

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

1. "Perspectives on Food Security," FSIS News and Notes, Dr. Elsa Murano, 10/31/2003.
2. The Centers for Disease Control; Disease Category webpage.
3. Directive 5420.1 - Homeland Security Threat Condition Response: Food Defense Verification Procedures.
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. Security Guidelines for Food Processors, USDA, FSIS publications.
6. Security Guidelines for the Transportation and Distribution of Meat, Poultry and Egg Products and Consumers, USDA, FSIS publications.
7. FSIS Model Food Security Plans, USDA, FSIS publications.
8. Industry Self Awareness Checklist for Food Security, 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 it is 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. There are approximately 6,500 federally-inspected and 2,550 state-inspected meat and poultry (slaughter and processing) plants 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 plants. 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.
- 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 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 deliberate contamination of food for human consumption with chemical, biological or radionuclear 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 – safeguarding the food supply against intentional 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 – guarding against unintentional contamination of food. HACCP plans and SSOPs, 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 each and 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 foodborne disease outbreaks provides insight into 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 plant in Wisconsin. The caller said liquid fat from the plant 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 nicotine-based 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 the potential for a larger number of deaths or illnesses. For instance, contamination of a 5,000 gallon commercial kettle could negatively impact 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 plant 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 breaches 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 may 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 Performance Based Inspection System (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 (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 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 Food Defense and Emergency Response (OFDER) in 2002 to coordinate the Agency's food defense activities. In 2009, the name was changed to the Office of Data Integration and Food Protection (ODIFP). 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
- 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. And 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 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. ICS utilizes the skills of those most qualified 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. Non-Routine Incident Management System (NRIMS) to track and manage non-routine incidents. A non-routine incident presents a grave or potentially grave threat to public health involving FSIS-regulated product. Examples of non-routine incidents include the following:

- Widespread, or life-threatening, human illnesses potentially implicating FSIS-regulated product;
- Deliberate contamination of FSIS-regulated product;
- Threat condition Orange or Red with a specific threat 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 activities were established for food safety reasons, but can be 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 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 following activities are underway:

- Enhanced import re-inspection, including creating a new import inspection position, the import surveillance liaison officer. These inspectors conduct a broader range of surveillance activities than traditional import inspectors. They

- also work to improve coordination with other agencies, such as U.S. Customs and APHIS, that share the responsibility of ensuring the safety of imported food products.
- 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 and 5420.4 that provide instruction on policy for field personnel. There may still be computer-based food defense training on CDs available in plants; 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>.

As part of FSIS' continuing effort to enhance the awareness and understanding of food defense issues among field personnel, ODIFP develops fictional scenarios, called Security Information Knowledge Exchange (SIKE), to stimulate discussion and aide field employees as they address these issues.

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 <http://www.aglearn.usda.gov>. 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 sessions, which include a presentation 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.

- *Industry Self-Assessment Checklist for Food Security*: created this self-assessment instrument to provide a tool for establishments to assess the extent to which they have secured their operations.
- *FSIS Security Guidelines for Food Processors*: 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 Model Food Security Plans*: identify the types of preventive steps that establishment operators may take to minimize the risk that their products will be subject to tampering or other malicious criminal activity.

- *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.

These publications are available for download at the following web address:

http://www.fsis.usda.gov/Food_Defense_&_Emergency_Response/Guidance_Materials/index.asp

If you have questions or need clarification about the above referenced, materials you can contact the FSIS Policy Development by electronically posting your question at <http://askfsis.custhelp.com>.

While food defense plans are not mandatory, they are strongly encouraged and sometimes they 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 these resources that FSIS provides, the food defense verification procedures 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 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. Examples of preplanned protective measure in a plant setting include identification being required of all plant employees, and 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. 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 DIRECTIVES

Now, let us talk more specifically about inspection personnel duties related to food defense. These duties are covered in FSIS Directives. There are eleven FSIS Directives related to Homeland Security:

- 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
- 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 the Agency Issuances section of MS Outlook Public Folders. These may be modified frequently to reflect new threat information gained through intelligence gathering activities conducted worldwide.

