels of immediate containers	References Parts 317.2 317.8 381.116	References Directive 6810.1 "Grademark Labeling on Meat and Poultry Products" Directive 7222.1 "Inspection Requirements for Food and Nutrition Service In-plant Control Programs"	Responsibilities Inspection program personnel are to select product and verify that the product's label is correct and a label approval is on file.

Procedure	Example	9 CFR	FSIS Issuance	Inspection Personnel
Code	Products	References	References*	Responsibilities
04B03 - Net	All products must carry a net	Parts	NBS Handbook	Inspection program
weight	weight statement and meet the net		133	personnel are to select an
	weight requirements whether the			appropriate retail-sized
	containers are catch weighed or		NIST Handbook	product and verify net weight
	bear a stated net content.		44	regulatory requirements by reviewing establishment
	Quantity of contents		* FSIS has	records and conducting net
	labeling		determined	weight/drained weight, scale
	Definitions and procedures for	317.18	inspectors are to	calibration, or tare weight
	determining net weight compliance		use NBS	checks.
	Scale requirements for	317.19	handbook 133 and	
	accurate weights, repairs,		NIST Handbook	For QC inspection
	adjustments, and replacement after		44 as the	verification, inspection
	inspection	317.20	definitive	program personnel are to
	Scales: testing of		references for	follow the QC program
	Handling of failed product	217.01	determinations of	requirements after evaluating
	quantity of contents	317.21	net weight	the program to ensure that
	Definitions and proceedures	317.22	compliance.	in compliance with not
	for determining not weight	301.121a		m compliance with net
	compliance	381 121h		requirements
	Scale requirements for	561.1210		requirements.
	accurate weights repairs			
	adjustments, and replacement after	381.121c		
	inspection Scales: testing of	00111210		
	Handling of failed product			
		381.121d		
		381.121e		

Procedure	Example	9 CFR	FSIS Issuance	Inspection Personnel
Code	Products	References	References	Responsibilities
04B04 General Labeling	This procedure is applicable to all products that bear a label. Marking Products and their Containers Labeling, Marking Devices, and Containers	Parts 316 317	Directive 7620.3, "Processing Inspectors' Calculations Handbook"	Inspection program personnel are to select an appropriate product and verify that: 1. the label contains all required information;
	Entry into Official Establishments; Reinspection and Preparation of Products	318 319	Directive 7120.1 "Safe and Suitable Ingredients Used in the Production of Meat and Poultry	2. the ingredients statement is accurate, (i.e., that all ingredients are listed in descending order of predominance);
	Limitations with respect to use of mechanically- separated species	319.6	Products"	 the label declares any proteinaceous substances* used in the ingredients statement;
	Definitions and	327.26 381	"Retained Water in Raw Meat and Poultry Products"	 the establishment used restricted ingredients as per regulatory requirements;
	or Composition Subpart N Labeling and Containers		Directive 7235.1, "Mandatory Safe Handling Statements on Labeling of Raw	5. the label is used on appropriate product; and6. a label approval is on file.
	Limitations with respect to use of Mechanically Separated (Kind of Poultry)	381.174	and Partially Cooked Meat and Poultry Products"	Verify the establishment meets the regulatory requirements for pre-stamping of imported product
	Food Ingredients and Sources of Radiation	424.21	Revision 1, "Sampling and Testing Procedures for Raw Poultry	When verifying restricted ingredient requirements or ingredient statement compliance, inspection program personnel are
	Consumer Protection Standards: Raw Products	441.10	Products Labeled 'Fresh'"	to observe the establishment formulating product and compare to the approved label.
				* NOTE: Proteinaceous substances can cause adverse reactions (i.e., allergic and non- allergic) in certain individuals, and therefore, such substances are of a food safety concern if not clearly declared in the ingredients statement.

Procedure	Fyample	0 CFR	FSIS Issuance	Inspection Personnel
Code	Droducts	References	Poforoncos	Responsibilities
04C02 Humane Handling and Slaughter (Livestock)	The establishment meets the criteria set forth in the regulations to ensure the humane handling and slaughter of livestock. The establishment takes action when either the establishment or FSIS determines that the establishment has not met the regulatory requirements.	Parts 313 500.1, 500.2, 500.3	Directive 6900.1, Revision 1, "Humane Handling of Disabled Livestock" Directive 6900.2, Revision 1, "Humane Handling and Slaughter of Livestock" FR Notice (September 9, 2004) systematic approach	 Verify compliance with the following categories: adequate measures for inclement weather truck unloading water and feed availability handling during antemortem inspection handling of suspect and disabled animals electric prod/alternative object use observations for slips and falls stunning effectiveness check for conscious animals on the rail check for sensibility

Procedure	Example	9 CFR	FSIS Issuance	Inspection Personnel
Code	Products	References	References	Responsibilities
O4C03 Livestock Product Examination	Example ProductsBoneless meat Meat carcassesPork skins for popping Returned productsProduct reconditioning Reinspection, retention, and disposal of meat 	Parts 318.2 318.5 318.6	References	Inspection rersonnel Responsibilities Inspection program personnel are to select an appropriate product/procedure and verify these regulatory requirements by reviewing establishment records and/or observing plant performance of activities. Inspection program personnel are to examine product to determine whether it is economically adulterated or misbranded (318.2b).

Procedure	Example	9 CFR	FSIS Issuance	Inspection Personnel
Code	Products	References	References	Responsibilities
04C04 Poultry Product Examination		Parts		Inspection program personnel are to verify compliance by
2	Finished Product	381.76		performing.
	Standards			- pre-chill FPS testing
	Rework/Reprocess/ Salvage Products	381.78 381.91 (b)		- post-chill FPS testing
	Poultry Carcasses Poultry Products and other articles entering or	381.84 381.86		- reinspection of carcasses, giblets
	at official establishments:	381.145 381.1		- inspection of returned products
	examination and other			- inspection of rework products
	Returned Products			- condition inspection of products in establishment
	Good commercial practices for poultry slaughter	381.65 (b)		- observation of slaughter practices

Products Cooked sausage (Maximums 30% fat	References Parts	References	Responsibilities
Cooked sausage	Parts		T
(waximums 50% fat and 40% fat +added water) Cooked sausage (10% added water) Italian sausage (fat) Smoked pork sausage (fat) Ground beef/ hamburger/ground pork (fat) Corned beef hash (fat and moisture) pH controlled product Moisture-protein controlled product Lard, leaf lard Advanced meat recovery products Mechanically-separated species Determination of added water in cooked sausages Definitions and standards of identity or composition Definitions and standards of identity or composition Samples of products to be taken for examination Sampling at official establishments Compliance procedures for meat derived from advanced meat/bone separation machinery and recovery systems Mechanically-separated species Mechanically-separated (kind) Withholding actions	301.2 381.1 318.22 319 381 Subpart P 318.9 381.146 318.24 319.5 381.173 500.3	Directive 10,210.1, Amendments 3 and 5, "Unified Sampling Form" Directive 7355.1, Revision 2 "Use of Sample Seals for Laboratory Samples and Other Applications"	Inspection program personna are to randomly select an appropriate product for verification. To verify compliance, inspection program personnel are to sele and process samples and mai to the designated laboratory a scheduled, or when there is reason to believe that produc does not comply with regulatory requirements.
taken for examination Sampling at official establishments Compliance procedures for meat derived from advanced meat/bone separation machinery and recovery systems Mechanically-separated species Mechanically-separated (hind)	318.9 381.146 318.24 319.5		
(kind) Withholding actions	500.3		
	Italian sausage (iat) Smoked pork sausage (fat) Ground beef/ hamburger/ground pork (fat) Corned beef hash (fat and moisture) pH controlled product Moisture-protein controlled product Lard, leaf lard Advanced meat recovery products Mechanically-separated species Determination of added water in cooked sausages Definitions and standards of identity or composition Definitions and standards of identity or composition Samples of products to be taken for examination Sampling at official establishments Compliance procedures for meat derived from advanced meat/bone separation machinery and recovery systems Mechanically-separated species Mechanically-separated (kind) Withholding actions	Italian sausage (rat)Smoked pork sausage(fat)Ground beef/hamburger/ground pork(fat)Corned beef hash (fat and moisture)pH controlled productLard, leaf lardAdvanced meat recovery productsMechanically-separated speciesDetermination of added water in cooked sausagesDefinitions and standards of identity or composition Samples of products to be taken for examination Sampling at official establishmentsStablishmentsCompliance procedures for meat derived from advanced meat/bone separation machinery and recovery systemsMechanically-separated speciesMechanically-separated speciesSils.1173Withholding actions	Italian sausage (rat)FormSmoked pork sausage (fat)Directive 7355.1, Revision 2Ground beef/ hamburger/ground pork (fat)Directive 7355.1, Revision 2Corned beef hash (fat and moisture)Laboratory Samples and OtherpH controlled product Moisture-protein controlled product Lard, leaf lard Advanced meat recovery productsJ18.22Water in cooked sausages Determination of added species318.22Determination of added species318.22Water in cooked sausages of identity or composition Sampling at official establishments319Compliance procedures for meat derived from advanced meat/bone sepcies318.24Sepcies Mechanically-separated species319.5Mechanically-separated species319.5Mechanically-separated species319.5Mechanically-separated (kind)381.173Withholding actions500.3

Procedure	Example	9 CFR	FSIS Issuance	Inspection Personnel
Code	Products	References	References	Responsibilities
Procedure Code 05B02 – Food Safety/Public Health Directed Sampling	Example ProductspH controlled productMoisture-protein controlled productMechanically-separated pork/poultryAdvanced meat recovery productsReady-to-eat productsGround beefBacon/Nitrosamine analysisSamples of products to be taken for examinationSampling at official establishments	9 CFR References Parts 301.2 318.9 381.1 381.1 381.146	FSIS Issuance References Directive 10,210.1, Amendment 1, "Unified Sampling Form" Directive 7355.1 Revision 2, "Use of Sample Seals for Laboratory Samples and Other Applications" Directive 10,240.3, "Microbial Sampling of Ready- to- Eat (RTE) Products for the FSIS Verification Testing Program" Directive 10,520.1, Revision 1, "Pumped Bacon Sampling Program- Nitrosamine	Inspection Personnel Responsibilities Inspection program personnel are to verify compliance by collecting, processing and mailing samples (bacon, species testing, <i>Escherichia</i> <i>coli</i> 0157:H7, <i>Salmonella</i> , <i>Listeria</i> , advanced meat recovery products, mechanically-separated species, etc.) to the designated laboratory, upon request from computer-generated instructions, or upon instructions from the Frontline Supervisor or District Office, or Washington Headquarters.
			Analysis"	

Instructions for Submission of Samples for Species Identification

When inspection program personnel collect samples for species testing, they are to collect at least one pound of product and put it in a plastic bag supplied by the laboratory. If the product is in a natural casing, inspection program personnel are to collect a sample of the emulsion.

1. Inspection program personnel are to complete FSIS Form 10,000-2 (form may be requested from Field Supply Center in Beltsville, MD) as follows:

- Block 7 -- establishment number
- Block 13-- date sampled
- Block 14—date mailed
- Block 21—check 'species identification' box
- Block 24—provide production lot sampled
- Block 24—provide declared species
- Block 25—inspector name (type or print)
- Block 26—badge number

2. Inspection program personnel are to attach a product label showing an ingredient statement to the 10,000-2 Form.

- 3. Inspection program personnel are to:
 - a. follow FSIS Directive 7355.1, Revision 2, Use of Sample Seals for Laboratory Samples and Other Applications;
 - b. ship the sample to the Eastern Laboratory in an insulated shipping container;
 - c. use sufficient frozen gel packs to keep the sample cold' and
 - d. ship via overnight contract courier, Monday thru Friday. For samples shipped on Fridays, be sure to mark Saturday delivery on package and include a Saturday delivery sticker on the box.

The results will be on the LEARN intranet site (see FSIS Directive 10,200.1) for receipt confirmation and sample results.

The laboratory will test the product against a panel of species anti-sera, report species results that correlate with the ingredient statement as "Acceptable", and report species results that indicate a species not declared on the ingredient statement is present, or one of the species on the ingredient statement is not present as "Not Acceptable".

Hazard Analysis and Critical Control Point (HACCP) Verification

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Slides	LEARNING OBJECTIVES
N/A	Scientific:
	 Given a scenario, use the verification methods in FSIS Directive 5000.1 Rev. 4 to determine whether an establishment meets HACCP regulatory requirements for a specific production.
	 Given a scenario, use the verification methods in FSIS Directive 5000.6 Rev. 1 to determine whether an establishment's HACCP prerequisite program adequately prevents identified hazards.
	3. Given a scenario, use the verification methods in FSIS Directive 5000.6 Rev. 1 to determine whether an establishment's records for its HACCP prerequisite programs support decisions made during the establishment's hazard analysis to designate particular hazards as Not Reasonably Likely to Occur (NRLO).
	4. Given a scenario, use the verification methods in FSIS Directive 5000.6 Rev. 1 and the <i>Meat and Poultry Hazards and Controls Guide</i> to analyze the adequacy of an establishment's hazard analysis.
	5. Given a scenario, use the verification methods in FSIS Directive 5000.1 Rev. 4 to verify that an establishment's corrective actions meet regulatory requirements when a deviation from a critical limit occurs at a critical control point (CCP).
	6. Given a scenario, use the verification methods in FSIS Directive 5000.1 Rev. 4 to verify that an establishment's corrective actions meet regulatory requirements when an unforeseen hazard occurs.
	Regulatory/Administrative:
	[None for this topic in this context.]

Slides HACCP VERIFICATION INTRODUCTION

3 Kickoff Activity: HACCP Refresher

Let's refresh our memory about the key points we remember about a HACCP task from Inspection Methods.

Fill in the nine steps:



4



Additional information:

HACCP VERIFICATION TASK

Table 1 below summarizes the steps that IPP perform during the HACCP verification task. Table 2 and Table 3 on the following pages provide a quick reference for the questions that IPP should seek answers to when verifying each of the HACCP implementation regulatory requirements.

Table 1 HACCP Verification Task Summary

	Select product type within the process category Ensure all product		
Step 1: Select Product Type	Select specific production.	process category are verified over time.	
and Specific Production	Verify all HACCP regulatory requirements at each CCP by following Steps 3-9	Select product type that the est. is currently producing.	
Stap 2: Paviawithe HACCP	Understand the monitoring and verification procedures and frequencies		
Plan for the Selected Product	Note the most recent signature date (must be entered into PHIS)	417.2(d)	
	Note changes to the HACCP plan and update the establishment profile		
Step 3: Verify Monitoring	Per Directive 5000.1	417.2(c)(4)	
Step 4: Verify Verification	Per Directive 5000.1	417.2(c)(7), 417.4(a)(2)(i)(ii)(iii)	
Step 5: Verify Recordkeeping	Per Directive 5000.1	417.2(c)(6), 417.5(a)(3), 417.5(b), 417.5(d), 417.5(e)(1), 417.5(e)(2), 417.5(f)-Note: contact supervisor if records are not made available	
	Per Directive 5000.1	417.5(a)(1)	
Step 6: Verify Implementation of Prerequisite program (PRP)/Other Control	Review PRP records for the specific production, Observe program implementation, Verify implemented as written, and Verify records continue to support decision that hazard is NRLTO		
Hazards Not Reasonably Likely to Occur (NRLTO)	Consider whether implemented in a manner that supports the Hazard Analysis decisions		
	Contact supervisor if uncertain whether implementation or records support the decision in the Hazard Analysis		
Step 7: Verify Corrective Action (CA)	Per Directive 5000.1 Initiate a directed HACCP verification task to verify CA when no routine HACCP verification task is available	417.5(c), 417.3(a), 417.3(b)	
Step 8: Verify Pre-shipment Review	Per Directive 5000.1	417.5(c)	
Step 9: Consider the Implications of any noncompliance	Document findings of compliance and noncompliance. Associate any previous noncompliances. Use systems based thinking per Directive 5000.1	417.6	

If IPP find that adulterated product may have entered commerce, they are to notify the DO personnel through supervisory channels immediately.

		Table 2
	Monitor	ing. Verification. and
	Recordk	eeping Requirements
Step 3 Monitoring	Step 4 Verification	Step 5 Recordkeeping
9CFR 417.2(c)(4)	9CFR 417.2(c)(7) 417.4(a)(2)(i)(ii)(iii)	Recordkeeping Requirement – 9CFR 417.2(c)(6)
1. Does the	1 Door the HACCP	 Does the HACCP plan set out a recordkeeping system that degree the magitaring of the CCP2
the monitoring	plan contain	 Do the records contain actual values & observations obtained
procedures and	procedures and	during monitoring?
frequencies that	frequencies for the	
are used to monitor	calibration of the	HACCP Records Requirement – 9CFR 417.5(a)(3)
each of the CCP to	process-monitoring	
ensure compliance	instruments?	 Do the records document the monitoring of CCP and critical limit Do the records include actual
with the critical	2 Dear the LIACOD	 Do the records include actual times, temperatures, or other qualifiable values, as presented in the establishment's UNCOD
innits?	2. Does the MACCP	quantiliable values, as prescribed in the establishment's HACCP plan?
2. Are the	procedures and	3. Do the monitoring, verification, and corrective action records
monitoring	frequencies for direct	include product codes, product name or identity, or slaughter
procedures being	observations of	production lot, and the date each record was made?
performed as	monitoring activities &	4. Are verification procedures and results documented?
described in the	corrective actions?	Is the time recorded when the verification activity was performed
HACCP plan?		6. Does the record contain the date the record was made?
0. A	3. Does the HACCP	Are process-monitoring calibration procedures & results recorded
3. Are the	plan list procedures	Personale Authenticity Persuirement 90000 (47.5/b)
nrocedures being	for the review of	Records Addienacity Requirement - 5CFR 417.5(b)
performed at the	records generated	1. Was each entry on the record made at the time the event
frequencies for the	and maintained in	occurred?
CCP listed in the	accordance with 9 CFR	2. Does each entry include the time?
HACCP plan?	417.5(a)(3)?	Was each entry on the record signed or initialed by the
		establishment employee making the entry?
4. Are the CL met?	4. Does the HACCP	4. Does each record include the date?
	plan list product	
	sampling as a verification activity?	Computerized Records Requirement – 9CFR 417.5(d)
		Are appropriate controls provided to ensure integrity of electronic
	5. Are process-	data and signatures?
	monitoring instrument	Description and Augit 1975 Days of Aug
	calibration activities	Record Retention and Availability Requirement – 9CFR
	Conducted as per the	417.5(e)(1) and (2)
	neour pair:	1 Are the records being maintained for the required amount of time
	6. Are direct	i.e., one year for slaughter and refrigerated products and two years
	observation verification	for frozen, preserved, or shelf-stable products?
	activities conducted as	2. Are the records kept on-site for 6 months?
	per the HACCP plan?	If the records are stored off-site, can they be retrieved in 24
		hours?
	7. Are records	
	generated in	Official Review of Records – 9 CFR 417.5(f)
	CEP 417 5(-)(2)	Are all moords, plans, and procedures maying by Dart 417 availab
	being reviewed by the	for official review?
	actablishment?	IN VIINAL ICTICH:

HACC	P VERIFICATION	TASK
	Table 3	
Prerequisite Pr	ogram Implementation, Co	orrective Action.
Pro-shipmont P	oview Requirements and	System Thinking
rre-sinpinent K	eview Requirements, and	System minking
Step 6	Step 7	Step 8
Prerequisite Program	Corrective Actions	Pre-shipment Review
Implementation		
Supporting Documentation	Corrective actions in response	Pre-shipment Review
Requirement – 9 CFR 417.5(a)1	to a deviation from a critical	Requirement – 417.5(c)
1. In the ortablichment implemention	limit – 9 CFR 417.3(a)	1. Has the establishment surjeyed
 is the establishment implementing the procedures in the program 	1 Did the establishment identify and	 mas the establishment reviewed the records associated with the
as written?	eliminate the cause of the deviation?	production of the product, prior
		to shipment?
2. Does the establishment	Did the corrective actions	
maintain records to support the	ensure that the CCP is brought	2. Has the pre-shipment review
including verification records and	under control?	establishment employee?
results from outside auditors?	3. Were measures implemented to	establishment employee:
	prevent recurrence of the deviation?	
3.Do the records show that the		
prerequisite program continues to	 Did the actions ensure that no 	
support the decision that the relevant	otherwise adulterated as a result of	Step 9
occur on an ongoing basis?	the deviation, enters commerce?	Consider the Implications
		Document
	Corrective Actions in Response	
	to a Deviation Not Covered by	
	an Unforeseen Hazard – 9CFR	
	417.3(b)	 Is there a pattern of repeated
Note: The Corrective		failure to implement the HACCP
Action requirement	 Did the establishment segregate 	procedures as written?
is verified at each	and hold all affected product?	2Is there reason to believe that the
occurrence. For	2. Did the establishment perform	establishment's food safety system
example, when the	a review to determine the	is not effectively preventing
IPP is performing the	acceptability of the affected	or controlling the applicable food safety bazards?
HACCP verification	product for distribution?	salety hazarus:
task and the IPP	3 Did the establishment take	3. Has product been prepared,
notices that the	necessary action with respect to the	packed, or held under insanitary
establishment had	affected product to ensure that no	conditions where it may have
a deviation from a	product that is injurious to health, or	rendered injurious to health?
critical limit, the IPP	otherwise adulterated as a result of the douistion onter commerce?	rendered injunious to rieditin:
would verify that the	are deviation, enters commerce?	4. Has the establishment produced
corrective action	4. Was a reassessment conducted	adulterated products or shipped
requirements	to determine whether the newly	adulterated products in commerce?
had been met	identified deviation or other	
	untoreseen hazard should be	

8

Slides	HACCP TASK SCENARIOS
5	Scenarios: Introduction
	On the following pages, you will be given three scenarios. Work in small groups to go through each scenario. Proceed at your own pace. Read each scenario and answer the corresponding questions.
	Before you begin, open up the folder of FSIS resources. Keep them open on your computer as you may need them to refer to as you complete the scenarios.
	• 9 CFR 310.22.pdf
	• 9 CFR 416 (416.1-416.6) - SPS-1.pdf
	 9 CFR 416 (416.11-416.17) - Sanitation SOP.pdf
	• 9 CFR 417.pdf
	• 9 CFR 424.21.pdf
	FSIS Compliance Guideline - HACCP Systems Validation.pdf
•	FSIS Directive 5000.1.pdf
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•	FSIS Directive 5000.6.pdf
•	FSIS Directive 6410.1.pdf
•	FSIS Directive 6420.2.pdf
•	FSIS Directive 7120.1.pdf
	ESIS Meat and Poultry Hazards and Controls Guide odf

Ideal Beef, Establishment 38. Ideal Beef is a one shift
d of cattle per day, fabricates beef, and produces ground
Task (HAV) is scheduled to be performed. You decide to e establishment's beef slaughter process. You request d analysis (HA) and HACCP plan, any Standard Operating equisite programs and associated records, and other
ntinued)
)

 Supporting Documentation: Estimating Cattle Age Using Dentition and FSIS BSE Information
Receiving Log
Cattle Age SOP Form
Corrective Action Logs
1. List the steps of an HAV task (Hint: Refer to the HAV Task Job Aid and FSIS Directive 5000.6).

 2. Is it appropriate to perform the 	e HAV task on the	e slaughter proce	ess?
3. Which establishment docume	nts would you req	quest to review?	
	nts would you req	quest to review?	
	nts would you req	quest to review?	
3. Which establishment docume	nts would you req	quest to review?	, , , , , , , , , , , , , , , , , , ,
3. Which establishment docume	nts would you req	quest to review?	
3. Which establishment docume	nts would you req	quest to review?	
3. Which establishment docume	nts would you req	quest to review?	

HAZARD ANALYSIS	VERIFICATION	$(H\Delta V)$	TASK
HAZARD ANALI SIS	VERIFICATION	(TAV)	IASK

Refer to Directive 5000.6 for additional questions and information about each step.

Step	Description	Verification Questions	Regs
1	Review flowchart and compare to production process.	» Does the flowchart represent the actual production process?	417.2(a)(2)
2	Review the hazard analysis and consider guidance in the FSIS Meat and Poultry HCG.	 » Does the flowchart or hazard analysis identify the intended use or consumers of the product? » Does the hazard analysis appear to consider the relevant food safety hazards for the establishment's process, product, and intended use? » For each hazard, does the establishment consider it RLTO or NRLTO? 	417.2(a)(2) 417.2(a)(1)
3	For each hazard the establishment considers RLTO, verify that the HACCP plan includes one or more CCPs to control it. <i>If no</i> <i>hazards are reasonably likely</i> <i>to occur, skip to Step 4.</i>	 » Does the establishment have one or more CCPs to control the hazard in each product or process where it is reasonably likely to occur? » Does the establishment have information to support the CCPs, CLs, monitoring, and verification procedures? 	417.2(c)(2) 417.5(a)(2)
4	For each hazard the establishment considers NRLTO, determine what evidence the establishment uses to support the decision, including prerequisite programs and other supporting programs (e.g. written programs, records, and employee activities).	 » Does the establishment prevent the hazard by implementing a prerequisite or other supporting program (SSOP, GMP, SOP, etc.)? – proceed to Step 5. » Does the establishment support the decision with other documentation besides a prerequisite or other supporting program? – proceed to Step 6. » Does the written program appear to be designed to prevent the relevant hazard? » Do the records and your observations indicate the program is consistently being implemented as written? » Do the records and your observations indicate that the program prevents the relevant hazard on an ongoing basis? 	417.5(a)(1)

	-		
Step	Description	Verification Questions	Regs
5	Review other supporting documentation.	 » Does the establishment have copies of the documents referenced in the hazard analysis? » Do the documents appear to apply to the current establishment process? 	417.5(a)(1)
6	Review establishment validation documents, including scientific supporting documents and validation data.	 Does the establishment maintain documents to support the scientific or technical basis for the CCPs and prerequisite programs used to support decisions in the hazard analysis? Does the establishment maintain in-plant validation data for the life of the plan? 	417 ₋ 4(a)(1)
7	Verify reassessment requirements. Check most recent signature date for each HACCP plan.	 Has the establishment reassessed at least once in the most recent calendar year? Has the establishment reassessed, if necessary, in response to any changes that could affect the hazard analysis? Has the establishment reassessed, if necessary, in response to any unforeseen hazard? 	417.4(a)(3) 417.3(b)
		» Has the establishment documented the results of the reassessment?	417.4(a)(3)
8	Document your findings.	 » No problems detected – document HAV results in PHIS. » Clear case of noncompliance – document HAV results on NR in PHIS and notify your supervisor. » Concerns about the establishment HACCP system – discuss situation with your supervisor for assistance in determining how to proceed. Document HAV results in PHIS. 	

9	Scena	ario 1: Discussion
	Based	on your review and performance of HAV task:
	1.	Is the establishment's HA adequate?
	2.	Does the establishment have appropriate supporting documentation for the hazards identified in the HA?
	3.	Does the establishment's execution of SOPs or pre-requisite programs and recorded data continue to support decisions made in the HA?
	4.	Did you observe noncompliance? Why or why not? If so, draft an NR using Form 5400-4 (on the following page).

FOOD SAFETY AND INSPER NONCOMPLIANCE RECOR	re CTION SERVICE D	TYPE OF NONCOMPLIANCE Food Safety Other Consumer Protection
1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
4. TO (Name and Title)		5. PERSONNEL NOTIFIED
6. RELEVANT REGULATION	15	6a. ASSOCIATED NR(s)
7. TITLES OF HACCP OR S DOCUMENTATION	SOP PLAN or OTHER SUPPORTING	7a. NAME OF CCP(S) or PREREQUISITE PROGR
8. INSPECTION TASK	9. VERIFICATION ACTVITY	
	Review & Observation	Recordkeeping D Both
	9a. AFFECTED PRODUCT INFO	RMATION
	9b. RETAIN/REJECT TAGS	
10. DESCRIPTION OF NON	COMPLIANCE	
11. SIGNATURE OF INSPEC	CTION PROGRAM EMPLOYEE	
11. SIGNATURE OF INSPEC	CTION PROGRAM EMPLOYEE	5 and/or 381.35 of 9 CFR
11. SIGNATURE OF INSPECT You are hereby advised of your m 12. PLANT MANAGEMENT F	CTION PROGRAM EMPLOYEE ight to appeal this decision as delineated by 306.5 RESPONSE:	5 and/or 381.35 of 9 CFR
11. SIGNATURE OF INSPEC You are hereby advised of your n 12. PLANT MANAGEMENT N This document serves as writte administrative action.	CTION PROGRAM EMPLOYEE ight to appeal this decision as delineated by 306.5 RESPONSE: en notification that your failure to comply with MANAGEMENT	5 and/or 381.35 of 9 CFR regulatory requirement(s) could result in additional regulator 14. DATE
11. SIGNATURE OF INSPEC You are hereby advised of your n 12. PLANT MANAGEMENT N This document serves as writte administrative action. 13. SIGNATURE OF PLANT	CTION PROGRAM EMPLOYEE ight to appeal this decision as delineated by 306.5 RESPONSE: en notification that your failure to comply with MANAGEMENT URE OF INSPECTION PROGRAM EMPLO	5 and/or 381.35 of 9 CFR regulatory requirement(s) could result in additional regulator 14. DATE 14. DATE 16. DATE
11. SIGNATURE OF INSPEC You are hereby advised of your in 12. PLANT MANAGEMENT f This document serves as writte administrative action. 13. SIGNATURE OF PLANT 15. VERIFICATION SIGNATION	CTION PROGRAM EMPLOYEE ight to appeal this decision as delineated by 306.5 RESPONSE: en notification that your failure to comply with MANAGEMENT URE OF INSPECTION PROGRAM EMPLO	regulatory requirement(s) could result in additional regulator 14. DATE IYEE 16. DATE

10	Scenario 2: HACCP Task
	A Slaughter HACCP verification task is scheduled for today. The establishment defines a "specific production" as all beef carcasses slaughtered and dressed on a shift. You review the establishment's HACCP plan and any SOPs or pre-requisite programs associated with cattle slaughter.
11	Scenario 2: HACCP Task (Continued)
	You decide to perform a Slaughter HACCP verification task for the specific production for 05/23/2018.
	Beef Slaughter HACCP Information.pdf
	Corrective Action Logs.pdf
	Organic Acid Spray Log. pdf
	Keep in mind: Refer to the 9 steps you would follow to perform the HACCP verification task that you listed previously.

12	Scena	ario 2: Discussion
	Based	on your performance of the task:
	1.	Which verification activity(ies) did you use?
	2.	Did the establishment meet all regulatory requirements for the specific production for 5/23/2018?
	3.	Did you observe noncompliance? Why or why not? If so, draft an NR using Form 5400-4 (on the following page).

U.S. Department of Agricultu FOOD SAFETY AND INSPE NONCOMPLIANCE RECOR	re CTION SERVICE D	TYPE OF NONCOMPLIANCE Food Safety Other Consumer Protection
1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
4. TO (Name and Title)		5. PERSONNEL NOTIFIED
6. RELEVANT REGULATION	NS	6a. ASSOCIATED NR(s)
7. TITLES OF HACCP OR S DOCUMENTATION	SOP PLAN or OTHER SUPPORTING	7a. NAME OF CCP(S) or PREREQUISITE PROGR
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	9a. AFFECTED PRODUCT INFO	RMATION
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13	Scenario 3
	While continuing your Slaughter HACCP Verification task, you discover that Fred Murtz, Ideal Beef's QA Technician, found one tongue to have tonsillar material.
14	Scenario 3: Discussion
	Review any establishment records associated with the incident and answer the questions below:
	Corrective Action Logs.pdf
	Pre-Shipment Review Log.pdf
	Zero Tolerance Check Form. pdf
	1. Based on your review of the documentation from 5/23/2018, did the establishment take the corrective action required by the regulations?

U.S. Department of Agriculture FOOD SAFETY AND INSPECTION SERVICE NONCOMPLIANCE RECORD TYPE OF NONCOMPLIANCE I. DATE 2. RECORD NO. 3. ESTABLISHMENT NO. 4. TO (Name and Title) 5. PERSONNEL NOTIFIED 6. RELEVANT REGULATIONS 6a. ASSOCIATED NR(s) 7. TITLES OF HACCP OR SSOP PLAN or OTHER SUPPORTING 7a. NAME OF CCP(s) or PREREQUISITE PROGR DOCUMENTATION 8. INSPECTION TASK 9. VERIFICATION ACT/ITY B Review & Observation Recordkeeping 9. AFFECTED PRODUCT INFORMATION 9b. RETAINIREJECT TAGS 10. DESCRIPTION OF NONCOMPLIANCE			
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15 Scenarios: Conclusion

Now that you have reviewed all of the information available to you, compare the NRs that you wrote to these example NRs.

NR #1

U.S. Department of Agriculture FOOD SAFETY AND INSPECTION S	ffice of Information and Regulatory A	ffairs, Office of Management and Budget. TYPE OF NONCOMPLIANCE
NUNCOMPLIANCE RECORD		Food Safety Other Consumer Protection
1. DATE 2. May 31, 2018	RECORD NO.	3. ESTABLISHMENT NO. 38
4. TO (Name and Title) Johnny Workman, Plant Superinte	endent	5. PERSONNEL NOTIFIED Gerri Garfunckle
6. RELEVANT REGULATIONS 417.3(a)(1,2,3,4) 417.5(b)		6a. ASSOCIATED NR(s)
7. TITLES OF HACCP OR SSOP PL DOCUMENTATION	AN or OTHER SUPPORTING	7a. NAME OF CCP(S) or PREREQUISITE PROGRAM
8. INSPECTION TASK	9. VERIFICATION ACTVITY	
HACCP Verification Slaughter	Review & Observation	ecord keeping D Both
	9a AFFECTED PRODUCT INFOR	MATION
	9b RETAIN/REJECT TAGS	
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The request for this informal determine whether establish DISCLOSURE STATEMEN including the time for review and reviewing the collection information, including sugge Washington, DC 20250: and	tion is voluntary. It is needed to monitor defer iments are in compliance. 9 CFR 301 and 9 (T: Public reporting burden for this collection of ing instructions, searching existing data sour of information. Send comments regarding th istions for reducing this burden, to Department to the Office of Information and Regulatory.	Its found in this inspection system. It is used by FSIS to CFR 381. FORM APPROVED OMB No. 0583-0089. OMB of information is estimated to average 7 minutes per response ces, gathering and maintaining the data needed, and complet s burden estimate or any other aspect of this collection of t of Agriculture, Clearance Officer, OIRM, Room 404-W, Affairs, Office of Management and Budget.
U.S. Department of Agricult	ure	TYPE OF NONCOMPLIANCE
FOOD SAFETY AND INSPE NONCOMPLIANCE RECOR	ECTION SERVICE RD	Food Safety Other Consumer Protection
1. DATE 5/28/2018	2. RECORD NO.	3. ESTABLISHMENT NO. 38
4. TO (Name and Title) Johnny Workman		5. PERSONNEL NOTIFIED Fred Murtz
6. RELEVANT REGULATIO 417.5(b)	NS	6a. ASSOCIATED NR(s)
7. TITLES OF HACCP OR DOCUMENTATION	SSOP PLAN or OTHER SUPPORTING	7a. NAME OF CCP(S) or PREREQUISITE PROGRAM
8. INSPECTION TASK	9. VERIFICATION ACTVITY	
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	9a. AFFECTED PRODUCT INFO	RMATION
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Looking back, do you have an issue with the actions that the establishment took?

If so, document the noncompliance on Form 5400-4.

