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.

Identify the steps taken to encourage an establishment to enhance its food security measures when food defense.

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.
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INTRODUCTION

This module will address food defense activities in FSIS. First, we'll 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'll talk about your role and inspection activities that are related to food security.

Let's start by reviewing the mission and vision of FSIS, because it's this infrastructure that has been called to task to address 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. We have over 7,600 inspectors including approximately 1,100 veterinarians present, at 6,500 slaughter and processing establishments every day, as well as, import stations throughout the nation. We have an enormous responsibility to ensure that we provide the safest food possible for the American public.

Prior to September 11, FSIS was focused primarily on protecting meat, poultry, and egg products from unintentional harm. The events of September 11, 2001, brought the issue of the vulnerability of our food supply to the forefront. We must accept the fact that an attack on our food supply is plausible. This meant that FSIS had to add functions to protect the food supply against intentional harm.

Food defense encompasses a broader range of considerations. Dealing with issues involving the possible intentional contamination of food due to a terrorist act requires addressing these factors:

- Physical security of buildings,
- Surveillance and monitoring activities to identify and help prevent intentional acts intended to disrupt the food supply,
- Personnel security, and
- Emergency response.

Bill Frist, a physician and former Senator, one of the original sponsors of the Bioterrorism Preparedness Act signed into law in 2002, has indicated that "…as we consider bioterrorism, we are most vulnerable in our food supply." We in FSIS must no longer conduct business as usual, but must consider the unusual everyday, in every way.

Food terrorism is term that is used worldwide to describe terrorist acts where there is use, or threatened use, of a biological, chemical, or radiological agent(s) against some component of food production; in such a way as to adversely impact the food industry or any component thereof, the economy, or the consuming public. Within FSIS, food terrorism is further focused down to how terrorism relates to meat, poultry and egg products. We cumulatively discuss intentional attacks on those food products that we regulate as "Food Defense".

There are several components to terrorism. Beyond food terrorism, bioterrorism is often defined as the use of biological agents that target humans, plants or animals; and, was exemplified in the September 11th attacks and anthrax letters that were used in 2001 against the American people. And finally, there are other terrorism components such as conventional, radiological, nuclear, chemical, and cyber that are typically directed at the human population. 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.

Overview of Food Defense Awareness

Before we cover some specifics about your responsibilities for protecting meat, poultry, and egg products from intentional harm, let's cover some basics of food defense awareness. 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.

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
- Agrobusiness 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.

Here are the reasons why the food supply is a plausible and possible target:

- With low security of facilities and personnel, it could be an easy target.
- 100% 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 that is designed to harm people; and, the situations which occur unintentionally.

Recent Examples of Attacks on the Food Supply

Recent history has shown that terrorists can, and will, use food as a weapon. Let's trace some of these incidents.

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 a study by Anne Dawson, Sarah Hassenpflug and James Sloan of the Monterey Institute of International Studies (Monterey California), found that the med fly poses perhaps the single greatest pest-related threat to California's multi-billion dollar agriculture export industry. The pest is responsible for the mass destruction of a wide variety of crops, and continues to plague farmers and growers throughout the world.

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.

In October 1996, Diane Thompson, 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; and, she sent a bogus E-mail message from her supervisor's computer. Her activities were discovered when she tried to alter hospital records to cover her tracks.

1996, police received an anonymous call from a worker at a rendering plant in Wisconsin. The caller said liquid fat from the plant had been contaminated. It was determined that chlordane was the contaminate, 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 on to 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.

What must a terrorist have to carry-out 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.

How can a terrorist organization gain technical capability? Can they recruit American food system workers? Or, gain knowledge by talking with food system workers during what appears to be simple 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.

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.

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 of these 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. The public could be shocked by some of the images the outbreak produces, 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.

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

Biological compounds used as chemical agents: 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 blood-forming 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 vapors irritate the mucosa of the nasal and upper respiratory system. 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 type of 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. As a consequence, 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.

