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USDA, Food Safety and Inspection Service

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United States Department of Agriculture

Food Safety and Inspection Service

1400 Independence Avenue, SW. Washington, D.C. 20250 MAR 2 8 2017

RE: FOIA-2017-00101 *SIKEs*

This is the final response to your Freedom of Information Act (FOIA) request, dated February 6, 2017, to the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS). You requested access to records regarding each Security Interactive Knowledge Exchange (SIKE) scenario. We received your request in our Office on February 7, 2017.

The FSIS FOIA staff works with subject matter experts across the Agency to locate responsive documents. For this request, we conducted a records search in the following offices: Office of Policy and Program Development, Office of the Chief Information Officer, Office of the Administrator, Office of Data Integration and Food Protection. FSIS' search began on February 9, 2017. Our search includes responsive records in FSIS' control on that date.

We have located 48 pages that respond to your request. After a thorough review, we have determined that one portion of the records fall within an exemption to the FOIA's mandatory disclosure requirements, as explained below. In particular, we have determined that this portion is exempt from disclosure under (b)(6) of the FOIA, 5 U.S.C. § 552, as amended. Accordingly, this request is granted in part.

Exemption 6 protects information that would constitute an unwarranted invasion of an individual's personal privacy. The types of information withheld under Exemption 6 include the names, addresses, or cell phone numbers of inspection personnel at risk of retaliation.

You may appeal this determination within 90 days from the date of this letter. Your appeal should include copies of your original request and this response, as well as a discussion of the reasons supporting your appeal. The envelope should be plainly marked to indicate that it contains a FOIA appeal. If you decide to appeal this determination, please send your appeal to:

Alfred V. Almanza
Acting Administrator
Department of Agriculture
Food Safety and Inspection Service
1400 Independence Avenue, S.W.
Room 2168, South Building
Washington, D.C. 20250-3700

Please be advised that your FOIA request, including your identity and the information made available, is releasable to the public under any subsequent FOIA requests. However, FSIS does not release your personal privacy information, such as home addresses, telephone numbers, or Social Security Numbers, all of which are protected from disclosure under FOIA Exemption 6.

If you have any questions about the way this request was handled, or about the USDA's FOIA regulations, please contact Anne-Marie Waddell at 202.720.0284 or via email at anne-marie.waddell@fsis.usda.gov.

Thank you for your interest in FSIS programs and policies.

Arianne M. Perkins

Director, Freedom of Information Act Staff

Office of Public Affairs and Consumer Education

Food Safety and Inspection Service

Enclosure

FOIA Case No. 17-101

*Note: These SIKES are out-of-date. Terms, websites, and references may not be applicable to present day operations.

You are a second shift inspector at a large slaughter/processing establishment producing ground beef. Today, threat condition Yellow (Elevated with no specific threat to food or agriculture) was declared by the Department of Homeland Security. As you know per FSIS Directive 5420.1 (Rev 3) you are to randomly perform one unscheduled food defense verification procedure (08S14-08S17) daily for the duration of the threat condition Yellow instead of a scheduled 04 procedure. You and the day shift inspector have worked out a random method of selecting the food defense verification procedures to be performed on either shift. There is no OCP (other consumer protection) 04 procedure scheduled today in your shift.

In the absence of a scheduled 04 (OCP) procedure, do you still perform an 08S procedure? Why?

FSIS Directive 5420.1 (Rev. 3) states that if there are no scheduled 04 procedures on a given day, inspection personnel are to randomly perform one of the food defense verification procedures (08S14-17).

You randomly selected and performed food defense verification procedure 08S17, Shipping and Receiving at 7:30pm. While observing the outer perimeter of the establishment you noticed trucks bringing in live cattle entering through the rear entrance. The rear entrance watchman/guard's tour of duty had ended at 6:00 pm and there was nobody at the gate to verify incoming live cattle deliveries.

Did a "Breach" occur? Why or why not? What action should you take?

• After reviewing Directive 5420.1 rev 3, you determined that a "breach" has occurred. Fences and gates are intact but the entrances are not secured against unauthorized entry.