	CTION SERVICE D	Food Safety Of Other Consumer Protection	
1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.	
4. TO (Name and Title)		5. PERSONNEL NOTIFIED	
3. RELEVANT REGULATION	IS	6a. ASSOCIATED NR(s)	
7. TITLES OF HACCP OR SE	SOP PLAN or OTHER SUPPORTING	7a. NAME OF CCP(S) or PREREQUISITE PROGRAM	
3. INSPECTION TASK	9. VERIFICATION ACTVITY		
	Review & Observation Re	cordkeeping Both	
	9a. AFFECTED PRODUCT INFORM	IATION	
	9b. RETAIN/REJECT TAGS		
1. SIGNATURE OF INSPEC	TION PROGRAM EMPLOYEE		
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Scei	Scenarios: Conclusion (Continued)					
Yes!	Yes! What was the noncompliance you found?					
Com	pare your new NR with	this sample one.				
NR #	3					
	The request for this information is volu determine whether establishments are DISCLOSURE STATEMENT: Public re including the time for reviewing instruc- and reviewing the collection of informa- information, including suggestions for Washington, DC 20250: and to the Off U.S. Department of Agriculture EOOD SAFETY AND INSPECTION SI	Intary. It is needed to monitor defects in compliance. 9 CFR 301 and 9 CF eporting burden for this collection of titons, searching existing data source titon. Send comments regarding this reducing this burden, to Department lice of Information and Regulatory Af ERVICE	found in this inspection system. It is used by FSIS to R 381. FORM APPROVED OMB No. 0583-0089. OMB nformation is estimated to average 7 minutes per response, s, gathering and maintaining the data needed, and completing burden estimate or any other aspect of this collection of of Agriculture, Clearance Officer, OIRM, Room 404-W, airs, Office of Management and Budget. TYPE OF NONCOMPLIANCE			
	NONCOMPLIANCE RECORD	ENVICE	Food Safety Other Consumer Protection			
	1. DATE 2. 06/06/2018	RECORD NO.	3. ESTABLISHMENT NO. 38			
	4. TO (Name and Title) Johnny Workman		5. PERSONNEL NOTIFIED Johnny Workman			
	6. RELEVANT REGULATIONS 417.3(b)(4)		6a. ASSOCIATED NR(s)			
	7. TITLES OF HACCP OR SSOP PL/ DOCUMENTATION Slaughter Hazard Analysis/HACCP	AN or OTHER SUPPORTING	7a. NAME OF CCP(S) or PREREQUISITE PROGRAM			
	8. INSPECTION TASK Slaughter HACCP	9. VERIFICATION ACTVITY Review & Observation Re	cordkeeping I Both			
		9a. AFFECTED PRODUCT INFORM	IATION			
	10. DESCRIPTION OF NONCOMPLIA	9b. RETAIN/REJECT TAGS				
	On May 31 2018, at approximately 11: 23 corrective action log. While executir tongues, the QA tech had found SRM (SRM was found and removed from 5 m analysis, SRMs were considered to be finding of SRM on tongues at the harve perform a reassessment of the hazard Workman, the Plant Superintendent, if conducted. I informed him of the nonco	00 am while performing the Slaughte g the written verification procedures (tonsillar tissue) on one tongue. The nore tongues and placed into an ined a potential hazard but NRLTO becai sting point of the process is conside analysis in accordance with 417.3(b) the establishment had conducted the ompliance with the corrective action r	r HACCP verification task, I reviewed the establishment's May for identifying, segregating, and disposing of SRMs on beef establishment held and examined all the tongues from the shift. lible container. On page 1 of the establishment's hazard use the establishment implements a SRM control program. The red to be an unforeseen hazard. The establishment must (4) when an unforeseen hazard occurs. I asked Johnny a reassessment. He replied that a reassessment was not egulations.			
	11. SIGNATURE OF INSPECTION PR	ROGRAM EMPLOYEE				
	You are hereby advised of your right to app	eal this decision as delineated by 306.5 ar	d/or 381.35 of 9 CFR			
	12. PLANT MANAGEMENT RESPON Contacted HACCP Consulting scheduled next week.	se: Group for help reassessing	HACCP. Plant review and Reassessment			
	This document serves as written notifica administrative action.	tion that your failure to comply with re	ulatory requirement(s) could result in additional regulatory or			
	13. SIGNATURE OF PLANT MANAGE	EMENT	14. DATE			
	15. VERIFICATION SIGNATURE OF	INSPECTION PROGRAM EMPLOYS	E 16. DATE			
	SIS FORM 5400-4	DISTRIB	JTION: Original & 1 Copy to Establishment, 1 Copy to Inspector			

Slides	KNOWLEDGE CHECK					
17-20	Knowledge Check 1					
	Match the definition with the correct term.					
	 Provides IPP with an approach to verify establishments' compliance with certain requirements of 9 CFR 417, including foundational elements such as flow charts, decision making documents, supporting documentation and supporting data. 					
	 Provides IPP with an approach to verify compliance with the implementation of establishments' HACCP plans as required by 9 CFR 417. 					
	Knowledge Check 2					
	The main role of inspectors (FSIS) is verification. What is the purpose of verification?					
	Knowledge Check 3					
	Where should critical control points (CCPs) be located?					
Slides	SUMMARY					
21	Review your score on the Summary screen and notes about this topic. Make note of any areas that you need to work on.					
	Please note that this score does not count toward your overall class grade. Rather, it helps you identify which areas you may need to study more in preparation for your exams. Your overall class grade only consists of the daily quizzes, midterm exam, and final exam. Any scores you receive on Knowledge Check questions or course activities are <u>not</u> counted. They are for your use only.					

5000.1 Walk Through

OBJECTIVES

To demonstrate mastery of Directive 5000.1, the trainee will:

- 1. Describe the inspection verification procedures performed to verify establishment compliance with the Sanitation Performance Standards.
- 2. Describe the inspection verification procedures performed to verify establishment compliance with Sanitation SOP regulations.
- 3. Describe the inspection verification procedures performed to verify establishment compliance with HACCP regulations.
- 4. Identify the procedure performed to verify compliance with generic *E. coli* requirements.
- 5. Describe the responsibility for inspection personnel to verify compliance with the *Salmonella* and *Campylobacter* performance standards.

Sanitation Performance Standards 9 CFR 416.1 – 416.6

SPS REGULATIONS

§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.

The regulation requires establishments to operate in a sanitary environment. Performance standards stated in the regulations are results-oriented, allowing the establishment flexibility in achieving the specified results. Simply put, the results expected are defined in the regulation but the means or methods to achieve the results are not specified. Although establishments can use different and varying means to meet the performance standards, the required results are always the same – establishments must operate under sanitary conditions in a manner that ensures product is not adulterated and in a way that does not interfere with FSIS inspection and enforcement of such standards.

Proper and effective sanitation practices and conditions are an essential part of all safe food manufacturing processes. Insanitary facilities and equipment and poor food handling and personal hygiene practices by employees create an environment in which pathogens and other food safety hazards can contaminate and adulterate products. Consequently, proper sanitation is a fundamental requirement under both the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA).

The Sanitation Performance Standards regulations significantly reduce the number of sanitation regulations and consolidate the sanitation requirements for both meat and poultry into part 416. This consolidation not only simplifies the sanitation regulation for the user, but also establishes uniform sanitation performance standards that would provide flexibility to establishments while maintaining the rigorous sanitation standards necessary to ensure food safety. The establishment's responsibility for maintaining sanitary conditions and preventing the contamination and adulteration of product remains unchanged.

For the HACCP and Sanitation SOP requirements to be successful, FSIS believes that it must reduce its reliance on detailed, command-and-control regulations. Command-and-control regulations prescribe step-by-step procedures establishments must use toward the goal of safe meat and poultry products. Such regulations can be incompatible with HACCP and Sanitation SOP requirements to the extent that they deprive establishments of the flexibility to innovate and deter them from assuming their full share of responsibility for food safety.

Insanitary conditions are defined as "a state, condition or occurrence in which any edible meat or poultry products may become contaminated or adulterated through exposure, slaughter, processing, handling, and packaging or by any other means."

§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.

Proper maintenance of the grounds around an establishment is essential for ensuring good sanitation. Establishments are responsible for preventing sources of adulteration of product even if the cause of the adulteration originates from conditions outside the designated boundaries of the establishment.

Establishments must implement and maintain an integrated pest control program to eliminate the harborage and breeding of pests on the grounds and within the establishment facilities and must safely and effectively use interventions, such as pesticides, fumigants, and rodenticides. This regulation does not require the integrated pest control program to be a written document. This regulation does not require that pest control substances be approved by FSIS prior to use.

The performance standards regulations also require the establishment to be responsible for the safe and effective use and storage of pesticides. Product must not be adulterated by the misapplication of pest control products. It is the establishment's responsibility to ensure that Environmental Protection Agency (EPA) requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) are followed, including the application of a pesticide or the safety of a chemical. Pesticides must also be properly stored, labeled, and applied in accordance with label instructions. It is important that such supporting documentation is on file in the establishment file.

Examples of failure to meet grounds and pest control performance standards are:

- an accumulation of old equipment outside providing harborage for rodents and insects
- storage of pesticides in an open container next to food ingredients

(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.

(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.

(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.

FSIS does not require establishments to be innovative in regard to facility construction or layout. The performance standards for construction do, however, provide establishments, regardless of size, the flexibility to design facilities and equipment in the manner they deem best to maintain the required sanitary environment for food production.

Buildings, walls, ceilings, and floors must be sound and in good repair to prevent insanitary conditions or the adulteration of product. The walls, floors, and ceilings should be made of durable materials impervious to moisture.

Example of failure to meet performance standards:

- flaking or chipping paint on the walls or ceilings of edible product areas
- · holes in glass board permitting moisture to penetrate the wood behind it

Doors and windows must also close properly and prevent the entrance of vermin.

Example of failure to meet performance standard:

- gaps around the outside doors

(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.

Establishments can process, handle, or store edible and inedible product in the same room as long as they are separated by time or space, in a manner that prevents the adulteration of the edible product or the creation of insanitary conditions.

Example of failure to meet performance standard:

• grinding meat and storing condemned product together in a room too small to keep employees and products separated

(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.

Specific regulatory requirements for lighting combine the meat and poultry lighting requirements into one performance standard. However, FSIS has reserved specific lighting requirements in meat establishments at postmortem inspection stations and in poultry establishments at the postmortem inspection stations and at reinspection stations (§ 307.2 and § 381.36 *et seq*).

While establishments have flexibility in providing lighting, illumination must be adequate in quality and quantity, and well distributed. It must allow for proper monitoring of sanitary conditions and processing conditions, and for examination of product for evidence of adulteration.

Examples of failure to meet performance standard:

• low lighting in the gizzard peeling area that prevents inspection of the product

· shadows on carcasses at final rail inspection preventing inspection of product

(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.

The Agency does not expect the establishment to completely eliminate all odors, vapors, and condensation. However, establishments must control ventilation to prevent adulteration of the environment that, in turn, can lead to adulteration of product or the creation of insanitary conditions.

Examples of failure to meet performance standard:

- diesel fumes from parked trucks being drawn into the establishment at receiving areas.
- excessive odors from condemned/inedible rendering area spreading onto slaughter floor.

(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;

It is the responsibility of the establishment to ensure that plumbing and sewage systems provide an adequate supply of potable water to the establishment to prevent product adulteration or creation of insanitary conditions.

Example of failure to meet performance standard:

- inadequate water pressure for cleanup
- plumbing system not providing adequate floor drainage

It is the responsibility of the establishment to ensure that plumbing and sewage systems remove waste and sewage from the establishment without adulterating product or creating insanitary conditions.

Example of failure to meet performance standard:

• plugged sewer line preventing cleanup water from draining from the establishment

(3) Prevent adulteration of product, water supplies, equipment, and utensils and prevent the creation of insanitary conditions throughout the establishment;

The design, installation and maintenance of an adequate plumbing system are key responsibilities of the establishment. Because plumbing systems carry water into establishments and convey water from the establishments, problems with plumbing systems can easily cause product contamination or adulteration.

Example of failure to meet performance standard:

• dead-end pipes on potable water lines

(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

Floor drainage must be adequate to prevent the spread of contaminants into the production environment during cleaning and normal operation.

Example of failure to meet performance standard:

• a stopped up drain in the cooler

Cross-connection between potable and non-potable water is not acceptable. The plumbing system must be installed and maintained to prevent adulteration. Back-flow devices must also be used as appropriate to prevent cross contamination of potable water sources.

Example of failure to meet performance standard:

• a water hose nozzle left submerged in the evisceration flow away drain

(6) Prevent the backup of sewer gases.

Example of failure to meet performance standard:

• sewer gas emitting from a floor drain in the smokehouse area

(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.

The establishment must ensure that sewage does not back up into processing areas. Documentation from a State or local authority approving private sewage disposal systems must be on-site and available to FSIS upon request.

Example of failure to meet performance standard:

 establishment has no documentation on file from state or local health authority for approval of private sewer or system

(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.

The water performance standard requires that potable water comply with EPA's National Primary Drinking Water regulations. Certifications of water potability provided by the state or local governments or other responsible entities are evidence that the establishment meets the EPA requirements.

Some meat and poultry establishments use private wells for their water supply. EPA does not require testing for these water sources, but FSIS requires it semi-annually. Generally, State or local governments do not test private wells for potability. Establishments can obtain such documentation from private laboratories.

Example of failure to meet performance standard:

• no documentation on file demonstrating that the municipal water supply complies with the National Primary Drinking Water regulations

(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.

FSIS expects establishments to produce ready-to-eat products that are free of pathogens; therefore, reuse water used to chill or cook ready-to-eat product must be free of pathogens.

In many cases establishments monitor water reuse activities as part of their HACCP plans because the water treatments or conditioning can eliminate or reduce hazards they have determined to be reasonably likely to occur. The requirement that water be reused only "for the same purpose" refers to reusing water from the ready-to-eat area only in the ready-to eat area, and reusing water from the not-ready-to-eat areas only in not-ready-to-eat areas. For example, chiller water or water from the final bird washer that is reconditioned can be reused in the scalder.

Example of failure to meet performance standard:

• reusing brine solution without filtering or treating

(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.

Establishments can reuse water in a manner that does not adulterate product or create insanitary condition. For example, an establishment's recirculating water in a chill tank for

raw poultry might add chlorine to the water to reduce the number of pathogens. An establishment reusing ice to chill raw poultry might bag the ice to prevent it from contacting product. The performance standards allow the reuse of water in numerous processing contexts, as long as the establishment takes actions necessary to ensure that the water does not adulterate product and that sanitation is not compromised.

Example of failure to meet performance standard:

• reusing ice from wax lined boxes to chill salvage parts without bagging it

(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.

Some establishments recondition their water through an advanced wastewater treatment facility, either onsite or under contract. To prevent establishments from using water from sewage lines, reconditioned water must never have contained human waste. Because reconditioned water is of high quality, it can be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas. Product, facilities, and equipment coming in contact with this reconditioned water must undergo a separate final rinse with potable, non-reconditioned water.

FSIS believes it is likely that most establishments will use the reconditioned water in this provision to wash equipment, floors, and carcasses on the kill floor, all of which can easily be rinsed.

Example of failure to meet performance standard:

• no final potable water rinse on product after using reconditioned water

(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.

Any water can be used for any purpose in edible or inedible product areas, provided it:

- has never contained human waste.
 Establishments must not reuse water from sewage lines, therefore, it is required that the reuse water never have contained human waste.
- has been conditioned to be free of pathogenic organisms.
 Reuse water must be free of pathogenic organisms to prevent their spread throughout the establishment, which could lead to cross-contamination of product.
- does not contact edible product.

Reuse water might contain coliforms or chemical or physical contaminants, so it cannot contact edible product.

Example of failure to meet performance standard:

• using treated or untreated water from the employee welfare area to clean antemortem pens.

(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.

To prevent contamination or adulteration of the product, establishment must not use water contaminated with pathogens, chemicals, or physical contaminants in edible product areas.

Example of failure to meet performance standard:

- using reuse water not meeting conditions of (g)(1) through (g)(5) to flush evisceration troughs in edible product areas
 - (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.

OSHA standards (29 CFR 1910.141) for lavatories must be followed when establishments are constructed or remodeled. FSIS does not regulate the number of lavatories required. The establishment must maintain lavatory facilities in good repair and in a sanitary manner.

Example of failure to meet performance standard:

• used toilet tissue piled on the floor in the welfare facility

(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.

Example of failure to meet performance standard:

• no hot water or soap in the toilet area

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

Leaking refuse receptacles allow the spread of pathogenic organisms into the environment, which could then lead to cross-contamination of product and product areas.

Example of failure to meet performance standard:

• holes in the bottom of trash receptacle in the dressing room with liquids draining onto the floor.

§ 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.

Establishments may select any method to clean utensils and equipment as long as they are maintained in a sanitary condition.

Example of failure to meet performance standard:

• meat residues from previous days use on the underside of a product transfer belt

(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.

Equipment and utensils must be designed in a manner that allows FSIS inspection personnel to view them for compliance with sanitary requirements. They must be located so that they are safely accessible to inspection prior to and during operation.

Example of failure to meet performance standard:

- a piece of equipment is constructed in a manner that prevents thorough cleaning Ex: a splashguard located over the auger to the meat grinder that prevents access the equipment for inspection
- when equipment is installed preventing inspection from making a sanitary condition
 determination

(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.

Inedible receptacles used for storing inedible product must be properly and conspicuously marked.

Example of failure to meet performance standard:

• unmarked inedible barrels

§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.

Generally, establishments clean their operations once a day; however, some establishments conduct chemical cleanup procedures less than once a day. Such extended cleanup procedures should be incorporated into the firm's Sanitation Standard Operating Procedures (Sanitation SOP) (See § 416.12). To ensure that extended cleanup procedures prevent insanitation and the adulteration of product, establishments might conduct microbiological testing to evaluate the effectiveness of the extended cleanup.

Example of failure to meet performance standard:

 accumulation of fat on a belt rubbing against metal guard creating oxidized fat on the belt

(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.

During the normal course of operations meat and poultry products should not come in contact with non-food contact surfaces. If non-food contact surfaces are not properly cleaned and sanitized, insanitary conditions could result, leading to potential adulteration of product.

Example of failure to meet performance standard:

• dried meat scraps on a wall located away from product but in a production area

(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.

It is required that meat and poultry products be neither adulterated nor misbranded through the misuse of proprietary substances and nonfood compounds. Documentation substantiating the safety of a chemical's use in a food-processing environment must be available for FSIS review. The documentation can vary with the nature and intended use of that chemical. For example, the establishment should have documentation showing that a pesticide used in the establishment is registered with EPA, and the label information for the pesticide should be on file. For a chemical sanitizer used on food contact surfaces, an establishment should have documentation showing that the compound complies with the relevant Food and Drug Administration (FDA) regulations in 21 CFR 178.1010. (Sanitizers meeting FDA requirements are usually identified as "Food Grade."). Meat and poultry establishments must ensure that all proprietary substances and nonfood compounds are safe for their intended use and used appropriately.

Example of failure to meet performance standard:

• no documentation showing that the sanitizers used in the facility are safe as used

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

As product moves through the process there might be elements in the environment that could adulterate it. Employees who move and handle product improperly are another possible source of contamination. The establishment must decide, depending upon the situation and the circumstances within the establishment, how the product should be protected through all phases of the process. For example, the establishment might cover the product when it is stored in the cooler to prevent contamination.

Example of failure to meet performance standard:

combos stored in tiered storage racks not appropriately covered creating an insanitary condition

§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.

The performance standards allow establishments to develop alternative or innovative means to ensure that employee hygiene practices do not result in product adulteration or contamination.

Example of failure to meet performance standard:

• an employee wiping his runny nose on the sleeve of his smock

(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.

The sanitation performance standards require establishments to develop acceptable policies for prescribing when garments must be changed during the day to prevent contamination or adulteration of product.

Example of failure to meet performance standard:

• an employee wearing a soiled smock from the raw product area entering the sausage drying room

(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.

FSIS has authority to take action against any unhygienic practice that could result in insanitary conditions or adulterated product. This includes handling procedures that might contaminate edible products or create insanitary conditions.

Example of failure to meet performance standard:

· an employee handling edible product with an open sore on her forearm

§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.

It is appropriate to take regulatory control action, which may include tagging affected areas, when an official establishment operates in a manner that leads to insanitary conditions or product adulteration. Regulatory control actions should remain in effect until the establishment has taken corrective action and has proposed effective preventive measures.

Sanitation Standard Operating Procedures 9 CFR 416.11— 416.17

SANITATION SOP REGULATIONS

§416.11 General Rules

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

The establishment is responsible for developing, implementing, and maintaining written sanitation standard operating procedures (Sanitation SOPs) that meet the requirements of part 416. FSIS believes that effective establishment sanitation is essential for food safety and for successful implementation of HACCP. Insanitary facilities or equipment, improper personal hygiene, and similar insanitary practices create an environment conducive to contamination of products. Direct and substantial links exist between inadequate sanitation and the contamination of meat and poultry products by pathogenic bacteria. Sanitation SOP clearly defines the establishment's responsibility to consistently follow effective sanitation procedures that will substantially minimize the risk of product contamination and adulteration.

§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).

It is a regulatory requirement that the establishment have written Sanitation SOPs describing the daily procedures conducted before and during operations to prevent direct contamination or adulteration of products.

IPP need to be able to read and understand the Sanitation SOP. This means that Sanitation SOPs written in a foreign language may need to be translated into English.

(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.

The Sanitation SOP written procedure is signed and dated by an official with overall sanitation authority or a higher-level official of the establishment. It is not required that the person be listed on the Grant of Inspection or the PBIS establishment profile. Written procedures must be signed upon initiation and whenever they are modified. For example, the establishment manager might sign the Sanitation SOP.

(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.

The written procedures must identify pre-operational sanitation procedures. At a minimum, Sanitation SOPs must address the cleaning of food contact surfaces of facilities, equipment, and utensils. The regulation does not specify how much detail Sanitation SOPs must contain. For example, the Sanitation SOP may describe the pre-operational procedures as follows. "The food contact surfaces in the facility will be cleaned with hot soapy water. Equipment that can be disassembled will be taken apart prior to cleaning. After cleaning, a sanitizer will be applied to product contact surfaces followed by a potable water rinse." When followed the procedures should be sufficient to ensure prevention of direct product contamination or adulteration.

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

The Sanitation SOP must contain:

- the frequency the procedures in the Sanitation SOP are conducted
- identification of the employee(s) responsible for the implementation and maintenance of the Sanitation SOPs (does not have to be the people performing the activities but the person responsible).

Establishments may identify individual(s) by name or job title. The individuals or positions identified do not have to have separate lines of authority from the production process. Production employees, lead line personnel, department forepersons, etc. may be identified. The employee(s) identified may or may not be the employee who actually performs the activities.

For example, the Sanitation SOP might specify that overheads are wiped every half-hour of operation to prevent product contamination or adulteration. The QA technician might be the person responsible for monitoring this procedure, but the QA manager is responsible for the overall implementation of Sanitation SOP.

§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.

Establishments are responsible for implementing the Sanitation SOP daily. They must perform their procedures before the start of operations as prescribed in their written preoperational procedures. An establishment may have several departments, starting at different times during the approved hours of operation. They may perform their preoperational procedures at staggered times prior to the approved starting time. In other words, the establishment does not have to perform pre-operational procedures in all the departments prior to starting operations in any one department.

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

Establishments are responsible for the daily implementation of all procedures identified in the Sanitation SOP that occur during operations. An example procedure is a Sanitation SOP that includes a procedure for using a footbath prior to entering the ready-to-eat area.

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

Establishments must monitor the Sanitation SOP procedures they conduct daily to ensure they effectively prevent direct product contamination or adulteration. For example, an establishment might have a procedure that calls for cleaning and examining all equipment prior to operations and a monitoring procedure that includes examining a random selection of representative equipment prior to operations.

§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.

Establishments should routinely evaluate the content and effectiveness of the Sanitation SOP and modify it accordingly. The Sanitation SOPs must be kept current. When facilities, personnel, or operations change, the establishment must still prevent direct product contamination and adulteration. For example, if the establishment changed their operations by expanding the facility and adding new pieces of equipment, they must reevaluate their written procedures and, if necessary, make changes to effectively prevent direct contamination or adulteration of product.

§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 SOP's or the procedures specified therein, or the implementation or maintenance of the Sanitation SOPs, may have failed to prevent direct contamination or adulteration of product(s).

The establishment must take corrective actions any time the establishment or FSIS determines that the Sanitation SOP has failed to prevent direct product contamination or adulteration of product. Sanitation SOP, and it can occur before or during operations. This applies to contamination or adulteration of direct product contact surfaces or direct product zones found by the establishment or FSIS procedures before or during operations. For example, in a poultry cut-up operation, the establishment has a procedure for the salvage of product that contacts the floor written into its Sanitation SOP. The Sanitation SOP says that the product will be removed from the floor promptly by an employee in the cut-up area and trimmed, washed, and treated with a chlorine rinse before it is returned to production. The Sanitation SOP further states that this procedure will be monitored once per hour by the QC technician. If the procedure were followed as written, corrective actions would not have to be implemented. However, if during a monitoring procedure the QC technician finds that the procedure is not followed, corrective actions must be implemented.

(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 or the procedures specified therein.

Establishments must initiate corrective actions when either the establishment or FSIS determines implementation of the procedures fails to prevent direct product contamination or adulteration. Establishments must implement all three parts of the corrective action, i.e., they must:

- · dispose of contaminated or adulterated product appropriately
- restore sanitary conditions
- prevent recurrence of failure

Corrective actions may also include reevaluation and modification of the Sanitation SOP or the procedures specified in it; however, it might not be necessary to modify the Sanitation SOP in every case.

The establishment is not required to document specifics in the Sanitation SOP regarding exactly which corrective actions will be taken in every single possible case of contamination or adulteration. They must, however, address all three parts of corrective action and include these actions in the records if product contamination or adulteration occurs.

§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.

Establishments must maintain daily records that document they are carrying out the sanitation procedures outlined in the Sanitation SOP, including the corrective actions taken. Establishment management may exercise flexibility in designing records. There is no set format, and records do not have to be included in the written Sanitation SOP.

For example, the SSOP might describe a hygienic procedure where all employees must wash their hands after returning from break and that the QC manager is responsible for monitoring the procedure. The record should document that employees were monitored after break before returning to work. If an employee was observed returning to work without washing his hands, a description of the incident and the three parts of corrective actions taken by the establishment must be documented.

(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.

Records may be maintained on a computer in lieu of hard copy as long as they are accessible to inspection personnel. The establishment must prevent tampering with the electronic records. It is up to them to determine how to ensure integrity of the electronic data.

(c) Records required by this part shall be maintained for at least 6 months and made accessible 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.

All Sanitation SOP records generated must be retained for six months. For oversight and enforcement purposes FSIS requires access to all establishment sanitation records. The establishment is required to keep records on-site for 48 hours and make them available to FSIS upon request. Afterwards, records may be stored off-premises as long as they can be provided to FSIS within 24 hours of a request for them.

§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.

FSIS verifies that Sanitation SOPs are developed, implemented, maintained, and that they are effective. FSIS also verifies that the establishment maintains daily records.
Hazard Analysis and Critical Control Point (HACCP) System 9 CFR 417.1 — 417.8

HACCP REGULATIONS

§417.1 Definitions.

For purposes of this part, the following definitions shall apply: Corrective action. Procedures to be followed when a deviation occurs.

Critical control point. A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical limit. The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Food safety hazard. Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

HACCP System. The HACCP plans in operation, including the HACCP plan itself.

Hazard. SEE Food Safety Hazard.

Preventive measure. Physical, chemical, or other means that can be used to control an identified food safety hazard.

Process-monitoring instrument. An instrument or device used to indicate conditions during processing at a critical control point.

Responsible establishment official. The individual with overall authority onsite or a higher level official of the establishment.

Above are the regulatory definitions for these specific terms when used throughout regulation 417.

§417.2 Hazard Analysis and HACCP Plan.

(a) Hazard analysis.

(1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the

particular type of product being processed, in the absence of those controls.

With the implementation of the Pathogen Reduction/HACCP (PR/HACCP) regulation, each federally inspected establishment either conducted or had conducted for it a hazard analysis. At a minimum a hazard analysis must be developed for each processing category in the establishment. The purpose of the hazard analysis is to identify biological, chemical, and physical hazards reasonably likely to occur in the process and to identify preventive measures to control those hazards. Regulation 417.1 defines preventive measures as physical, chemical, or other means that can be used to control an identified food safety hazard. FSIS is unaware of any meat or poultry production process that can be deemed categorically to pose no food safety hazards. All three types of hazards (biological, chemical, or physical) must be considered at all steps in the process, e.g. receiving, storage, and grinding.

(2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.

The flow chart is often a simple schematic picture of the process used to produce the product for an example of process flow charts refer to "Regulated Industries" module, p 30-42). The establishment should verify the process flow chart by walking through the establishment and comparing the steps in the process to the flow chart. Examples of steps in a slaughter process might include antemortem, stunning, head removal, evisceration, carcass splitting, final trim, and cooling. Steps in a processing establishment might include receiving, formulation, cooking, and cooling. Examples of steps that have been overlooked by establishments are returned product and rework.

The establishment should consider whether "at risk" populations, such as the elderly or children, are intended consumers of the product.

(3) Food safety hazards might be expected to arise from the following:
(i) Natural toxins;
(ii) Microbiological contamination;
(iii) Chemical contamination;
(iv) Pesticides;
(v) Drug residues;
(vi) Zoonotic diseases;
(vii) Decomposition;
(viii) Parasites;
(ix) Unapproved use of direct or indirect food or color additives; and
(x) Physical hazards

FSIS believes an establishment should consider the ten areas above when performing a hazard analysis.

The establishment should consider all potential food safety hazards at all steps in the process. If an establishment determines that a food safety hazard is reasonably likely to occur, they must address it with a critical control point somewhere in the process. During the initial stages of the hazard analysis, the establishment might list many different potential hazards. During assessment, however, they might find that many hazards are not

reasonably likely to occur. For example, an establishment might determine that product contamination is a potential hazard at the receiving step. After assessing the situation, the establishment determines that this is not a food safety hazard likely to occur in the process because they have a procedure in their Sanitation SOP that addresses the situation.

(b) The HACCP plan.

(1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:

(i) Slaughter—all species.

- (ii) Raw product—ground.
- (iii) Raw product—not ground.
- (iv) Thermally processed—commercially sterile.
- (v) Not heat treated—shelf stable.
- (vi) Heat treated—shelf stable.
- (vii) Fully cooked—not shelf stable.

(viii) Heat treated but not fully cooked—not shelf stable.

(ix) Product with secondary inhibitors—not shelf stable.

(2) A single HACCP plan may encompass multiple products within a single processing category identified in this paragraph, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice.

Every product must be produced under a HACCP plan when a hazard analysis reveals a food safety hazard likely to occur within the process. The establishment may develop one HACCP plan to control hazards for all products in the same processing category. For example, if an establishment produces different fully cooked products such as franks and cooked beef, they could be included in the same HACCP plan.

An establishment may develop one HACCP plan for a product that passes through multiple process categories. As an example, if an establishment slaughters and produces cut-up chicken, the product passes through both "slaughter" and "raw intact" (raw not ground) processes. The establishment may use two HACCP plans or it may address the entire slaughter and cut-up process under one HACCP plan. If an establishment slaughters chickens, produces cut-up chicken, and produces mechanically separated chicken, it would need a minimum of two HACCP plans.

The processing category is determined by the product label when it leaves the establishment. For example, certain products such as country hams and lard may be in different processing categories depending on the establishment process and I

(3) HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance

with the requirements of part 318, subpart G, or part 381, subpart X, of this chapter.

Establishments producing thermally processed commercially sterile products are not required to address microbiological hazards if the product is produced in accordance with the canning regulations. However, the hazard analysis must still consider physical and chemical hazards at every step in the process because the current canning regulations exclusively address microbial hazards. For example, if the establishment determines foreign material is a food safety hazard likely to occur in the process, there must be a CCP somewhere in the process to control foreign material.

(c) The contents of the HACCP plan. The HACCP plan shall, at a minimum: (1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.

Each establishment must provide a list of the food safety hazards identified while conducting the hazard analysis. Some commonly identified hazards are pathogens such as *Listeria*, *E. coli* O157:H7, and foreign material, such as metal.

(2) List the critical control points for each of the identified food safety hazards, including, as appropriate:
(i) Critical control points designed to control food safety hazards that could be introduced in the establishment, and
(ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;

If a food safety hazard is identified in the hazard analysis, and is determined to be reasonably likely to occur, there must be a critical control point somewhere in the process to address it. As an example, if a biological hazard is identified at the receiving step in an establishment that produces fully cooked product, the CCP to control the hazard might be lethality at the cooking.

(3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product are met;

Regulation 417.1 defines a critical limit as the minimum or maximum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate or reduce to an acceptable level the occurrence of the identified food safety hazard. (Note: critical limits may also be expressed as a range if the decision making documents support that limit, such as in the case of the use of lactic acid as an antimicrobial intervention. If the establishment utilizes FSIS Directive 7120.1 to support the critical limit for lactic acid, the range would be 2% to 5% lactic acid in solution.) Critical limits are expressed as numbers or specific parameters and need to be measurable. Establishments must have documents supporting the selection of CCPs and critical limits. The documents should be scientific, regulatory, or technical, and show that when the critical limits are achieved, the product produced will be safe.

For example, an establishment that slaughters 4-pound birds put a CCP in the cooler 4 hours post-evisceration. The critical limit is that the average internal temperature of three carcasses must be 40° F or less. While performing a monitoring check the establishment records temperatures of 39° F, 39° F, and 42° F. The average for the three is 40° F. The average temperature critical limit does not meet the regulatory requirement of 417.1 because each carcass must meet the 40° F critical limit.

(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

The monitoring procedures and frequencies in the HACCP plan must describe a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for use in future verification. Reading the monitoring procedures and frequencies in the HACCP plan should allow visualization of what is taking place during the monitoring of a CCP. The establishment should use monitoring records to track process control. Continuous monitoring is always preferred when feasible. For example, an establishment, which uses a smokehouse to cook hams, may use a continuous time and temperature recording device to chart the time and temperature of the product in the ovens as it is cooked. When continuous monitoring is not possible, discontinuous monitoring must be performed often enough to show that the process is under control. An example of a continuous operation with discontinuous monitoring is an establishment that cooks chicken patties on a conveyor and measures the internal temperature of 10 patties every 30 minutes.

(5) Include all corrective actions that have been developed in accordance with §417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point; and

The HACCP plan must contain the corrective actions taken when a deviation from a critical limit occurs. An establishment may simply state "the regulatory requirements of 417.3(a) will be met when a deviation occurs" to satisfy this regulatory requirement. A prudent establishment would consider the different causes of a deviation and work through scenarios to address them. This additional information is not required to be part of the official HACCP plan.

(6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

The HACCP plan shall list the records used to document monitoring critical control points. Records must contain actual values and observations obtained during monitoring. An example of such a HACCP record is the monitoring log. Actual values and observations must be entered on the monitoring log at the time the event occurs.

(7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with §417.4 of this part.

Verification procedures and frequencies must be present in the HACCP plan. The verification procedures should be very clear. Anyone reading the verification procedures in

the HACCP plan should be able to visualize what takes place when the verification procedure is performed.

(d) Signing and dating the HACCP plan.

(1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.
(2) The HACCP plan shall be dated and signed:
(i) Upon initial acceptance;
(ii) Upon any modification; and
(iii) At least annually, upon reassessment, as required under §417.4 (a)
(3) of this part.

The HACCP plan must be signed and dated when the establishment develops and implements the HACCP plan, when it is modified, and to indicate the annual reassessment has been performed.

(e) Pursuant to 21 U.S.C 456, 463, 608, and 621, the failure of an establishment to develop and implement a HACCP plan that complies with this section, or to operate in accordance with the requirements of this part, may render the products produced under those conditions adulterated.

If an establishment does not develop and implement a HACCP plan as required by Part 417 of the regulations, any product produced without a HACCP plan may be determined to be adulterated.

§417.3 Corrective actions.

(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

- (1) The cause of the deviation is identified and eliminated;
- (2) The CCP will be under control after the corrective action is taken;
- (3) Measures to prevent recurrence are established; and

(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

When there has been a deviation from a critical limit, the establishment must implement all four parts of corrective actions. They must:

- identify and eliminate the cause of the deviation
- ensure the CCP is under control after the corrective action is taken
- prevent recurrence of the deviation
- · ensure that no product injurious to health or otherwise adulterated enters commerce

Affected product is generally considered to be that produced since the last acceptable monitoring result recorded by the establishment.

(b) If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:
 (1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform a review to determine the acceptability of the affected product for distribution;

(3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;

(4) Perform or obtain reassessment by an individual trained in accordance with §417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

If a deviation from a critical limit occurs that is not covered by a specified corrective action or if an unforeseen hazard is identified, the establishment must implement the following corrective actions:

- segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;
- perform a review to determine the acceptability of the affected product for distribution;
- take action, when necessary, with respect to the affected product to ensure that no
 product that is injurious to health or otherwise adulterated, as a result of the deviation
 enters commerce;
- perform or obtain reassessment by an individual trained in accordance with § 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

(c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with §417.4 (a)(2)(iii) and the recordkeeping requirements of §417.5 of this part.

Whatever an establishment does to fulfill all four parts of corrective action should be documented in the HACCP records. The records must be available for FSIS review.

§417.4 Validation, Verification, Reassessment.

(a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.