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 the FSIS Office of International Affairs.
- Processing – 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).

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 Threat Conditions yellow, orange, and red. The other Directives cover the duties of other FSIS officials regarding distribution, communications, information technology, human health monitoring, public affairs, import re-inspection, etc.

Let us look at Directive 5420.1 in more detail. First, this directive details the food defense verification procedures inspection program personnel will follow when the Department of Homeland Security declares a threat condition Yellow, Orange, or Red. The overarching purpose of these food defense verification procedures is for offline inspection personnel to identify and attempt to mitigate any potential vulnerabilities in establishment security that could permit intentional contamination. A potential vulnerability is any point in the food production process where some measure should be but is not implemented to protect against deliberate contamination. For example, if an establishment fails to somehow control or monitor access to an area where non-meat food ingredients are stored and mixed, then it might be possible for someone (e.g., a disgruntled employee) to deliberately contaminate such ingredients without detection.

Directive 5420.1 also specifies what to do in the event of an actual terrorist attack on the establishment or surrounding area. In such a situation, the IIC will immediately take measures to make sure inspection program personnel are safe and will notify the District Office (DO). The DO will then notify the appropriate local authorities. In addition, the DO may request the activation of the Food Safety and Inspection Service (FSIS) Emergency Management Committee (EMC) through the senior executive leadership in the Office of Field Operations (OFO) (see FSIS Directive 5500.2, Non-Routine Incident Response).

Here are the food defense verification procedures outlined in Directive 5420.1:

- **08S14** – Observe the security of the plant’s water systems especially well water and ice storage facilities, and water reuse systems; pay special attention to water used to prepare injection solutions and water and ice used in emulsification (for the production of deli meats and hot dogs); and, to a lesser extent, check water used to prepare surfactant, antimicrobial agent sprays, and chill tank recharge. Suggested activities include determining whether or not the establishment controls access to private wells, appropriately secures potable water lines or storage tanks, and appropriately secures ice storage facilities.
- **08S15** – Observe production processes (i.e., raw product handling, processing, and packaging of final product) where exposed products are being handled for indications of attempts to introduce contaminants into the product; observe, in particular, operations where the establishment mixes bulk products (i.e., process monitoring by establishment personnel at balance tanks, grinding/emulsification of meat and poultry products, solution injection in preparation areas, and liquid egg product tanker loading areas); and observe whether the plant has procedures in place to prevent deliberate contamination (e.g., camera surveillance, closed systems, or restricted access of personnel to sensitive production areas). Suggested activities include checking a production process (e.g., ground beef production area, egg products breaking room) for evidence of possible intentional product contamination, verifying the calibration of equipment, and checking to determine if the plant has implemented a system to restrict access to sensitive processing areas where bulk products are mixed or processed (e.g., camera surveillance, color-coded uniforms, identification badges, and sign-out sheets).
- **08S16** – Observe products in cold and dry storage areas for evidence of tampering; pay special attention to bulk product ingredients that will undergo mixing, such as combo bins of meat trim and poultry parts used for grinding or emulsification; check dry ingredients, including spices, breading materials, and those used in injection solution preparations, for indication of tampering; observe the use and storage of any hazardous materials in the establishment; verify whether entry into such storage areas is controlled and that usage logs are maintained and current; pay special attention to cleaning materials, particularly those used in clean-in-place systems; pay special attention to areas where bulk products are mixed (e.g., storage silos); and verify the control of laboratory reagents and cultures. Suggested activities include verifying that the establishment has developed and implemented: access control procedures to dry ingredient areas; access control procedures to raw product storage areas; access control procedures to finished product storage areas; control procedures for access and use of hazardous chemicals; and procedures to check all products in storage for evidence of tampering.
- **08S17** – observe loading dock areas and vehicular traffic in and out of the establishment; report immediately all unattended deliveries on loading docks and unmarked vehicles parked on the premises to establishment management; verify that the establishment secures, when possible, dry and cold products stored in on-site trailers and parks trailers in a restricted access area of the facility; verify

that the facility security staff routinely checks the trailers' physical integrity (e.g., locks, seals, and general condition); and pay special attention to deliveries of liquid egg products to storage silos, of combo bins of meat trim, and of dry ingredients. Suggested activities include checking to determine whether the plant has procedures in place to restrict or control access to the loading dock area and observing incoming raw materials to verify that the establishment checks deliveries against shipping documents.