•

. You documented your finding in PBIS by entering an unscheduled procedure 08S17 with a trend indicator "S" since there was no evidence of product adulteration. You immediately notified establishment management and discussed your findings. You also prepared a Memorandum of Interview (MOI) on FSIS Form 5420.1 that documented this breach in security. During your interview with plant management you referred them to the FSIS website http://www.fsis.usda.gov/pdf/Elements of a Food

Defense Plan.pdf listed in FSIS Directive 5420.1. You electronically sent a copy of the MOI to your Frontline Supervisor, District Office and to IF-OFDER.

Do you do another unscheduled food defense verification procedure the following day specifically for 08S17? Why or why not?

Scenario 02-2006 Food Defense Verification Procedure May 01, 2006

You are a Consumer Safety Inspector (CSI) assigned to a large chicken slaughter and processing establishment. The current Department of Homeland Security threat condition is YELLOW (Elevated) with no specific threat to the food and agricultural sector. As instructed in FSIS Directive 5420.1 after performing all your food safety procedures, you performed a food defense procedure instead of a scheduled 04C01 procedure. To perform an unbiased procedure, you drew a random number from the computer. That number corresponded to 08S14 (Water systems).

The plant is supplied primarily by the municipal water system but has two wells on premises as secondary sources of water. These two wells are frequently used to reduce the water bill. You checked the inside water systems and found no breach or potential breach of food security. You then proceeded to check the two well sites. You observed that one of the wells was locked, but the other appeared to have been tampered with by someone. The lock was intact, but the hasp was pried open from the door jamb. Upon further evaluation you observed that the possible tampered well was online at the time of your inspection.

Did a breach occur? What action, if any, do you take?

Discussion: The maintenance supervisor informs you that he had no knowledge of any tampering of the well, and that the broken door hasp must have been a very recent occurrence. Since the establishment's well water system is an area that could allow someone to deliberately introduce contaminants or adulterants, you informed the Inspector in Charge (IIC) of the situation. After a teleconference with the District Manager and the Eastern Laboratory in Athens, the IIC as advised by the district and lab collected a water sample from the tampered well and a companion sample from the intact well, and sent both samples to the FSIS Eastern laboratory for comparison. In this instance, you were instructed by the District Manager to do this even though FSIS does not routinely run water potability samples. The water samples, as you secured them, showed no indication in odor or visible appearance of possible contamination. The IIC also instructed you to further verify if the company had any record of this "breach" on any of their daily records. Your records-review produced no evidence of any documentation. You documented the 08S14 procedure with an "S". You accompanied the IIC to the MOI (Memorandum of Interview) discussion with the establishment. You and the IIC further informed the establishment that in the event the water sample result came back as nonpotable, an NR would be issued changing the "S" with a "T". You also provided the establishment with the OFDER website (http://www.fsis.usda.gov/Food Security & Emergency Preparedness/Index.asp) for information on countermeasures the establishment could adopt to protect water systems.

After your interview with the plant management, you wrote an MOI (FSIS Form 5420.1). You also attached a USDA Retain/Reject tag to the valve which connects the well water to the plant water supply to preclude further use of water from this source and advised plant management accordingly.

Further Discussion: The plant has taken an additional precaution of hiring a night watchman to patrol the outside premises and has discontinued water use from the tampered well. On the next day the FSIS lab had notified the District Office that the water sample from the well that appeared to have been tampered with had an unacceptable level of total Arsenic (200 ppb or 200 microgram/liter; the EPA acceptable level is 10 ppb). The companion water sample had 5 ppb total Arsenic, and was acceptable. The District Office informed the IIC of the test results and that an Enforcement Investigation and Analysis Officer (EIAO) was on her way to the establishment to review and document the event, and for data collection for the Non Routine Incident Report (NRIR). The IIC was also instructed to share the information on the test results with plant management and to request that they have records available for the EMC (Emergency Management Committee; refer to Directive 6500.1) through the District Office as soon as possible. The establishment voluntarily retained product suspected to be contaminated with Arsenic.

Do you need to take any further action? Why?

Discussion: Because there was evidence of product adulteration you wrote a Noncompliance Record (NR). You attached the NR to the MOI and gave it to the establishment. You sent electronic copies of the MOI to your Frontline Supervisor and to the District Office through the IIC, and assisted the EIAO in her investigation.

Note: An NR does not take the place of an MOI. If contamination of product is discovered during the performance of a food defense procedure both an NR and an MOI should be written. Directive 5000.1should be followed if enforcement action is recommended.