(1) Initial validation. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

It is the establishment's responsibility to develop a HACCP plan and to ensure its adequacy. Establishments may use independent consultants, process authorities, or employees trained as per 417.7 to develop and validate the plan. Validation means scientifically demonstrating that a HACCP system, as designed, effectively controls the food safety hazards identified in

the hazard analysis. While no particular validation method must be used, the data assembled to support a HACCP plan are usually of two types:

- theoretical principles from process authorities, scientific data etc.
- in-plant observations, measurements, test results, or other information demonstrating that control measures achieve the intended food safety objective

Validation must demonstrate that the HACCP plan is scientifically sound. Establishments must support the critical limits selected. They may use Appendices A or B ("Compliance guidelines for cooling heat-treated meat and poultry products"), modeling programs, or other scientific support for their critical limits. For example, a slaughter establishment with steam pasteurization has a CCP with a critical limit at 180° F for 10 seconds at the carcass surface. The establishment supported this critical limit with a scientific journal article that indicated steam applied at 180° F for 10 seconds to the carcass surface reduces pathogens by 1 log. The establishment also had records demonstrating their ability to meet the parameters of steam at 180° F for 10 seconds on the carcass surface.

FSIS believes validated data for any HACCP plan must also include some practical data or information reflecting initial validation in implementing the HACCP plan. Validation must demonstrate that the monitoring can be performed by the establishment as per the HACCP plan and when the monitoring is performed the establishment can meet the critical control points and critical limits.

(2) Ongoing verification activities. Ongoing verification activities include, but are not limited to:
(i) The calibration of process-monitoring instruments;
(ii) Direct observations of monitoring activities and corrective actions; and
(iii) The review of records generated and maintained in accordance with § 417.5(a)(3) of this part.

Verification procedures must ensure the HACCP plan functions as intended. All plans must, at a minimum, include three types of ongoing verification: calibration of process monitoring equipment, observation of monitoring activities and corrective actions, and records review, except for cases where one or more of the minimum ongoing verification activities are not necessary. Such scenarios may be when there are no process monitoring devices used (e.g. visual inspection at zero tolerance CCP), or in a one person operation where direct observation can not be performed. Validation and reassessment are two additional types of verification.

For example, a verification procedure for equipment calibration might look like this: "A handheld dial thermometer is placed in slush ice water and calibrated to within $\pm 1^{\circ}$ of 32° F." The establishment should have supporting data that this procedure effectively calibrates dial thermometers.

(3) Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with §417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of §417.2(c) of this part.

HACCP plans are dynamic and evolving. The establishment should reassess its HACCP plan whenever any significant change in the processing environment occurs. Changes in product formulation, addition or removal of equipment, an increase in the amount of production, and the addition of new customers are just a few examples of instances when an establishment needs to reassess. The HACCP plan must be immediately modified if the reassessment reveals that the plan is no longer adequate. The individual performing the reassessment must be trained as per 417.7. FSIS believes that reassessment encompasses the different types of evaluation, from re-analyzing the verification procedures for an updated CCP to repeating the validation procedures when necessary.

(b) Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

Even if an establishment previously did not have a HACCP plan, changes such as product formulation, new slaughter or processing methods, or the use of new raw materials should cause the establishment to reassess its hazard analysis. If any changes result in identification of a food safety hazard, the establishment should then develop a HACCP Plan.

For example, an establishment received pork pellets cooked by another establishment. The producing establishment certified that lethality adequate to control the pathogen of concern was applied, that the product was tested, and that sample results were negative. The receiving establishment addressed employee hygiene and product handling in the Sanitation SOP. The receiving establishment determined there were no food safety hazards likely to occur in the process of popping and packaging the pellets, so they did not have a HACCP plan for the process. At a later time the establishment decided to start popping raw pork skins. When the incoming materials changed, the establishment reassessed the hazard analysis to determine if a food safety hazard was likely to occur.

§417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(1) The written hazard analysis prescribed in §417.2(a) of this part, including all supporting documentation;

The hazard analysis and all supporting documents must be in the establishment file. Supporting documentation varies from establishment to establishment because the decision making process differs. Examples of supporting data establishments might have for the hazard analysis are historical data and scientific journal articles.

(2) The written HACCP plan, including decision making documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

The establishment must have supporting data for CCPs and critical limits. Supporting data may include FSIS regulations, FSIS Guidelines, the FDA food code, journal articles from reputable publications, etc. Establishments may use universities, extension services, and industry associations for assistance in gathering supporting documentation. One example of supporting data for a critical limit is using Appendix B to support a stabilization CCP.

The establishment must also have supporting documentation for their monitoring procedures. The establishment must be able to support that the monitoring frequency is adequate to demonstrate process control.

This regulation also requires the establishment to have supporting documentation for verification procedures and frequencies listed in the HACCP plan. The establishment must have documents that explain how the verification procedures were determined and what information was used to determine the frequencies for these procedures.

(3) Records documenting the monitoring of CCP's and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

This regulation lists specific information that the establishment must document on their records when HACCP activities are performed. When monitoring each CCP and its critical limits, actual values must be recorded, e.g. times, temperatures, or other quantifiable values. The establishment must also document all corrective actions, calibration of process-monitoring instruments, and verification procedures and frequencies.

(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and includes the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

The establishment shall make all entries on the records at the time the specific event occurs and sign or initial the entry. Each time a monitoring procedure is performed, the establishment must record the time, product identity, actual value and initials of the person performing the monitoring. Example: date: 9/9/01, time: 8:02 a.m., product identity: Lot A6 - chicken carcasses, actual value: 39°F, initials: MPT. When the establishment performs a verification procedure, the records must include the verification procedure performed and the results of that procedure, as well as the date, time and initials or signature of the person performing verification. For example, when the establishment performs a direct observation, the record entry might show "direct observation performed, monitoring performed as per the HACCP plan".

(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with §417.7 of this part, or the responsible establishment official.

Before shipping product, an establishment must review all records associated with the production of that product. As part of the pre-shipment review the establishment needs to insure that all critical limits have been met and all corrective actions are taken, if necessary.

There are many ways an establishment can perform pre-shipment review. They may perform it on a time basis, on specific production, or continuously as the product goes through the process. For example, an establishment might conduct pre-shipment review every hour and conduct records review verification daily. If the pre-shipment review is performed continuously, it is possible that the only documentation on the records at the time of review will be monitoring entries. If monitoring records are the only ones available, the review still satisfies the regulatory requirement. In addition, the frequency at which the verification procedures are performed may not correspond to the frequency at which the preshipment review is performed. The verification procedures should be reviewed, if available, at the time the pre-shipment review is performed.

(d) Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

The establishment may maintain records on computer provided they have controls to protect record integrity. Even though the establishment is keeping records on the computer, they must be readily accessible to Agency personnel.

(e) Record retention.

(1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.

(2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.

(f) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying.

It is the establishment's responsibility to maintain the records for the required amount of time per the regulation. If the establishment chooses to store the records off-site after 6 months, then the establishment must be able to provide them, upon request, within 24 hours. If the records are kept on-site after the first 6 months, they must be available upon request. Both

the hazard analysis and HACCP plan should be available upon request. If an FSIS inspector working the second shift at an establishment, requests a copy of the HACCP plan, the establishment should be able to provide it to the inspector at that time.

All of the records specified by 417.5 must be available to FSIS upon request. Along with the records, a prudent establishment would keep the HACCP plan corresponding to those records if changes at some point have been made to the HACCP plan.

§417.6 Inadequate HACCP Systems.

A HACCP system may be found to be inadequate if:

(a) The HACCP plan in operation does not meet the requirements set forth in this part;

(b) Establishment personnel are not performing tasks specified in the HACCP plan;

(c) The establishment fails to take corrective actions, as required by §417.3 of this part;

(d) HACCP records are not being maintained as required in §417.5 of this part; or

(e) Adulterated product is produced or shipped.

If establishment personnel do not perform procedures as specified in the HACCP plan, if corrective actions are not taken, or if HACCP records are not maintained, the HACCP system may be inadequate. For example, an establishment had several deviations from a critical limit. When implementing corrective actions, they failed to address 417.3(a)(3), "measures to prevent recurrence are established." If the establishment repeatedly did not meet that regulatory requirement, the system could be deemed inadequate as per 417.6(c).

§417.7 Training.

(a) Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:

(1) Development of the HACCP plan, in accordance with §417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product; and

(2) Reassessment and modification of the HACCP plan, in accordance with §417.3 of this part.

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.

Training is essential to the success of HACCP. The establishment must use trained individuals to develop, conduct reassessments of, and make modifications to HACCP plans. It is not required that the individual be an employee of the establishment or be on-site for the establishment to operate.

§417.8 Agency verification.

FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:

(a) Reviewing the HACCP plan;

(b) Reviewing the CCP records;

(c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;

(d) Reviewing the critical limits;

(e) Reviewing other records pertaining to the HACCP plan or system;

(f) Direct observation or measurement at a CCP;

(g) Sample collection and analysis to determine the product meets all safety standards; and

(h) On-site observations and record review.

FSIS uses various steps to verify that HACCP plans are adequate. These are further described in FSIS Directives 5000.1 and 5400.5.

Process Control Verification

E. coli Testing – LIVESTOCK

§310.25 Contamination with microorganisms; process control verification criteria and testing; pathogen reduction standards.

(a) Criteria for verifying process control; E. coli testing.

(1) Each official establishment that slaughters livestock must test for Escherichia coli Biotype 1 (E. coli) Establishments that slaughter more than one type of livestock or both livestock and poultry, shall test the type of livestock or poultry slaughtered in the greatest number.

FSIS requires all livestock slaughter establishments to conduct microbial testing for generic *E. coli*, Biotype 1, an *E. coli* specie that is commonly found in the intestinal tract of food animals. Generic *E. coli* is an excellent indicator of fecal contamination, which is the primary pathway for contamination of meat and poultry with pathogens such as *E. coli* O157:H7, *Salmonella*, and *Campylobacter*. The testing requirement helps establishments determine the adequacy of their process control for fecal contamination. Using an Agency baseline study FSIS established verification performance criteria that reflect the prevalence of *E. coli* contamination on carcasses. Not all species tested by establishments have performance criteria available. The Agency is currently conducting field surveys to develop additional criteria.

FSIS *E. coli* criteria are <u>guidelines</u>, not regulatory standards. FSIS does not use company test results by themselves to take regulatory action. *E. coli* test results are considered in conjunction with other information. The company test results can support more objective assessments and help determine whether establishments meet current statutory requirements for sanitation and the prevention of adulteration. The generic *E. coli* test results play an integral role in the successful implementation of HACCP in livestock slaughter establishments.

If the establishment only slaughters one species and it is not listed in the *E. coli* regulations, the establishment is not required to test for generic *E. coli*.

The establishment must test the species that it slaughters in greatest number (major species) and that is listed in the regulations. When the major species slaughtered in a multiple-species slaughter establishment is not required by regulation to be tested the establishment must test the species produced in the next greatest number that is listed in the *E. coli* regulations.

§ 310.25 (a)(1) Continued

The establishment shall: (i) Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section; (ii) Obtain analytic results in accordance with paragraph (a)(3) of this section; and (iii) Maintain records of such analytic results in accordance with paragraph (a)(4) of this section. (2) Sampling requirements.

(i) Written procedures. Each establishment shall prepare written specimen collection procedures which shall identify employees designated to collect samples, and shall address location(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. The written procedure shall be made available to FSIS upon request.

§ 310.25 (a)(2)(i) requires that the establishment identify the employee(s) who will collect samples. The establishment procedure may simply designate a company position or title to identify the sample collector.

The regulation also requires that carcasses be selected at random. The establishment determines the methods by which randomness is achieved. For example, random number tables, computer-generated random numbers, or drawing cards may be used. In cattle, each half-carcass represents one unit eligible for sampling. Both the "leading" and "trailing" sides of a carcass should have an equal chance of being selected within the designated time frame. In swine, each whole carcass represents one unit eligible for sampling.

The location requirement in the regulation refers to the place within the establishment where the sample is collected. The half-carcass or carcass eligible for sampling should be selected from those in the cooler 12 or more hours after slaughter. The location of selection may also be at the transfer chain, a rail, or a similar place that contains carcasses that have chilled 12 hours or more. In cases where the carcasses are inaccessible in the cooler, or employee safety is jeopardized, it is acceptable to select random samples before carcasses enter the cooler. Selected carcasses may be chilled in a more accessible area and sampled after 12 hours. Similar random sample selection methods are used in establishments conducting hot-boning operations, but the samples are selected after the final wash.

If more than one shift is operating at the establishment, the sample can be taken from either shift, provided the sample selection time is based on the appropriate sampling frequency. The half-carcass or carcass for sampling must be selected at random from all the eligible half-carcasses or carcasses. The time of sampling is based on the appropriate sampling frequency. Sample selection method in establishments conducting hot-boning operations on whole or split carcasses are selected at the end of the slaughter line prior to chilling.

Finally, the written procedure must declare the actions the establishment will take to ensure the sample is handled in a manner that protects the integrity of the sample.

(ii) Sample collection. The establishment must collect samples from all chilled livestock carcasses, except those boned before chilling (hotboned), which must be sampled after the final wash. Samples must be collected in the following manner;

(A) For cattle, establishments must sponge or excise tissue from the flank, brisket and rump, except for hide-on calves, in which case establishments must take samples by sponging from inside the flank, inside the brisket, and inside the rump.

(B) For sheep, goat, horse, mule, or other equine carcasses, establishments must sponge from the flank,

brisket and rump, except for hide-on carcasses, in which case establishments must take samples by sponging from inside the flank, inside the brisket, and inside the rump. (C) For swine carcasses, establishments must sponge or excise tissue from the ham, belly and jowl areas.

§ 310.25 (a)(2)(ii) requires carcasses to be hot-boned be sampled after the final wash. There are two sampling methods an establishment may use to collect *E. coli* samples: excision sampling and sponging. Establishments slaughtering cattle and swine may choose either method. These are described as follows:

- Excision sampling involves aseptically cutting a surface section from the carcass (8 x 6 x ½ inch thick for beef and 10 x 5 x ½ inch thick for swine) and either sending the excision sample for laboratory analysis or running the analysis in-house. Excising tissue from a carcass is a destructive method of sampling.
- Sponging involves aseptically swabbing a sterile sponge on a surface of the carcass (10 cm x 10 cm for beef, swine, and equines; and 10 cm x 5 cm for sheep and goats) and either sending the sponge to the laboratory for analysis or running the analysis in-house. Sponging is a nondestructive method of sampling.

Samples must also be taken from specific sites on cattle and swine carcasses, sheep, goat, horse, mule, or other equine carcasses. The three sites from which either excision or sponging samples must be taken on **cattle** carcasses are the:

- Flank
- Brisket
- Rump

In the case of **hide-on** calves, sheep, goats, horses, mules, or other equines the three sites from which sponging samples must be taken are **inside** the:

- Flank
- Brisket
- Rump

In the case of **swine**, the three excision or sponging samples must be taken from the:

- Belly
- Ham
- Jowls

FSIS assumes that meat establishments following the "*Guidelines for E. coli testing for Process Control Verification in Cattle and Swine Slaughter Establishments*" will conduct their sampling in a manner that does not jeopardize the integrity of the sample or the reliability of the test results. Because these guidelines are not regulatory requirements, the establishment may choose to use a comparable sampling technique and not be out of compliance.

(iii) Sampling frequency. Slaughter establishments, except very low volume establishments as defined in paragraph (a)(2)(v) of this section, must take samples at a frequency proportional to the volume of production at the following rates:

(A) Cattle, sheep, goats, horses, mules, and other equines: 1 test per 300 carcasses, but, a minimum of one sample during each week of operation.

Swine: 1 test per 1,000 carcasses, but a minimum of one sample during each week of operation.

The required frequency of *E. coli* testing is based on production volume.

(iv) Sampling frequency alternatives. An establishment operating under a validated HACCP plan in accordance with §417.2(b) of this chapter may substitute an alternative frequency for the frequency of sampling required under paragraph (a)(2)(iii) of this section if,

(A) The alternative is an integral part of the establishment's verification procedures for its HACCP plan and,

(B) FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishment's processing controls.

In some cases an establishment operating under a validated HACCP plan may substitute an alternative frequency for the frequency in the regulation. This is allowed when the alternative frequency is an integral part of the establishment's verification procedures for its HACCP plan. An example is the case in which *E. coli* testing is built into a critical control point in the HACCP plan. The m/M criteria or the statistical process control upper limit is the critical limit for the CCP. The establishment that slaughters 9,000 cattle per year includes alternative testing frequency in the HACCP plan to sample once per week for a total of 52 samples per year, not 30 samples as would be required by the 1 test per 300 carcasses frequency.

In smaller establishments slaughtering no more than 50 animals per year, not more than 25% of the carcasses will be sampled.

(v) Sampling in very low volume establishments.

(A) Very low volume establishments annually slaughter no more than 6,000 cattle, 6,000 sheep, 6,000 goats, 6,000 horses, mules or other equines, 20,000 swine, or a combination of livestock not exceeding 6,000 cattle and 20,000 total of all livestock. Very low volume establishments that collect samples by sponging shall collect at least one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first. Very low volume establishments collecting samples by excising tissue from carcasses shall collect one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until one series of 13 tests meets the criteria set forth in paragraph (a)(5)(i) of this section.

SPECIES	VERY LOW VOLUME REQUIREMENT
Cattle	Annually slaughter < 6,000 head
Horses, Mules, Equines	Annually slaughter < 6,000 head
Sheep, Goats	Annually slaughter < 6,000 head
Swine	Annually slaughter < 20,000 head

Whether the establishment collects samples by sponging or the excision method, the regulation requires that at least one sample be collected each week of the year that the establishment slaughters. The sample year begins on June 1 of each year. Starting the first full week of operation after June 1st the establishment must collect samples as required until 13 samples and test results have been accumulated.

There is no regulatory limitation on the maximum number of tests that can be performed weekly to meet the thirteen tests requirement of § 310.25 (a)(2)(iv). It is hypothetically possible for the establishments to collect all thirteen samples in one week and meet regulatory requirement for the production year.

(B) Upon the establishment's meeting requirements of paragraph (a)(2)(v)(A) of this section, weekly sampling and testing is optional, unless changes are made in establishment facilities, equipment, personnel or procedures that may affect the adequacy of existing process control measures, as determined by the establishment or FSIS. FSIS determinations that changes have been made requiring resumption of weekly testing shall be provided to the establishment in writing.

After the initial 13 tests are completed for the production year, further *E. coli* testing is optional for the establishment. However, if the establishment determines that there have been changes (remodeling, new equipment, new employees, or new procedures) that affect how well the process works, the establishment must resume weekly testing. Another series of 13 tests can establish the effectiveness of the changed process.

If FSIS determines there have been changes that affect the process, the information must be provided to the company in writing. The establishment would then be required to resume *E. coli* testing to judge the process control.

(3) Analysis of samples. Laboratories may use any quantitative method for analysis of E. coli that is approved as an AOAC Official Method of the AOAC International (formerly the Association of Official Analytical Chemists) or approved and published by a scientific body and based on the results of a collaborative trial conducted in accordance with an internationally recognized protocol on collaborative trials and compared against the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.

(4) Recording of test results. The establishment shall maintain accurate records of all test results, in terms of CFU/cm² of surface area sponged or excised. Results shall be recorded onto a process control chart or table showing at least the most recent 13 test results, by type of

livestock slaughtered. Records shall be retained at the establishment for a period of 12 months and shall be made available to FSIS upon request.

(5) Criteria for evaluation of test results. (i) An establishment excising samples from carcasses is operating within the criteria when the most recent E. coli test result does not exceed the upper limit (M), and the number of samples, if any, testing positive at levels above (m) is three or fewer out of the most recent 13 samples (n) taken, as follows:

Types of Livestock or Pouttry	Loweer limit of marginal range (m)	Upper limit of marginal range (M)	Number of samples tested (n)	Maximum number permitted in marginal range (c)
Cattle	Negative*	100 CFU/cm ²	13	3
Swine	10 CFU/cm ²	10,000 CFU/cm ²	13	3

ts
1

*Negative is defined by the sensitivity of the method used in the baseline study with a limit of sensitivity of at least 5 CFU/cm² carcass surface area.

Cattle and swine slaughter establishments may choose either excision or sponge sampling, however, the performance criteria of "m" (minimum value) and "M" (maximum value) is currently only available for excision samples. Table 1 above shows the "m" and "M" values for *E. coli* performance criteria set forth by the Agency for the species that have had a baseline study completed.

Establishments must document or record *E. coli* test results. Each test result must be recorded in terms of colony forming units per square centimeter (cfu/cm²) for excision and sponging results. As stated earlier, the *E. coli* performance criteria, or "m" and "M", are not enforceable regulatory standards.

E. coli test result levels are separated into three categories for the purpose of process control verification:

- acceptable, marginal (represented by "m")
- unacceptable (represented by "M")

Marginal results ("m") are those within the worst 20% of overall industry performance in terms of *E. coli* counts. More than three marginal results in the last 13 tests are deemed unacceptable.

Results above "M" are within the worst 2% of overall industry performance. Any single test result exceeding "M" is deemed unacceptable.

The "m" and "M" values are applied to a moving window of 13 test results. Only the last 13 test results are evaluated to determine if the performance criteria are met. Any single test result exceeding "M" is unacceptable. More than three results exceeding the marginal limit in the last 13 tests is also unacceptable.

The establishment may elect to use a table type form or a control chart to plot *E. coli* results. Examples of these types of documents follow.



The above example is a control chart. The E. coli test results are plotted vertically using the E. coli CFU/cm² axis. Each sample result is plotted, starting at Test Number "1" in the horizontal axis and moving to the right. The heavier dark line (at 100 CFU/cm²) represents the upper limit of the marginal range or big "M". The lighter dark line (at 0 CFU/cm²) represents the lower limit of the marginal range or little "m".

Test #	Date	Time Collected	Test Result (cfu/cm ²)	Result unacceptable?	Result marginal?	Number marginal or unacceptable in last 13	Pass/Fail ?
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							

This is an example of a table form. The *E. coli* test results are entered from the top down as they are received. The results are evaluated using a moving window of the last thirteen samples collected. <u>Example</u>: Test #1 thru 13, 2 thru 14, 3 thru 15, 4 thru 16, etc., would be used to determine if the *E. coli* test results meet the m/M criteria. With each new test result recorded the window would move ahead one result so that a set of thirteen sample results is maintained at all times. The column "Result unacceptable" is marked "yes" if the upper control limit ("M") has been exceeded and the column "Results marginal" is marked "yes" if the result of the *E. coli* sample is above the lower control limit ("m"), but not above "M". The "number marginal or unacceptable in the last 13" column tracks the number of results in the marginal range within the last thirteen results.

To illustrate the use of *E. coli* performance criteria, *E. coli* sample results covering a period of seventeen tests have been plotted on each of the two types of formats previously illustrated. The data plotted on both forms is from an establishment that slaughters cattle and samples were taken using the excision method (refer to Figure 1 and Figure 2).



Test #	Date	Time Collecte d	Test Result (cfu/cm ²)	Result unacceptable?	Result marginal?	Number marginal or unacceptabl e in last 13	Pass/Fail ?
1	10-07	08:50	10	No	Yes	1	Pass
2	10-07	14:00	Negative	No	No	1	Pass
3	10-08	07:10	50	No	Yes	2	Pass
4	10-08	13:00	Negative	No	No	2	Pass
5	10-09	10:00	Negative	No	No	2	Pass
6	10-09	12:20	Negative	No	No	2	Pass
7	10-10	09:20	80	No	Yes	3	Pass
8	10-10	13:30	Negative	No	No	3	Pass
9	10-11	10:50	Negative	No	No	3	Pass
10	10-11	14:50	Negative	No	No	3	Pass
11	10-14	08:40	50	No	Yes	4	Fail
12	10-14	12:00	Negative	No	No	4	Fail
13	10-15	09:30	Negative	No	No	4	Fail
14	10-15	15:20	Negative	No	No	3	Pass
15	10-16	07:30	Negative	No	No	3	Pass
16	10-16	11:40	Negative	No	No	2	Pass
17	10-17	10:20	120	Yes	No	3	Fail

Figure 2

The following observations can be made from the above data. First, test number eleven documents the fourth test result in the marginal ("m") range. Therefore, the establishment has entered an unacceptable process control status because the fourth marginal result exceeds the limit of no more than three marginal results in the past 13 consecutive tests.

Secondly, tests number twelve and thirteen are negative, therefore, in the acceptable range. However, if you consider the last 13 test results, or the 13-test moving window, there are still more than three results in the marginal range. The company has marked its record to show that it is still in a failing mode because of the four marginal test results. In reality this is *not* an unacceptable result because tests twelve and thirteen are negative, indicating the process is back in control. The failure documented on the table for tests twelve and thirteen cannot be gleaned as evidence of a new problem. The log or documentation of corrective action taken for the first failure at test number eleven should be adequate to verify that the problem was addressed.

Third, at test number fourteen the number of marginal results in the last thirteen tests window is reduced to three. The marginal result for test number one is dropped and replaced by an acceptable result as the 13-test window moves ahead one line; i.e. the moving window is tests 2 through 14.

The fourth observation possibly made from the data annotated on the records is that the test result for test number seventeen exceeds 100 cfu/cm², the "M" value for cattle. Any result over 100 cfu/cm² is automatically unacceptable. It only takes one test in the "M" range to indicate the establishment may not have adequate process control.

(ii) Establishments sponging carcasses shall evaluate E. coli test results using statistical process control techniques.

If the sponging method is selected, the establishment must use statistical process control for evaluating test results.

If the cattle or swine establishment is using the sponge technique, statistical process control must be used, not the "m" and "M" criteria. Charts or tables of the sample results must show at least the most recent 13 test results, if they are available.

(6) Failure to meet criteria. Test results that do not meet the criteria described in paragraph (a)(5) of this section are an indication that the establishment may not be maintaining process controls sufficient to prevent fecal contamination. FSIS shall take further action as appropriate to ensure that all applicable provisions of the law are being met.

Whenever an establishment determines that its *E. coli* test results do not meet "m" and "M" performance criteria it must take corrective action to bring the process back into control. In the case of establishments using statistical process control, when *E. coli* test results do not meet *E. coli* limits set by the establishment, corrective action to regain process control must be taken.

Although the establishment is required to make corrections to its process to regain control of contamination, it is **not** required to document those corrective actions.

(7) Failure to test and record. Inspection shall be suspended in accordance with rules of practice that will be adopted for such proceedings upon a finding by FSIS that one or more provisions of paragraphs (a) (1)-(4) of this section have not been complied with and written notice of same has been provided to the establishment.

When establishments do not evaluate their test results §310.25(a)(5), they might not be maintaining process controls sufficient to prevent fecal contamination. The District Office will be notified of these instances. District management and will decide what further action should be taken to ensure all applicable provisions of the law are being met.

Microbiological Sampling for Poultry Slaughter (other than Ratite) Operations

The purpose of the new sampling requirements is to ensure that establishments monitor and evaluate the effectiveness of their procedures to prevent contamination of carcasses by enteric pathogens and visible fecal material on an ongoing basis. Fecal contamination is a principal source of pathogenic organisms that contaminate poultry carcasses. Under the Modernization of Poultry Slaughter Inspection final rule establishments that slaughter poultry, other than ratites, are required to perform microbiological sampling and analysis, for example, testing for *Salmonella, Campylobacter*, or indicator organisms such as aerobic plate count (APC), total coliform, Enterobacteriaceae, and *Escherichia coli*, Biotype I, also known as generic *E. coli*.

Because establishments have differences in their operations, each establishment has the flexibility to develop a sampling plan and determine the microbial organism that will accurately monitor the effectiveness of its process control procedures.

Microbiological test results that represent the level of microbiological contamination at key steps in the slaughter process are necessary for the establishment to provide comprehensive objective evidence to demonstrate process control. Process control consists of the programs and procedures that an establishment implements to ensure its process prevents contamination of poultry carcasses and parts, including contamination with pathogens and fecal material. Process control also ensures that the resulting product meets applicable standards or definitions.

Inspection Program Personnel (IPP) Responsibilities

In poultry slaughter establishments (other than ratite), IPP are to conduct verification tasks, as outlined in Directive 5000.1 following the verification instructions in Notice 64-14. The PHIS verification task that IPP perform depends on how the establishment has incorporated its written procedures for preventing contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the entire slaughter and dressing operation in its HACCP system. For instance:

- If the establishment's written procedures are part of its HACCP plan, IPP are to verify HACCP regulatory requirements by performing the <u>Slaughter HACCP verification</u> <u>task</u> when it has been scheduled in PHIS.
- If the establishment's written procedures are part of its Sanitation SOPs, IPP are to verify that the establishment meets all Sanitation SOP regulatory requirements by performing the **Operational SSOP Review and Observation task** when it has been scheduled in PHIS.
- If the establishment's written procedures are part of another prerequisite program or other control measures, IPP are to verify the implementation of such program by performing the <u>Slaughter HACCP verification task</u> when it has been scheduled in PHIS.

IPP are to perform the appropriate PHIS verification task on a **routine** basis at the frequency specified in the establishment's task list. IPP are also to initiate a **directed** verification task if they observe noncompliance with the requirements in 381.65(g) and (h) while performing other tasks or when instructed to do so by supervision or other policy issuances.

IPP are to verify that the poultry slaughter establishment:

- Developed a written sampling program that identifies the specific microorganisms being tested and location/frequency where samples are collected,
- Incorporated its written sampling program for preventing contamination by enteric pathogens into its HACCP system,
- Implements and maintains its written sampling program,
- Maintains scientific and technical documentation to support the decisions that the establishment made in designing the sampling program,

Maintains daily records documenting the implementation and monitoring of its procedures including sample results

Microbiological Sampling and Analysis Verification

Each poultry slaughter establishment's written procedures for preventing contamination of carcasses and parts with enteric pathogens and fecal material must include sampling and analysis for microbial organisms.

The regulations require each establishment to maintain scientific and technical documentation to support the judgments that the establishment made in designing the sampling program. The regulations prescribe the minimum requirements for the location and frequency of sampling, based on the establishment size and production volume. Each establishment must maintained daily records to document the implementation and monitoring of their procedures including records documenting the test results of its sampling plan.

Note: Establishments may use *Salmonella* Initiative Program (SIP) microbial data as part of their sampling plan to monitor their process control, provided they meet minimum frequencies and location requirements.

A Microbiological Testing of Raw Poultry Summary Chart (Attachment 2 of this handout) is provided as a reference for the establishment size, sampling frequencies, and sampling locations requirements. It is a quick and easy inspection aid when conducting the PHIS verification task.

IPP must understand what each statement of the regulation means in order to conduct the appropriate PHIS verification task. IPP address the requirements of 9 CFR 381.65(g) and (h) as follows:

1. Sampling requirements – Microbial Indicator Organism paragraph (g) of section 381.65

Each establishment must develop its own sampling program/procedure that identifies the specific microbiological organisms (i.e., *Salmonella, Campylobacter*, or other enteric organisms) for which the establishment will test to monitor the effectiveness of its process control procedures that prevent contamination of carcasses and parts with enteric pathogens and fecal material.

Note: Very small and very low volume poultry slaughter establishments (as defined below) operating under **Traditional Inspection** can choose to continue conducting generic *E. coli* testing at post-chill to meet the requirements under the Modernization of Poultry Slaughter Inspection final rule. FSIS considers the requirements under the former §381.94(a) regulations for generic *E. coli* testing of poultry to be scientifically validated **"safe harbor"** for monitoring process control.

2. Sampling requirements – location (paragraph (g)(1) and paragraphs (g)(1)(i) and (ii) of section 381.65) and technique

Poultry slaughter establishments are codified by size and annual slaughter volume, according to regulation 381.65(g)(1)(i) and (ii), and FSIS Notice 64-14.

- Very small establishments are establishments with fewer than 10 employees or annual sales of less than \$2.5 million.
- Very low volume (VLV) establishments annually slaughter no more than 440,000 chickens, 60,000 turkeys, 60,000 ducks, 60,000 geese, 60,000 guineas, 60,000 squabs or a combination of all types of poultry not exceeding 60,000 turkeys and 440,000 birds total.

The location refers to the place within the establishment where the sample is collected. Very small establishments and VLV establishments operating under **Traditional inspection** are required to collect samples for microbial organisms at the **post-chill point** in the process. All other establishments must collect samples at both the **pre-chill and post-chill** locations.

The pre-chill location for sampling is any point in the slaughter process from re-hang to just prior to the chiller. The post-chill location for sampling is a point in the slaughter process after the carcass exits the chiller and after all slaughter interventions are completed, which is the same point in the process that FSIS collects samples for *Salmonella* and *Campylobacter* verification testing.

Carcasses must be selected at the required points in the process (pre and post chill). At the post-chill site, samples should be collected after the final wash and the application of any final antimicrobial interventions. A drip time of at least 60 seconds should be observed before sample collection to prevent excessive antimicrobial carryover in the collected sample.

Note: Antimicrobials used during processing steps may make it harder to detect live bacteria in the collected sample if the carcass is not allowed adequate drip time before collecting the sample. Consequently, antimicrobial carryover (residual) can result in altered test results (lower bacterial counts), may invalidate the test results, and may not provide a true representation of the establishment's process control.

The sampling methods for collecting carcass samples may include the nondestructive sponge technique for sample collection from turkeys and geese (back and thigh) and a whole bird rinse technique for sample collection from chickens, guineas, ducks, geese, and squabs. All carcass samples should be taken using aseptic techniques.

The establishment must provide scientific or technical support for their sampling technique and sample site on the carcass. If IPP have concerns with the establishment's support, they should contact the District Office through supervisory channels.

3. Sampling requirements – frequency paragraphs (g)(2)(i) and (ii) of section 381.65

VLV establishments must collect and analyze samples at least once during each week of operation starting June 1 of every year. If, after consecutively collecting 13 weekly samples, a VLV establishment can demonstrate that it is effectively maintaining process control, it may modify its sampling plan. In this case the establishment would need to document the

changes and maintain documentation showing that the changes allow the establishment to continue to effectively monitor process control.

Seasonal VLV operations must complete all microorganism testing during whichever months it operates. For example, a seasonal duck slaughter establishment that operates from September through December must begin testing during its first full week of operations and complete 13 tests before operations end in December.

All other establishments (including very small establishments) must collect and analyze a pair of samples, one at pre-chill and one at post-chill, at the following frequencies:

- Chickens: once per 22,000 carcasses but at a minimum of once during each week of operation;
- Turkeys, ducks, geese, guineas, and squabs: once per 3,000 carcasses but at a minimum once each week of operation.

Slaughter volume does not always match frequency rates in the regulations. Establishments should account for extra slaughter volume. This can be done by conducting additional microbiological tests. For example, a chicken establishment that slaughters 40,000 birds per day should test at least once a day at the 22,000 birds per test frequency. However, the remaining 18,000 birds should also be accounted for to monitor process control. To account for the extra slaughter volume, the establishment could "carry over" the 18,000 extra birds to the next day's volume and conduct two (2) microorganism tests on the second day.

4. Random selection of carcasses

Samples should be collected randomly at the frequency determined by the establishment as part of its sampling plan. At a minimum, the establishment must collect samples at the frequency specified under 9 CFR 381.65(g)(2). If more than one shift is operating at the establishment, the sample can be taken on any shift. Different methods of selecting the specific carcass for sampling could be used, but the method used should include the use of random numbers to ensure that testing data is not biased. Examples of methods include random number tables, calculator or computer-generated random numbers, or drawing cards.

The carcass that is sampled should be selected at random from all eligible carcasses. If there are multiple lines or chillers, randomly select the line or chiller for sample collection for that interval. Each line or chiller should have an equal chance of being selected at each sampling interval within the relevant time frame (based on the sampling frequency for the plant).

The establishment must provide scientific or technical support the decisions it made in designing the sampling program.

5. Sample analysis and testing method

To obtain the most accurate results, samples should be analyzed as soon after collection as possible. If samples must be transported to an off-site laboratory, they should be refrigerated and then shipped refrigerated, on the same day they were collected, via an

overnight delivery or courier service to the laboratory. A sample should arrive at the laboratory and be analyzed no later than the day after it is collected.

In addition, establishments should ensure that microbiological testing is reliable and meets its food safety needs. Each establishment needs to determine whether sample analysis will be performed by an outside or on-site laboratory. FSIS has available the compliance guideline "*Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory*" if the establishment decides to use an outside laboratory to analyze microbiological samples. This guidance document should be particularly useful to very small establishments when they are selecting a commercial or private laboratory to analyze establishment microbiological samples.