Nerve agents: 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 in terms of how they work, and the kinds of harmful effects they cause. However, nerve agents are much more potent than organophosphate pesticides.

Heavy metals: 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. It is also 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, 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, reviewing the agents and what we currently know about them is still important for our enhanced awareness of these agents.

The Centers for Disease Control (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's 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)

Anthrax

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 which 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 almost always 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>

Botulism, or "limber neck" in waterfowl, is caused by toxins produced by *Clostridium botulinum*. It is a gram positive, spore-forming, toxin-producing obligate anaerobic bacillus. The spores are ubiquitous in soil.

Botulism was first discovered by a German physician, Justinius Kerner in 1793. He called the substance "wurstgift", and found it in spoiled sausages. During this period of time, 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 7 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; and pigs, dogs, and cats are fairly 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 foodborne 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 dyspnic. 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 which 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 of time; and, 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*)

<u>Brucellosis</u>

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 via:

- 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 3 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 in nature; such as abortions, epididymitis, orchitis, and also fistulous withers in horses.

The following indicates the specific brucellosis species, host and whether it is a human pathogen:

- 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 meteorologic 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 fairly 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, 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

Nipah

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 swine herd 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 also 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. Nipah virus can be readily inactivated by

detergents. 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 plant conditions worsen or remain unstable. Additionally, the federal government has extensive plans, and practices emergency response around nuclear facilities in the U.S.

Federal Efforts to Address Food Defense

The following is an overview of federal activities related to food defense.

Homeland Security Presidential Council

This presidential level council has oversight of all homeland security issues, including food defense. It is responsible for issuing all Presidential Directives related to homeland security. Food and agriculture is a subgroup represented on the council through the Interagency Food Working Group.

Department of Homeland Security

The mission of the Department of Homeland Security includes preventing terrorist attacks within the U.S, reducing America's vulnerability to terrorism, minimizing damage, and ensuring recovery from attacks that do occur.

Public Health Security and Bioterrorism Act of 2002 – Section 332

This new legislative measure has allowed FSIS to enhance our existing authorities. FSIS may utilize existing authorities, such as those provided by the Bioterrorism Act of 2002, to give high priority to enhancing and expanding the capacity to conduct activities to enhance the ability of the agency to inspect and ensure the safety/wholesomeness of meat & poultry products.

Operation Liberty Shield

An example of applying the principles of Section 332 occurred at the beginning of the war in Iraq when the federal government was on heightened orange 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, in-plant IIC's initiated new security-based inspection measures as part of PBIS. 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 increased its coverage. FSIS's 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 inspection tasks that were not related to food safety 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. This is different from Homeland Security Advisory System. It involved a temporary enhancement of the Homeland Security Advisory System. Details of the activities are classified.

Agriculture Border Controls

In the past, agriculture border controls were maintained by the USDA-APHIS-Plant Protection and Quarantine. These responsibilities have since been transferred to the Department of Homeland Security (DHS), Customs and Border Protection (CBP) as of March 1, 2003. DHS CBP is responsible for monitoring over 300 ports of entry into the US and is constantly on the lookout for imported animal and plant material. Under the CBP are the following offices:

- Customs Service,
- Border Patrol,
- Immigration and Naturalization Service, and
- Agricultural Inspections.

There are more than 40,000 employees working to safeguard our borders and ports!

The Homeland Security Advisory System

FSIS observes the Homeland Security Advisory System, which categorizes threat conditions for the public and enforcement agencies. These conditions include Low, Guarded, Elevated, High, and Severe. Each condition has a color that signifies the risk level involved. The threat conditions are updated based on intelligence information on terrorist activities.

The Low condition indicates a low risk of terrorist attacks. The color associated with the Low condition is green. The following protective measures may be applied:

- Refining and exercising preplanned protective measures,
- Ensuring personnel receive training on government-wide, departmental, or agency-specific protective measures; and
- Regularly assessing facilities for vulnerabilities, and taking measures to reduce them.