Scenario 03-2006 Food Defense Verification Procedure May 08, 2006

You are a Public Health Veterinarian (PHV) assigned to a large hog slaughter and processing establishment. The current Department of Homeland Security threat condition is YELLOW (Elevated) with no specific threat to the food and agricultural sector. As instructed in FSIS Directive 5420.1, after performing all your food safety procedures you performed a food defense procedure instead of a scheduled 04C01 procedure. To perform an unbiased procedure, you drew a random number 08S15 (Processing Manufacturing) from the computer and decided to check the carcass spray area.

While inspecting the post-carcass wash acetic acid spray-wash system you did not smell the characteristic "vinegar" odor that is typically present in the area where acetic acid is used. You went to see the maintenance supervisor and in the maintenance shop you noticed an electrical transformer with liquid material leaking on its sides. You know that electrical transformers can contain materials, including polychlorinated biphenyls (PCB's), which are poisonous and should not be in an area near food or food equipment.

Did a potential food tampering occur? What action, if any, do you take?

Discussion: You immediately notified the foreman that you suspect the sprayed liquid was not 2% acetic acid as written, as a mandatory antibacterial step, in the company's HACCP plan. The foreman immediately checked the sprayer, agreed with you, and shut down production. You immediately notified the District Office and your Frontline Supervisor of your findings. You requested permission from the District Manager (DM) to send a fat sample to the lab for PCB analysis. The DM approved the request and you shipped a fat sample to the Western lab requesting PCB analysis. You retained all the carcasses for that day's production with a USDA Retain/Reject tag. You recorded Procedure 08S15 in PBIS with Trend Indicator "T". You also wrote an NR (FSIS Form 5400-4) for violation of Task Code 03J01 (HACCP; monitoring), citing Reg 417.2(4). You conducted an interview with the establishment, and wrote an MOI (Form 5420.1). You further informed the establishment that in the event the carcass contained any PCB residues, you would initiate required regulatory action in consultation with the District Office. You also requested that the company

determine the last time the sprayer was checked (calibration and verification of recordkeeping) to indicate if any carcasses produced on prior days could be involved.

Further discussion: A few days later the District Office notified you that the fat sample had unacceptable levels of PCB's, and that an Enforcement Investigation and Analysis Officer (EIAO) was on her way to the establishment. The DM asked you to gather preliminary production numbers from the establishment while a recall committee is being formed. The plant management notified the police, who initiated an investigation as to how the liquid from the transformer got into the carcass spray system.

Do you need to take any further action? Why?

Further discussion: Any detectable amount of PCB's in a hog carcass for human food is a violation, and the carcass needs to be condemned (21 CFR 109.30). You attached the NR to the MOI and gave a copy of both to the establishment. You performed an 03J02 procedure to follow up on your 01 procedure. You sent a copy of the MOI to your Frontline Supervisor and the District Office, and e-mailed the MOI to IF-OFDER (OFDER e-mailbox).

Do you need to take any further action? Why?

Further discussion: Additional FSIS testing demonstrated that carcasses slaughtered the day before you conducted Task 08S15 were not contaminated. The company condemned the retained carcasses and contracted out the disposal of the hog carcasses in a hazardous waste land fill, because PCB levels exceeded allowable limits for routine disposal.

SIKE Scenario 04-06 Incoming Raw Materials April 20, 2006

You are a Consumer Safety Inspector (CSI), Inspector in Charge (IIC) at a one-shift egg breaking and processing plant. The current Department of Homeland Security threat condition is YELLOW (Elevated) with no specific threat to the food and agricultural sector. As the IIC, you reviewed FSIS Directive 5420.1 rev 3 and found that, as per VII A.2, you are required to perform one of the Food Defense Verification Procedures listed in Section IX B daily. You randomly selected to perform 08S17 (Shipping and Receiving) instead of the scheduled 04A04.

Earlier that day the foreman notified you that a tanker truck of unpasteurized "liquid egg yolk" was arriving at about 2:00 PM. After performing all your food safety procedures for the day, you performed Procedure 08S17 on the incoming tanker truck. When the tanker arrived, you noticed that the truck had an unlocked/unsealed hatch.

Does the situation as described constitute a potential food security vulnerability? Why or why not? What action should you take?