FSIS has also made available a list of *Foodborne Pathogen Test Kits Validated by Independent Organizations* for the detection of relevant foodborne pathogens (i.e., *Salmonella, Campylobacter, E. coli* O157:H7, and *Listeria spp.* including *L. monocytogenes*). This list is intended to be informational and is not an endorsement or approval of any particular testing method, regardless of its inclusion in the list.

Poultry slaughter establishments (other than ratite) must include the analysis of microbial organisms in their sampling procedures as part of their HACCP system (381.65(g)). Therefore, scientific and technical documentation must be provided to support the design of the sampling program. The Agency recommends that the industry follow the guidelines in the document titled "FSIS Compliance Guideline: HACCP Validation" published on May 2013. The documentation can be found in the FSIS website at:

http://www.fsis.usda.gov/wps/wcm/connect/a70bb780-e1ff-4a35-9a9a-3fb40c8fe584/HACCP_Systems_Validation.pdf?MOD=AJPERES

IPP are to review the establishment's written programs, scientific and technical support, and records to verify that the laboratory analyzes the samples using an AOAC Official Method or one validated by another recognized independent testing body. When in doubt about whether the laboratory testing procedure is acceptable, IPP should go through the supervisory chain-of-command to the District Office for assistance.

6. Records of test results – paragraphs (g)(2)(iii) and (h) of section 381.65

Official poultry slaughter establishments must maintain daily records documenting the implementation and monitoring of its procedures required under paragraph (g) including accurate records of all test results from its sampling plan for at least one year. These records can be maintained in an electronic format on a computer, provided there are measures in place to ensure the integrity of the electronic data. These records must be readily accessible for review by IPP upon request.

IPP are to verify that the establishment maintains daily records documenting the implementation and monitoring of its procedures, makes these records available for IPP to review and retains these records for one year, and implements appropriate controls to ensure the integrity of electronic data if records are maintained on computers

7. Criteria for evaluation of test results

Poultry slaughter establishments should use statistically valid approach or statistical process control (SPC) to interpret their microbiological test results as previously discussed in this handout. Establishments gather initial test results and set the upper control limit that is used to assess whether the slaughter process is under control. As long as the test results remain below the upper control limit, the slaughter process is considered under control.

In cases where an establishment does not have the resources or capacity to develop and implement their own statistical control limits or procedures, establishments can utilize the results from FSIS nationwide livestock or poultry surveys. The tables below demonstrate the indicator organism median values for chickens and turkeys.

	Median (CFU/mL)			
	Generic E. coli	APC	Enterobacteriaceae	Total Coliform
Carcass – Rehang	540	28,000	1,600	940
Carcass – Post Chill	20	260	20	20

Table 1 - Indicator Organism Median Values for Chickens

Table 2 - Indicator Organism Median Values for Turkeys

	Median (CFU/mL) Generic E. coli APC Enterobacteriaceae Total Coliform				
Carcass – Rehang	22	1,800	50	40	
Carcass – Post Chill	<1.2	18	<1.2	<1.2	

An establishment sample value that is higher than the corresponding one listed in the table indicates the establishment may not be maintaining process control and may be less likely to meet applicable performance standards. Sample values lower than the one listed in the table indicate the establishment may be maintaining process.

SPC usually includes the use of a control chart, which plots data over time but also displays an upper control limit for specific measurements and a centerline (the average), above and below which there is an equal number of sample results. A sample result above the upper control limit would indicate the likely presence of a special cause of variation that should be addressed. Results within control limits indicate simply that the process is in control.

The example below shows a SPC chart for a poultry slaughter operation which plots test results for an indicator organism in terms of sample number, along the horizontal X-axis, against Log cfu/ml on the Y-axis. This chart illustrates a pattern of an indicator organism test results that would be seen in a well-controlled system. In a well controlled system, the majority of the test results will be clustered around a central value (the average). It is important to note that even in a well-controlled system there is some frequency of isolated results above the acceptable level.



As part of its process control procedures, an establishment should define the actions it will take if the microbiological test results obtained through its sampling are above the limits it has set. The establishment should delineate what its actions will be, who will take each action, how the outcome of these actions will be documented, and how it will be verified.

FSIS has made available the *FSIS Compliance Guidelines for the Control of* Salmonella *and* Campylobacter *in Raw Poultry*. The guidelines summarize known control points for *Salmonella* and *Campylobacter* in the pre- and post-harvest production process. Establishments should use this compliance guide to improve management practices, to ensure effective dressing operations and to assist in investigating when there is a loss of control of the slaughter process.

When IPP review the establishment's records that document its microbiological test results, they should look for trends in the test results that indicate a loss of process control. For example, IPP are to look for:

- A significant number of test results that exceeded the establishment's upper control criteria, if the establishment has such criteria,
- Instances where the test results exceed the establishment's criteria by a large amount over a relatively short period of time (e.g., days or weeks); or
- Test results that show a trend of worsening performance over a relatively long period of time (e.g., days, months, seasonal).

Very Small or Very Low Volume Establishments that Slaughter Poultry under Traditional Inspection Using the Safe Harbors to Monitor Process Control

The Agency considers former provisions 381.94(a)(2)(i), (a)(3), and (a)(5)(i) as safe harbors if very small and very low volume establishments slaughter poultry under Traditional Inspection chooses to test for generic *E. coli* at post chill as the indicator microorganism.

These establishments use the M/m values in the following table and a moving window of the last 13-documented test results to evaluate process control.

Type of poultry	Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of Samples tested (n)	Maximum number permitted in the Marginal range
Chickens	100 cfu/ml	1,000 cfu/ml	13	3

An establishment is operating within the criteria when the most recent generic *E. coli* test result does not exceed the upper limit (M), and the number of samples, if any, testing positive at levels above (m) is three or fewer out of the most recent 13 samples (n) taken.

Whenever a prudent poultry slaughter establishment determines that its generic *E. coli* test results do not meet m/M performance criteria, it should take necessary actions to bring the slaughter process back into control.

8. Sample Integrity

Even though the regulatory requirements in 9 CFR 381.65(g) for poultry slaughter microbiological testing programs do not specifically address the handling of the samples to ensure sample integrity, a prudent establishment should include a description of how samples are handled ensure the sample integrity. Remember, the regulation requires each poultry slaughter establishment to incorporate their written procedures in its HACCP system which must comply with the 9 CFR 416 or 417 regulations.

Poultry Slaughter Operations and Procedures – 381.65(g) and 381.65(h)

Sec. §381.65 Operations and procedures, generally

(g) Procedures for controlling contamination throughout the slaughter and dressing operation. Official poultry slaughter establishments must develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the entire slaughter and dressing operation. Establishments must incorporate these procedures into their HACCP plans, or sanitation SOPs, or other prerequisite programs. At a minimum, these procedures must include sampling and analysis for microbial organisms in accordance with the sampling location and frequency requirements in paragraphs (g)(1) and (2) of this section to monitor their ability to maintain process control.

(1) Sampling locations. Establishments, except for very small establishments operating under Traditional Inspection or very low volume establishments operating under Traditional Inspection must collect and analyze samples for microbial organisms at the pre-chill and post-chill points in the process. Very small establishments operating under Traditional Inspection and very low volume establishments operating under Traditional Inspection must collect and analyze samples for microbial organisms at the process.

(i) Very small establishments are establishments with fewer than 10 employees or annual sales of less than \$2.5 million.

(ii) Very low volume establishments annually slaughter no more than 440,000 chickens, 60,000 turkeys, 60,000 ducks, 60,000 geese, 60,000 guineas, or 60,000 squabs.

(2) Sampling frequency. (i) Establishments, except for very low volume establishments as defined in paragraph (g)(1)(ii) of this section, must, at a minimum, collect and analyze samples at a frequency proportional to the establishment's volume of production at the following rates:

(A) *Chickens.* Once per 22,000 carcasses, but a minimum of once during each week of operation.

(B) *Turkeys, ducks, geese, guineas, and squabs.* Once per 3,000 carcasses, but at a minimum once each week of operation.

(ii) Very low volume establishments as defined in paragraph (g)(1)(ii) of this section must collect and analyze samples at least once during each week of operation starting June 1 of every year. If, after consecutively collecting 13 weekly samples, a very low volume establishment can demonstrate that it is effectively maintaining process control, it may modify its sampling plan.

(iii) Establishments must sample at a frequency that is adequate to monitor their ability to maintain process control for enteric pathogens. Establishments must maintain accurate records of all test results and retain these records as provided in paragraph (h) of this section.

(h) *Recordkeeping requirements.* Official poultry slaughter establishments must maintain daily records sufficient to document the implementation and monitoring of the procedures required under paragraph (g) of this section. Records required by this section may be maintained on computers if the establishment implements appropriate controls to ensure the integrity of the electronic data. Records required by this section must be maintained for at least one year and must be accessible to FSIS.

Salmonella and Campylobacter Performance Standards Verification Testing

Introduction

The pathogen reduction program is an integral part of the FSIS food safety strategy. It stimulates improvements in food safety practices by establishing guidelines and ensuring proper process control. FSIS established performance standards for *Salmonella* in July 1996, as part of the *Pathogen Reduction; Hazard Analysis Critical Control Point (PR/HACCP) Systems; final rule.*

In May 2010, FSIS published a Federal Register Notice (Docket No. FSIS-2009-0034) The PR/HACCP Final Rule established *Salmonella* performance standards that are used to verify process control in meat and poultry slaughter and processing establishments that produced certain classes of product (9 CFR 310.25(b)(1) and 381.94(b)(1), respectively). The performance standards were developed using national baseline studies conducted before the rule's implementation. Only the performance standards for livestock carcasses and certain raw ground meat products (9 CFR 310.25(b)) are still applicable.

Since then, FSIS has conducted additional prevalence and risk assessments for pathogens in FSIS regulated products, revised the performance standards to meet public health goals, and has published a number of Federal Register Notices (FRN).

- FSIS published new performance standards in 2010 and 2011 for *Salmonella* and *Campylobacter* for chilled carcasses in young chicken (broiler) and turkey slaughter establishments. The Agency has identified *Campylobacter* as part of FSIS's pathogen reduction strategy and established *Campylobacter* performance standards for poultry carcasses.
- In December 2012, FSIS informed establishments that produce not ready-to-eat (NRTE) ground or otherwise comminuted chicken and turkey products that they were required to reassess their HACCP plans (FRN Docket No. 2012-0007; April 21, 2014) as a result of two multi-state outbreaks linked to ground turkey products. FSIS also expanded the *Salmonella* sampling beyond ground chicken and turkey to include all forms of non-breaded, non-battered comminuted Not-Ready-to-Eat (NRTE) poultry products to determine the prevalence of *Salmonella* and *Campylobacter* in NRTE comminuted poultry, and to develop pathogen reduction performance standards for these products.
- In 2014, FSIS published the Modernization of Poultry Slaughter Inspection; Final Rule (Federal Register Docket No. FSIS-2011-0012; August 21, 2014) to facilitate pathogen reduction in poultry products, improve the effectiveness of poultry slaughter inspection, make better use of Agency's resources, and remove unnecessary regulatory obstacle to innovation. In this publication, FSIS informed industry that it was removing the codified *Salmonella* pathogen reduction performance standards for poultry (9 CFR 381.94(b)). Furthermore, in another publication (Federal Register Docket No. FSIS-2012-0038; June 5, 2014), FSIS announced that it will analyze for *Salmonella* all raw beef samples collected for shiga

toxin-producing *E. coli* (STEC) analysis including the follow-up samples in response to STEC positive results. In addition, the raw ground beef samples portion for *Salmonella* analysis increased from 25 grams to 325 grams. FSIS will gather data necessary to determine the prevalence of *Salmonella* in ground beef and beef trim to propose new performance standards for ground beef.

 In January 2015, the Agency identified new Salmonella and Campylobacter performance standards for raw chicken parts and NRTE comminuted poultry products. (FRN Docket No. FSIS-2014-0023; January 26, 2015). It also announced that it will use the results of routine sampling throughout the year, using a moving window approach, to assess whether the establishment's processes are effectively addressing pathogens on poultry carcasses and other products derived from these carcasses. In this publication, FSIS is also implementing an exploratory sampling of raw pork products for pathogens of public health concern, as well as indicator organisms.

Why Salmonella and Campylobacter?

Salmonella was selected as the target pathogen because it is the leading cause of foodborne illness among enteric pathogens, it is present at varying frequencies on all types of raw meat products, and it can easily be tested for in a variety of products. Furthermore, improvements in process control that result in reductions in *Salmonella* are expected to result in reductions of other pathogens found in the intestines of animals.

Campylobacter species, specifically *C. jejuni* and *C. coli*, are most often isolated from the intestinal tract of poultry as well as in poultry products. *Campylobacter* bacteria are the second most frequently reported cause of food borne illness, and *Campylobacter jejuni* is the most common strain causing illness.

Salmonella and Campylobacter can be transmitted to humans by eating foods contaminated with animal feces. The goal of the newly revised Salmonella and Campylobacter testing program is to protect the consumer from contaminated products, especially from fecal contamination, by verifying that each establishment's performance meets the new performance standards for poultry as well as the Salmonella performance standard for meat products as codified in 9 CFR 310.25(b). In addition to reporting individual Salmonella and Campylobacter sample results to establishments, FSIS posts nationwide Salmonella and Campylobacter data on its website on a quarterly basis.

FSIS collects raw meat and poultry products samples from establishments and test the samples for *Salmonella* and *Campylobacter* to verify that establishments are meeting the pathogen reduction performance standards. Pathogen reduction performance standards for raw products are an essential component of FSIS food safety strategy as they provide a direct measure of progress in controlling and reducing the most significant hazards associated with raw meat and poultry products. Accordingly, the collection of samples in establishments by inspection program personnel is a significant Agency priority.

Salmonella and Campylobacter Verification Testing

Testing is conducted in plants by FSIS personnel, who collect both carcass and ground product samples.

The *Salmonella* and *Campylobacter* verification sampling is conducted in establishments by FSIS inspection program personnel (IPP). IPP will collect samples using on-going scheduled sampling (routine sampling) using a moving window approach to assess process control for all *Salmonella* performance standards.

It is important for IPP in establishments slaughtering or producing raw intact or raw nonintact chicken and turkey products to update the establishment's Public Health Information System (PHIS) profile information as per FSIS Notice 12-15. The Agency has made changes to the product group options in the PHIS establishment profile to identify establishments that produce specific types of raw intact and non-intact chicken and turkey products.

Products Eligible for Sampling

Raw ground products, sampled and *analyzed for Salmonella* include:

- Ground and chopped raw meat from cattle carcasses (beef or veal which may or may not contain added ingredients, spices, or seasonings), that meet the standards of identity for ground and chopped beef (9 CFR 319.15(a)) and hamburger (9 CFR 319.15(b)). Sampled products may contain meat derived from advanced meat recovery (AMR) systems, but AMR meat by itself is not sampled.
 - Products that are **not** sampled in this program include beef patties as defined in 9 CFR 319.15(c), and fabricated steaks and similar products as defined in 9 CFR 319.15(d).

Note: Salmonella verification sample sets for raw ground beef products have been <u>discontinued</u> with the exception at establishments that recently exceeded the performance standard and are in 'Category 3' (FSIS Notice 28-14). FSIS also discontinued collecting MT43S samples in very low volume grinding establishments. In addition, raw beef samples collected for STEC analysis are also analyzed for *Salmonella*.

Note: FSIS is not currently sampling and testing for *Salmonella* in steers or heifers, cows or bulls, or market hogs per FSIS Directive 10,250.1.

IPP also collect the following poultry samples, using a moving window sampling approach, to be <u>analyzed for **both** *Salmonella* and *Campylobacter* as described in Directive 10,250.1, Notice 22-15, and FSIS Notice 31-15.</u>

- Poultry carcasses
 - young chicken carcasses including broilers, fryers, roasters, and Cornish game hens, as described in 9CFR 381.170(a), and
 - young turkey carcasses

• NRTE comminuted poultry

NRTE comminuted poultry is any non-breaded, non-battered, raw NRTE chicken or turkey product that has been processed to reduce the particle size which may or may not contain added ingredients. NRTE comminuted poultry includes:

- ground (Ground product group category) ground chicken or turkey for any purpose (e.g., packed for consumer or for any type of further processing); or
- (2) mechanically separated (Mechanically Separated product group) mechanically separated chicken or turkey, as defined in 9 CFR 381.173; or
- (3) hand or mechanically-deboned and further chopped, flaked, minced, or otherwise processed to reduce particle size. Chicken or turkey product, other than ground or mechanically separated falls under the Other Non-intact product group. These products include:
 - NRTE comminuted chicken product may be derived from any age chicken, including young chickens (broilers, fryers, and roasters), fowl, capons, and roosters, as defined in 9 CFR 381.170(a)(1); and
 - NRTE comminuted turkey product may be derived from any age turkey, including young turkeys, yearling turkeys, and old turkeys, as defined in 9 CFR 381.170(a)(2).

Note: These products include final (consumer-ready) products or intermediary product for further processing as NRTE product that are destined for sale as NRTE product for consumers.

Note: The Agency *does not* collect samples of chickens/turkeys or chicken/turkey products produced under a *religious exemption* and not bearing the mark of inspection. Products from any product class diverted for pet food manufacture without the mark of inspection are also <u>not</u> sampled. In addition, FSIS does not currently sample eligible product for *Salmonella* testing from poultry establishments that produces less than 1,000 pounds per day.

As explained in the January 26, 2015 Federal Register Notice (Docket Number FSIS-2014-0023), FSIS began exploratory sampling of chicken parts as well as of raw pork products for pathogens of public health concern as instructed in FSIS Notice 16-15 and FSIS Notice 23-15.

- Raw Chicken Parts Sampling Project: FSIS Notice 16-15 instructs IPP to collect raw chicken parts (finished product) to be analyzed for *Salmonella* and *Campylobacter*. Chicken parts that are subject to sampling include those that are non-intact (that have been needle injected with clear liquid or marinated in a clear solution, mechanically tenderized, vacuum tumbled, or similarly processed; refer to Attachment 1 of the notice). Definitions are found in 9 CFR 381.170(b), Standards for kinds and classes, and for cuts of raw poultry. Eligible chicken parts for sample collection include:
 - Legs: whole legs (no backbone attached), drumsticks, thighs, and cut up or portioned leg meat (3/4 inch larger in at least one dimension),
 - Breasts: whole and half breasts (with or without ribs), boneless and skinless breasts, tenderloins and tenders, and cut up portioned breast meat (3/4 inch larger in at least one dimension), and
Wings: whole wings (with or without the wing tip), mixed wing sections, drummettes, mid-sections (flats), wing tips, and boneless wings

Note: Chicken half carcasses and quarter carcasses are not eligible for collection under this sampling program.

- Raw Pork Products Exploratory Sampling Project (RPPESP): As stated in FSIS Notice 23-15, IPP are to collect samples at establishments that produce raw pork products as part of the nationwide RPPESP. These samples are analyzed for *Salmonella* as well as for indicator organisms. The eligible raw pork products include:
 - Raw intact pork products retail cuts, tray ready cuts, foodservice cuts, or portion cuts prepared for consumers that have not been tenderized, injected, pumped, or vacuum tumbled; and
 - Raw non-intact pork products retail cuts, tray ready cuts, foodservice cuts, or portion cuts prepared for consumers that have been tenderized, injected, pumped, or vacuum tumbled; ground pork, mechanically separated pork, AMR pork, pork sausage, patties or other formed products; and other comminuted pork.

Circumstances in Which Sampling is not Warranted

Even though most raw meat and poultry products are subject to *Salmonella* testing, there is a narrow set of circumstances in which sampling is not warranted. According to FSIS Directive 10,250.1, when an establishment processes all its products into ready-to-eat (RTE) product or diverts all of its raw products to another federally-inspected establishment for further processing into a RTE product, FSIS will exclude the establishment from the *Salmonella* verification testing program.

If an establishment claims that all products are processed into RTE product, IPP are to verify this during the performance of a HACCP procedure, by observing that all the products are actually further processed into RTE product in the establishment, or by reviewing records to ensure that all products are further processed into RTE products in the establishment.

The Performance Standards

FSIS replaced its existing *Salmonella* sampling set-approach with a routine sampling approach for *ALL* FSIS-regulated products subject for *Salmonella* and *Campylobacter* verification testing. This includes broiler and turkey carcasses, chicken parts, comminuted poultry, ground beef (tested for *Salmonella* only), and beef manufacturing trimmings (tested for *Salmonella* only). *Salmonella* and *Campylobacter* performance standard verification samples are taken as part of a moving window and the results are used to determine if an establishment is meeting the performance standard on a continuous basis. When assessing process control under a moving window approach, FSIS intends to evaluate, over a certain period of time, a number of sequential results from a single establishment. Thus, given the fixed timeframe of one year (52 weeks) for which an establishment has been sampled, FSIS would assess the first moving window by evaluating the number of samples taken within the 52-week period.

As an example, if an establishment has five *Salmonella* positives within 52 samples (one sample per week for a year), then the establishment passed the performance standard if the performance standard allows five positive samples among 52 samples. When the next sample is taken (week 53, in this example), the moving window would shift forward the fixed timeframe of one year (52 weeks); that is, the original week 1 (and the original first sample) is excluded, while the most recent week is included in the new 52-week moving window. This shifting is repeated with each new week and allows FSIS to continuously assess the process control of an establishment.

The charts below shows the maximum acceptable percent positive results or number of positives results allowed in the moving window before the establishment fails to meet the performance standard. A test is considered positive when any *Salmonella* or *Campylobacter* organisms are found.

Product	Maximum Acceptable % Positive		Performance Standard	
	Salmonella	Campylobacter	Salmonella	Campylobacter
Broiler Carcasses^	7.5	10.4	5 of 51	8 of 51
Turkey Carcasses^	1.7	0.79	4 of 56	3 of 56
Comminuted Chicken*	25.0	1.9	13 of 52	1 of 52
Comminuted Turkey*	13.5	1.9	7 of 52	1 of 52
Chicken Parts*	15.4	7.7	8 of 52	4 of 52

Salmonella/Campylobacter Performance Standards for Poultry

 ^ The maximum percent positive for Salmonella and Campylobacter under the performance standards for young chicken and turkey carcasses is listed in FSIS Directive 10,250.1
 * Developed proposed performance standards published in the FRN Docket No. FSIS-2014-0023

Note: The new *Salmonella* performance standards are to be applied to sample results in place of the performance standards for young chickens (as broilers) and ground chicken and ground turkey codified in 9 CFR 381.94(b).

For highest-volume establishments, FSIS expects to collect 52 samples within the 52-week moving window. In this case, to assess process control (at establishments producing products with performance standards measured in 52 samples), one need only to count the number of positives test results within the 52-week moving window. For example, the proposed performance standard for *Salmonella* in raw chicken parts is eight positives out of 52 samples. Assuming that 52 samples were collected from the establishment within a 52-week moving window, if the establishment has eight or fewer *Salmonella* positives within that 52-week timeframe, then it would pass the performance standard. If, on the other hand, the establishment has nine or more *Salmonella* positives within that same 52-week timeframe, then it would fail the performance standard.

To assess process control in establishments that FSIS samples less often than weekly (i.e., lower volume establishments), FSIS will assess establishment performance (as percent positive) based on the (likely variable) number of samples collected and positive results within the 52-week moving window. To illustrate this point, if a small establishment producing raw chicken parts is sampled fewer than 52 times in the 52-week moving window, only 26 times, for example, with three of those samples testing positive for Salmonella, 26 will be the denominator while three be the numerator. This gives

the establishment a percent positive of 11.5 (($3 \div 26$) X 100 = 11.5%). In this example, the resulting percent positive is less than 15.4, the acceptable percent positive for the proposed performance standards for *Salmonella* in raw chicken parts. As such, the establishment would pass the performance standard.

Salmonella Performance Standards for Ground Beef¹

Product class	Pathogen	Performance standard	Number of samples tested	Sampling Method	Maximum number of positives to achieve standard	Revised Standard Implemented
Ground Beef	Salmonella	7.5%	53	One sample per event	5	N/A

¹ As per Directive 10,250.1

For ground beef, an establishment can have no more than 5 positive sample results out of 53 samples in the moving window.

Sampling Procedures

The purpose of the *Salmonella* and *Campylobacter* verification sampling program is to verify the establishment's process control for *all applicable products*. *All* eligible products produced at an establishment will be scheduled for sampling during the month under routine sampling. For example, if an establishment produces more than one product type (chicken carcasses, chicken parts, and NRTE comminuted chicken) that is eligible for sampling, then all of those products will be scheduled for sampling during the month. IPP are to collect samples in accordance with the step-by-step directions found in FSIS Directive 10,250.1 and FSIS notices for all product classes including young chicken and turkey carcasses.

Salmonella and Campylobacter verification sampling is a **directed** sampling task. Taking into account risk factors including production volume and past establishment testing performance (i.e., positive Salmonella and Campylobacter test results), FSIS will establish the sampling frequency accordingly for a particular establishment. The Public Health Information System (PHIS) displays sampling tasks (including the sampling project code) on the establishment task list for the sampling programs that apply to the establishment.

The specific sampling methodologies for the product classes to be sampled are explained in detail in FSIS Directive 10,250.1 and applicable FSIS notices.

IPP collect samples using a carcass sponge swab, a whole bird rinse, or taking a specific amount of ground/comminuted product using the sampling technique as described in FSIS Directive 10,250.1 and in published FSIS notices. Even though the Agency is not collecting livestock carcasses samples, the sampling procedures for cattle and hog carcasses are also included in the directive in case they are needed for special purposes.

Turkey carcasses are sampled using a sponge sample technique. Sponge sampling of turkey carcasses uses two sponges, one that is analyzed for *Salmonella* and the other for *Campylobacter*. Sponge sample sites are to the left and right of the back and thigh as per instructions delineated in the directive.

Chicken carcasses are sampled using whole bird rinses; IPP are to collect 100 ml rinsate.

Note: For poultry carcasses, at the post-chill sampling location, IPP are to determine a random time at which the carcass will reach the end of the drip line or the equivalent point in air-chill systems. IPP are to randomly select a poultry carcass from the post-chill area (after all interventions have taken place) and to allow drip time to prevent dilution of the sample.

Chicken parts are sampled by collecting approximately 120 ml of rinsate from 4 lbs. \pm 10% of the eligible raw chicken parts.

The amount of ground product collected (final package or aseptically when not in final package) by the IPP will depend on the sampling project code as follows:

- Ground beef products, as well as raw beef trim samples collected for routine and follow-up projects for *E. coli* O157:H7 and other STECs are sampled as per instructions in FSIS Directive 10,010.1.
- NRTE comminuted poultry products are sampled by collecting sufficient product to fill the two provided Whirl-Pak bags up to the fill-line indicated on each bag, following the instructions as described in FSIS Notice 31-15. The total weight of the two bags of samples should be approximately <u>two pounds</u>. This larger sample size will provide consistency as the Agency moves toward analyzing each sample for both pathogens.

For the RPPESP, IPP will be collecting fresh, not frozen, raw pork samples in final packaging, whenever possible, corresponding to 2 lbs.

In establishments that produce more than one type of product subject to testing, **all** eligible products produced will be scheduled for sampling during the month under routine sampling.

Defining Categories

If the sample under the routine *Salmonella* verification sampling meets the *Salmonella* and *Campylobacter* performance standards (i.e., the maximum acceptable percent positive allowed under the moving window approach), it passes. If the sample results in the moving window exceed the maximum percent positive allowed, the establishment has not met the performance standard.

FSIS uses categories in evaluating an establishment's level of process control and for scheduling *Salmonella and Campylobacter* performance standard verification testing. For all products sampled under routine *Salmonella* verification sampling, FSIS has modified the time component of the categories definitions as follows:

Category 1 – Consistent Process Control: Establishments that have achieved 50 percent or less of the performance standard during all completed 52-week moving windows over the last six months. This performance demonstrates the **best process control** for this pathogen.

Category 2 –Variable Process Control: Establishments that meets the standard for all completed 52-week moving windows but have results greater than 50 percent of the standard during any completed 52-week moving window over the last six months. This performance demonstrates **intermediate process control** for this pathogen.

Category 3 – Highly Variable Process Control: Establishments that have exceeded the performance standard during any completed 52-week moving window over the last six months. This performance demonstrates the **least process control** for this pathogen and means the establishment has failed the *Salmonella* performance standard.

The Agency will also post the following information on the FSIS Web site:

http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-andreports/microbiology/salmonella-verification-testing-program/.

- Beginning July 1, 2015, FSIS will begin web-posting individual establishment category information for chicken and turkey carcasses.
- Until July 2015, FSIS will continue to web-post existing Category 3 poultry carcass establishments.
- The Agency will post aggregate reports quarterly showing the categories 1/2/3 distribution for each relevant product class subject to FSIS *Salmonella* and *Campylobacter* testing, as applicable.
 - FSIS will continue to post aggregate reports for chicken and turkey slaughter establishments showing category distribution for current performance standards for carcasses.
 - Starting in March 2015, FSIS will begin posting aggregate reports showing the category 1/2/3 distribution for chicken parts as data becomes available, and comminuted chicken and turkey using historical data and new results beginning in March based on the proposed performance standards.

Agency Actions

Under the new performance standards and under the new moving window approach, when an establishment does not meet a performance standard (i.e., the number of positive samples within a specified timeframe exceeds the maximum acceptable for that product class), FSIS will immediately conduct follow-up samples that will be analyzed for both *Salmonella* and *Campylobacter*, where applicable. Specifically, either 16 or eight follow-up samples will be collected depending on the size and production volume of the establishment. The Agency will analyze the follow-up sampling data independent of the moving window approach to assess whether the establishment is making or has made changes to its food safety system to improve its process control.

In addition, when the establishments do not meet the performance standards, FSIS will conduct a for-cause Food Safety Assessment (FSA) at the establishment that produced the product.

Even when establishments meet the performance standards, if FSIS *Salmonella* or *Campylobacter* verification testing data from an establishment show a high number of positives or serotypes of human health significance, FSIS may perform Incident Investigation Team testing or conduct a for-cause FSA that includes collection of samples or take other appropriate actions (additional sanitary dressing verification procedures) at the establishment that produce the product.

Salmonella Regulations, Livestock, 310.25(b)

Sec. 310.25 Contamination with microorganisms; process control verification criteria and testing; pathogen reduction standards.

(b) Pathogen reduction performance standard; *Salmonella*. (1) Raw meat product performance standards for *Salmonella*. An establishment's raw meat products, when sampled and tested by FSIS for *Salmonella*, as set forth in this section, may not test positive for Salmonella at a rate exceeding the applicable national pathogen reduction performance standard, as provided in Table 2:

Class of product	Performance Standard (percent positive for Salmonella) ^a	Number of samples tested (n)	Maximum number of positives to achieve Standard (c)
Steers/heifers	1.0%	82	1
Cows/bulls	2.7%	58	2
Ground beef	7.5%	53	5
Hogs	8.7%	55	6
Fresh pork sausages	^b N.A.	N.A.	N.A.

Table 2--Salmonella Performance Standards

^a Performance Standards are FSIS's calculation of the national prevalence of Salmonella on the indicated raw product based on data developed by FSIS in its nationwide microbiological data collection programs and surveys. Copies of Reports on FSIS's Nationwide Microbiological Data Collection Programs and Nationwide Microbiological Surveys used in determining the prevalence of Salmonella on raw products are available in the FSIS Docket Room.

^b Not available; values for fresh pork sausage will be added upon completion data collection programs for those products.

(2) Enforcement. FSIS will sample and test raw meat products in an individual establishment on an unannounced basis to determine prevalence of Salmonella in such products to determine compliance with the standard. The frequency and timing of such testing will be based on the establishment's previous test results and other information concerning the establishment's performance. In an establishment producing more than one class of product subject to the pathogen reduction standard, FSIS may sample any or all such classes of products³.

³ A copy of FSIS's ``Sample Collection Guidelines and Procedure for Isolation and Identification of Salmonella from Meat and Poultry Products" is available for inspection in the FSIS Docket Room.

(3) Noncompliance and establishment response. When FSIS determines that an establishment has not met the performance standard:

(i) The establishment shall take immediate action to meet the standard.

(ii) If the establishment fails to meet the standard on the next series of compliance tests for that product, the establishment shall reassess its HACCP plan for that product and take appropriate corrective actions.

(iii) Failure by the establishment to act in accordance with paragraph (b)(3)(ii) of this section, or failure to meet the standard on the third consecutive series of FSIS-conducted tests for that product, constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan, in accordance with part 417 of this chapter, for that product, and will cause FSIS to suspend inspection services. Such suspension will remain in effect until the establishment submits to the FSIS Administrator or his/her designee satisfactory written assurances detailing the action taken to correct the HACCP system and, as appropriate, other measures taken by the establishment to reduce the prevalence of pathogens.

Export Certification

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Slides	LEARNING OBJECTIVES
N/A	Scientific:
	[None for this topic in this context.]
	Regulatory/Administrative:
	 Demonstrate facility in using the Export Library and FSIS Directive 9000.1 for the following: Locating requirements of individual countries Locating instructions for export certification Locating documents used in export certification
	• Locating documents used in export certification
	 2. Identify the appropriate export circumstances for the following: Letterhead certificate Replacement certificate Transit certificate Continuation form Export certificates that cannot be certified
	 Recognize CSI inspection activities for export certification, evaluate the accuracy and completeness of sample applications and certificates, and distinguish the CSI's role from the PHV's role in export certification.
	 Describe some circumstances where you are justified in your refusal to sign an export certificate and the follow-up actions you would take in documenting this.
	5. Recognize accountable items in export certification, such as stamps, logs, and other documents.

Slides	EXPORT REVIEW
2	 Purpose of Export Certification Instills confidence in US meat and poultry products worldwide FSIS is authorized to issue official certificates for export of inspected and passed products to any foreign country Certification activities verify that all products are wholesome and the requirements of the importing country are met
3	FSIS Directive 9000.1 • FSIS Directive 9000.1: • Provides clear set of instructions for Inspection Program Personnel • Clarifies purpose of Export Library • Clarifies inspection verification activities for FSIS Form 9060-6 and FSIS Form 9060-5

Review Questions

4

What is the 9060-6?

- Export certificate
- Export certificate checklist
- □ Application for export

Who fills out the 9060-6?

- 🗆 Fl
- D PHV

What is the 9060-5?

- □ Application for export
- □ Export certificate checklist
- Export certificate

Who verifies the information on the 9060-5 is correct and signs with professional degree if indicated?

- D PHV
- 🗆 FI

How does the PHV verify information is accurate with regards to country requirements prior to signing?

- □ Consult online export library
- □ Read all FSIS directives
- Phone a friend

Slides	SCENARIO
Sildes	SCENARIO
5	Scenario – Part 1
	You, Jim Bakeon, are a new PHV at a young chicken slaughter establishment. It is the third day at your duty station and the phone rings at 8:00am. It's a consigner, Benjamin Waffle, from an ID warehouse requesting that some export documents be presented for your review and signature around 1:00pm today. He mentions that there will be a replacement certificate accompanying the folder since the original was lost. You vaguely remember something about replacement certificates from your training but have your FLS on speed dial just in case. He asks if he can come back around 3:00pm to pick them up.
6	Scenario 1 – Part 1 (continued)
	When you come back to the office from giving afternoon breaks, you notice some folders on your desk and open them up. When looking through the documents and reading the export application, you get an uncomfortable feeling and realize that these ham products weren't even produced at your duty station.

-	
7	Question 1
	 True or False: You can refuse to sign an export certificate based on the fact that the products being shipped weren't produced at your duty station or inspected by IPP at the current establishment.
8	Questions 2 & 3
	2. What are some options that you have to ensure or gain familiarity with the products involved?
	3. Does the Certifying Official have to be directly associated with the inspection of the product?

9	Question 4
	4. Can the Certifying Official refuse to sign FSIS Form 9060-5?
10	Scenario – Part 2
	You decide to call the CSI from the originating federally inspected establishment since this is your first time conducting exports. You call over to est-711 Hog Heaven and CSI Peg Benedict assures you that she has been performing inspection for over 20 years.
11	Scenario – Part 2 (continued)
	She states that hogs are receiving ante-mortem and post-mortem inspection as evidenced by HATS activities in PHIS and that the line is fully staffed with FIs. She sends you some sampling results and says you can call her back any time if you need help.