For example, in FSIS, we may provide training or exercise our Continuity of Operations Plans (COOP). The plant may have its own plans or measures for which it conducts training of its employees, or exercises, on a regular basis. An example of a preplanned

protective measure in a plant setting is identification being required of all plant employees, or background checks being done on employees hired to work at the plant.

The Guarded condition represents a general risk of a terrorist attack. The color associated with the Guarded condition is blue. In addition to the previously outlined protective measures, the following measures may be applied in reaction to the Guarded condition:

- Checking communications with designated emergency response or command locations;
- Reviewing and updating emergency response procedures; and
- Providing the public with necessary information.

In FSIS, we conduct special surveillance activities along with normal inspection activities. The plant may also implement specialized surveillance activities. In January of 2005, FSIS issued a series of Directives that establishes how functional areas within FSIS will respond under heightened alert conditions. This new Series, the 5420 Directive Series, contains instructions for actions under the yellow, orange and red threat conditions. Prior Directives did not include the elevated condition of yellow. We will discuss this Series further after we discuss the aforementioned heightened conditions.

The Elevated condition represents circumstances that indicate a significant risk of terrorist attacks. The yellow color associated with the Elevated condition; as in real life, tells us to proceed with caution. In addition to the previously outlined protective measures, the following may be applied in reaction to the Elevated condition:

- Increasing surveillance of critical locations;
- Coordinating emergency plans with nearby jurisdictions;
- Assessing further refinement of protective measures within the context of the current threat information; and
- Implementing, as appropriate, contingency and emergency response plans.

The High condition indicates that there is a high risk of terrorist attacks. The color associated with High condition is orange. In addition to the previously outlined protective measures, the following may be applied:

- Coordinating necessary security efforts with armed forces or law enforcement agencies;
- Taking additional precaution at public events;
- Preparing to work at an alternate site or with a dispersed workforce; and
- Restricting access to essential personnel only.

The Severe condition represents a severe risk of terrorist attacks. The color associated with the severe condition is red. In addition to the previously outlined protective measures, the following may be applied:

- Assigning emergency response personnel and pre-positioning specially trained teams;
- Monitoring, redirecting or constraining transportation systems;
- Closing public and government facilities; and

- Increasing, or redirecting personnel to address critical emergency needs.

FSIS Food Defense Initiatives

FSIS conducts food defense initiatives in each of these areas.

- Food Defense and Emergency Preparedness
- Employee Safety and Health
- Continuity of Operations (COOP)
- Communications and Awareness
- Laboratory Capability
- Training and Education
- International Food Security

For food defense and emergency preparedness, FSIS has conducted vulnerability assessments (similar to a risk assessment) for domestic and imported products. FSIS has also developed strategies for the prevention and detection of threat agents. The Emergency Response Team (ERT) has also been established.

For employee health and safety, FSIS has identified and developed response plans to exposure to bioterrorism agents; and, procured analytical detection equipment.

FSIS managers follow a Continuity of Operations/COOP plan that enables other parts of the agency to take over headquarters' or other key offices' duties. The goals of a COOP are to:

- secure alternative headquarters site,
- maintain essential/mission critical functions and capabilities, and
- maintain communications and cyber security.

In communication, FSIS has produced educational and awareness materials; and, participated in national, state, and local conferences to improve collaboration. We have also established backup communication abilities to maintain operations in case of emergency.

In the laboratories, FSIS has conducted security assessments, improved security and obtained screening equipment and methods for threat agents. FSIS is 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).

Training and education initiatives include the "Food Security Guidelines for Food Processors," the "Food Security Guidelines for Transportation," and the "Food Security Guidelines for Consumers." Tabletop exercises have been conducted for headquarters and field staff to improve readiness to respond to a biosecurity event. Along with the issuance of the new 5420 Directive Series, a Food Security Checklist for Industry was made available to them for further guidance on how to establish food security activities for their facilities.