Discussion:

After reviewing Directive 5420.1 rev 3 you determined that a "potential food security vulnerability" has occurred. In addition, as per CFR 590.504(o) (2), tanker trucks with unpasteurized liquid egg product are to move under seal and certificate between official establishments for pasteurization, repasteurization or heat treatment. Therefore you have discovered a potential food defense vulnerability and food safety violation. You documented this on your "Daily Report of Plant Operations" (PY-203), and retained the product with a USDA Retain/Reject tag until pasteurization. You then met with the establishment management to discuss the potential food defense vulnerability. You referred the establishment operator to the FSIS Food Security Guidelines for Food Processors and the FSIS food defense web page: http://www.fsis.usda.gov/Food Security & Emergency Preparedness/Index.asp for further resources.

You wrote a Memorandum of Interview (MOI) On Form 5420.1 to the establishment operator. You also e-mailed an electronic copy of the MOI to the Frontline Supervisor, the District Office and IFOFDER (e-mail address of OFDER).

<u>Scenario 05-2006 Food Defense Verification Procedure Employee</u> Behavior (08S16)

You are a Consumer Safety Inspector (CSI) assigned to a Small Corn Dog Manufacturing establishment. The establishment buys Frankfurters and uses battering and breading to manufacture their Corn Dogs. The current Department of Homeland Security threat condition is YELLOW (Elevated) with no specific threat to the food and agricultural sector. As instructed in FSIS Directive 5420.1, rev 3, after performing all your food safety procedures, you performed a food defense procedure instead of a scheduled 04C01 procedure. To perform an unbiased procedure, you drew a random number from the computer. That number corresponded to 08S16 (Storage Areas).

The plant was manufacturing 100,000 Corn Dogs for the Memorial Weekend Fair. Corn meal and flour for the batter and breading are stored in an on-premises warehouse at the edge of the plant, which is often unlocked. The company manager has put off writing a food security plan saying that he knew every body in his plant, and a small plant like his did not need a written plan.

While performing the 08S16, you observed an employee looking nervous and sweating despite being in the battering/breading room with a temperature of 45 Degrees Fahrenheit, and you expressed concern to the Plant Manager. The plant manager agreed that something seemed wrong. After some questioning, the employee confessed to the manager the cause of his nervousness. The employee had a chronic gambling problem and owed money to a bookie. Because of that the employee had been targeted by a terrorist organization to aid them in a plot. The terrorists taught the employee to cut paper sacs and patch the bags so as to be undetected, and gave him an off-white colored powder to add to several bags in the warehouse that would be used for the Fair's corn dog order. The employee did not know the identity of the off-white colored powder.

The company retained the entire day's production and sent a sample to a private lab for testing. You also collected a pound of sample and stored in the freezer for future reference.

Did a breach occur? What action, if any, do you take?

Discussion: Your observation of the suspicious employee led you to notify the Plant Manager, and ultimately the unearthing of the terrorist plot. You informed the Frontline Supervisor and District Manager of the situation, and recorded the 08S16 procedure with an "S" because there was currently no evidence of adulteration. You conducted an interview with plant management and notified them that in the event the battering/breading sample result came back positive for an adulterant, an NR may be issued. You also provided the establishment with the OFDER website (http://www.fsis.usda.gov/Food Security & Emergency Preparedness/Index.asp) for information on countermeasures the establishment could adopt, and with information to write a food defense plan.

After your interview with the plant management, you wrote an MOI on FSIS Form 5420.1.

Further Discussion: In a few days the private lab had notified the company that the battering sample had a high concentration of a rodenticide. You changed the trend indicator from an "S" to a "T" in the PBIS system and wrote an NR. The company voluntarily condemned the entire batch of product and a few bags of ingredients that might have been contaminated. You observed the disposal process yourself.

Scenario 06-2006 Food Defense Verification Procedure September 25, 2006

You are a Consumer Safety Inspector (CSI), assigned to a small Ground Beef processing establishment. The current Department of Homeland Security threat condition is YELLOW (Elevated) with no specific threat to the food and agricultural sector. As instructed in FSIS Directive 5420.1 after performing all your food safety procedures, you performed a food defense procedure instead of a scheduled 04C01 procedure. To perform an unbiased procedure, you drew a random number from the computer. That number corresponded to 08S15 (Processing/Manufacturing).