As mentioned, Directive 5420.1 instructs FSIS Field Personnel on performing these food defense verification procedures based on the threat condition declared by the Department of Homeland Security. Let us briefly examine the expectations for performing these procedures (NOTE: you should review Directive 5420.1 for more detail and to ensure no updates have been issued).

- Threat Condition Elevated (Yellow), High (Orange) or Severe (Red) with no specific threat to the food and agricultural sector: Offline inspection personnel are to randomly perform one of the Food Defense Verification Procedures once, per plant, per day instead of one of the scheduled 04 procedures. If there are no scheduled 04 procedures on a given day, inspection personnel may randomly perform one of the Food Defense Verification Procedures once, per plant, per day instead of one of the scheduled Food Safety Procedures. In multi-shift plants, performing 08S procedures should be alternated across shifts on a weekly or biweekly basis. The 08S procedure is recorded as an “unscheduled” procedure.
- Threat Condition High (Orange) with a specific threat to the food and agricultural sector: Offline inspection personnel are to randomly perform three of the Food Defense Verification Procedures daily per shift instead of all scheduled 04 procedures and/or as many (up to 3) Food Safety Procedures as necessary to ensure three 08S procedures are performed. The three 08S procedures are again recorded as “unscheduled” procedures.
- Threat Condition Severe (Red) with a specific threat to the food and agricultural sector: Offline inspection personnel are to perform ALL four of the Food Defense Verification Procedures daily per shift instead of all scheduled 04 procedures and/or as many (up to 3) Food Safety Procedures as necessary to ensure three 08S procedures are performed. The four 08S procedures are again recorded as “unscheduled” procedures.

DOCUMENTING FOOD DEFENSE VERIFICATION ACTIVITIES

When offline inspection program personnel perform an 08S procedure and do not find a food defense vulnerability or concern, they are to record the procedure as performed in the computerized Performance Based Inspection System (PBIS).

When offline inspection program personnel perform an 08S procedure, 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 procedure as performed by recording trend indicator “S.” If there is evidence of product adulteration, the trend

indicator becomes “T,” and a Noncompliance Record (NR) must also be issued as a consequence of the affected product.

In cases where a 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 PBIS and record the plant response after discussing the findings.

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 food defense plan; however, there is currently no regulatory requirement for food defense plans. As such, an establishment does not have to provide inspection program personnel 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 O8S procedures. In addition, ODIFP may occasionally instruct inspection personnel to securely submit information about the food defense plan through PBIS. 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.

SUMMARY

Defending the food supply against intentional attacks is a critical function. Field personnel, both in and outside of plants, serve as an early alert system. Implementation of food defense verification procedures serves to protect the public, which is essential to our mission, and ensures the security of our food, a vital component of homeland. Suspicious activities in plants should be reported to the district manager through supervisory channels or by calling the FSIS 24 hr emergency hotline at 1-866-395-9761.

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. There are also other terrorism components such as conventional, radiological, nuclear, chemical, and cyber that are typically directed at the human population. This appendix discusses various components of bioterrorism. It is important for the FSIS personnel to be aware of these bioterrorism components from the standpoint of serving as a first line of monitoring for animal diseases of great economic significance (e.g., foreign animal diseases) that could be introduced through an act of terrorism and 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

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 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.

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 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)

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 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 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.

Botulism

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 its 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.

Tularemia

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 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 vaccine's 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 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 an outbreak is suspected the state veterinarian and state public health veterinarian should be contacted 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.

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. 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.