For FSIS workforce training, a food defense training program was delivered by a contractor. It took a unique approach because it presented topics that familiarized participants with techniques to prevent 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.

The three day training was provided for individuals at the district office level. The one day training was for employees in the plant. We included our local partners within that district, such as State, FDA, and APHIS representatives, as well as local first responders in this training. The training was completed in September 2004. However, on-going food defense training is being done for FSIS employees. Efforts include Face-to-Face Food Security Awareness training sessions around the country; a computer based training CD delivered to field employees in the Office of Field Operations and the Office of International Affairs, to small and very small establishments, and to our oversea partners; and, via introductory courses such as this one.

For international food defense, the following activities are underway:

- Upgrading import reinspection (including 20 new Import Surveillance Liaison Officers).
- 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.

In response to President Bush's issuance of the Homeland Security Presidential Directive which called for establishing a single, comprehensive national incident management system; FSIS along with other agencies, have adopted the Incident Command System.

The Incident Command System was designed in the early '70s. It's a standardized on-scene 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. The Incident Command Management System utilizes the skills of those most qualified to take command of the particular situation until the emergency has been abated.

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. Continued training in incident response will be offered to FSIS employees through AgLearn.

FSIS also has a number of surveillance activities underway. For example, FSIS has implemented, and continues to enhance, its national Consumer Complaint Monitoring System (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. Many of these activities were established for food safety reasons, but are used for food security as well.

The field-based Epidemiology Officers offer another source for surveillance. The Epidemiology Officers assigned to, and responsible for support to, specific District Offices 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 Eastern Lab.

FSIS has also developed publications to promote food security activities by all food businesses. These publications encourage industry to take steps to ensure the security of their operations. For example, the, "FSIS Security Guidelines for Food Processors," was created to assist Federal and State inspected plants that produce meat, poultry, and egg products in identifying methods to strengthen their biosecurity protections and procedures. While many plants may utilize guidelines from other government and private sector organizations and agencies, businesses and plants 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 plant 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 plants. FSIS has provided these guidelines to its field employees; who will assist in directing plants that seek further clarification or advice.

FSIS has also issued the, "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 foodborne 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.

Meat and poultry product recalls are another method that industry can use to protect the public, and be proactive in food defense. A recall is a voluntary procedure used by industry to call back products that may be contaminated, adulterated, or misbranded. Recall effectiveness checks are used to substantiate the effectiveness of the recall. By using this defense system, industry can enhance the tracking and detention of food that has been intentionally adulterated.

Let's summarize the key food defense initiatives available to industry. These 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

Copies of guidelines plans and checklist are available at http://www.fsis.usda.gov; or, you can call 202-720-9113 to request copies. If you have questions or need clarification about the above referenced, materials you can call the FSIS Technical Service Center at 800-233-3935.

FSIS Food Shield System

Now that you have a good understanding of the big picture, let's focus more on what your duties are in relation to food defense. You are an important part of the FSIS Food Shield system.

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-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 FSIS' Office of International Affairs.
- Processing-is the slaughter and processing steps of the chain.
- Distribution-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).

The FSIS In-Plant Team's major area of responsibility falls within the processing part of the system.

Now, let's take a closer look at what's meant by a food shield. There are different types of food shields. They can be categorized as:

Personnel Functions
Agency personnel and the functions they perform, or may perform, which provide onsite active human surveillance.

Screening/Monitoring Systems
Provide sentinel surveillance (e.g., PBIS, AIIS, PCP, Meat and Poultry Hotline, CCMS).

Vulnerability Assessment Countermeasures
Defense measure recommendations that aid industry by identifying potential improvements in physical security, personnel security, and operational/process security; or, actions FSIS can take to enhance the defense of the food supply chains.

The Office of Field Operations' personnel that are involved in these activities include the FSIS Inspector-In-Charge (IIC), the FSIS Public Health Veterinarians (PHVs), the FSIS Enforcement and Investigation Analysis Officers (EIAO), and the FSIS Inspectors. Let's get a general overview of each In-Plant Team member's response in this process under heightened alerts.