The plant receives raw materials (combo beef) from several suppliers, and produces Hamburger patties for several major chains of restaurants nation wide. Today they were planning to make two large batches of Hamburger patties. You monitored the meat grinding area. While you were entering the grinding room, you noticed a pest control contract employee near the grinder, unsupervised. After the pest control contract employee left the area, an hourly worker came to you. He told you in confidence that he observed the pest control contract employee dump some white powder from a plastic bag into the grinder. The hourly employee also urged you not to reveal his name to the plant management, lest he might lose his job for tipping an inspector. You thanked him, but firmly suggested to him that he should tell this to the plant manager himself, in case the meat might harm some people, and in case a criminal investigation was conducted later on. He reluctantly went to the plant manager. The Plant Manager conducted an investigation, and informed you of the situation. You informed the plant manager that you would like to collect a pound of ground beef sample, and send it to a lab for analysis. The plant voluntarily retained the product. You informed the District Office of the situation, and that you were collecting a pound of fresh ground beef sample to send it to a lab. The District office called you back with the address of a specialty lab and special instructions for sampling and shipping procedures. After two days the result came back positive for strychnine. The plant launched a police case against the pest control company.

Did a breach occur? What action, if any, do you take?

Discussion: You had an interview with the Plant Management as per Dir 5420.1, X.A., where you discussed the need to have supervision of outside contractors in production areas, and where you directed them to the OFDDER website (http://www.fsis.usda.gov/Food Security & Emergency Preparedness/Index.asp). After the interview you wrote an MOI on Form 5420.1. You checked trend indicator "T" for product adulteration in PBIS, and completed an NR (as per Directive 5420.1 X.A.3). The District office informed you that an Enforcement Investigation and Analysis Officer (EIAO) is on her way to the establishment to review and document the event, and for data collection for the Non Routine Incident Report (NRIR). You were also instructed to have production records available for the EMC (Emergency Management Committee; refer to Directive 6500.1) through the District Office as soon as possible.

Do you need to take any further action? Why?

Discussion: You attached the NR to the MOI and gave it to the establishment. You sent an electronic copy of the MOI to your Frontline Supervisor, to the District and to IF-OFDER. You also helped the EIAO in her investigation.

Scenario 07-2006 Food Defense Verification Procedure October 02 2006

You are a consumer Safety Inspector (CSI), assigned to a large turkey ready- to- eat (RTE) processing establishment. The current Department of Homeland Security threat condition is YELLOW (Elevated) with no specific threat to the food and agriculture sector. As instructed in FSIS Directive 5420.1 rev 3, after performing all your food safety procedures, you performed a food defense procedure. To perform an unbiased procedure, you drew a random number from the computer that corresponded to 08S15 (Processing/Manufacturing).

The plant receives raw turkeys, injects them with brine solutions and smokes them to be RTE. On this day the plant is injecting a large batch of turkeys with a brine solution which will enter the smokehouse the next day. A person stole a van from a smokehouse repairing company and entered the establishment through the main security gate, telling the guard he was there to repair a smokehouse. He takes his tool box, in which he has a few bags of arsenic, dons a white coat and white hat, and finds the brine room adjacent to the smokehouses. He dumps one bag of arsenic in each of four large brine vats. A smoke-house employee notices that the person was not their regular repair man, and who was also not aware that any smokehouse needed repairs. He asks the Smokehouse Foreman if he ordered any repairs. He had not, so the two went to the brine room, but the imposter repair man had left. The Smokehouse Foreman called the smokehouse maintenance company and was informed that a company vehicle was missing and presumed stolen.

Did a breach occur? What action, if any, do you take?

The Plant Manager informed you about the situation and the stolen vehicle. You went to the brine room and a company employee told you that the smokehouse maintenance person was in the brine room with his tool box without supervision. You saw the four full brine tanks, and although you did not notice any thing unusual, you wanted to collect a sample. You called your District Office, and relayed the information you had, and the District Manager authorized you to collect one sample from each tank. She also gave you the address of a specialty lab and special sampling and shipping instructions. The results received two days later indicated high levels of arsenic (200 ppb; the allowable level in drinking water is 10 ppb). The plant notified the police to initiate a criminal investigation.