12	Scenario – Part 2 (continued)
	Then you decide to call the federally inspected processed ham facility where the carcasses were further processed and cured into diced ham. CSI Mary Nara answers the phone and says that she has been performing export activities for over 5 years as well as preparing export applications independently for a few years. She mentions that all of the FSIS micro results in the last year have been negative, they have a very good history of SPS and SSOP compliance and have had no recalls or consumer complaints since she has worked there.
14	Question 5
	5. You ask Inspector Nara if the boxes for export were stamped in her presence and she replies, "No, they are pre-stamped by establishment employees." Is this acceptable?
15	FSIS Directive 9000.1 and FSIS Form 9060-6
	 Sign application for export Retain copy and documents for filing Provide FSIS Form 9060-5 (export certificate) Issue export stamp Allow establishment to stamp product After stamping, secure export stamp

15	Scenario – Part 3
	You are satisfied that the export application is properly and accurately filled out and are comfortable after speaking to all IPP involved with producing the product. You now move on to the export certificate which is what you (Jim Bakeon), the PHV or Certifying Official, will sign.
16	Question 6
	6. What are some other PHV responsibilities in reviewing the export certificate?
17	Scenario – Part 4
	Now you turn your attention to the replacement certificate, often referred to as the "in lieu of" certificate.

18	Questions 7 & 8
	7. What is a replacement certificate?
	8. What are some reasons that a replacement certificate may be issued?
19	FSIS Directive 9000.1: Replacement Certificates
	 FSIS Form 9060-6 is submitted to request new FSIS Form 9060-5 If possible, must accompany original and all supporting documents If original was lost, letter from the exporter to the Certifying Official stating that original will be returned if found

20 **FSIS Directive 9000.1: Replacement Certificates (continued)**

Before signing replacement certificates, verify the following:

- Statement "Issued in lieu of certificate #_____."
- The export mark on the product covered by this certificate shows certificate #
- Obtains superseded certificate (if possible)
- Statement "Superseded by certificate #_____."
- Attaches to Inspector copy and files

	12. DESCRIPTION OF PRODUCT (including Product Code)	13. HACCP CAT.	14. SPECIES	15. MATURITY LESS THAN	16. FROZEN/ SHELF- STABLE	17. NET WEIGHT	18. NO. OF PACKAGES	19. TYPE OF PACKAGES	20. SHIPPING/ IDENTIFICATION MARKS	21. EST.NO. ON PRODUCT
	Diced Ham	03C	Pork	30 MOS. Yes	Yes	5000 1bs (2268 kgs)	100	CS	MARINO	M45325
							_			
	22, TOTAL NET WEIGHT				23. TOT	AL NO. OF PAC	KAGES			
	5000 1bs (2268 kgs) 24. ADDITIONAL STATEMENT				100					
	Under penalty of law, I certify that the prod documentation to FSIS program employee 25. APPLICANT SIGNATURE	ducts covered b s upon reques	t, 26	cation for ex	port meet	the inspection re	quirements fo	the country	y of destination. 7. DATE	I will provide
	Benjamin M	cordance with A	Be gency policy	enjamin V	Waffle	9			02/08/	2018
	28. CERTIFYING OFFICIAL'S SIGNATUR		29. Ma	29. PRINTED NAME AND TITLE Mary Nara			30	30. DATE 02/08/2018		
	9									
Question						cian t	he 90	50-5	5? Wh	y or w
Question 9. Ba	ased on your reviev	v, are	you	goin	g to	Sigiri				
Question 9. Ba	ased on your reviev	v, are	you	goin	g to	Sigiri				

23	Scenario – Part 6
	You contact the exporter and they promptly return to your duty station. You explain your reasoning behind your refusal to sign the export certificate. They ask if they can return tomorrow with the corrected forms. You say you will see them tomorrow.
24	Question 10
	10.What are the required actions after you, PHV Jim Bakeon (the Certifying Official), have refused to sign the 9060-5?
25	FSIS Directive 9000.1: FSIS Form 9060-5
	Refusal to sign Export Certificates: • If there are questions about: • FSIS Form 9060-6 • FSIS Form 9060-5 • Letterhead Certificates • Any other documentation

	For questions on any of the documentation, contact:The exporterThe Inspection Program Personnel
	The Policy Development Staff
26	Scenario – Part 7
	The consigner returns the following day with the correct forms with the corrected dates. You have discussed the issue with your FLS and you are ready to sign. The CSI has taken the last government pen to evisceration for pre-chill tests. You find a pen in your drawer and sign.

27	Scenario – Part 7 (continued)							
	The 9060-5 looks like this:							
	18. I CERTIFY that the meat, meat food product or meat byproduct specified hereon is from animals that received both antemortem and postmortem inspection and were found sound and healthy and that it has been inspected and passed as provided by law and regulations of the Department and is sound and wholesome. 19. I CERTIFY that the poultry, poultry products or poultry food products specified above came from birds that were officially given an antemortem and postmortem inspection and passed in accordance with applicable laws and regulations of the United States Department of Agriculture and are wholesome and fit for human consumption.							
	By order of the Secretary of Agriculture Secretary of Agriculture By order of the Secretary of Agriculture Secretary of Agr							
	This certificate is receivable in all courts of the United States as prima facie evidence of the truth of the statements therein contained. This certificate does not excuse failure to comply with any of the regulatory laws enforced by the United States Department of Agriculture.							
	FSIS FORM 9060-5 (06/29/2018) ALL PREVIOUS EDITIONS OBSOLETE ORIGINAL							
28	Question 11							
	11. Is this acceptable?							
29	You Signed!							

30	FSIS Directive 9000.1: Certifying Official Recap
	As the Certifying Official, your responsibilities include: Receiving completed FSIS Form 9060-6 You may or may not have inspected the product Verifying other documentation as required by importing country, Letterheads, and FSIS Form 9060-5 Verifying all information through the Export Library Signing originals in anything other than black ink Using your professional degree, if required
Slides	SUMMARY
31	Review your score on the Summary screen and notes about this topic. Make note of any areas that you need to work on.
	Please note that this score does not count toward your overall class grade. Rather, it helps you identify which areas you may need to study more in preparation for your exams. Your overall class grade only consists of the daily quizzes, midterm exam, and final exam. Any scores you receive on Knowledge Check questions or course activities are <u>not</u> counted. They are for your use only.

Export Certification

Objectives

After completing this module, you will be able to:

- 1. Locate and access current export information and USDA partner websites on the Internet.
- 2. Evaluate and verify all information on FSIS Form 9060-6 and FSIS Form 9060-5.
- 3. Describe how to perform the Inspection Verification Procedures outlined in FSIS Directive 9000.1, FSIS Directive 9040.1, and FSIS Notice 38-14
- 4. List the reasons why a Certifying Official would not sign an FSIS Form 9060-5
- 5. Generate and file Memoranda of Interviews related to Export Certification.
- Describe the required AMS documents for Export Verification and Less Than 30 Months of Age Verification Quality System Assessment Programs (EV/QSA).
- 7. Describe the notification procedure if an establishment fails to meet the requirements of its approved EV/QSA Program.
- 8. Conduct export certification duties according to Agency guidance.

Resource Materials

- FSIS Directive 9000.1 Export Certification
- FSIS Directive 9000.2 Inspection and Export Certification of Livestock Intestines or Casings
- FSIS Directive 9010.1 Export Products returned to the US
- FSIS Directive 9040.1 Re-inspection of Product
- FSIS Notice 35-15 PHIS Modification in Preparation for the Implementation of Export Certification within PHIS
- FSIS Notice 24-15 Export of Product with a Country Label Designation Different from the Export Certificate Designation
- FSIS Notice 19-15 Requirement for a Special Certification Statement For Export of Raw Poultry and Raw Poultry Product To Canada
- FSIS Notice 61-14 Clarification of Re-Inspection Procedures for Product presented for Export at Official Establishments
- FSIS Notice 38-14 Certifying Products under Export Verification and Less Than 30 Months of Age Verification Quality System Assessment (EV/QSA) Programs
- FSIS Notice 30-13 Verification and Enforcement Activities Related to Export Certification Reimbursable Services (expired)
- FSIS Export Library

- ImportExport@fsis.usda.gov
- askFSIS

Web sites

Export Library FSIS Policy Development Division Agriculture Marketing Service

Introduction

Before we get into the details regarding export certification, let's cover some basics. First, what is meant by the term "export?" The Webster's Dictionary definition of the word "export" is, "to send goods from one country to another for the purpose of sale." In this case, we are interested in meat, poultry, and egg products which are inspected and passed for wholesomeness by FSIS at official FSIS slaughter and processing establishments, and approved cold storage establishments that are being exported from the U.S. to other countries throughout the world.

What is the purpose of export certification? The export certification process provides assurance that US meat and poultry products are in compliance with the importing country's requirements. As the competent authority, FSIS issues official certificates for export of inspected and passed products to any foreign country. The certification activities performed by Inspection Program Employees verify that all requirements of the importing country are met.

Statutory and Regulatory References

Federal Meat Inspection Acts 21 U.S.C 615-618

- 21 USC 615 Inspection of carcasses and parts offered for export
- 21 USC 616 Authorizing inspectors and certificates
- 21 USC 617 Clearance prohibited to vessel without certificate
- 21 USC 618 Certificates and copies

Let's review the regulatory references related to your export certification duties. There are several provisions of the FMIA related to exported product. 21 USC 615 states: "The Secretary shall also cause to be made a careful inspection of the carcasses and parts thereof of all cattle, sheep, swine, goats, horses, mules, and other equines, the meat of which, fresh, salted, canned, corned, packed, cured, or otherwise prepared, is intended and offered for export to any foreign country, at such times and places and in such manner as he may deem proper." This gives FSIS the authority to conduct inspections of products to be exported.

21 USC 616 states that the Secretary may appoint inspectors who will be authorized to give an official certificate stating the condition of the meat that is inspected.

21 USC 617 indicates that any shipper must have a certificate that indicates the meat to be shipped is sound and wholesome at the time of shipping.

21 USC 618 states that the official certificates of the condition of the meat be distributed to FSIS, the owner/shipper, and the vessel that will transport the meat to another country.

Livestock Regulations:

- 9 CFR 322.1 Marking products for export
- 9 CFR 322.2 Issuing export certificates
- 9 CFR 322.3 Transferring products for export
- 9 CFR 322.4 Clearance of vessels and transportation

Now, let's review the regulations that relate specifically to your export duties. There are a number of regulations that relate to export certification. We will highlight a few of the most significant ones. First, let's review the regulations that cover products from livestock. 9 CFR 322.1 covers marking products for export using official stamps. 9 CFR 322.2 has some general instructions about issuing export certificates. The certification process shows that the product has been inspected and passed, and is not adulterated or misbranded. 9 CFR 322.3 addresses the transfer of products from tanks to containers on vessels. 9 CFR 322.4 states that vessels or carriers destined to a foreign country cannot receive or transport edible products unless or until an official export certificate has been issued. Exceptions to this are inspected and passed ship stores, and not more than 50 pounds of inspected and passed product for the exclusive use of the consignee that are not for distribution or sale.

Poultry Regulations:

9 CFR 381.104 – Official marks

9 CFR 381.105 – Certification process 9 CFR 381.106 – Certificate form 9 CFR 381.107 – Country requirements

9 CFR 381.104 through 112 cover the export requirements related to poultry products. We will just highlight the requirements in 381.104 through 107. 9 CFR 381.104 shows the official mark of inspection used for poultry products that have been inspected and passed and will be exported. 9 CFR 381.105 explains the process of export certification. Just as was true for establishments under the livestock regulations, establishments that produce poultry products for export must apply for this service. 9 CFR 381.106 covers the specific form used for export certification. 9 CFR 381.107 explains that the exporter is responsible for providing any unofficial documentation needed by the foreign country where the product will be shipped. It indicates that these certificates may cover articles that are exempted from the definition of poultry product.

Export Directives and Notices

Now, let's look at an overview of the specific instructions outlined in FSIS Directives and Notices regarding your responsibilities for export certification.

FSIS Directive 9000.1 – Export Certification covers the FSIS forms and verification activities related to export certification. We will review the FSIS Forms and the instructions contained in this directive in detail.

FSIS Directive 9000.2 – Inspection and Export Certification of Livestock Intestines or Casings covers how to decide if casings or intestines are eligible for the mark of inspection and how to certify them for export. There are special requirements for certifying casings that are not covered in this training material.

FSIS Directive 9000.6 – Export Certification of Egg Products From Other Than Official Egg Products Plants gives instruction for issuing certificates for egg products exported from locations other than where they were produced. There are special requirements for certifying egg products for export that are not covered in this training material.

FSIS Directive 9010.1 – Export Products returned to the US covers export product returned to the U.S. It might be refused by the foreign government, rejected by the buyer, or returned for a number of other reasons. Regardless of the reason, if exported product is returned to an establishment in your assignment, the District Office may ask you to verify that the returned product is not adulterated or misbranded. This directive will not be covered in detail in this course. FSIS Directive 9040.1 – Re-inspection of Product intended for Export provides instructions for performing a sensory evaluation or re-inspection of product to determine the eligibility of the product for export. The purpose of this re-inspection is to determine if the product has become adulterated or unwholesome after production and during storage.

FSIS Directive 12,600.1 Voluntary Reimbursable Inspection Services addresses non-mandatory services for which the Agency receives reimbursement.

FSIS Directive 12,600.2 Reimbursable Overtime Inspection Services at Meat and Poultry Establishments provides instruction on how to determine whether overtime inspection services need to be provided and how to do so during reimbursable overtime periods.

FSIS Notice 35-15-PHIS Modification in Preparation for the Implementation of Export Certification within PHIS provides instruction to IPP regarding the new menu that appeared in PHIS on June 28, 2015. Upon activation of the electronic certification system this function will be turned on. It currently is non-functional. The menu is on the left navigational menu and includes Export approvals and 9060 Application with sub-menus.

FSIS Notice 24-15- Export of Product with a Country Label Designation Different from the Export Certificate Designation covers export eligibility for products that have labels showing that the product was produced to meet a specific country's requirements. Several countries designate additional labeling requirements, which are included in the Export Library. These additional labeling statements must be placed on or within cartons or packages intended for export and are applied in addition to U.S. labeling requirements. The primary purpose of these labeling requirements is to make clear that the product(s) have been processed under conditions that meet that country's import requirements. It does not say, nor is it intended to mean, that the consignment may be exported only to the country designated on the label.

IPP may issue original or replacement export certification documents for the export of products that bear labels designating a different country. These products may be exported to:

1. The designated country, provided all pertinent Export Library requirements have been met for the country designated on the label; or,

2. Any other country provided all pertinent Export Library requirements to export the product to that country have been met. Before signing the certificates, IPP are to advise the exporters to work closely with the importer for information regarding eligibility of the product. FSIS Notice 19-15-Requirement for a Special Certification Statement for Export of Raw Poultry and Raw Poultry Product to Canada-Provides PHVs instructions for including a special certification statement in the remarks section of the Certification for Export of Meat and Poultry Products to Canada (FSIS Form 9135) or on FSIS Letterhead Certificate. Required when certifying raw poultry or raw poultry products to Canada indicating they are free of Highly Pathogenic Avian Influenza.

FSIS Notice 61-14-Clarification of Re-Inspection Procedures for Product presented for Export at Official Establishments-This notice clarifies what reinspection procedures to perform when product for export is presented at official establishments.

FSIS Notice 38-14 – Certifying Products under Export Verification and Less Than 30 Months of Age Verification Quality System Assessment (EV/QSA) Programs provides instructions for carrying out FSIS' export certification for meat and poultry products produced and exported under EV/QSA programs.

FSIS Notice 30-13 – Verification and Enforcement Activities Related to Export Certification and Reimbursable Services covers under what circumstances IPP charge for reimbursable services when performing export certification activities. It also covers how to document noncompliance and when voluntary export certification reimbursable services can be denied or withdrawn by the District Office (expired).

EXPORT CERTIFICATION

FSIS Directive 9000.1 Export Certification.

This Directive provides a clear set of standards for the District Offices and Inspection Personnel to follow. As specified in FSIS regulations, upon application by an exporter (applicant), an FSIS inspection program employee is authorized to issue official export certificates for the shipment of inspected and passed products to any foreign country. This directive also states the importance of reviewing the importing country's requirements in the Export Library prior to signing documents and certificates.

FSIS Form 9060-6 Application for Export

The applicant provides a completed FSIS Form 9060-6 (Application for Export) to an inspection program employee.

Upon receiving an application for export, an inspection program employee reviews the application to verify that it is complete and that all pertinent information is included.

Verification activities include that the requirements of the receiving country have been met. If there are any questions regarding the importing country's requirements, visit the Export Library or call the Import/Export Coordination and Policy Development Staff, OPPD, at ImportExport@fsis.usda.gov or at (855) 444-9904.

If there are concerns that each product listed on the application is eligible for export to the country listed on the application:

- 1. Discuss concerns with exporter
- 2. Document a Memorandum of Interview addressing what was discussed, and whether the concerns were adequately addressed
- 3. Provide a copy of the Memorandum of Interview to the applicant and maintain a copy in the inspection files.

Perform a sensory evaluation of the product to determine its eligibility for export. Observe product for off-condition odor, torn or damp cartons which may indicate that it is or may become adulterated or unwholesome.

- 1. If there are signs of insanitary product handling and storage, examine the product per FSIS Directive 9040.1.
- 2. Take any necessary actions when the product may be adulterated as provided in FSIS Directive 5000.1 (at official establishments) or FSIS Directive 8410.1 (at non-official establishments).
- 3. If there is any reason to question whether the products are properly identified and labeled to meet FSIS regulatory requirements and the requirements of the importing country, examine the product as set out in FSIS Directive 9040.1. If the product is not properly labeled or misbranded, take the appropriate action as provided in 9 CFR 500 and FSIS Directive 5400.5, (at official establishments) or FSIS Directive 8410.1 at non-official establishments).
- 4. If the product in the container or the labeling of the product does not meet the requirements of the importing country, discuss the concerns with the applicant and prepare a Memorandum of Interview.

Verify that the foreign language sticker, if required, shows no wording other than what is shown on the approved label. Also, verify that the exporter, supplying the foreign language sticker, has a letter which certifies that the sticker is an accurate translation of the wording on the approved label. After verifying the information on the application for export is correct, performing a sensory evaluation of the product, and determining that the product is properly labeled, then complete the following steps.

1. Sign the application.

2. Retain a copy of the application and any accompanying documents for filing.

- 3. Return the originals to the applicant.
- 4. Provide FSIS Form 9060-5 (export certificate) for completion by the exporter.
- 5. Issue the export stamp.
- 6. Allow the establishment to stamp product.
- 7. Secure the stamp after the establishment finishes stamping the product.

Under some conditions, pre-stamping of product is allowed. Pre-stamping is when the establishment stamps the boxes and completes the export certificate when you are not present. First, verify the establishment has identified an employee who is responsible for the custody of the stamp and the certificate. Then, verify the establishment has procedures to make sure the stamp will be applied in a clear and legible fashion only on boxes that are in sound condition. Remember that boxes that are torn or damp may indicate that product is not wholesome. Then, determine that the establishment is aware that the stamp must be returned once they complete stamping the product. If at any time you feel it is necessary, you can re-inspect the product that was pre-stamped.

Computer Generated Stamps

An establishment may use a computer generated export stamp (sticker) as long as the establishment identifies the number of stickers produced before applying them to product and provides the inspection program employee with any unused stickers.

Letterhead Certification

In some cases, USDA/FSIS letterhead certification is necessary and is issued for certain products when specified in the individual country requirements. This information can be found in the Export Library. If the exporter submits a letterhead certificate along with the export certificate, verify that:

- 1. The current version of the letterhead certificate found in the Export Library was submitted.
- 2. No statements on the letterhead certificate have been changed.

- 3. The letterhead certificate is dated by the exporter.
- 4. Any certification required by another USDA Agency (e.g., AMS) is provided along with the completed letterhead.

After reviewing the documents and before signing the certificate:

- 1. Check the certificate for accuracy and corrections.
- 2. Check the boxes indicating that the animal received ante- and postmortem inspection.
- 3. Check for attachments and ensures that the exporting firm has lined-out any unused space.
- 4. Do not initial minor erasures or alterations, unless this is acceptable to a foreign country. (See Export Library to verify if receiving country permits erasures or alterations). Most countries do not allow this, or the use of white out. It is best to reissue the certificate if there are errors.

Sign the original certificate in the signature block in **other than** black ink, all continuation sheets, and other certifications, including letterhead certifications. If the importing country requires a PHV's signature, the certifying official is to include his or her professional degree.

Do not stamp the certificate with the export stamp unless required by a receiving country as specified in the Export Library.

Refusal to Sign Export Certificates

Do not sign the certificate if there are questions about the information on FSIS Form 9060-6, FSIS Form 9060-5, or any other certificates, including letterhead certificates. Contact the inspection program employee who signed the application, the exporter, or the Export Program Staff to address all questions. Any communication that the certifying official has with the exporter should be documented in a Memorandum of Interview. If a certifying official refuses to sign a certificate, the reasons for refusal will be reviewed by the next-line supervisor. Based on the review, the next-line supervisor will take further actions.

Replacement Certificates

A certificate replacing an original export certificate is a re-certification of the product's condition **at the time of the initial export certification**. A replacement certificate for a lot **does not** represent that lot's current condition. A replacement certificate may be issued in situations such as, but not limited to:

- 1. The original certificate did not carry required information
- 2. The original certificate carried incorrect information
- 3. The name of the consignee or exporter has changed
- 4. The certificate has been lost

The replacement certificate must be dated with the same issuing date as that shown on the original certificate

FSIS Form 9060-6 is submitted to request a new certificate and must be accompanied by (if possible) the original and all copies of the original certificate. **Exception**: In the case of lost certificates, the exporter should provide a letter of assurance to the certifying official stating the certificate will be returned if found.

Before signing a replacement certificate, an inspection program employee:

- Verifies that the following statement is in the top left margin or in the "Remarks" block of the new certificate: "Issued in lieu of" certificate no.
 _____. The export mark on the product covered by this certificate shows certificate no.
 _____."
- 2. Obtains the superseded certificate (if possible), and:

3. Verifies that it is marked in the left margin or in the "Remarks" block with the number of the certificate which supersedes it (e.g., "Superseded by No._____")

4. Attaches it to the "inspector's" copy of the replacement certificate and files it in the government office.

Inventory and Accountable Items

Official export stamps must be controlled at all times. Export certificates, stamps, and pertinent inventory records must be maintained under official government lock or seal when not in use. The inspection program employee does not have to be present in order for the establishment to apply the export stamp to boxes. However, when the stamp is not in use, it must be secured by FSIS personnel.

The inspection program employee at each establishment must maintain an accurate inventory record of export certificates issued and voided certificates.

Re-inspection of Product intended for Export

FSIS Directive 9040.1 Re-Inspection of Product intended for Export

This directive provides inspection program personnel with the procedures for reinspecting product that has been presented for export. These responsibilities and procedures apply whether the product is located at the establishment or offsite at a non-official establishment, such as a cold storage facility. This directive was revised to provide for the examination of boxes or containers in situations where inspection program personnel have a reason to question whether the product as labeled meets the importing country's requirements.

9 CFR 322.2 and 381.105, provide for the re-inspection and certification of products for export. The purpose of re-inspection is to verify the product's safety, wholesomeness, identity, and eligibility for export.

Inspection program personnel conduct a re-inspection of product for export after they receive and review FSIS Form 9060-6, Application for Export. As set out in FSIS Directive 9000.1 Export Certification, inspection program personnel are to verify that each product listed on the application complies with the meat and poultry products regulations and the importing country's requirements. Remember to check the Export Library for updates.

If the application is in order, inspection program personnel perform an organoleptic examination of the shipping cartons for signs of poor product handling, or storage. If the cartons are sound, inspection program personnel proceed by following the instructions in FSIS Directive 9000.1, sign FSIS Form 9060-6, and issue FSIS Form 9060-5 and the export stamp.

FSIS responsibilities when product is determined to be unsound or unwholesome

If inspection program personnel find signs of poor product handling and storage while conducting the organoleptic examination of the shipping cartons at either official or non-official establishments, they are to take the following steps.

1. Do not sign the application.

2. In official establishments and non-official establishments, randomly select up to **5 percent** of the boxes or containers. In considering the percentage of boxes to select, inspection program personnel should consider the basis for their concern and the need to expose the contents of boxed product to the environment.
In an **official establishment**, request the applicant to open the selected sample of boxes or containers in a manner that will not create insanitary conditions or lead to product adulteration.

At official establishments when any of the product is determined to be unsound or unwholesome, issue a Non-Compliance Record under the appropriate HACCP Verification task and take the appropriate enforcement actions described in FSIS Directive 5000.1.

In a **non-official establishment**, request the applicant to open the selected sample of the boxes or containers in a sanitary environment, or have the selected samples of the boxes or containers moved to a facility where boxes can be opened in a sanitary environment.

At a non-official establishment, if the product is found to be adulterated, unwholesome, damaged, mislabeled or misbranded, do not sign the export application (FSIS Form 9060-6) for the export certificate and not issue a blank export certificate (FSIS Form 9060-5). Not signing these documents is the regulatory control.

At official and non-official establishments, when the establishment refuses to open the boxes, do not to sign the application and document in a Memorandum of Interview why the applicant will not open the boxes. Provide a copy of the memorandum to the applicant and maintain a copy in the inspection files.

FSIS responsibilities when the information of FSIS Form 9060-6 does not meet requirements.

If inspection program personnel have reason to question whether the product is properly identified and labeled to meet the importing country's requirements, use the inspection methodology outlined in FSIS Directives 5400.5 and 5000.1.

Re-inspect the open boxes to ensure that it is properly labeled, not misbranded and is eligible for export to the country listed on the application.

Take and document enforcement or detention actions if necessary.

FSIS responsibilities, in official or non-official establishment, if product in the container or the labeling does not meet the importing country's requirements.

- 1. Discuss concerns with the Applicant.
- 2. Document a Memorandum of Interview.

3. Provide a copy of the Memorandum to the Applicant and maintain a copy in the inspection files.

Direct questions to the Import/Export Coordination and Policy Development Staff, IECPDS, at ImportExport@fsis.usda.gov or at (855) 444-9904.

Certifying Products under Export Verification and Quality System Assessment (EV/QSA) Programs

Notice 38-14 provides IPP with revised instructions for effecting FSIS' certification process for meat products exported under EV/QSA programs. The need for an EV/QSA program to produce meat and poultry products exported to a country is identified in the destination country's requirements, which are documented in the Export Library.

The AMS Quality Assessment Division administers the EV/QSA programs. The Quality Assessment Division is responsible for reviewing and approving companies as eligible suppliers of meat and meat products under the EV/QSA programs and for maintaining approved supplier lists and product lists for individual countries. The EV/QSA programs outline the specified product requirements for individual countries. See the web page link below for additional information:

http://www.ams.usda.gov/lsg/lsarc.htm

Approval of establishments under an EV/QSA Program and related FSIS Responsibilities

When an establishment requests to be approved for participation in an AMS EV/QSA program, AMS will advise the Import Export Coordination and Policy Development Staff, OPPD, via e-mail of the establishment's request at ImportExport@fsis.usda.gov.

- Upon receipt of the AMS e-mail, IECPDS is to acknowledge receipt of the notification by replying to the e-mail at <u>QAD.AuditService@ams.usda.gov</u>.
- 2. IECPDS is to forward the AMS e-mail to the District Office (DO) where the establishment is located.
- 3. The DO is to ensure that any IPP, who may be involved with the certification of product for export under an EV/QSA program, receive appropriate training prior to conducting EV/QSA-related exports.

If the establishment passes the initial AMS audit and is approved for an EV/QSA program, IECPDS will receive an electronically-transmitted copy of the audit. IECPDS is to promptly notify the DO of the approval. If AMS finds minor deficiencies that don't affect the establishment's eligibility to participate in the program, IECPDS should email the DO with that information. The DO should then instruct you to be aware of the deficiencies. At the first weekly meeting after receiving such a report, you should ask establishment managers about changes made in response to the AMS report and what effect the changes had on their program. Contact your supervisor if you have concerns that the establishment is not adequately addressing deficiencies.

As a requirement of an approved EV/QSA program, the establishment is to maintain a copy of all EV/QSA program audit reports. These audit reports must be made available to FSIS review when needed.

If an establishment is delisted by AMS, EPS will be notified of the delisting by AMS. IECPDS is to notify the DO via e-mail, and the DO is to notify the affected in-plant IPP.

Verification Procedures for EV/QSA Programs

IPP are to determine whether the establishment has an AMS-approved EV/QSA program. This determination can be made by asking the establishment whether it has such a program at the weekly meeting and by accessing the FSIS Export Library (Export Requirements for Countries with an Approved USDA Export Verification Program) and following the links to the AMS web site that maintains the list of approved establishments. See the following link: http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products/EV-Programs

IPP are to be aware of the location and contents of the establishment's approved EV/QSA program Quality Systems Assessment (QSA) Manual to verify export requirements relating to proper execution of the program.

IPP will find a list of products intended for export approved under the EV/QSA Program in the establishment's QSA Manual as required under the EV/QSA program. The list is to include all items that are intended for export, the specific product code numbers, and a detailed description of each item. Maintaining this information is an AMS requirement as part of an approved EV/QSA program. The unique product identification system can be accessed by authorized FSIS inspection personnel from http://inside.fsis.usda.gov/fsis/public/static/index.jsp.

In situations where a supplier and fabricator are separate establishments, the fabricator is to maintain a list of establishments that are approved EV/QSA suppliers, as required by AMS. In addition, AMS requires that the fabricator maintain a list of products that each EV/QSA supplier is approved to provide under its approved EV/QSA program. As part of the approved EV/QSA program, these establishment records are subject to FSIS review.

If, based on their verification activities, IPP are concerned that an AMS-approved EV/QSA establishment is not properly executing its EV/QSA program (for

example, attempting to ship product that is not eligible for the importing country), they are **not to sign** export applications for the product in question and are to:

- 1. Notify AMS at <u>QAD.AuditService@ams.usda.gov</u> and provide the following information in the notification:
 - Establishment name, address, and number;
 - Product type, product code, and quantity of product;
 - Date of production, lot number, and shift;
 - Date and nature of observation;
 - Name of country for which product is intended;
 - Export certificate number (if applicable);
 - Any other information to verify claim; and
 - Name of IPP documenting concerns.
- Send a courtesy copy of the notification to their immediate FSIS supervisor and to IECPDS (<u>ImportExport@fsis.usda.gov</u>) and maintain a copy of the message in the inspection office export file.
- 3. Take the appropriate enforcement actions and issue a Non-compliance Record if any of the problems with the EV/QSA requirements are also regulatory non- compliance.

Verification Procedures for Product Intended for Export under EV/QSA Programs

Upon receiving FSIS Form 9060-6, Application for Export Certificate, IPP are to verify that (following the procedures in FSIS Directive 9000.1):

- 1. The establishment is on the AMS EV/QSA list as approved to export to the importing country, and that the product was derived from animals slaughtered after the date the establishment received AMS approval to export that type of product to that country; and
- 2. Each of the products listed on the application is eligible for export to the country under the country specific EV/QSA program, and each product is produced under an AMS EV/QSA program.

After determining that the establishment itself is eligible to export to the importing country, and that the specific products are eligible to be exported to that country, IPP are to re-inspect the product as set out in FSIS Directives 9000.1 and 9040.1.

If the application or product is not acceptable (for reasons such as, the application is not complete, or the regulatory requirements have not been met), IPP **are not to sign** the application and are to notify AMS that the establishment

is not properly executing its EV/QSA program, using the procedure listed in the above section.

When you receive the appropriate export certification documents, verify that the documents are complete and accurate, and that the EV/QSA program requirements were met.

If any of the documents are not accurate,

- Notify the establishment and explain the problem;
- Document the problem in a memorandum of interview; and
- Maintain copies of the documents in question and the memorandum of interview in the government file.

If all the documents are acceptable, sign all certifications and keep a copy in the government file along with the certifications.

All time involved with EV/QSA-related verification activities is charged as a reimbursable service, even when these activities are conducted these activities during the established tour of duty. Supervisory personnel are to ensure that IPP are appropriately billing the establishment for these activities. (See FSIS Directives 9000.1; 12,600.1; and 12,600.2.)

Day in the Life: Poultry

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LEARNING OBJECTIVES

1. Apply the course concepts learned so far to successfully complete the day in the life: poultry scenario.

INTRODUCTION AND PREPARATION (5:00 AM)

A. Scenario Introduction

Brainstorm answers to the following questions and mark your answers below.

How are you going to prepare for this IPPS assessment?

What are you going to evaluate and how?
What resources would you want?

Review each of the following documents. You can take notes here.
Directive 4430.3 Rev 4
IPPS Supervisory Guide
IPPS Assessment Form
CSI Nickels' First IPPS
Which of the documents did you find most helpful and why?

What elements or sub-elements are you required to assess during the second IPPS assessment for CSI Nickels, assuming that you do not plan to conduct another IPPS assessment during this rating year?
Are there other elements that you want to assess?
PRE-OPERATIONAL REVIEW AND OBSERVATION TASK (5:15 AM)
B. Pre-Operational Task Introduction
Is the response that CSI Nickels provided correct? Why or why not?

NR Documenting the Noncompliance Notes:
You review CSI Nickels' finalized NR. What methods have you used to assess CSI Nickels' performance so far?
What, if any, feedback do you give her?
What does the IPPS form look like at this point?

C. Agenda for the Day
What methods would you use to assess CSI Nickels' performance of AM inspection?
As you and Wanda are leaving the ante-mortem inspection area, you see these cages. What concerns do you have?
Looking at the chickens, which set of cages do you think they came from?
<u>Is CSI Nickels' response</u> (regarding the FSIS Directive that provides guidance on how to verify poultry slaughter establishments maintain adequate procedures for preventing contamination with fecal material and enteric pathogens throughout the slaughter process) <u>true or false?</u>
SPS VERIFICATION (7:45 AM)
What does the IPPS form look like at this point?

D. Ver	ifying Establishment Compliance
Has C	SI Nickels answered correctly?
NR AA	A8149126070216N/1 Notes:
What	does the IPPS form look like at this point?
E. Giv	ing Breaks
What e	element(s) have you just evaluated?
What o	does the IPPS form look like at this point?

ZERO TOLERANCE VERIFICATION (9:00 AM)
F. Performing a Poultry Zero Tolerance Task
After reviewing CSI Nickels' NR, answer the following questions.
CSI Nickels' NR Notes:
Was proper inspection technique followed for performing the Poultry Zero Tolerance task?
Is the RCA supportable?
Is the NR supportable?
Is the NR clear and concise, and does it contain a good description of the noncompliance?
What does the IPPS form look like at this point?

FI ANN BLACK (10:00 AM)

G. Personnel Situation

Group Discussion:

H. Export Process

What guidance would you look at to see if CSI Nickels is performing the export certification task correctly?

Is the product (boneless skinless chicken breasts) eligible for export to Cambodia?

Are there any additional requirements that must be met?

Compare the Export Certificate to the application and export library. Then answer the following questions.

• Are all the requirements met and is the documentation acceptable?

• Are appropriate boxes checked?

• Is unused space lined out?

• Why is this important?

I. Export Process Conclusion

What method(s) did you use to verify CSI Nickels' performance for Export Certification on the IPPS assessment?

What does the IPPS form look like at this point?

SPS VERIFICATION (11:15 AM)

J. Regulatory Control Action (RCA)

Notes:

K. RCA Solution

NR AAA8149126070216N/2 Notes:

HACCP & NRS (12:00 PM)

NR AAA8149896060216N/1 Notes:

NR AAA8149569062116N/1 Notes:

•	Since the above two NRs were associated, what other documentation of due process should be available?
• Vhat d	What method did you use to assess this during the IPPS?
•	So far, do you have any concerns about CSI Nickels?
•	Do you have any concerns about the establishment?

Hov her	ow can you assess CSI Nickels on her knowledge of this er perform it?	directive without observ
Wo dire	ould it be appropriate to let CSI Nickels have a copy of th rective while you assess her on its contents?	e new revision of the

airective?		

• Since there have been changes in policy, would your questions focus on these changes?

• Come up with one scenario to pose to CSI Nickels to assess her knowledge of the new revision of the directive and share it.

What does the IPPS form look like at this point?	
ZERO TOLERANCE CHECKS (12:20 PM)	
M. Salmonella and Campylobacter Testing	
What series of FSIS Directive gives guidance to IPP concerning sampling?	
What directive gives guidance to IPP concerning Salmonella/Campylobacter sampling?	
Did she put on the gloves correctly to perform sampling?	
What immediate feedback do you give?	
 Given what you've seen today in CSI Nickels' current and previous NRs, is there a question you'd like to have answered about any previous FSIS sample results? 	