The Inspector-In-Charge

- Informs facility management of the current elevated threat level
- Performs food defense verification procedures
- Performs additional procedures (e.g., sample products based on threat information), as directed
- Deploys inspection personnel to facilities of concern based on threat information

Public Health Veterinarians

- Observe live animals in official establishments for signs or symptoms of specific diseases
- Notify APHIS when signs or symptoms of Foreign Animal Disease (FAD) are noted during antemortem or postmortem inspection

Inspectors – Perform Food Defense Verification Procedures as instructed by IIC

The activities performed by each of the In-Plant Team Members are dictated by the elevated threat condition declared by the Department of Homeland Security, Office of Food Defense and Emergency Response (OFDER). We'll talk more about this when we discuss Directive 5420.1, Revision 3.

The Performance Based Inspection System (PBIS) plays a significant role in food defense as well. Through PBIS we can use it to generate inspection assignments,

gather and record food defense related information, and track food security verification procedures as separate tasks under PBIS code 08S03 through 08S13; per FSIS Directive 5420.1, Revision 3.

FSIS Directives

Now, let's talk more specifically about your duties related to food defense. Your duties are covered in FSIS Directives. There are eight Homeland Security Directives:

- 5420.1 — Homeland Security Threat Condition Response: Food Defense Verification Procedures
- 5420.2 — Homeland Security Threat Condition Response: Handling of FSIS Laboratory Samples under Declared Heightened Threat Conditions
- 5420.3 — Homeland Security Threat Condition Response: Monitoring and Surveillance of Products in Commerce
- 5420.4 — Homeland Security Threat Condition Response: Emergency Procedures for the Office of International Affairs Import Inspection Division
- 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 — Non-Routine Incident Response

As you access these Directives, review the issuance date to ensure that you have the most recently issued instructions. These may be modified in the near future to reflect new threat information gained through the intelligence gathering activities conducted worldwide. Therefore, it is imperative that you are aware of the issuance of all Directives.

The first Directive in the series outlines the duties that are relevant to the field team during yellow, orange and red alerts. The other Directives cover the duties of program investigators and other FSIS Offices regarding distribution, communications, information technology, human health monitoring, public affairs, and import re-inspection. Let's look at the first Directive in more detail.

FSIS Directive 5420.1, Revision 3 states that when the threat conditions of yellow, orange or red exists, the FSIS Office of Food Defense and Emergency Preparedness will issue an e-mail letter to all employees notifying them on the heightened threat condition. In summary, you'll be asked to take these actions:

- monitor establishment operations for any unusual activity that may be related to food defense.
- inform the establishment management of the unusual activity, and perform food defense verification procedures explained in the Directive.
- act on specific instructions from the District Office under the threat conditions.

Here are the food defense verification procedures outlined in the Directive:

- 08S14 – Observe the security of the plant's water systems
- 08S15 – Observe production processes
- 08S16 – Observe products in cold and dry storage areas for evidence of tampering
- 08S17 – Observe loading dock areas and vehicular traffic in and out of the establishment

As we discussed earlier, Directive 5420.1, Revision 3 guides FSIS Field Personnel in performing these food defense verification procedures; based on the threat condition declared by the Department of Homeland Security. Let's review each of the threat levels under which the Field Personnel will be performing these activities.

Threat Condition Elevated (Yellow), High (Orange) or Severe (Red) with no specific threat to the food and agricultural sector:

Inspection personnel are to randomly perform one of the Food Defense Verification Procedures (08S03-08S13) instead of one of the following ISP Procedure Codes: a 04A01-04A04, or 04B01-04B04, or 04C01. Perform them as unscheduled procedures, and after all food safety procedures are performed.

Threat Condition High (Orange) with a specific threat to the food and agricultural sector:

Inspection personnel are to randomly perform three of the Food Defense Verification Procedures (08S08-08S13) daily instead of the scheduled 04 procedures on a given day. They should be performed as unscheduled procedures, and performed after all food safety procedures are performed.