<u>Discussion:</u> You had an interview with Plant Management as per Directive 5420.1 review 3 X. A.2. that discussed the need for supervision of outside contractors in production areas, and directed them to the OFDER website for more information (http://www.fsis.usda.gov/Food Security & Emergency Preparedness/Index.asp). After the interview you wrote an MOI on FSIS form 5420.1. You checked trend indicator "T" for product adulteration in PBIS, and completed an NR. The District Office informed you that an Enforcement Investigation and Analysis Officer (EIAO) is on her way to the establishment to review and document the event and to collect data for the Non Routine Incident Report (NRIR). Since no one knew whether any of the contaminated brine was injected into the turkeys, or how many turkeys were involved, you retained the entire

day's production. You were instructed to have production figures available for the Emergency Management Committee (EMC) through the District Office as soon as possible (refer to Directive 6500.1). Since the brine was not supposed to be injected the next day, no turkey was involved. The Plant's HACCP records indicated that those four batches of brine were not used for injection. After the EIAO's investigation was concluded you released the entire retained lot of previous day's turkeys.

Do you need to take any further action? Why?

<u>Discussion:</u> You attached the NR to the MOI and gave it to the establishment. You sent an electric copy of the MOI to your Frontline Supervisor, to the District and to IF-OFDER.

Scenario 08-2006 Food Defense Verification Procedure October 12, 2006

You are a Consumer Safety Inspector (CSI) in a processing plant. The current Department of Homeland Security threat condition is YELLOW (Elevated) with no specific threat to the food and agricultural sector. As instructed in FSIS Directive 5420.1 after performing all your food safety procedures you performed a food defense procedure instead of a scheduled 04C01 procedure. To perform an unbiased procedure, you drew a random number from the computer. That number corresponded to 08S15 (Processing/Manufacturing).

This plant makes several types of sausages including German sausage, Cervelat (Thuringer) and Blood sausage. Today they will be making a 500 pound batch of Thuringer. While performing the 08S15 procedure you visited the ingredient mixing area. The door to the dry ingredient room was open and nobody was in the area. You noticed a plastic bag labeled "Compound 1080" lying on top of the trash can, empty except for a bit of flour-like powder in the bottom. Because you did not think there was a listed ingredient by that name you investigated further. You found the sausage foreman and brought him to the ingredient room to show him the bag. The foreman did not know what "Compound 1080" was, but informed you that he had just added the dry ingredients to the meat in the chopper before you found him.

Did a potential food defense vulnerability occur? What action, if any, did you take?

Discussion: You called the Technical Service Center in Omaha to gather additional information about the nature of the chemical. A Staff Officer told you that it is one of the most highly poisonous rodenticides known, and is only available to licensed pest control operators and the Wild Life Management service. He also told you that FSIS laboratories do not have the capabilities to test for this compound, but he gave you the address of a specialty laboratory that has the ability to test for "Compound 1080".

Did a potential food defense vulnerability occur? What action, if any, do you take?

Discussion: You called your Front Line Supervisor (FLS), who instructed you to remain in the plant and try to find out where the bag came from, and

that he was coming to the plant shortly. He also instructed you to check the combo bins in the cooler for any white powder. Two of the combo bins had their plastic coverings partially removed and appeared to have been sprinkled with a white powder substance. You applied a USDA Retain/Reject tag to those two combo bins. You called the District Office (DO) to let them know your findings and inform the office of your conversation with the Technical Service Center. The District Manager (DM) told you that arrangements are being made with a specialty lab for a sample to be analyzed. Although the plant did not know how this empty bag of "Compound 1080" got in the ingredient room, they decided to voluntarily retain the products until the lab results come back. The plant informed you that Thuringer had not been produced for many months and, therefore, there were no earlier batches to be concerned with. You took a one pound sample each of the raw ground product and the combo bins, making sure that you had put on a pair of gloves, and sent it overnight to the specialty lab as arranged by the DM. You wrote "Compound 1080 Suspected" on the sample form, and requested that the lab check for it. Your Front Line Supervisor asked you to call him after receiving the lab result. The plant management said they had called the police to investigate the potential contamination incident.

What further action do you need to take?