•	If so, what questions do you have?
•	Where would you find answers to those questions?
٠	What does the IPPS form look like at this point?
	isceration Machine
••	
/vnat	aid you observe at each step of the process?
•	This employee is helping to manually eviscerate birds incompletely eviscerated by

 This employee is helping to manually eviscerate birds incompletely eviscerated by machine.

•	These birds are being rinsed on the evisceration line by Outside Bird Wash 1.
•	These birds are also being rinsed on the evisceration line in the next two pictures by Outside Bird Wash 2.
•	This bird is also receiving a rinse on the evisceration line by Outside Bird Wash 3.

Is there noncompliance in any of these pictures?			
PRE-CHILL TEST (1:00 PM)			
O. Pre-Chill Test			
Did CSI Nickels answer correctly (regarding the lighting requirement for FPS re-inspection stations)?			
P. Sampling at the Pre-Chill Station			
Carcass 1 Notes:			
Carcass 2 Notes:			
Carcass 4 Notes:			
Carcass 5 Notes:			

 Carcass 8 Notes: Carcass 10 Notes: • Q. Pre-Chill Sampling Task Results • What is the subgroup total for this Pre-chill Sampling Task? • How would you respond to the CSI Wanda not scoring correctly? **R. Finished Product Standards Testing** Finished Products Standards Table Notes:

FINISHED PRO	DUCT STANDAR	RDS	
	SIS AND NELS	Т	NTIS
Prechill Processing Nonconformance			
Tolerance (T) Subgroup Absolute Limit (T+5) Action Number Start Number	25 30 22 11		30 35 25 13
Prechill Trim Nonconformance Tolerance Number (T) Subgroup Absolute Limit (T+5) Action Number Start Number	12 17 15 8		12 17 15 8
Postchill Nonconformance Tolerance Number (T) Subgroup Absolute Limit (T+5) Action Number Start Number	5 10 10 5		10 15 14 7

Finished Products Standards Testing Chart Notes:



Did CSI Nickels answer correctly?	
-----------------------------------	--

S. Another Poultry Zero Tolerance Task

NR AAA81493900070216N Notes:

VERIFICATION OF ESTABLISHMENT'S CORRECTIVE ACTIONS (1:30 PM)

• Is the required information included in the NR?

• Is the NR properly associated to the past previous noncompliance?

• Are the correct regulations cited in the NR?

 Based on what is documented in the NR, is there anything else that CSI Nickels is required by policy to do?

• Beyond what is required by policy, is there anything else you or CSI Nickels might want to do because of facts documented in the NR?

Т.	Ante-Mortem	Inspection	and	Environmental	Conditions
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What could have caused this?

Review the following documents and then answer the question below.

1. FSIS PHIS Directive 6100.3, Ante-Mortem and Post-Mortem Poultry Inspection

2. FSIS Notice 44-16, Instructions for Writing Poultry Good Commercial Practices Noncompliance Records and Memorandum of Interview Letters for Poultry Mistreatment

3.	FSIS Directive 6000.1, Rev. 1, Responsibilities Related to Foreign Animal Diseases (FADs) and Reportable Conditions
4.	FSIS Directive 6020.1, Rev. 1, Enhanced Inspection of Poultry in Response to a Notification of a Highly Pathogenic Avian Influenza Outbreak
What /	Agency issuance would not be helpful in making this decision?
•	What should you do?
•	What questions might you want to ask?

- The main question, perhaps, is: is the cause of so many birds dying a FAD, bioterrorism event, or environmental? To determine this the PHV may ask:
 - What is the onsite holding area like?
 - Is there shelter?
 - Are the birds crowded on the truck (overheating)?
 - Were any boards or tarps that restrict air circulation left on the trucks after arrival?
 - Are the fans used to cool the birds upon arrival operating correctly?
 - How many birds are in this lot?
 - How does the establishment determine lots?
 - Where did these birds come from?
 - How long were they hauled?
 - How many trucks are hauling birds from the same source?
 - How many other trucks, if any, have been presented like this to the establishment with 50% or other high numbers of DOAs?
 - What was the weather like where they came from?
 - Have we been notified of a HPAI or other reportable animal disease outbreak by APHIS and the District Office?
 - What are the AM symptoms of the birds if any are still alive?
 - Are they gasping, exhibiting sinusitis, any discharges, coughing, diarrhea, ocular swelling, neurological signs, etc.?
 - Has there been indication or notification that the birds have been exposed to toxins in the feed or in some other manner?
 - Has notification of a food defense threat to the food and agricultural sector been issued?

If you determine that the deaths are due to environmental causes, does the HMSA apply?

Based on the observations of the truck, you conclude that the likely cause of the high death rate of the birds is due to:
Would it be wrong to inform your supervisor and get guidance on whether APHIS should be contacted?						
Should you contact the DVMS?						
Are you going to document this event? If so how?						
LIVE HANG (1:45 PM)						
U. Condemning DOA Birds						
The banging of DOAs on the live bang line is:						
The hanging of DOAS on the live hang line is.						

What regulatory citation covers the disposition of poultry DOAs?							
What should you do and in what order?							
V. Solution to U.S. Reject Tag							
The noncompliance above should be documented in a:							

NR AAA8149138070216N/1 Notes:
BREAK (2:20 PM)
W Romaining Afternoon Agenda
W. Remaining Alternoon Agenda
What do you have left to do?

•	How would you prioritize these tasks?						
	GCP & MOIS (3:00 PM)						
Accord the GC	ling to the policy guidance in FSIS Notice 44-16, what information should you capture in CP MOI?						

X. SSOP Review and Observation Task						
Based on what you observe in the cut-up/debone department, is this a noncompliance?						
What corrective actions are required?						
The most recent noncompliance with the same cause was documented four months ago. Should this noncompliance be associated?						
NR AAA8249990270216N Notes:						
Y. Process Control Charts Did CSI Nickels answer correctly?						

What c	loes the IPPS form look like at this point?

CONCLUSION (4:00 PM)

Z. Agenda Accomplished!

It's been a long day and a busy day, but a productive day.

- You've done an IPPS assessment and provided feedback.
- You've watched CSI Nickels document a lot of noncompliance with 9 CFR 381.65(g) and 9 CFR 417.5(a)(1), plus 417.2(c)(4).
- You've written a GCP MOI and documented noncompliance with 9 CFR 416.4(d) and 381.71(a).
- You've handled a potential disciplinary problem.
- You've consulted with the FLS and the DVMS.
- You've helped protect the public's health.

Additional Conclusion Notes:

Day in the Life: Beef

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LEARNING OBJECTIVES

1. Apply the course concepts learned so far to successfully complete the day in the life: poultry scenario.

ANTE-MORTEM INSPECTION (9:00 AM)

It is right before the company mid-morning break and it's already been a long morning. It's been raining over the vast majority of your part of the country for the last three days and you're tired of gray skies. Luckily, the establishment has plenty of cattle to start as 2/3 of the pens were filled last night before 6:00 PM for today's slaughter. About half of those were hauled from feedlots over 100 miles away.

Dr. Wright, the PHV who has been conducting ante-mortem inspection, enters. Dr. Wright informs you that the drains of two pens in the ante-mortem area were plugged, resulting in quite a mess but fortunately, the drains are now unplugged. You remember that the same thing happened last week and ask if this will be documented. Dr. Wright says that it isn't necessary as the problem is not being alleviated.

CSI Jones walks into the office and tells you that he just performed a Livestock Zero Tolerance task. During the task, he found a 2 inch by 3 inch fecal smear on the brisket of the fourth beef carcass he randomly selected during the task. He verbally informed establishment management of the noncompliance and is going to document the noncompliance in PHIS.

Answer the following questions based on the information provided to you during the scenario.

1. Do any of the previously stated factors possibly have an effect on the expected levels of hide contamination of the cattle?

2. Since there was a Zero Tolerance failure, according to FSIS policy, what else must be done?

3. What other questions do you have pertaining to the Livestock Zero Tolerance task noncompliance?

4. Would it make a difference if this is the first Zero Tolerance failure in the last three months versus the fourth Zero Tolerance failure in the last month? If so, why?

5. If this is the first failure in 3 months, what is/are the correct regulatory citation(s) for the noncompliance?

6. If this is the fourth failure in the last month, might there be additional regulatory citations? If so, what are they apt to be?

If this is the fourth failure in the last month, what other documentation would you expect to find other than additional NRs?
What else, although not required by FSIS policy, might you want to do? <i>Hint: What other task might you want to perform?</i>

7.

8.

,	What microbial data would you want to look at?
	Is there any review and observation verification that you might want to perform associated with the microbial data?
•	How are you going to divide the responsibility of performing the tasks?
-	
-	
-	

12. What effect might the drain problem in ante-mortem have on this situation?	
13. Is there anything that you need to talk about with Dr. Wright?	
14. Are there any disciplinary actions that you need to take with Dr. Wright?	

HUMANE HANDLING (10:25 AM)

That same morning, you are verifying HAT Category VIII, Stunning Effectiveness, as a part of your Livestock Humane Handling task. You are observing an establishment employee stun cattle in the knocking box. You observe the employee effectively stun twelve cattle in a row on the first attempt using a pneumatically operated penetrating captive bolt stunner.

The next animal, a steer, enters the stunning area and is restless, throwing its head. The employee does not chase the steer's head, waiting until it calms down before attempting to stun it. When the employee attempts to stun it, the steer moves its head at the last second, and the bolt penetrates the forehead off-center. The steer is bleeding from the head and vocalizes loudly. The employee remains calm and immediately stuns the steer again, rendering the steer insensible.

You have verified that the establishment has a robust systematic approach for humane handling and slaughter, as well as a good history of properly stunning animals.

Does this represent noncompliance?

If it is a noncompliance, is it egregious?

What action should be taken by inspection personnel?

35-9

MAKING DISPOSITIONS (11:30 AM)

Moments ago, you are notified that there are three cattle that have been railed out for disposition. You go to the disposition area. A Food Inspector tells you that all three animals are form the same lot of cattle and that many of them in the lot have abscesses.

A. Disposition 1

You examine the carcass and viscera of the first animal, a steer. There are multiple wellencapsulated abscesses in the lungs and liver, some of which have been broken during evisceration and are draining pus. There are two well-encapsulated abscesses attached to the pleura. There are four well-encapsulated abscesses attached to the peritoneum. The kidneys both have white areas indicating past infarcts. The carcass is well fleshed and all other viscera are normal.

Go through your disposition thought process and determine what disposition you would make on this steer.



Image 1



Image 2



Image 3



Image 4



Image 5



Image 6

Based on what you see, what disposition would you make on this carcass?

B. Disposition 2

You examine the carcass and viscera of the second animal, a heifer. The cranial and ventral aspects of the lungs are bluish and consolidated, involving approximately 1/2 of the lung. There is some organized fibrin on the pleural surfaces of the lung and thorax. The tracheobronchial and mediastinal lymph nodes are enlarged, but have normal architecture with no hemorrhage. Other lymph nodes are normal. There are two well-encapsulated abscesses in the liver. There is a small hemorrhage surrounding a small diameter puncture wound in the left chuck area with a slightly larger hemorrhage deeper in the chuck. The kidneys, spleen, peritoneum, and all other viscera are normal. The carcass is well fleshed.

Go through your disposition thought process and determine what disposition you would make on this heifer.



Image 1



Image 2

Based on what you see, what disposition would you make on this carcass?

C. Disposition 3

You examine the carcass and viscera of the third animal, a steer. There are multiple wellencapsulated abscesses in the liver. Some of these abscesses have red rings around them. There are several well-encapsulated abscesses on the dorsal 1/3 of the lung. There are 6-8 ecchymotic hemorrhages on the dorsal lung and multiple petechial hemorrhages on the dorsal lung. The mediastinal lymph nodes are enlarged, edematous, and reddened. You observed a few petechial hemorrhages on their cut surfaces. The heart has petechial hemorrhages on the outer surface of the heart cap and a few petechial hemorrhages on the kidneys and peritoneum. The carcass is well fleshed and all other viscera are normal.

Go through your disposition thought process and determine what disposition you would make on this steer.



Image 1

Image 2





Image 4



Based on what you see, what disposition would you make on this carcass?

Would you take tissues for residue testing on any of the above cattle?

If so, which ones?

PERSONNEL SITUATION (1:00 PM)

As you are leaving the disposition area, FI Garcia approaches you and tells you that FI Shaunessy is in a good mood today because her date with an establishment QA went well last night.

Is there something you need to do at this point? If so, what?

ZERO TOLERANCE VERIFICATION (2:05 PM)

CSI Jones tells you that while performing a Review and Observation verification of the establishment's corrective actions for the zero tolerance failure in the cooler, he found two carcasses in the cooler with scattered specks of rail dust on them.

Is this a noncompliance?

If so, how would it be documented?

What regulation would be cited?

If this noncompliance had occurred previously in the last two or three months, what other regulation would be cited?

COLLEAGUE PHONE CALL (2:45 PM)

You get a phone call from a colleague new to the agency, assigned to a hog slaughter operation. Your colleague says that they just got back in from performing ante-mortem inspection and saw some weird lesions on some of the hogs. They say they are emailing you some pictures they took and want your advice on what they should do.

Below is the email from your colleague.

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File Messa	ge Insert Options	Format Text Review	Adobe PDF Q 1	fell me what you want to	do.,			
Xor	tit .	EXALE-12-14	11 3	1 🔤 📝	Follow Up *	D,		
Paste Second	Painter B J U Z	$ -A\cdot \equiv\equiv\equiv\equiv \equiv\boxtimes$	Address Check	Attach Attach Signature	Assign Policer + Low Importance	View		
Clipboard	G.	Have fed	Matters	tidude	Tags	My Tempiakes		~
To	You@fsis.usda.ge	ov						
12	1							-
Send Subject	AM inspection images							-
Hi there mortem	e! Thank you and inspection.	so much for agre Take a look at th	eeing to lo em and le	ok at the ima t me know w	ages I took of so that you think! T	me hogs t hank you	today during ante-	
174	Attachment	:1		Attachment	2		Attachment 3	
		K					20	
	Attachment	4		Attachment 5	i		Attachment 6	

After	looking at your	colleague's pictures	of the hogs,	what should you advise him to do?
				······································

SPLIT SAW SITUATION (3:30 PM)

You observe that an establishment employee hits an abscess with the split saw while splitting a carcass and then proceeds to split the next carcass without cleaning or sanitizing the split saw.

Is this a noncompliance?

If so, what regulation would apply and how would you document it?

END OF DAY WRAP-UP (4:30 PM)

The FLS calls half an hour before the end of your shift and asks how your day is going. How would you respond?

Homeland Food Defense

OBJECTIVES

The objectives for this module are:

- 1. Describe the risk that intentional contamination presents to meat, poultry, and egg products establishments.
- 2. Discuss potential public health, psychological, social, and economic consequences associated with attacks on the food supply.
- 3. Define key food defense terms.
- 4. Describe historical events that highlight the need for concern and action regarding protecting the food supply against intentional contamination.
- 5. Discuss why food defense and emergency response functions of FSIS fit with the Agency's mission of ensuring that meat, poultry, and egg products are safe, wholesome, and correctly labeled and packaged.
- 6. Identify some of the food defense and emergency response activities FSIS is doing to meet the challenges of food defense.
- 7. Explain steps FSIS is taking to promote the adoption of preventive strategies by the private industries to ensure the security of the U.S. meat, poultry, and egg products supply.
- 8. Describe the purpose of each food defense procedure with respect to identifying potential food defense vulnerabilities in a meat, poultry, or egg products establishment.
- 9. Identify the steps taken to encourage an establishment to enhance its food security measures when food defense vulnerabilities are identified.

REFERENCES

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- 4. Protecting America's Meat, Poultry and Egg Products: A Report to the Secretary on the Food Security Initiatives of the FSIS, January 31, 2003
- 5. Food Defense Guidelines for Slaughter and Food Processing Establishments, USDA, FSIS publications
- 6. Security Guidelines for the Transportation and Distribution of Meat, Poultry and Egg Products and Consumers, USDA, FSIS publications
- 7. FSIS General Food Defense Plan, USDA, FSIS publications

8. Food Defense Self Assessment Checklist for Slaughter and Processing Facilities, USDA, FSIS publications

INTRODUCTION

This module will address food defense activities in FSIS. First, we will cover an overview of what food defense means and what activities FSIS has taken to ensure that meat, poultry, and egg products are protected from intentional harm. Then, we will talk about your role and inspection activities that are related to food security.

Let us start by reviewing the mission and vision of FSIS, because this infrastructure is tasked with addressing food terrorism. As you know, FSIS is USDA's public health regulatory agency that ensures meat, poultry and egg products are safe, wholesome, and accurately labeled. These products account for one third of consumer spending for food with an annual retail value of \$120 billion.

The FSIS infrastructure is extensive. There are approximately 6,500 federally inspected and 2,550 state-inspected meat and poultry (slaughter and processing) establishments in the United States. There are over 7,600 inspectors assigned to the federally inspected establishments and import facilities alone. There are approximately 1,200 veterinarians assigned to work in one or a number of federally inspected meat and poultry establishments. We have an enormous responsibility to ensure that we provide the safest food possible for the American public.

Prior to September 11, FSIS focused primarily on protecting meat, poultry, and egg products from contamination that is not premeditated but unintentional. The events of September 11, 2001, brought the issue of the vulnerability of our food supply to the forefront. Tommy Thompson, a former Secretary of the Department of Health and Human Services (DHHS), has stated, "For the life of me, I cannot understand why the terrorists have not attacked our food supply because it is so easy to do". Bill Frist, a physician, former Senator, and one of the original sponsors of the Bioterrorism Preparedness Act signed into law in 2002, has stated that "...as we consider bioterrorism, we are most vulnerable in our food supply.". We in FSIS must make consideration of the "unusual" a part of how we routinely conduct business by remaining ever vigilant of possible attacks on the food supply and wary of situations that appear out of the ordinary. We must accept the fact that an attack on our food supply is plausible. This means that FSIS has had to add functions to protect the food supply against intentional harm.

Here are reasons why the food supply is a plausible and possible target:

- With low security of facilities and personnel, it could be an easy target.
- One hundred percent of our population eats 100% of the time.
- Food terrorism can cause sickness and death.
- Food terrorism can cause disruptions in the food supply without deaths.
- Food terrorism can destroy brand names.

- It can be used for economic gains on the futures markets.
- It may be difficult to distinguish between intentional, deliberate contamination designed to harm people and the situations that occur unintentionally.

FOOD DEFENSE TERMINOLOGY

Food Security – When all people at all times have both physical and economic access to enough food for an active, healthy life. Food security includes both physical and economic access to food that meets people's dietary needs and food preferences. Therefore, the concept of food security certainly includes but encompasses much more than the idea of food defense.

Food Terrorism – an act or threat of <u>deliberate</u> contamination of food for human consumption with chemical, biological or radio nuclear agents for the purpose of causing injury or death to civilian populations or disrupting social, economic, or political stability. Within FSIS, food terrorism is further focused down to how terrorism relates to meat, poultry and egg products.

Food Defense – is safeguarding the food supply against <u>intentional</u> acts of tampering or contamination. Food defense encompasses a broad range of considerations. Defending food from intentional contamination requires measures in addition to food safety because it is hard to predict how the terrorist might manage an attack on the food in a particular operation. Therefore, a HACCP plan will not necessarily protect against intentional contamination. However, a food defense plan considers how someone might get into a particular operation and how some agent could be added to the process. Such vulnerable areas are not likely to be identified in a HACCP plan. Dealing with issues involving the possible intentional contamination of food due to a terrorist act requires addressing these factors:

- Physical security of buildings,
- Surveillance activities to identify/prevent acts intended to disrupt the food supply,
- Personnel security, and
- Emergency response

Food Safety – is guarding against <u>unintentional</u> contamination of food. HACCP plans and Sanitation SOPs, which are developed based on what can be predicted to happen if we do not put safety measures at critical points, are used to guard against unintentional contamination. While the United States has a well-functioning *food safety* infrastructure to protect the public against the unintentional contamination of food, *food defense* encompasses a broader range of considerations.

Critical Infrastructure – The Patriot Act of 2001 defined critical infrastructures as systems and assets, whether physical or virtual, so vital to the United States that the incapacity or destruction of such systems and assets would have a debilitating impact on security, national economic security, national public health or safety, or any combination of those matters. The critical infrastructures specified by the Patriot Act of 2001 were:

- Agriculture and Food
- Water
- Public Health
- Emergency Services
- Government
- Defense Industrial Base
- Information and Telecommunications
- Energy
- Transportation and Shipping
- Banking and Finance
- Chemical/Hazardous Material Industry
- Postal Service
- National monuments and icons

Supply Chain - continuous process including every step involved in food production and food reaching the consumer; often referred to as farm-to-table or farm-to-fork.

Agricultural Bioterrorism - use of biological, chemical, radiological, or other agents against food and fiber production to produce fear, cause economic damage, harm public health, or have some other adverse impact.

Incident Command System (ICS) – a nationally established management system used to respond effectively to an emergency involving one or more jurisdictions.

EXAMPLES OF ATTACKS ON THE FOOD SUPPLY

History has shown that terrorists can, and will, use food as a weapon. A review of a few noteworthy intentional food borne disease outbreaks provides:

- the kinds of foods and the points in their production where intentional contamination could have catastrophic consequences
- the potential magnitude of the public health impact of a carefully planned intentional attack on the food supply, and
- some of the types of individuals and their motivations for intentionally attacking the food supply

In 1972, members of a U.S. fascist group called Order of the Rising Sun were found in possession of 30-40 kilograms of typhoid bacteria cultures, with which they planned to contaminate water supplies in Chicago, St. Louis, and other Midwestern cities.

In 1984, two members of an Oregon cult headed by Bhagwan Shree Rajneesh cultivated *Salmonella* (food poisoning) bacteria, and used it to contaminate restaurant salad bars in

an attempt to affect the outcome of a local election. Although some 751 people became ill, and 45 were hospitalized; there were no fatalities.

In early March 1989, someone created a scare that grapes from Chile imported into the USA would be contaminated with cyanide. On March 11, the United States Food and Drug Administration (FDA) spotted three suspicious-looking grapes on the docks in Philadelphia, in a shipment that had just arrived from Chile. Two of the grapes had puncture marks. They were tested and found to contain low levels of cyanide. The FDA impounded 2 million crates of fruit at ports across the country and warned consumers not to eat any fruit from Chile, which included most of the peaches, blueberries, blackberries, melons, green apples, pears, and plums that were on the market at the time.

October 1996, a former laboratory employee at the St. Paul Medical Center in Dallas, pleaded guilty to engaging in her own personal act of food-borne terrorism by intentionally contaminating pastries. She had access to the highly toxic bacteria, *Shigella dysenteriae*, stored in the laboratory; she contaminated the pastries and left them in an employee break room, and she sent a bogus e-mail message from her supervisor's computer notifying laboratory employees of the free snacks in the break room. Her activities were discovered when she tried to alter hospital records to cover her tracks.

In 1996, police received an anonymous call from a worker at a rendering establishment in Wisconsin. The caller said liquid fat from the establishment had been contaminated. It was determined that chlordane was the contaminant, an organochlorine pesticide that is environmentally stable, accumulates in the fat of animals, and is considered a food adulterant at very low levels (0.3 ppm in animal fat). This fat found its way to feed manufacturers and eventually onto nearly 4,000 farms in Wisconsin, Minnesota, Michigan and Illinois. Within two days, all major customers were notified and the feed was replaced. Luckily, milk samples taken from some of the dairy herds that had eaten the affected feed were negative or contained levels well below those that which poses a health hazard to humans. Total costs for disposing of the contaminated feed (4,000 tons) and fat (500,000 pounds) was almost \$4 million; however, as numerous state and federal agencies became involved in dealing with this issue, the final price tag was likely much higher.

On January 3, 2003, the Michigan Department of Agriculture's Food and Dairy Division and the U.S. Department of Agriculture were notified by a supermarket of a planned recall of approximately 1,700 pounds of ground beef because customers had complained of illness after eating the product. The contaminant in the ground beef returned by customers with reported illness was identified as nicotine from nicotinebased pesticide used by the supermarket. An employee of the supermarket was arrested and charged with deliberately poisoning the ground beef at the supermarket.

LESSONS LEARNED FROM VULNERABILITY ASSESSMENTS

Being aware of what terrorists do, how they do it, when and where they do it can help us be more effective in identifying and preventing their activities. How can a terrorist organization gain technical capability? Can they recruit American food system workers? Can they gain knowledge by talking with food system workers using what appear to be

simple and innocent questions about their jobs while sitting at a baseball game or standing in line at a grocery store? Food system workers are a prime information target; and, that includes you. What must a terrorist have to carryout an attack? A terrorist must have the following to conduct food terrorism activities:

- Have access to the food for a sufficient amount of time to tamper with it;
- Be technically capable of introducing a contaminant;
- Be able to perform the operation without discovery; and
- Be competent enough to avoid detection of the adulterated product down stream in the production's distribution life cycle.

Based upon its vulnerability assessments, FSIS has identified foods with certain characteristics as being at higher risk of intentional contamination. These characteristics include large batch size, uniform mixing, short-shelf life, and ease of access. Large batch size places a food product at high risk because it facilitates the contamination of a large quantity of product all at the same time. In turn, a large number of individuals may consume the contaminated product. The larger the number of consumers the greater is the potential for a larger number of deaths or illnesses. For instance, contamination of a 5,000-gallon commercial kettle could negatively affect a much larger number of individuals than contamination of a 5-gallon food service pot. Uniform mixing places a product at high risk for contamination because adding agents before or during mixing steps results in contamination of all of the servings in a batch, improving the efficiency of an attack. Short shelf life places a food product at risk because these products may be consumed before public health officials are able to identify the cause of illness and to take action to prevent further illnesses. Ease of access increases a products risk for adulteration because carrying out an act requires access to the product or its raw materials. The more accessible a site the more likely it will be a target.

The intentional food contamination incidents above also provide some examples of the types of individuals that might be motivated to adulterate food products.

- Attacks from internal sources are possibly the most difficult to prevent because they typically know what procedures are followed in the establishment and often know how to bypass many security controls that would detect or delay an external intruder. Disgruntled insiders are generally motivated by their own emotions and self-interests. They may be mentally unstable, operating impulsively with minimal planning. This may be the most difficult group to stop because they may have legitimate access to the product.
- Criminals who are sophisticated may possess relatively refined skills and tools and are generally interested in high-value targets. Unsophisticated criminals have more crude skills and tools and typically have no formal organization. They are generally interested in targets that pose a low risk of detection.
- Protestors are usually politically or issue-oriented. They generally act out of frustration, discontent, or anger. They are primarily interested in publicity for their cause, and, as a result generally do not intend to injure people, but may be

superficially destructive. They are usually unsophisticated in their tactics and planning. However, some protest groups have adapted tactics similar to terrorists. In this way, they may be moderately sophisticated and moderately destructive. In fact, they may target individuals for harm.

- Subversives, also known as saboteurs, assassins, guerrillas, or commandos are sophisticated, highly skilled, and capable of meticulous planning. Subversives typically operate in small groups with objectives including death, destruction, and targeting personnel, equipment, and operations.
- Terrorists are usually politically or ideologically oriented. They typically work in small, well-organized groups. They are typically well funded, sophisticated, and capable of efficient planning. Terrorists may use other types of aggressors to accomplish their goals. Their objectives include death, destruction, theft, and publicity.

CONSEQUENCES / IMPACTS

Food security has economic, health, societal, psychological, and political significance. Deliberate contamination of the food supply could cause significant public health consequences and widespread public fear. It could also have a devastating economic impact and result in the loss of public confidence in the safety of our food and in the effectiveness of government.

Intentional and unintentional breeches in food security could have a significant effect on health care expenses, lost wages, consumer confidence, trade embargoes, etc. The Centers for Disease Control and Prevention (CDC) reports there are three types of economic effects that may be generated by an act of food terrorism:

- Direct economic losses attributable to responding to the act including: medical costs, lost wages for the victims, containment, decontamination and disposal costs
- Indirect multiplier effects from compensation paid to affected producers and the losses suffered by affiliated industries, such as suppliers, transporters, distributors, etc.
- International costs in the form of trade embargoes imposed by trading partners

FSIS FOOD DEFENSE STRATEGY

The nation's awareness of terrorism has been heightened and there is an intense focus on ensuring the protection of the nation's critical infrastructures. Section 332 of the Public Health Security and Bioterrorism Act of 2002 established that the Secretary of Agriculture might utilize existing authorities granted by the FMIA, PPIA, and EPIA to give high priority to enhancing and expanding the capacity of FSIS to conduct activities related to food defense. Homeland Security Presidential Directive (HSPD) 7 established a national policy for Federal departments and agencies to identify and prioritize critical infrastructures and key resources and to protect them from terrorist attacks. HSPD-9 established a national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies. HSPD-9 outlines roles and responsibilities for USDA, DHHS, and the Environmental Protection Agency (EPA) in planning for, preventing, and responding to such emergencies.

An example of applying the expectations of Section 332 of the Bioterrorism Act occurred at the beginning of the war in Iraq when the federal government was on heightened alert. We had real concern that our nation would be the subject of a terrorist attack in retaliation for the war. "Liberty Shield" was the code word for the government's heightened alert reactions. During that time, FSIS put into effect a number of "prevention" measures that would be the basis of our future actions and response to changes in threat conditions. For example, Inspectors-In-Charge (IICs) initiated new security-based inspection measures as part of the Public Health Inspection System (PHIS). Import inspectors also increased security oversight. Laboratory sampling was increased so that 50% of all samples included analysis for a threat agent, and the Consumer Complaint Monitoring System (CCMS) increased its coverage. FSIS epidemiologists enhanced their surveillance efforts for human illnesses, looking for possible links to unusual disease signs.

During Operation Liberty Shield, instructions were provided to field Public Health Veterinarians and inspectors to replace certain Non-Food Safety Consumer Protection inspection procedures with targeted inspection and sampling for a dozen or so biological, chemical, or radiological agents. Since then, FSIS continues to randomly test for these agents on an ongoing basis to maintain surveillance and monitoring for terrorism.

The example of Operation Liberty Shield points to the fact that efforts to improve the security of the food supply in particular must focus on prevention, early detection, containment of contaminated product, and mitigation and remediation of any problems that do occur. These efforts are not without significant challenges, including the following:

- There is no strong statutory authority to mandate security measures.
- As a discipline, food defense is in its infancy; therefore, development of education and training, surveillance methods, and data analysis techniques is ongoing.
- Many points along the farm-to-table continuum could be targets of agricultural bioterrorism in general and food terrorism specifically.

FSIS created the Office of Data Integration and Food Protection (ODIFP) in 2002 to coordinate the Agency's food defense activities. The mission of ODIFP is to develop and coordinate all FSIS activities to prevent, prepare for, respond to, and recover from non-routine emergencies resulting from intentional and non-intentional contamination affecting meat, poultry, and egg products. ODIFP serves as the agency's central office for homeland security issues and ensures coordination of its activities with the USDA Homeland Security Office, the White House, the Department of Homeland Security (DHS), the Food and Drug Administration (FDA), and other Federal and State government agencies with food-related responsibilities, and industry. ODIFP has a comprehensive strategy for dealing with food defense challenges including:

• Vulnerability assessments

- Emergency preparedness and continuity of operations (COOP) planning
- Surveillance and data analysis, including predictive analytics
- Outreach and training
- Promoting food defense research

Vulnerability assessments, which are similar to risk assessments, help to prepare for, prevent, and mitigate the effects of an attack on the food supply in several ways. First, they can be used to identify products most at risk for adulteration. Second, they can be used to identify likely threat agents for attacking the food supply. Third, they can identify potential sites of contamination within a food processing system that are the most attractive targets. Finally, they can facilitate the development of countermeasures to minimize or reduce risks. In doing so, vulnerability assessments can focus limited resources towards the foods and agents of greatest concern.

In response to President Bush's issuance of the Homeland Security Presidential Directive that called for establishing a single, comprehensive national incident management system FSIS along with other agencies, have adopted the Incident Command System (ICS). ICS was designed in the early '70s. It is a standardized onscene incident management concept that allows responders from multiple agencies to adopt a flexible, integrated organizational structure to cope with an emergency. The organizational structure is specific to the ICS concept, and does not necessarily align with the organizational structure of any of the responding agencies. Thus, the Incident Commander, and those he/she commands, may not all be from one agency or the head of any particular agency. ICS utilizes the skills of those most gualified to take command of the particular situation until the emergency has been abated. In order to ensure a seamless FSIS response, certain FSIS employees (DO and above) have been required to complete the ICS training. ICS courses are available through AgLearn. To date, FSIS has entered into cooperative agreements with the Department of Homeland Security, the Department of Health and Human Services Food and Drug Administration and the National Association of State Departments of Agriculture's (NASDA) to ensure that a prevention and response mechanism between federal and state agencies could be enacted under the ICS system.

ODIFP developed the FSIS supplement to the USDA's Continuity of Operations Plan (COOP). A COOP identifies critical essential functions, succession and delegation of authority, and essential documents, and then attempts to define how the Agency will maintain mission critical functions and capabilities, communications, and security under non-routine circumstances. Examples of non-routine circumstances might be a large-scale attack on the country, a natural disaster, or an avian influenza pandemic (more examples given below). If there were an attack on headquarters in Washington, DC for example, the headquarters COOP enables other parts of the Agency to take over the functions of headquarters at other locations. Regarding an avian influenza pandemic, ODIFP has done extensive planning to ensure the safety and health of FSIS employees and the delivery of essential functions. More generally, FSIS has identified and developed response plans to help protect employees from exposure to bioterrorism agents, including procurement of analytical detection equipment.

FSIS has established the Emergency Management Committee (EMC), a standing committee that may be activated at anytime to address and manage the Agency's

response to a non-routine incident involving the adulteration of FSIS–regulated product or to manage a significant event or potential public health issue that requires coordination and sharing of resources among program areas. The National Biosurveillance Information System (NBIS) tracks and manage significant incidents. A significant incident presents a grave or potentially grave threat to public health involving FSIS-regulated product. Examples of significant incidents include the following:

- Widespread, or life-threatening, human illnesses potentially implicating FSISregulated product;
- Deliberate contamination of FSIS-regulated product;
- Threat alerts that there is an "imminent threat" or "elevated threat" specific to the food and agricultural sector;
- Widespread animal disease with potentially significant public health implications for FSIS-regulated product;
- Ineligible foreign product in the United States
- High risk products in the US as identified by Customs and Border Protection;
- Suspicious activities observed by program personnel while performing their normal duties.
- Natural disasters (e.g., hurricanes, tornadoes, earthquakes);
- Terrorist attacks on the nation's critical infrastructures; and
- Other Incidents of National Significance (INS) that result in the activation of the Emergency Support Function -11 (ESF-11), which are described in the Agriculture and Natural Resources Annex to the National Response Plan

From time-to-time, the EMC may need to form an Incident Investigation Team (IIT) to investigate and provide information regarding a particular emergency incident. These IIT reviews typically would be in response to an illness or outbreak in which a meat, poultry, or egg product produced by the establishment has been implicated; significant or repetitive contamination or adulteration incidents; or repetitive microbiological sampling failures as a result of either the Agency or establishment testing (e.g., *Escherichia coli* O157:H7, *Listeria monocytogenes*, or *Salmonella*). These teams would utilize specially developed protocols and methodologies to gather the necessary information.

FSIS also has a number of surveillance activities underway. For example, FSIS continues to enhance the CCMS. The CCMS is a surveillance system that monitors and tracks food-related consumer complaints. It is a potentially powerful tool in serving as a sentinel system for terrorist attacks on the food supply. FSIS also participates in FoodNet, and maintains a regulatory sampling database. FSIS has a liaison at the CDC in Atlanta. Some of these are activities were established for food safety reasons, but can be used for food security as well.

The Office of Public Health Science (OPHS) Epidemiology Officers offer another source for surveillance. The Epidemiology Officers with District Offices oversight have taken on an important surveillance and response role for food defense, as part of their

responsibilities. They conduct regular surveillance activities, and have specialized roles to respond to food defense emergencies.

Enhanced laboratory capability was established with FERN (The Food Emergency Response Network). FERN was established in February of 2005. Working with FDA, FERN's mission is to expand and manage an existing group of more than 90 federal, state, and local laboratories with the capability to detect and identify biological, chemical, and radiological agents. FERN is located alongside the FSIS Eastern Lab. In its own laboratories, FSIS has conducted security assessments, improved security, obtained screening equipment and methods for threat agents, and developed protocols that ensure proper chain of custody and other controls on all samples taken at official establishments. FSIS continues to develop a Biosafety Level 3 laboratory to test for threat agents in food products (such as *Mycobacterium tuberculosis*, St. Louis encephalitis, and *Bacillus anthracis*).