Threat Condition Severe (Red) with a specific threat to the food and agricultural sector:

Inspection personnel are to perform ALL of the Food Defense Verification Procedures (08S03-08S13) daily instead of the scheduled 04 procedures on a given day. If there are no scheduled 04 procedures for that day, perform all of the ISP codes 08S03-08S13.

Any findings found during the performance of the verification procedures should be discussed with plant management at the weekly meeting. The IICs shall document the discussion in a memorandum of interview (MOI). The MOI should be kept on file, and copies forwarded through the supervisory channels. Always remember to report any

potential breaches immediately to the District Office, to the Technical Service Center and to establishment management.

FSIS Directive 5420.2 discusses the activation of the Emergency Response activities and increase testing for possible food security risks. The Emergency Response Plan includes precautions for sample security, special transport of samples to the laboratories, and reporting of laboratory reports. Be familiar with this Directive, and how it works in unison with your activities also.

Domestic Vulnerability Assessment Countermeasures-Actions by FSIS

Let's look at one more aspect of the food defense by FSIS. FSIS has also conducted vulnerability assessments, and developed some counter measures to address the points in our system that make the food vulnerable.

We can use a Food Security Risk Coefficient process to determine the best use of the workforce. The current function of the Food Security Risk Coefficient is that it is used as a metric that describes industry implementation of food security measures based on FSIS guidelines and vulnerability assessment results. For future efforts, this system, based on FSRC data, the Agency may elect to make future changes in inspection procedures; and/or, revise assignment of resources to more vulnerable facilities and perform specific procedures for high FSRC facilities.

Other measures that can be used are specific to the environment.

Physical and Personnel Security – Slaughter

- Ensure proper calibration of equipment
- Ensure security of information management systems
- Train PHVs in signs and symptoms of foreign animal diseases and other agents
- Continue food defense training for FSIS employees to enhance food defense awareness
- Implement food defense selected actions planned under heightened alert conditions (Directive 5420.1)

Physical and Personnel Security - Processing

- Ensure proper calibration of equipment
- Ensure security of information management systems
- Train PHVs in signs and symptoms of foreign animal diseases and other agents

Operational/Process Security - Processing

- Ensure product integrity by conducting trace back /trace forward reviews based on threat information
- Consider random implementation of selected food security actions planned under heightened alert conditions (Directive 5420.1) under routine conditions.

Physical Security - Transportation

- Continue random inspections on tanker trucks containing liquid egg products
- Partner with DOT Volpe National Transportation Systems Center

Personnel Security – Transportation

- Establish an ongoing dialogue with trucking companies that transport meat, poultry, or egg products on food security issues.
- Share food security awareness training to the transportation industry
- Foster use of Transportation Worker Identification Credential (TWIC) for food transporters

By implementing these measures and all of the other strategies that we discussed, we are protecting the public not only from foodborne illnesses; which is essential to our mission, but also to ensure the security of our food, a vital component of homeland security. Food safety and security is everyone in the food supply chain's responsibility and public health is everyone's benefit. Everyone along the farm-to-table continuum needs to do their part.

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 plant in mind. As you review the Food Security Checklist for Industry, think about how you would share the information on the checklist with a plant representative. Remember that the Food Security 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 a plant representative. For example, give your group members a brief description of the plant you had in mind when completing the checklist. Then, pick 1-3 areas to discuss with the plant representative. Share ideas about how you would encourage plant management to take steps to adopt measures outlined in the Food Security 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.

PLANT 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 plant incident. This scenario is realistic, in that something very much like this has happened in an FSIS-regulated plant. 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 plant 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:

    a. three categories of biological agents: 1, 2 and 3
    b. put those biological agents that are easily disseminated from person-to-person, 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 Homeland Security Threat Condition Red with a specific threat directed at the food supply?

    a. Tell the plant 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 food defense verification procedures.