For international food defense, the activities are as follows:

- Conducting vulnerability assessments of imported products
- Participating in the Federal-wide International Trade Data System (ITDS), a multi-department, multi-agency initiative to establish a single, automated system for sharing data on the inspection and certification of products moving in foreign commerce

FSIS workforce training in food defense has primarily focused on prevention of terrorist activities, rather than responding to an event. The training covered a multi-dimensional team approach to homeland security – involving the interaction of personnel at the local, state, federal, and private sector; and, reinforced reporting lines for suspicious activities. It also focused on our field employees.

Currently available training materials include FSIS Directives 5420.1 that provides instruction on policy for field personnel. PHV trainees need to read FSIS Directive 5420.1 on Food Defense Verification. There may still be computer-based food defense training on CDs available in establishments; however, much of the information is outdated and the training is in the process of being updated. An online course on food defense awareness developed cooperatively by the FDA and USDA is available at

http://www.fda.gov/ora/training/orau/FoodSecurity/default.htm.

For those interested in ICS training, which is currently not mandatory for in-plant inspection personnel, AgLearn offers several courses on ICS. AgLearn can be accessed through <u>http://www.aglearn.usda.gov</u>. USDA eAuthentication credentials are required to login.

Training and education initiatives for industry are discussed below under the heading Industry Outreach.

FSIS has identified high priority areas for research and development pertaining to food defense, such as testing methods for certain threat agents. The agency is working with Department of Homeland Security's National Biodefense Analysis and Countermeasures Center (NBACC) and the interagency Technical Support Working Group (TSWG) on

several studies pertaining to the use of certain threat agents in food. The results of these research activities influence the agency's capability to test for different threat agents, the amount of testing, and which agents to test for, and informs vulnerability assessments.

INDUSTRY OUTREACH

There currently are no regulatory requirements specific for food defense; however, FSIS encourages the private industry to develop and implement food defense plans aimed at minimizing their risk of a food terrorism incident. Key components of such food defense plans are:

- Improve physical security to limit unauthorized access
- Improve personnel security
- Conduct food defense awareness training for employees
- Monitor product loading, unloading, and silo/tanker cleaning
- For transportation firms confirm eligibility, training, and background information of both company and contract drivers
- Enhance process security thru system monitoring procedures
- Monitor water/ice used in emulsification and solution preparation processes
- Require product integrity and chain of custody information
- Use tamper-evident packaging for products
- Enhance recall systems to ensure food that has been intentionally adulterated can be accurately and efficiently tracked and detained

FSIS routinely conducts Regulatory Education and "How To" sessions, which include presentations and hands-on workshops on food defense. The food defense presentation is intended to heighten awareness, and encourage processors to seriously consider the potential for and consequences of attacks on the food supply so that they will implement strategies designed to minimize the chances of such an attack. In an effort to help private industry minimize their risk, FSIS has developed publications to promote food defense activities by all food businesses. These publications encourage industry to take steps to ensure the security of their operations, and have been designed to be especially helpful to small and very small establishments that may not have the resources of larger corporations. Currently available food defense publications are summarized below.

- Food Defense Self-Assessment Checklist for Slaughter and Processing Facilities: created this self-assessment instrument to provide a tool for establishments to assess the extent to which they have secured their operations.
- Food Defense Guidelines for Slaughter and Processing Establishment: created to assist Federal and State inspected establishments that produce meat, poultry, and egg products in developing preventive food defense measures. While many establishments may utilize guidelines from other government and private sector

organizations and agencies, businesses and establishments that do not have access to this specialized security-planning advice should find these guidelines helpful in improving and preparing food security plans. These guidelines are currently voluntary, but establishment officials will be well served by adopting and implementing them because they are developed to meet the particular needs of meat, poultry, and egg producing establishments. FSIS has provided these guidelines to its field employees who will assist in directing establishments that seek further clarification or advice.

- General Food Defense Plan: FSIS has urged establishments to develop functional food defense plans with control measures to help prevent intentional adulteration of products. A functional food defense plan has the following characteristics:
 - it is written
 - the measures described in the plan are implemented
 - the measures are periodically tested
 - the plan is reviewed at least annually and revised if needed

If the establishment is not implementing elements of its plan, inspection program personnel cannot take action on that fact because there is no regulatory requirement for such plans.

 Guidelines for Transportation and Distribution of Meat, Poultry, and Egg Products: Similar to the "FSIS Security Guidelines for Food Processors," these guidelines are voluntary and designed to assist small shippers and distributors by providing a list of safety and security measures that these entities should take to strengthen their food safety and food security plans. Protecting food during transportation and storage is a critical component in our defense against all types of food borne contaminants. These guidelines address points in the transportation and distribution process where potential contaminants could be introduced, including loading and unloading, and in-transit storage. FSIS encourages shippers, transporters, distributors, and receivers to develop and implement controls to prevent contamination of products through all phases of distribution, and to have plans in place in the event of accidental or deliberate contamination. Both of these guidelines are available on the FSIS website in several languages.

These publications are available for download at the following web address:

By clicking on the following link Food Defense and Emergency Response or type

http://www.fsis.usda.gov/wps/portal/fsis/topics/food-defense-defense-and-emergency-response

If you have questions or need clarification about the above referenced, materials you can call the FSIS Policy Development Division at 800-233-3935 or electronically post a question at http://askfsis.custhelp.com.

While functional food defense plans are not mandatory, they are strongly encouraged and sometimes may be required by a processor's customers in the supply chain. Food

defense plans do not need to be lengthy to be effective. In fact, depending on the complexity of an operation, the plan may be as short as one page. The three basic steps in developing a food defense plan are:

- 1. Assess the operation for possible vulnerabilities
- 2. Develop a plan to minimize identified vulnerabilities
- 3. Implement the plan

In addition to the resources that FSIS provides, the Food Defense Verification (FDV) tasks described below are a means by which inspection personnel can help an establishment identify potential vulnerabilities in a particular operation and encourage establishment management to take action to minimize those vulnerabilities.

THE NATIONAL TERRORISM ADVISORY SYSTEM

On January 27, 2011, the Department of Homeland Security (DHS) announced that it would discontinue the color-coded Threat Condition alerts of the Homeland Security Advisory System. On April 27, 2011, DHS initiated a new system, the National Terrorism Advisory System (NTAS). Under the new NTAS system, DHS coordinates with other federal entities to issue formal, detailed alerts when the Federal government receives information about a specific or credible terrorist threat. These alerts include a clear statement that there is an "imminent threat" or "elevated threat". The alerts also provide a concise summary of the potential threat, information about actions being taken to protect public safety, and recommended steps that individuals, communities, businesses, and governments can take.

The NTAS alerts are based on the nature of the threat. In some cases, alerts are sent directly to law enforcement or affected areas of the private sector. In others, alerts are issued more broadly to the American people through official and media channels – including a designated DHS webpage (www.dhs@gov/alerts), as well as social media tools, including Facebook and Twitter (@NTASAlerts). Additionally, NTAS has a "sunset provision", meaning that individual threat alerts are issued with a specified end date. Alerts may be extended if new information becomes available or if the threat evolves significantly.

FSIS DIRECTIVES

Now, let us talk more specifically about your duties related to food defense. Your duties are covered in FSIS Directives. There are eleven FSIS Directives related to Homeland Security:

- 5420.1 Food Defense Verification Tasks and Threat Notification Response Procedures for the Office of Field Operations
- 5420.2 Homeland Security Threat Condition Response: Handling of FSIS Laboratory Samples under Declared Heightened Threat Conditions
- 5420.3 Food Defense Surveillance Procedures and National Terrorism Advisory System Alert Response for the Office of Program Evaluation, Enforcement and Review
- 5420.5 Homeland Security Threat Condition Response: Intelligence Reports and Communications
- 5420.6 Homeland Security Threat Condition Response: Information Technology Monitoring Procedures
- 5420.7 Homeland Security Threat Condition Response: Human Health Monitoring and Surveillance
- 5420.8 Homeland Security Threat Condition Response: Communication and Public Affairs Procedures
- 5500.2 Significant Incident Response
- 5500.3 Incident Investigation Team Reviews
- 5500.4 Products Intentionally Adulterated with Threat Agents

When reviewing any of these Directives, make sure that you have the most recently issued version by downloading the particular Directive from the FSIS website or from PHIS – Home Page – My Dashboard tab. These may be modified frequently to reflect new threat information gained through intelligence gathering activities conducted worldwide. Therefore, it is imperative that you review these Directives following notification of any modifications or updates.

FSIS conducts verification activities throughout the food production process. The food production process consists of a series of processes along the farm to table chain. The order of these processes is:

- Production is the growth of food products and shipment of the products to the slaughter or processing facilities. The shipping portion of this process also accounts for imported products, which is reviewed by the FSIS Office of International Affairs.
- Processing is the slaughter and processing steps of the chain.
- Distribution is the movement of the processed product into commerce.
- Retail/Consumption the final step when the product reaches the retail service industry (institutional facilities and/or grocers).

Obviously, the FSIS in-plant inspection team's major area of responsibility falls within the processing part of the system. The first Directive in the series outlines the duties that are relevant to the in-plant inspection team under an imminent threat or elevated threat alert. The other Directives cover the duties of other FSIS officials regarding distribution, communications, information technology, human health monitoring, public affairs, etc. As a PHV, you should familiarize yourself with these other important directives, if it applies to your duties.

Let us look at Directive 5420.1 in more detail. First, this directive describes Food Defense Verification (FDV) tasks that Inspection Program Personnel (IPP) is to perform and the frequency with which these procedures are to be performed in the Public Health Information System (PHIS). These tasks have a priority 6 in the Establishment Task List. The frequency with which these tasks are to be performed is based on factors that affect the vulnerability to intentional adulteration:

- <u>Nature of the food product</u> in general, the following characteristics are associated with foods most vulnerable to intentional adulteration:
 - large batch size
 - uniform mixing
 - short shelf life
 - accessibility to the product
- <u>Product volume</u> establishments that produce a greater volume of product may be a more desirable target for intentional adulteration because a greater volume of adulterated product can lead to greater public health consequences.

In addition, the directive describes additional actions that are required when DHS issues an NTAS alert. The purpose of these verification tasks is to identify potential weaknesses in the food defense of an establishment that could make it vulnerable to deliberate contamination. A potential weakness can be any part of the food production system where a measure should be implemented to protect it from deliberate contamination, but such a measure is found to be missing or not in place. Examples may include unrestricted access to water system or to a processing room, uncontrolled access to a restricted ingredient area, to mention a few.

Directive 5420.1 describes the actions that the FSIS Office of Data Integration and Food Protection (ODIFP) will take to notify employees, stakeholders, and the public, as appropriate, when DHS issues an NTAS alert or when an NTAS alert ends. Inspectorsin-Charge (IIC) are to ensure that any notifications distributed to field employees pursuant to this directive are available to food inspectors, and inform establishment of the NTAS alert status. In case of significant incident, the FSIS Emergency Management Committee may be alerted or activated and other response actions taken pursuant to Directive 5500.2, Significant Incident Response.

When the Federal government receives information about a specific or credible terrorist threat to food or agriculture, the frequency with which FDV tasks are performed will increase, and additional actions may be needed to reduce the threat of intentional adulteration of food products. Given what is required in responding to a credible threat of a terrorist attack, IPP must clearly understand their roles and what will be required of them to respond properly to that threat.

All IPP in meat and poultry establishments and processed egg products plants are to perform FDV tasks listed in Directive 5420.1 and documented in PHIS. Following is a brief description of each:

• <u>Water System FDV Task</u>: to assess vulnerable points for this task, IPP are to verify whether the establishment restricts access to water systems and associated activities on the premises.

- <u>Processing/Manufacturing FDV Task</u>: to assess vulnerable points for this task, IPP are to verify whether the establishment restrict access to processing and manufacturing areas and associated activities on the premises
- <u>Storage Areas FDV Task</u>: to assess vulnerable points for this task, IPP are to verify that storage areas are secure from intentional adulteration activities.
- <u>Shipping and Receiving FDV Task</u>: to assess vulnerable points for this task, IPP are to verify whether the establishment restrict access to shipping and receiving areas and activities on the premises.

PHIS will automatically generate the minimum number of routine FDV tasks to the Establishment Task List (one per week), unless a Threat Notification is issued. Table 1 provides the frequency for which IPP are to perform FDV tasks based on threat notification status. Following is a summary version of Table 1 as per Directive 5420.1 followed by a description for each notification status:

Establishment Details	No Threat Notification has been issued	Elevated Threat Notification has been issued	Imminent Threat Notification has been issued
Domestic	One / week	Four / day + the	Four / day + the
Establishments – Most		routinely	routinely
Vulnerable;		scheduled weekly	scheduled weekly
High Volume		task	task
Domestic	One / week	two / day + the	Four / day + the
Establishments – Most		routinely	routinely
Vulnerable;		scheduled weekly	scheduled weekly
Low Volume		task	task
Domestic	One / week	Two / day + the	Four / day + the
Establishments –		routinely	routinely
Least Vulnerable;		scheduled weekly	scheduled weekly
Regardless of Volume		task	task

No Active NTAS Alerts or No Threat Notification has been issued:

- IPP in meat and poultry establishments that produce most vulnerable products in high volume establishments are to perform one routine FDV task per week. Establishment details: are domestic establishments producing any product other than thermally processed commercially sterile product (i.e., most vulnerable) in a combined volume greater than 12,000 lbs. /day for meat and poultry (i.e., high volume).
- IPP in meat and poultry establishments that produce most vulnerable products in low volume establishments are to perform one routine FDV task per week. Establishment details: are domestic establishments producing any product other than thermally processed – commercially sterile product (i.e., most vulnerable) in a combined volume less than 12,000 lbs. /day for meat and poultry (i.e., low volume).

• IPP in meat and poultry establishments that produce least vulnerable products at any volume are to perform one routine FDV task per week. Establishment details: are domestic establishments producing thermally processed – commercially sterile product (i.e., least vulnerable) regardless of volume.

When threats has been issued, in addition to routinely schedule FDV tasks, IPP are to schedule the prescribed number of directed FDV tasks, identified in Table 1, to their task calendar for the types of product being produced and claim those tasks that day, unless otherwise directed by the DO.

NTAS Alert with Elevated Threat Notification has been issued:

- IPP in meat and poultry establishments that produce most vulnerable products in high volume establishments are to perform four FDV tasks per day in addition to the routinely scheduled weekly task. Establishment details: are domestic establishments producing any product other than thermally processed – commercially sterile product (i.e., most vulnerable) in a combined volume greater than 12,000 lbs. /day for meat and poultry (i.e., high volume).
- IPP in meat and poultry establishments that produce most vulnerable products in low volume establishments are to perform two FDV tasks per day in addition to the routinely scheduled weekly task. Establishment details: are domestic establishments producing any product other than thermally processed – commercially sterile product (i.e., most vulnerable) in a combined volume less than 12,000 lbs. /day for meat and poultry (i.e., low volume).
- IPP in meat and poultry establishments that produce least vulnerable products at any volume are to perform two FDV tasks per day in addition to the routinely scheduled weekly task. Establishment details: are domestic establishments producing thermally processed – commercially sterile products (i.e., least vulnerable), regardless of volume.

NTAS Alert with Imminent Threat Notification has been issued:

- IPP in meat and poultry establishments that produce most vulnerable products in high volume establishments are to perform four FDV tasks per day in addition to the routinely scheduled weekly task. Establishment details: are domestic establishments producing any product other than thermally processed – commercially sterile product (i.e., most vulnerable) in a combined volume greater than 12,000 lbs. /day for meat and poultry (i.e., high volume).
- IPP in meat and poultry establishments that produce most vulnerable products in low volume establishments are to perform four FDV tasks per day in addition to the routinely scheduled weekly task. Establishment details: are domestic establishments producing any product other than thermally processed – commercially sterile product (i.e., most vulnerable) in a combined volume less than 12,000 lbs. /day for meat and poultry (i.e., low volume).
- IPP in meat and poultry establishments that produce least vulnerable products at any volume are to perform four FDV tasks per day in addition to the routinely scheduled weekly task. Establishment details: are domestic establishments

producing thermally processed – commercially sterile products (i.e., least vulnerable), regardless of volume.

Note: Frequency of task performance based on nature of the food product and product volume, recognizing that certain product types produced at higher volumes may be more vulnerable to intentional adulteration. For establishments producing multiple product types and volumes, additional tasks should be scheduled based on the most vulnerable product produced (i.e., products other than thermally processed – commercially sterile product and products produced at a higher volume per day).

DOCUMENTING FOOD DEFENSE VERIFICATION ACTIVITIES

When IPP perform a FDV task and do not find a food defense vulnerability or concern, they are to record the task as performed in the computerized Public Health Inspection System (PHIS).

When IPP perform a FDV task, and find that there is a food defense vulnerability or food defense concern, but that there is no evidence of product adulteration, they are to record the task as performed and document a Food Defense MOI. If there is evidence of product adulteration, IPP will schedule and perform a directed HACCP, SSOP or other appropriate inspection task to record the observed non-compliance citing the applicable regulations.

Note: As per Directive 5500.4, when IPP become aware of a situation involving product that has been <u>intentionally</u> adulterated with threat agents (biological, chemical, or radiological materials), the IPP should verify and ensure that the product **is not disposed of** until they have been notified by the Incident Commander through supervisory channels that the agency's investigation is complete.

In cases where food defense vulnerability is identified, there are additional steps inspection personnel must take. These include:

- verbally notifying establishment management and discussing the findings (NOTE: This can take place at the next weekly meeting), and
- completing FSIS Form 5420-1, Food Defense Memorandum of Interview (MOI), in PHIS and record the establishment response after discussing the findings; provide establishment's management with a copy of the completed FSIS Form 5420-1.

If the same vulnerability is found a second and third time, the same procedures are followed. If after the third occurrence, though, the establishment expresses no intention of addressing the situation, then inspection personnel should notify the District Office through supervisory channels. Inspection program personnel are not to further review or document the specific potential vulnerability identified in the three repeat MOIs until the District Office provides further instructions. If the procedure is randomly selected, inspection program personnel are to direct verification procedures to establishment activities other than the one specifically identified in the third MOI. The District Office will request the ODIFP review the situation and provide further guidance.

ACCESS TO AN ESTABLISHMENT'S FOOD DEFENSE PLAN

As mentioned previously, FSIS encourages establishments to develop a functional food defense plan; however, there is currently no regulatory requirement for food defense plans. As such, an establishment does not have to provide IPP access to its food defense plan or any associated documents (e.g., employee personnel files). It is beneficial if inspection personnel are permitted access to the plan, as it may be useful in determining specific verification activities when performing the food defense verification tasks. If the establishment shares its plan, do not keep or make copies of the written plan. Inspection personnel also cannot show or share anything about the plan with any outside source because it includes sensitive security information.

If the establishment has a functional food defense plan, IPP need to update the establishment's profile; review annually. In addition, at least annually, IPP will receive an alert through PHIS indicating that the Food Defense Survey task has been added to the establishment task list. When the IPP schedules the task and claims it, the "Qnaire" tab will be active, indicating the presence of a questionnaire. IPP will enter the answers to all the questions and record the task as completed. The IPP are to complete the Food Defense Plan Survey task in lieu of performing one FDV task

SUMMARY

Defending the food supply against intentional attacks is a critical function. FSIS field personnel both in and outside of establishments serve as an early alert system. Implementation of FDV tasks serves to protect the public, which is essential to our mission, and ensures the security of our food, a vital component of homeland security. Report any suspicious activities in establishments to your district manager through supervisory channels or call the FSIS 24 hr. emergency hotline at 1-866-395-9761.

WORKSHOP

FSIS FOOD SECURITY GUIDELINES TO INDUSTRY

Approximate time for this unit: 1 hour

INSTRUCTIONS:

Break up into small groups (e.g., 5-6 persons). First, individually review the Workshop checklist. Take about 15 minutes to complete it with one specific establishment in mind. As you review the Food Defense Self Assessment Checklist for Slaughter and Processing Facilities, think about how you would share the information on the checklist with an establishment representative. Remember that the Food Defense Guidelines are voluntary. They are not required by regulation. Then, as a group take about 15 minutes to discuss how you would share the information on the checklist with an establishment representative. For example, give your group members a brief description of the establishment you had in mind when completing the checklist. Then, pick 1-3 areas to discuss with the establishment representative. Share ideas about how you would encourage establishment management to take steps to adopt measures outlined in the Food Defense Guidelines.

(See checklist in the training materials.)

Note: The checklist is intended to be used as a training tool. It is not an official Agency form.

ESTABLISHMENT INCIDENT SCENARIO

Approximate time for this unit: 1 hour

Working in small groups of 5-6 people each, you are going to be read a scenario about a reported in establishment incident. This scenario is realistic, in that something very much like this has happened in an FSIS-regulated establishment. Then, each group will develop their response. Someone in each group should record group decisions, and be prepared to report them for the group.

You have 20 minutes to answer these questions in your group:

Regardless of whether you were talking to the inspector on the phone or in the establishment with the inspector:

What questions would you ask?

What actions would you advise the inspector to take, or if you were there, what actions would you take?

QUESTIONS

INSTRUCTIONS:

Based on the information provided in the presentation and your training materials, select the most appropriate response for each of the following items.

- 1. Food defense is:
 - a. intentional contamination of food
 - b. planning to protect physical facilities, surveillance and monitoring activities, personal and emergency procedures
 - c. making sure people are happy
 - d. giving all FSIS officials secret powers to enforce food safety
- 2. The Centers for Disease Control and Prevention (CDC) has: (See Appendix below)
 - a. three categories of biological agents: 1, 2 and 3
 - b. put those biological agents that are easily disseminated from person-toperson, result in high mortality and have a potential for major public health impact in Category A
 - c. put Brucellosis, Glanders, Q-Fever, Staphylococcal enterotoxin, Salmonella, E. coli O157:H7 and Shigella in the highest category for biological threat agents
 - d. categorized emerging pathogens that can be engineered for mass dissemination as Category B (e.g., Nipah and Hanta viruses)
- 3. FSIS has food defense initiatives in the following areas:
 - a. works closely with the White House and Department of Homeland Security to coordinate food defense efforts
 - b. has three laboratories and one special microbial outbreak laboratory that ensure proper chain of custody and other controls on all samples taken at official establishments
 - c. been training the entire workforce on how best to prevent terrorists activities rather than responding to an event after the fact
 - d. conducted Operation Liberty Shield and replaced certain inspection tasks that were not related to food safety with targeted inspection and sampling for approximately a dozen biological, chemical and/or radiological agents and continues to randomly test for these agents on an on-going basis
 - e. All of the above
- 4. Which of the following should IICs do in a NTAS Alert with Imminent Threat to Food or Agriculture?
 - a. Tell the establishment that everyone must go home to protect themselves
 - b. Report potential breaches to the Department of Homeland Security
 - c. Observe incoming animals for unusual signs and report it to APHIS only because they are in charge of animal health and not FSIS
 - d. Conduct all FDV tasks

APPENDIX: BIOTERRORISM OVERVIEW

There are multiple components to bioterrorism. Beyond just food terrorism, bioterrorism is often defined as the use of biological agents that target humans, plants, or animals; and, was exemplified in anthrax letters that were used in 2001 against the American people. In addition, other terrorism components such as conventional, radiological, nuclear, chemical, and cyber are typically directed at the human population. This appendix discusses various components of bioterrorism. It is important for the FSIS PHV to be aware of these bioterrorism components from a professional perspective as well as from the standpoint of serving as a first line defense. They will be monitoring animal diseases of great economic significance (e.g., foreign animal diseases) that could be initiated through an act of terrorism causing public health threats that could be introduced through the food supply.

Types of Agents Used by Terrorists

Weapons of Mass Destruction:

Terrorists often use Weapons of Mass Destruction. These include chemical, biological, radiological agents, or high yield explosives. Some examples of chemical weapons used by terrorists are arsenic, cyanide, and pesticides. Examples of biological weapons that terrorists use include anthrax, botulinum, and toxin. Radiological weapons examples used by terrorists include Cesium-137, Strontium-90, and Cobalt-60. When Weapons of Mass Destruction (WMDs) are used, there are four possible areas of impact. They include harm to the economy, disruption of society, psychological disturbance, and political disturbance.

Chemical agents

<u>Biological compounds used as chemical agents</u>: You should be aware of some of the typical ways in which the chemical agents used by terrorists affect the human body. Here are some examples:

Vesicants: Terrorists may use a biological agent that acts as a vesicant such as a powder. These agents burn and blister the skin or any other part of the body they contact. They act on the eyes, mucous membranes, lungs, skin, and bloodforming organs. They damage the respiratory tract when inhaled and cause vomiting and diarrhea when ingested. Examples of biological agents that have this effect are *Sulfur mustard* in its pure state is colorless and odorless. It is extremely toxic to the unprotected eyes, skin, and respiratory system. If a victim survives the initial encounter, the mustard continues to destroy the body's immune defenses and can complicate treatment of acquired infection. *Nitrogen mustards* are more toxic than sulfur mustards and are easily manufactured. Lewisite placed on the skin causes immediate burning sensation, and its odor is readily apparent. Severe damage to the eyes occurs almost immediately after exposure. Lewisite is absorbed into the body, and distributed as a systemic poison to various organs.

Blood: Biological agents also affect the blood. A typical effect of a biological agent is that they prevent blood from carrying O2 effectively. For example, *arsenic* can be reacted with zinc and sulfuric acid to form arsine, which is a colorless gas with an unpleasant odor similar to garlic. Arsine is a blood agent but it is referred to as a nerve poisoning due to its secondary effects. Arsine causes the destruction of red blood cells and subsequently the tissues of the kidney, liver, and spleen. Arsine is used today for industrial processing of gallium arsenide chips in the semiconductor industry.

Choking/Pulmonary: These biological agents cause choking and affect the pulmonary system in humans, but they are not food related.

Incapacitating: Some biological agents that can be introduced in food can incapacitate the individuals affected. For example, *BZ*, 3-quinuclidinyl benzylate, is a member of the belladonna group of compound (glycolates) that includes atropine, scopolamine, and many others.

Emetics: In many cases, chemical agents, when ingested or inhaled, induce vomiting. Among the vomiting agents that have the most significant effects are diphenylchlorarsine (DA), diphenylcyanoarsine (DC), and adamsite (DM). These agents can be dispersed as aerosols and produce their effects by inhalation. Some minor eye irritation also might occur. Emetics produce a feeling of pain and sense of fullness in the nose and sinuses. This is accompanied by a severe headache, intense burning in the throat, tightness and pain in the chest, irritation of the eyes and lacrimation. Coughing is uncontrollable, and sneezing is violent and persistent. Nausea and vomiting are prominent. Mild symptoms, caused by exposure to very low concentrations, resemble those of a severe cold. The onset of symptoms may be delayed for several minutes after initial exposure, especially with DM. Therefore, effective exposure may occur before the presence of the smoke is suspected. If a protective mask is available and put on by an individual after these symptoms are noticed, the symptoms will increase for several minutes, despite adequate protection. Consequently, the victim may believe the mask to be ineffective, and by removing it, cause further exposure. On leaving the scene of the attack, the victim's symptoms subside rather rapidly, and the severe discomfort vanishes after about one-half hour. At high concentrations. effects may last for several hours. Because of their arsenical properties, when these chemical agents are introduced, the affected foods become poisonous.

Tearing: The chemical agents used for terrorism that cause tearing are not typically introduced through food.

<u>Nerve agents:</u> Some of the nerve agents that can be used by terrorists to affect food products include the following:

- Tabun (GA) volatile, liquid/vapor
- Sarin (GB) volatile, liquid/vapor
- Soman (GD) volatile, liquid/vapor
- VX low volatility, liquid
- Pesticides methyl parathion, malathion, diazinon

All of these agents are cholinesterase inhibitors when they are ingested or inhaled. Cholinesterase is an enzyme needed for the proper functioning of the nervous systems of humans, other vertebrates, and insects. They are all pesticides, which act like organophosphates and carbamates to inhibit cholinesterase. Nerve agents are the most toxic and rapidly acting of the known chemical warfare agents. They are similar to pesticides, called organophosphates, based on their properties and the kinds of harmful effects they cause. However, nerve agents are much more potent than organophosphate pesticides.

<u>Heavy metals:</u> Heavy metals can also be used by terrorists to affect food products. The most dangerous ones include the following:

- Arsenicals
- Mercury
- Cyanide
- Thallium

Arsenic: The primary symptoms of acute inorganic arsenic poisoning in humans are painful dysesthesias, decreased deep tendon reflexes, decreased pain, touch, and temperature sensation. Individuals who have arsenic poisoning may also experience nausea, anorexia, vomiting, epigastric and abdominal pain, and diarrhea. These symptoms are so severe that they often end in death. Chronic exposure to low levels of arsenic has led to nasal septum perforation, dermatological symptoms (lesions, necrosis, etc.), and an increase in the incidence of lung and lymphatic cancers.

Mercury: The heavy metal mercury is not well absorbed by the human gastro intestinal tract, but there is good pulmonary absorption of mercury vapors, especially methyl mercury.

Cyanide: Cyanide is rapidly absorbed from the stomach, lungs, mucosal surfaces, and unbroken skin; is a rapidly acting poison that can exist in various chemical forms. Examples of simple cyanide compounds include hydrogen cyanide, sodium cyanide, and potassium cyanide. Hydrogen cyanide is a colorless gas with a faint, bitter, almond-like odor. Sodium cyanide and potassium cyanide are both white solids with a bitter, almond-like odor in damp air. Cyanide and hydrogen cyanide are used in electroplating, metallurgy, in the production of chemicals, photographic development, making plastics, fumigating ships, and some mining processes. Effects begin within seconds of inhalation and within 30 min of ingestion. A bitter almond odor may be detected on the breath. Later effects include coma, convulsions, paralysis, respiratory depression, pulmonary edema, arrhythmias, bradycardia, and hypotension. Antidotal therapy: Amyl nitrite, sodium nitrite, and sodium thiosulfate with high-dose oxygen should be given as soon as possible.

Thallium: Thallium is a toxic heavy metal. Most cases of thallium toxicity occur after oral ingestion. Gastro intestinal decontamination, activated charcoal, and Prussian blue (potassium ferric hexacyanoferrate) are recommended in thallium ingestion.

Biological Agents and Toxins

Before discussing the diseases, it is important to understand the weaponization of an agent. If an agent has been "weaponized", characteristics of the pathogen may have been altered to make it a more effective weapon.

For example:

- the transmission of a pathogen may be enhanced or the virulence increased;
- the organism may have been altered to make it resistant to antibiotics it would otherwise be susceptible to;
- may allow an organism to evade the normal protective immunity induced by vaccine, or it may even alter the clinical signs; it is difficult to know

However, when evaluating these agents, and what we currently know about them is still important for our enhanced awareness.

The CDC divides biological agents and toxins into three categories:

- Category A High priority
- Category B Second highest priority
- Category C Third highest priority

Be aware that the CDC changes the agents listed in these categories as additional information becomes available. Let us discuss each of these in more detail.

Category A

The biological agents and toxins that fall into Category A can be easily disseminated, or transmitted person-to-person. They cause high mortality, with potential for major public health impact. Their introduction might result in public panic, and social disruption. They require special action for public health preparedness. Following are the agents and toxins that are currently listed in Category A:

- Anthrax (Bacillus anthracis)
- Botulism (Clostridium botulinum toxin)
- Plague (Yersinia pestis)
- Smallpox (Variola major)
- Tularemia (Francisella tularensis)
- Viral hemorrhagic fevers (e.g., Ebola)

<u>Anthrax</u>

Anthrax results from infection by *Bacillus anthracis*, a spore forming gram-positive aerobic rod. Anthrax can be found as a spore in the soil worldwide; it is particularly common in parts of Africa, Asia, and the Middle East. In the United States, foci of infection occur in South Dakota, Nebraska, Mississippi, Arkansas, Texas, Louisiana, and California, with smaller areas in other states.

Spores can remain viable for decades in the soil or animal products, such as dried or processed hides, and wool. Spores can also survive for 2 years in water, 10 years in

milk, and up to 71 years on silk threads. However, the vegetative organisms are thought to be destroyed within a few days during the decomposition of unopened carcasses (exposure to oxygen induces spore formation).

There are three forms of the disease in humans:

1) Cutaneous anthrax that develops after skin infections – this form is characterized by a papular skin lesion, which becomes surrounded by a ring of fluid-filled vesicles (as shown in picture). Most lesions (malignant carbuncle) are non-painful and resolve spontaneously; but disseminated, fatal infections occur in approximately 20% of cases.

2) Intestinal anthrax develops after eating contaminated meat. The initial symptoms may be mild malaise and gastrointestinal symptoms. Severe symptoms can develop and rapidly progress to shock, coma, and death.

3) Pulmonary anthrax occurs after inhaling spores in contaminated dust. Natural infections are mainly seen among workers who handle infected hides, wool, and furs (Wool Sorter's Disease). Symptoms may include fever, tiredness, and malaise; a nonproductive cough and mild chest pain may be present. Thereafter follows an acute onset of severe respiratory distress, with fatal septicemia and shock within one to two days. Fatalities may be prevented if treated early; however when symptoms are flu-like and non-specific, early treatment is not sought.

In animals, sheep, cattle, and horses are very susceptible, while dogs, rats, and chickens are resistant to disease. In ruminants, sudden death may be the only sign. However, the disease may manifest as flu-like symptoms; chronic infections often have edema.

In the 1950's and 1960's, *B. anthracis* was part of the U.S. bioweapons research program. In 1979, there was an accidental release of aerosol anthrax from a military compound in the Soviet Union. The neighboring residents experienced high fevers, difficulty breathing, and a large number died. Fatality estimates ranged from 200-1,000. In 1992, Russian President Boris Yeltsin finally acknowledged that the release occurred from a large-scale military research facility. In 1991, Iraq admitted it had done research on *B. anthracis* as a bioweapon.

There are several characteristics of *B. anthracis* make it attractive as a bioweapon. It is widely available and relatively easy to produce. The spores are infective, resistant, and remain infective when aerosolized. A lethal dose for inhalation of spores is low and mortality is high; the case-fatality rate for inhalational anthrax could approach 100%. Untreated pulmonary and intestinal infections are usually fatal, especially, if recognized too late for effective treatment. Person-to-person transmission of anthrax is very rare and has been reported only in cases of cutaneous anthrax.

Vaccines are available for humans who have a high risk of infection. The efficacy of the vaccine against inhalation of *B. anthracis* is unknown, and reactogenicity of the vaccine is mild to moderate. Vaccines are available for livestock. Natural strains of *B. anthracis* are usually susceptible to a variety of antibiotics, but effective treatment depends on early recognition of the symptoms. Treatment for cutaneous anthrax is usually effective, but pulmonary and intestinal forms are difficult to recognize and mortality rates are much higher. Prophylactic antibiotics are appropriate for all exposed humans. Anthrax spores

are resistant to heat, sunlight, drying, and many disinfectants, but are susceptible to sporicidal agents or sterilization.

<u>Botulism</u>

Toxins produced by Clostridium botulinum cause botulism, or "limber neck" in waterfowl. It is a gram positive, spore-forming, toxin-producing obligate anaerobic bacillus. The spores are ubiquitous in soil.

A German physician, Justinius Kerner in 1793, first discovered botulism. He called the substance "wurstgift", and found it in spoiled sausages. During this period, sausage was made by:

- 1. filling a pig's stomach with meat and blood,
- 2. boiling it in water; then
- 3. storing it at room temperature, which were ideal conditions for clostridial spores to survive

Botulism gets it name from "botulus", which is Latin for sausage.

United States federal regulations for food preservation resulted following several outbreaks of botulism. In the U.S., botulism spores germinate and release seven different antigenic types of neurotoxins; classified as A through G. Different neurotoxin types affect different species.

Only a few nanograms of the toxin can cause severe illness; and, all cause flaccid paralysis. Neurologic clinical signs, including generalized weakness, dizziness, dysphagia, and flaccid paralysis are similar in all species affected. In humans, gastrointestinal symptoms may precede the neurologic symptoms because the preformed toxin is ingested. In animals, many species of mammals and birds can be affected. Clinical disease is most often in wildfowl, poultry, mink, cattle, sheep, and horses. Ruminants and horses will often drool, while humans experience dry mouth. Paralysis of the respiratory muscles leading to death may occur in 24 hours in severe cases. Waterfowl are especially sensitive; pigs, dogs, and cats are moderately resistant.

Botulinum toxins are known to have been weaponized by several countries and terrorist groups in the past. It was part of the U.S. bioweapons program. Iraq has produced large volumes of this toxin, and the Aum Shinrikyo cult in Japan tried to use it unsuccessfully in 1990. The botulinum toxins are relatively easy to produce and transport. Botulinum toxin is extremely potent and lethal; and, is the single most poisonous substance known. Signs of a deliberate release of the toxin; either via aerosol, food, or water, is expected to cause clinical illness similar to food borne illness. Additionally, uncommon toxin types, such as C, D, F, or G, may be the culprits; and thus, raise suspicion of an intentional release.

In endemic areas, toxoids are typically used in horses, cattle, sheep, and goats; and investigational toxoids for high-risk laboratory workers are available. However, these toxoids are not effective for post-exposure prophylaxis. Botulinum antitoxin (trivalent) is sometimes used in animals, but response depends on the type of toxin causing the disease and the species of animal. In humans, if given early, the antitoxin may decrease the severity of disease and shorten the duration of symptoms. It has severe side effects,

and is only used on a case-by-case basis. The U.S. Army has an investigational heptavalent antitoxin. Antibiotics may be warranted if a wound is involved, but immediate intensive care may be the only treatment. Botulinum toxins can be inactivated by sunlight in 1 to 3 hours; as well as bleach, sodium hydroxide, or chlorinated water. The spores are very resistant in the environment but moist heat (120°C for at least 15 min) will destroy them.

<u>Tularemia</u>

Tularemia, or "rabbit fever", is caused by *Francisella tularensis*, a gram negative bacteria. The disease can be transmitted by:

- ingestion of infected, undercooked meat (rabbit);
- bites from infected ticks, and less commonly deerflies;
- through direct contact with blood or tissues of infected animals (especially rabbits); and
- inhalation of contaminated dust

Initial symptoms are flu-like; and they include fever, chills, headache, and myalgia. In humans, there are six clinical forms of tularemia – glandular and ulceroglandular are the most common presentation of this disease. An ulcer may or may not be present at site of infection, and local lymph nodes are enlarged.

Oculoglandular occurs when conjunctiva become infected by rubbing eyes with contaminated fingers, or by splashing contaminated materials in the eyes. The oropharyngeal presentation is caused by ingestion of organism in contaminated food (undercooked meat), or water.

Typhoidal and pneumonic forms usually occur following inhalation, or hematogenous spread of the organism. Both of these forms tend to present as atypical pneumonia; and most fatalities occur with these forms, and can be as high as 30-60% if untreated.

In animals, the full spectrum of clinical signs is not known. Sheep, young pigs, horses, dogs, and cats are susceptible to tularemia. Signs of septicemia such as fever, lethargy, anorexia, and coughing are most commonly seen. In wildlife, clinical disease is not often seen and animals are found dead or moribund. However, when infected hares and cottontails are observed, they behave strangely in that they are easily captured because they run slowly, rub their noses and feet on the ground, experience muscle twitch, are anorectic, have diarrhea, and are dyspneic. These lagomorphs are an important reservoir for human infection. Older swine and bovine seem to be resistant to disease and are asymptomatic.

In the 1950-60's, the United States military developed weapons that aerosolized *F. tularensis*, and it is suspected that other countries may have included this organism in their bioweapons research program as well. There are many characteristics that make *F. tularensis* a good agent for bioterrorism. It is stable, survives in mud, water, and dead animals for long periods; has previously been stabilized as a bioweapon. Only a low dose is needed to cause inhalational disease. Case fatality rates of the typhoidal and pneumonic forms are reported to be 30-60% if untreated. In 1969, the World Health Organization (WHO) estimated that if 50kg of virulent *F. tularensis* particles were

aerosolized over a city with 5 million people, the result would be 250,000 illnesses and 19,000 deaths. Recently, the CDC estimated the economic losses associated with an outbreak of tularemia to be \$5.4 billion for every 100,000 people exposed.

Person-to-person transmission has not been documented with a tularemia infection; so, secondary spread is of little concern. However, infectious organisms can be found in blood and other tissues; care must be taken when handling infected material. Antibiotics are generally effective if given early in the infectious process, and as a prophylaxis. There is a live attenuated vaccine (given intradermally or by scarification) that is available to individuals at high risk for exposure to the bacteria. The vaccines efficacy against high dose respiratory challenge is unknown. Disinfection of the bacteria is easily accomplished with many common disinfectants. However, the bacteria are stable at freezing temperatures for months to years.

Category B

The biological agents and toxins that fall into Category B are moderately easy to disseminate. They cause moderate morbidity, and low mortality. They require specific enhancements of the CDC's diagnostic capacity, and enhanced disease surveillance. The following agents and toxins are in Category B:

- Brucellosis (*Brucella* spp)
- Epsilon toxin (Clostridium perfringens)
- Food threats (Salmonella, E. coli O157:H7, Shigella)
- Glanders (Burkholderia mallei)
- Melioidosis (Burkholderia pseudomallei)
- Psittacosis (Chlamydia psittaci)
- Q Fever (Coxiella burnetii)
- Ricin toxin (castor beans)
- Staphylococcal enterotoxin
- Typhus (Rickettsia prowazekii)
- Viral encephalitis (VEE, WEE, EEE)
- Water safety threats (Vibrio cholera, Cryptosporidium parvum)

Brucellosis

Brucellosis, or undulant fever, is caused by various species of *Brucella*, a gram negative, facultative intracellular rod. The organism can persist in the environment and indefinitely if frozen in aborted fetuses or placentas. Transmission occurs thru:

- Ingestion-of infected food, or consuming infected unpasteurized milk or dairy products,
- Inhalation-of infectious aerosols (a means of infection in abattoirs); or
- Contact with infected tissues through a break in the skin or mucous membranes.

Brucellosis can involve any organ or organ system, and have a very insidious onset with varying clinical signs. The one common sign in all patients is an intermittent/irregular fever with variable duration; thus, the term undulant fever.

There are three forms of the disease in humans. In the acute form (<8 weeks from illness onset), symptomatic, nonspecific, and flu-like symptoms occur. The undulant form (< 1 yr. from illness onset and symptoms) include undulant fevers, and arthritis. In the chronic form (>1 yr. from onset), symptoms may include chronic fatigue-like syndrome and depressive episodes. Illness in people can be very protracted and painful; and can result in an inability to work, and loss of income. In animals, the clinical signs are mainly reproductive, such as abortions, epididymitis, orchitis, and fistulous withers in horses.

The following indicates the *Brucella* species, the bacterial host, and human pathogenesis:

- B. abortus > cattle, bison, elk or horses > yes
- B. melitensis > goats, sheep or cattle > yes
- B. suis > swine, hares, reindeer, caribou, or rodents > yes
- B. canis > dogs, or other canids > yes
- B. ovis > sheep > no

In the 1950's when the U.S. bioweapons research program was active, *Brucella suis* was the first agent weaponized. The World Health Organization prepared a bioterrorism scenario looking at aerosolized *B. melitensis* (which has more serious consequences for humans than *B. suis*) spread along a line with the prevailing winds with optimal meteorological conditions. It was assumed that the infectious dose to infect 50 (ID50) percent of the population would require inhalation of 1,000 vegetative cells. The case fatality rate was estimated to be 0.5% with 50% of the people being hospitalized and staying an average of seven days. It is highly infective, and moderately stable in this form. Incubation period in humans is one week up to several months, which often complicates the diagnosis due to the latency of clinical signs. Person-to-person transmission is very rare.

Prolonged antibiotics are necessary to penetrate these facultative intracellular pathogens. Combination therapy has shown the best efficacy for treatment in humans. Vaccinating calves has helped eliminate infection in these animals, thus decreasing possible exposure to humans. Strict adherence to federal laws of identifying, segregating and/or culling infected animals is essential to success. Properly protect yourself to prevent exposure to tissues and body secretions of infected animals by wearing gloves, masks, goggles, and coveralls. Pasteurization or boiling milk and avoidance of unpasteurized dairy products will help decrease human exposure to brucellosis. The organism is susceptible to many disinfectants.

Equine Encephalitis

Encephalitis is the only viral group in the list of Category B agents. This group of equine encephalitis viruses is RNA viruses in the Alphavirus genus. Eastern, Western, and Venezuelan Equine Encephalitis viruses are transmitted by mosquitoes.

The female mosquito takes a blood meal from a viremic host, generally birds for EEE and WEE, and birds and horses for VEE. The virus replicates in the salivary glands of the mosquito and is transmitted back to birds or to dead end hosts, such as humans and horses, where overt disease occurs. In humans, infections can be asymptomatic or

cause flu-like illness. In a small proportion of cases viral encephalitis can occur, and lead to permanent neurological damage or death.

Horses, donkeys and mules have similar clinical signs as humans. The disease in these animals often precedes human cases by several weeks. EEE and VEE have mortality rates of 40-90%; WEE has a lower mortality rate, ranging from 20-30%. Birds are asymptomatic carriers. The detection of viremia in sentinel birds is detected via ELISA.

VEE was tested in the U.S. bioweapons program in the 1950s and 1960s. It is thought that other countries have also weaponized VEE. All U.S. stocks of VEE were destroyed, along with the other agents that were part of the program. VEE can be produced in large amounts by unsophisticated and inexpensive systems. The virus can be aerosolized or spread by releasing infected mosquitoes. Humans are highly susceptible. Approximately 90-100% of exposed individuals could become infected and have clinical signs, although most are mild. Equids would also be susceptible, and disease would occur simultaneously with human disease. There is a low overall human case-fatality rate.

Antibiotics are not effective for treatment, and there are no effective antiviral drugs available. Treatment involves supportive care. There is a trivalent formalin inactivated vaccine available for horses for WEE, EEE, and VEE in the United States; but the human vaccines is limited to those who are researchers, and at a high risk of exposure. All of the virus types are unstable in the environment.

Category C

The agents that fall into Category C include emerging pathogens that could be engineered for mass dissemination in the future because of availability, ease of production and dissemination, the potential for high morbidity and mortality rates, and major health impact. Following are the agents that fall into Category C:

- Nipah virus
- Hanta virus

<u>Nipah</u>

Nipah virus (a Paramyxovirus) was discovered in Malaysia in 1999, and causes a severe respiratory disease in pigs and severe encephalitis in humans. The reservoir for the virus is thought to be fruit bats, which are called flying foxes. Suspected transmission of the virus occurs from bats roosting in fruit trees close to pig confinements. The virus then spreads rapidly through the swineherd by direct contact, or aerosolization (usually coughing). It can then be passed to humans, dogs, cats and other species.

Transmission can also occur from direct contact with infected body fluids. To date, no person-to-person, or bat-to-person transmission, has been reported. In humans, the incubation period is 3-14 days. Initial symptoms include fever, headache, dizziness, drowsiness, disorientation and vomiting. Some cases show signs of respiratory illness. In severe cases, rapidly progressive encephalitis can occur, with a mortality rate of 40%.

In swine, Nipah virus is highly contagious and easily spread. Many pigs are asymptomatic. Clinical signs include acute fever (>104° F), tachypnea and dyspnea with

open mouth breathing, and a loud, explosive barking cough may be noted. Occasionally, neurological signs can occur. Clinical signs in pigs were noted 1-2 weeks before illness in humans making swine a sentinel for human disease. Disease in other animal species is poorly documented. Other species demonstrate respiratory and neurological signs.

Nipah virus is described as an emerging pathogen with potentially high morbidity and mortality, as well as a major health impact. Currently transmission of the disease involves close contact with pigs, but aerosolization may be a possible bioterrorism method of dispersal. The potential for this virus to infect a wide range of hosts and produce significant mortality in humans makes this virus a public health concern.

Nipah virus is a very dangerous pathogen and is classified as a Biolevel 4 agent. If you suspect an outbreak, contact your state veterinarian and state public health veterinarian IMMEDIATELY! Avoid all contact with potentially infected species (pigs, dogs, cats) until the proper authorities are consulted. Detergents can readily inactivate Nipah virus. Routine cleaning and disinfection with sodium hypochlorite, or several commercially available detergents, is expected to be effective.

Radiological/Nuclear Agents

"Nuclear" involves a fission reaction (nuclear weapon, nuclear power plant, satellites, and waste processing facility). It requires special nuclear material, such as plutonium and/or uranium. "Radiological" involves radionuclides, which can be dispersed or deposited. Accidents such as the reactors at Three Mile Island in Pennsylvania (small release) and Chernobyl in Russia (large catastrophic release), have taught us about the effects on the agriculture and the food supply. Those lessons focus on making decisions to evacuate if establishment conditions worsen or remain unstable. Additionally, the federal government has extensive plans, and practices emergency response around nuclear facilities in the U.S.

Targets and Pathways

There are many methods of delivery and points in the agriculture process that an agent could be introduced. Covert, or stealth, introductions will go unnoticed for a longer period than overt introduction because we will be treating it as if it occurred under natural conditions. The simultaneous release of three to four highly contagious, foreign animal pathogens in several locations around the country at key points would be overwhelming.

High-density population areas represent tempting terrorist targets. Most lack even rudimentary monitoring capabilities. Some examples include:

- Urban population centers,
- Business centers,
- Transportation nodes,
- Special events (e.g., political conventions, Super Bowl, Olympics, etc.), or
- Agribusiness and national food supply infrastructure.

Terrorists can exploit multiple pathways. They can introduce biological, radiological, chemical, or other types of harmful agents into the population in a variety of ways, including:

- Air dispersion (line and point source),
- Public transportation,
- Water supplies,
- Food distribution systems, and
- Mail distribution systems

Consequences

While the topic of food defense is highly concerned with the intentional introduction of foreign agents, there is the possibility that international travelers might bring one or more microbial agents into the U.S. accidentally. At first onset, an intentional outbreak of a disease in animals or crops is hard to differentiate from a natural outbreak, which delays finding the true source. False claims and hoaxes can be introduced to diminish public confidence in food safety for particular commodities or products. A false report of one case of BSE occurring in the U.S. would send the beef industry into a tailspin for a brief time, losing perhaps tens of millions of dollars or more in overall costs. Foreign trading partners might hear of the rumor and implement a trade ban. The perpetrator relies upon the media to do the damage for him/her by spreading the rumors and presenting fiction as fact. Clues generated by an outbreak might point toward an intentional introduction.

The impact and consequences from a foreign animal disease such as Foot and Mouth Disease (FMD) in the U.S. could be severe. Harsh restrictions on movement would be enacted. We would see road closures, quarantined farms, and animal movement ceased. Access to campsites, state parks, wilderness areas, lakes, city parks, and zoos may be denied.

The psychological impact and mental health of livestock producers, veterinarians and the local community could be negatively affected if entire herds are quarantined and destroyed. Some of the images the outbreak produces could shock the public and alter their buying habits as consumers. It is unlikely that a terrorist attack would create mass food shortages, but movement restrictions could complicate availability temporarily.

Food Defense Self-Assessment Checklist for

Slaughter and Processing Plants

Outside Security

1. What food defense measures does your plant have in place for the exterior of the building?

	Yes	No	N/A
Are the plant's grounds secured to prevent entry by unauthorized persons (<i>e.g.</i> , by locked fence, gate or entry/exit doors)?			
Is there enough lighting outside the building to properly monitor the plant at night/early morning?			
Do emergency exits have self-locking doors and/or alarms?			

2. Are the following secured with locks, seals, or sensors when unattended (after hours/weekends) to prevent entry by unauthorized persons?

	Yes	No	N/A
Outside doors and gates?			
Windows?			
Roof openings?			
Vent openings?			
Trailer (truck) bodies?			
Tanker truck hatches?			
Railcars?			
Bulk storage tanks/Silos?			

3. Does your facility have food defense procedures for people and/or vehicles entering the plant and/or parking in your lot?

	Yes	No	N/A
Does the property have a controlled or guarded entrance?			
Are <u>employee</u> vehicles identified using placards, decals, or some other form of visual identification?			
Are authorized <u>visitor/guest</u> vehicles identified using placards, decals, or some other form of visual identification?			

General Inside Security

4. Does your facility have food defense measures inside the establishment?

	Yes	No	N/A
Is there an emergency lighting system in the facility?			
Does your plant have <u>monitored</u> security cameras (CCTV)?			
Does your plant have an emergency alert system that is tested regularly?			
Are the locations of controls for emergency alert systems clearly marked?			
Are all restricted areas (<i>i.e.</i> , areas where only authorized employees have access) clearly marked?			
Are visitors, guests, and other non-employees (<i>e.g.</i> , contractors, salespeople, truck drivers) restricted to non-product areas unless accompanied by an authorized employee?			
Does local law enforcement (including the fire department) have up-to-date copies of facility layouts/blueprints?			
Are procedures in place to check toilets, maintenance closets, personal lockers, and storage areas for suspicious packages?			
Do you regularly take inventory of potentially dangerous tools and utensils (<i>e.g.</i> , knives)?			
Do you regularly take inventory of keys to secured/sensitive areas of the facility?			
Are ventilation systems constructed in a manner that provides for immediate isolation of contaminated areas or rooms?			

 Are the controls for the following systems restricted (*e.g.*, by locked door/gate or limiting access to designated employees) to prevent access by unauthorized persons? (Helpful information is provided at the following website: www.cdc.gov/niosh/bldvent/2002-139.html)

	Yes	No	N/A
Heating, Ventilation, and Air Conditioning systems?			
Propane Gas?			
Water systems?			
Electricity?			
Disinfection systems?			
Clean-in-place (CIP) systems or other centralized chemical systems?			

6. Does your plant collect and analyze samples in-house for microbiological, chemical or physical hazards?

Yes

No [Go to Question 8]

7. Which of the following food defense procedures does your facility have in place for its in-plant laboratory facilities, equipment, and operations?

	Yes	No	N/A
Is access to the in-plant laboratory facility restricted to authorized employees? (<i>e.g.</i> , by locked door, pass card, etc.)			
Is a procedure in place to control receipt of samples received from other establishments?			
Is a procedure in place to receive and securely store reagents?			
Is a procedure in place to control and dispose of reagents?			

- 8. Does your facility use a computer system to monitor processing operations?
 - Yes



No [Go to Question 10 under Slaughter and Processing Security]

9. Does your facility have food defense procedures in place for its computer systems?

	Yes	No	N/A
Is the access to the system password-protected? (Helpful information is provided at the following website: http://www.umich.edu/~policies/pw-security.html)			
Are firewalls built into the computer network?			
Is the system using a current virus detection system?			

Slaughter and Processing Security

10. Which of the following food defense procedures does this facility have in place for its slaughter and processing operations?

	Yes	No	N/A
Is access to product production/slaughter and holding pen areas restricted to establishment employees and FSIS inspection personnel only?			
Are lines that handle and transfer products, water, oil, or other ingredients monitored to ensure integrity?			
Are packages of ingredients examined for evidence of tampering before use?			
Is access to in-plant irradiation equipment and materials restricted?			
Are records maintained to allow easy trace-back of raw materials to suppliers?			
Are records maintained so as to allow easy trace-forward of finished products to vendors?			

Storage Security

11. Which of the following food defense procedures does your facility have in place for its storage areas?

	Yes	No	N/A
Is access to raw product storage areas, including cold and dry storage areas restricted (<i>e.g.</i> , by locked door/gate or other) to designated employees?			
Is an access log maintained for raw product storage areas?			
Is access to non-meat ingredient storage areas restricted to designated employees only?			
Is an access log maintained for non-meat ingredient storage areas?			
Is access to finished product storage areas restricted to designated employees?			
Is access to external storage facilities restricted to designated employees only?			
Do you conduct regular security inspections of storage facilities (including temporary storage vehicles)?			
Do you maintain records on facility security inspections results?			
Is the inventory of restricted ingredients (i.e., nitrites, etc) checked against the actual use of such ingredients on a regular basis?			
Are product labels and packaging held in a controlled manner to prevent theft and misuse?			
Is the inventory of finished products regularly checked for unexplained additions and withdrawals from existing stock?			

12. Which of the following food defense procedures does your facility have in place for the storage of hazardous materials/chemicals such as pesticides, industrial chemicals, cleaning materials, sanitizers, and disinfectants?

	Yes	No	N/A
Is the access to inside and outside storage areas for hazardous materials/chemicals such as pesticides, industrial chemicals, cleaning materials, sanitizers, and disinfectants restricted in some manner to allow use by designated employees only?			
Is a regular inventory of hazardous materials/chemicals maintained?			
Are discrepancies in daily inventory of hazardous materials/chemicals immediately investigated?			
Are the storage areas for hazardous materials/chemicals constructed and safely vented in accordance with national or local building codes?			
Is a procedure in place to receive and securely store hazardous chemicals?			
Is a procedure in place to control disposition of hazardous chemicals?			

Shipping and Receiving Security

13. Does your facility have food defense procedures in place for its shipping and receiving operations? (Helpful information is provided at the following website: http://www.fsis.usda.gov/oa/topics/transportguide.htm)

	Yes	No	N/A
Are trailers on the premises maintained under lock and/or seal when not being loaded or unloaded?			
Are tanker trucks on the premises maintained under lock and seal when not being loaded or unloaded?			
Is the loading and unloading of vehicles transporting raw materials, finished products, or other materials used in food processing closely monitored?			

14. Does your facility have food defense procedures in place for handling outgoing shipments?

	Yes	No	N/A
Are outgoing shipments sealed with tamper-evident seals?			
Are the seal numbers on outgoing shipments documented on the shipping documents?			
Are tanker trucks and/or rail cars inspected to detect the presence of any material, solid or liquid, in tanks prior to loading liquid products?			
Do you keep records of the above-referenced inspections of tanker trucks and/or rail cars?			
Are chain-of-custody records maintained for tanker trucks and/or rail cars?			

15. Which of the following food defense procedures does your facility have in place for handling incoming shipments?

	Yes	No	N/A
Is access to loading docks controlled to avoid unverified or unauthorized deliveries?			
Is advance notification from suppliers (by phone, e-mail, or fax) required for all incoming deliveries?			
Are suspicious alterations in the shipping documents immediately investigated?			
Are all deliveries checked against the roster of scheduled deliveries?			
Are unscheduled deliveries held outside facility premises pending verification?			
Are off-hour deliveries accepted?			
If off-hour deliveries are accepted, is prior notice of the delivery required?			
If off-hour deliveries are accepted, is the presence of an authorized individual to verify and receive the delivery required?			
Are less-than-truckload (LTL) or partial load shipments vehicles checked?			
Are incoming shipments of raw product, ingredients, and finished products required to be sealed with tamper-evident or numbered seals (and documented in the shipping documents)? Are these seals verified prior to entry?			
Do you check incoming shipments of raw product, ingredients, and finished products at the receiving dock for evidence of tampering?			
Is the FSIS Public Health Veterinarian notified immediately when animals with unusual behavior and/or symptoms are received?			
Are the feed and drinking water supplies for live animals protected from possible intentional contamination?			
Are transportation companies selected with consideration of the company's ability to safeguard the security of product/animals being shipped?			
Do the transportation companies perform background checks on drivers and other employees who have access to product/animals?			
Have your ingredient suppliers taken steps to strengthen food defense in their facilities and during transport?			
When choosing your compressed gas vendor do you consider whether or not they have implemented food defense measures?			
When choosing your packaging materials and labels vendor do you consider whether or not they have implemented food defense measures?			

16. Does this facility allow returned goods, including returns of U.S. exported products, to enter the plant?

Yes

No [GO Question 18 under Water and Ice Security]

17. Which of the following food defense procedures does this facility have in place for returned goods?

	Yes	No	N/A
Are all returned goods examined at a separate designated location in the plant for evidence of possible tampering before salvage or use in rework?			
Are records maintained of returned goods used in rework?			
Does the plant follow the procedures outlined in FSIS Directive 9010.1 for return of U.S. exported products?_(Helpful information is provided at the following website: http://www.fsis.usda.gov/opped/rdad/fsisdirectives/9010-1.pdf)			

Water and Ice Security

18. Which of the following food defense procedures does your facility have in place for its water and ice supply? (Helpful information is provided at the following website: http://www.epa.gov/region1/eco/drinkwater/pdfs/drinkingH2Ofactsheet.pdf)

	Yes	No	N/A
Is access to water wells restricted? (<i>e.g.</i> , by locked door/gate or limiting access to designated employees)			
Is access to ice-making equipment restricted?			
Is access to ice storage facilities restricted?			
Is access to storage tanks for potable water restricted?			
Is access to water reuse systems restricted?			
Are <u>potable</u> water lines periodically inspected for possible tampering? (i.e., visual inspection for physical integrity of infrastructure etc.)?			
Are <u>non-potable</u> water lines inspected for possible tampering (i.e., visual inspection for physical integrity of infrastructure, connection to potable lines, etc.)?			
Have arrangements been made with local health officials to ensure immediate notification of the plant if the potability of the public water supply is compromised?			

Mail Handling Security

19. Which of the following food defense procedures does this facility have in place to ensure mail handling security?

	Yes	No	N/A
Is mail handling activity conducted in a separate room or facility away from in-plant food production/processing operations?			
Are mail-handlers trained to recognize and handle suspicious pieces of mail using U.S. Postal Service guidelines? (Helpful information is provided at the following website: http://www.usps.com/news/2001/press/serviceupdates.htm)			

Personnel Security

20. Which of the following food defense procedures does your facility have in place for ensuring that personnel adhere to the security requirements?

	Yes	No	N/A
Are background checks conducted on all employees and contractors (both permanent and seasonal) who will be working in sensitive operations?			
Do all plant employees receive training on security procedures as part of their orientation training?			
Are employees, visitors, and contractors (including construction workers, cleaning crews, and truck drivers) identified in some manner at all times while on the premises?			
Does your plant control access by employees and contractors entering the plant during <u>working</u> hours (<i>e.g.</i> coded doors, receptionist on duty, swipe card, etc.)?			
Does your plant control entry of employees and contractors into the plant during <u>non-working</u> hours (<i>e.g.</i> access limited by key card or code number)?			
Does your plant have a way to restrict temporary employees and contractors (including construction workers, cleaning crews, and truck drivers) to areas of the plant relevant to their work?			
Is there some manner to identify personnel with their specific functions/assignments/departments (<i>e.g.</i> , corresponding colored uniforms)?			
Is an updated shift roster (i.e., who is absent, who the replacements are, and when new employees are being integrated into the workforce) kept by management for each shift?			
Does your plant allow personal items within production areas?			
Do you inspect employee lockers?			
Are employees and/or visitors restricted as to what they can bring (cameras, etc.) into the plant?			
Are employees prohibited from removing company-provided clothing or protective gear from the premises?			

Food Safety Education

OBJECTIVE

At the end of this module, you will be able to:

- 1. explain the goal of the FSIS food safety education program.
- 2. identify the highest risk populations for foodborne illnesses

INTRODUCTION

This module will introduce you to the FSIS food safety education program.

FSIS public educational programs have considerable science-based planning strategies to:

- reach the "general public;"
- utilize marketing principles to "sell" food safety behaviors; and
- target those most at-risk for foodborne illness.

The success of food safety education has been recently documented in studies. For example, consumer's knowledge and use of food safety practices is increasing. Consumers are demonstrating a greater awareness of foodborne pathogens and risks.

Recent consumer research has proven that consumers report making changes in how they handle and prepare food. These behavior changes have been attributed to food safety education information provided by the media

Consumers are confident in themselves and the food supply. However, many do not follow some recommended safe handling practices. Because of the last point, FSIS has partnered with many organizations and agencies to improve safe handling practices.

FOOD SAFETY EDUCATION PROGRAMS

FSIS has 5 key education programs to reach the general public. They include the following:

- 1. The USDA Food Safety Mobile
- 2. The Meat and Poultry Hotline
- 3. The Fight BAC![™] Campaign
- 4. Cooking for Groups
- 5. Science and Food Supply Program for High School

The USDA Food Safety Mobile:

This is the newest addition to the successful FSIS consumer educational campaign.

The USDA Food Safety Mobile, a bus, travels all over the country. FSIS personnel who are staffing the bus attend a variety of local events and use those events as opportunities to educate the public about the practices for safe food handling. The schedule of the Food Safety Mobile is posted in an Outlook public folder, and on the FSIS website. If the bus is in your area, work with your supervisor to make sure those at work; and, in your community are aware of it. You can also let the Food Safety Education staff know of an event planned in your area and it may be possible to have the bus there if planned well enough in advance.

The Meat and Poultry Hotline:

The Meat and Poultry Hotline is one of the most important public service outreach activities. It is staffed by food safety experts who can answer a variety of questions from all types of callers. The Hotline receives over 100,000 calls annually. Most callers want to know basic food safety information. Any Information that callers share about food safety complaints is entered into the FSIS Consumer Complaint Monitoring System so that emerging or on-going problems can be investigated.

The Fight BAC!™ Campaign:

The Fight BAC! [™] Campaign is an example of FSIS partnership In action. This has been a successful public service campaign for several years now with all aspects of the food industry including retail stores, restaurants, consumer groups, states and other government agencies. All of these groups distribute the brochures of the campaign. You may have seen the public service announcements on television or heard them on the radio. Your children may have brought some of the campaign materials home from school.

The Fight BAC message is simple:

- Clean off BAC.
- Separate don't cross contaminate and spread BAC.
- Cook to the right temperature to kill BAC.
- Chill foods properly- don't let BAC grow!

This is a simplified version of basic food safety principles. The Fight BAC caricature is very popular with kids!

Cooking for Groups:

Cooking for Groups has been another key public service campaign. FSIS has produced a Volunteer's Guide to food safety. Currently over 370,000 brochures have been Distributed in English and 70,000 have been distributed in Spanish. This guide reached over 60 million people when it was released through newspaper articles.

Science and Food Supply Program for High School:

FSIS has joined a national coalition with the CDC to deliver science-based food safety information to schools. This coalition information is being provided throughout the US educational system.

Go to the website www.FoodSafeSchool.org for more information on the latest materials and activities.

One of the most successful Food Safety in Schools program is the supplementary curriculum for Middle Level and High School Classrooms called "Science and Our Food Supply", including food safety from A to Z - or everything from acidification to zoonoses/zoonosis. This curriculum was co-funded by the Food and Drug Administration and the National Science Teachers Association. The video "Dr. X and the Quest for Food Safety," received an Emmy award from the National Academy of Television Arts and Sciences, Mid Atlantic Region for its creative and entertaining approach to teaching food safety.

The modules are:

- 1. Understanding bacteria
- 2. Farm
- 3. Processing and Transportation
- 4. Retail and Home
- 5. Outbreak and Future Technology

To keep up with the latest information on Science and Our Food Supply, you can log onto to FDA's website: <u>FoodSafety.gov</u>.

FSIS has partnered with <u>Health Schools, Healthy People Program SNAP</u> – School Network for Absenteeism Prevention, a hands-on initiative for middle schools that's designed to help keep students in school and learning by improving overall health through promoting clean hands. The Centers for Disease Control and Prevention reports that hand washing is the most important thing you can do to keep from getting sick (<u>CDC</u> <u>- Handwashing: Clean Hands Save Lives</u>). Schools can use the SNAP program to increase student and staff hand cleaning and help them stay healthy. SNAP offers a free educational poster-toolkit that makes it easy to incorporate clean hands education into middle school curricula. The SNAP Toolkit has been piloted in schools in more than 40 states and Canada. You can get a school in your local area involved too - by downloading the SNAP Toolkit from the FSIS web site.

FOOD SAFETY EDUCATION MESSAGES

The following are some key food safety facts shared with the public in the public awareness campaigns:

THERMY

Cooking studies have shown that color is not a reliable indicator of food safety. Since E. coli O157:H7 is a major pathogen of concern for products FSIS regulates, the Agency worked closely with USDA Agriculture Research Service (ARS) to determine if consumers could really tell if a hamburger was cooked to a safe level by using the traditional method of looking at the color of the meat and juices. The study showed that cooking for food safety by color can be misleading. One out of 4 hamburgers turns brown before it reaches a safe temperature. The ARS concluded that using a food

thermometer is the only reliable way to determine if food is safely cooked. In 1994 Hotline survey, less than 50% of the callers reported that they owned a food thermometer. Most of those who had a thermometer used it only for the Thanksgiving turkey, if at all. Very few reported that they used it for all types of meat and poultry products.

Consumer attitudes about using a food thermometer included:

- Inconvenience -- "It's a hassle."
- Added expense to purchase a thermometer.
- Experience they feel it is not necessary to use a thermometer "they know when food is done".
- They have been cooking for years without experiencing any ill effects.

After receiving the results of this study, FSIS conducted scientific focus group studies to see what would cause people to change their behaviors to begin using thermometers to help them determine when food had been cooked to a safe temperature. The key finding of these studies was that behavior change is possible under the following circumstances.

Parents of young children are most likely to change behavior -but for their children only. Upscale cooks interested in quality foods might consider use of a thermometer to avoid overcooking.

After much development, FSIS launched the national campaign character "THERMY" who teaches: It's safe to bite when the temperature is right!



The Multi-Faceted Campaign included life-sized Thermy's visiting public relations and education events, brochures in several languages with specific temperature guidelines for all meat and poultry products, promotions using the T-stick in hamburgers and food thermometers for all cooked meat and poultry products.

Question: What temperature should ground hamburger reach to kill all pathogens? Answer: 160 degrees F (71 degrees C) internal middle temperature, or when the T Stick turns black after 5 seconds inside the hamburger. If ground beef is still pink inside, don't eat it. This is critically important especially for the young, elderly or immunocompromised. FSIS believes the Thermy campaign has been successful. A 2001 national survey shows:

- 1. 60% own a food thermometer, up from 46% in 1998;
- 2. 6% use a thermometer when cooking hamburgers; up from 3% in 1998;
- 3. Industry sales data show an increase in sales of thermometers.

Listeria

Another key educational campaign concerns *Listeria*. It targets persons who are most at risk from the effects of listeriosis. Listeriosis primarily affects pregnant women (the fetus) and infants, senior citizens, and persons with weakened immune systems and chronic illnesses.

FSIS conducted focus groups with pregnant women. We found that they were confident in their ability to handle food safely, but did not always follow safe practices. They were also unfamiliar with *Listeria monocytogenes* and the dangers of listeriosis; and, they were not aware that they are at risk. The study also found that these women did not get any type of food safety information from their doctors. They did not know to cook hot dogs and luncheon meats and did not know to avoid certain cheeses and other foods that have been implicated in outbreaks of listeriosis. They had not made any food handling changes since becoming pregnant. However, they were very willing to change when provided the information.

The focus group analysis findings were that:

- The best way to educate pregnant women on steps they must take to prevent listeriosis is through their doctor or caregiver.
- Obstetricians, nurses and other care providers must be made aware to inform patients.
- Information should be widely disseminated through books, magazines, and web sites.

The Agency also published Listeria Facts with the CDC and distributed them throughout the public health and medical communities. Currently a low-literacy brochure is also under development.

Education package for senior citizens

Another key public service educational campaign for high risk consumers is the educational package for senior citizens entitled, "To your health! Food Safety for Seniors." It includes a video and a brochure. It is distributed to senior centers and educators.

FSIS is working on reaching immuno-compromised audiences. There is research underway at Ohio State University through a CSREES grant on the following:

• HIV/AIDS populations

- Bone marrow transplant patients
- Solid organ transplant patients
- Senior citizens
- Solid organ cancer patients

One of the most successful public service partnerships is the one that produced the Physicians Primer. The American Medical Association, CDC, FDA Center for Food Safety and Applied Nutrition and FSIS partnered to produce, "Diagnosis and Management of Foodborne Illnesses: A Primer for Physicians".

In summary, our public health educational, and regulatory goal, is to eliminate BAC.

DIRECTIVES

There are two Directives related to communicating and interacting with groups outside of FSIS that you should be familiar with. One is Directive 1050.1. It covers the guidance on requesting participation at meetings and events, such as the ones we have been talking about, like fairs or other public events where we can promote the food safety message, including recruiting events. The other is Directive 1240.1. It covers communicating with external entities, such as the media, Congressional staff, and others. Please review both of these directives and be aware that you are responsible for following this guidance.

Additionally, the new web-based Meetings Attendance System was added to the meeting request references on April 26, 2005. This system allows FSIS staff to enter information about outside meetings into the automated system, where that information is available for immediate review by the Assistant Administrators and the Administrator. Once you have entered your information in the system, you will receive an email message acknowledging that your request has been entered. Once reviewed, you will receive another email once your request has been acted on. This system does not replace the other steps as discussed in the Directives, but does help with the coordination of speaking engagements.

It's important that the message we deliver is accurate and consistent with Agency policy.