Discussion: You had written one MOI for a Food Defense Verification Task (08S16) a month earlier because the dry ingredient room was not secured. You had also written an MOI for unauthorized personnel in the production area two months ago (08S15). The plant's response to both MOI's had been to study the situations further and get back to you. The plant does not have a written food defense plan. In order to confirm that no other product might be adulterated you performed a record review of the last two days' production. You recorded the 08S15 procedure in PBIS with the trend indicator "S". You had an interview where you discussed the situation with plant management. You also told the plant management that if the lab sample came back positive for the rodenticide you would change the "S" to a "T". You wrote an MOI on FSIS Form 5420.1. In two days the District Office called you to tell you that the lab results indicated that the Thuringer and both combo bins contain Compound 1080 and that all products produced in the last two days should be retained for further inspection and investigation

by an FSIS team and other Federal and local officials. The DO also informed you that an EIAO was coming to the plant to conduct a records review.

What other action do you take?

Discussion: You wrote an NR (5400-4) under Task Code 03I01 (Product with Secondary Inhibitors-Not Shelf Stable) for a monitoring violation because the plant's HACCP plan states that all ingredients, including raw material, will be checked visually for any extraneous material before grinding. You retained the entire batch of the affected product in the cooler until the plant can comply with 417.3 (a) and 417.4 (a) (3). You also changed the trend indicator for the 08S15 procedure from "S" to "T" in PBIS. You sent a copy of FSIS Form 5420.1 to your FLS, District and IF-OFDER.

Note: In real life scenario concerning a hazardous substance like "Compound 1080", a HAZMAT team may be dispatched to the scene to conduct sampling and investigation.

09-06 SIKE- RANDOMIZATION OF FOOD DEFENSE PROCEDURES

Randomization of food defense procedures by inspection personnel is important to make the ensuing data meaningful. There are several reasons behind randomization. First of all it is unbiased and hence scientifically acceptable by all concerns. Secondly it eliminates the impulse to perform only convenient procedures like outside premises and loading dock, for example. While the examples cited are important areas concerning an establishment's food defense plan, randomization makes these procedures meaningful. For example when these procedures are plotted on a monthly graph, the result does not skew to one or two procedures; rather the graph has a symmetrical appearance. While the inspection personnel are not required to plot any monthly graphs, data analysis by TSC and HQ personnel traditionally has revealed skewed graphs involving the examples cited. While it is hoped that the revised Directive 5420.1 may reduce that phenomenon, it is very important for the inspection personnel to randomize procedure selection.

Another important point is not to perform the same procedure over and over again, when a potential breach on a vulnerable node has been identified to the establishment. If a reasonable time is requested by the establishment management, and agreed upon in your MOI, it serves no purpose to repeat the same procedure for the same breach at the same location before the agreed upon date expires. One could always choose a different venue.

The attached Microsoft Excel graph is the creation of (b) (6) in the Lawrence District. This is an easy way to generate the random number by pressing computer key F-9. Once the instruction is followed one arrives at one random number between one to four. Number one will correspond to 08S14 and number four will correspond to 08S17. As an alternate, one could directly choose a number between 14 and 17.

Once the cursor is placed on the "Code" the graph also shows the written procedure to follow. And the number of total procedures to be performed at any threat level is written on the graph. For example, one needs to perform only one 08S procedure during code "Yellow".

Many times the TSC receives calls from inspection personnel as to which shift perform the 08S procedure in a two shift or three shift establishment. This decision is left to the discretion of the IIC. The Directive only mentions one 08S procedure per day per establishment during code "Yellow".

If you have any question please contact the TSC at 800-233-3935.

08S RANDOM PROCEDURE GENERATOR
FOOD DEFENSE VERIFICATION PROCEDURES

Number	Code	Title	No Specific Food Security Thre
1	08S14	Water Systems	Yellow Orange Red
2	08S15	Processing / Manufacturing	
3	08S16	Storage Areas	
4	08S17	Shipping / Receiving	

Place Cursor over each individual code to read it's description

Scenario 10-2007 Food Defense Verification Procedure

You are a consumer Safety Inspector (CSI), assigned to a large chicken ready-to-eat (RTE) processing establishment. The current Department of Homeland Security threat condition is YELLOW (Elevated) with no specific threat to the food and agriculture sector. As instructed in FSIS Directive 5420.1 rev 3, after performing all your food safety procedures, you performed a food defense procedure. To perform an unbiased procedure, you drew a random number from the computer that corresponded to 08S14 (Water Systems).

The plant receives raw chicken breasts, processes them with other ingredients, and makes chicken nuggets for the school lunch program. On this day the plant is producing a batch of 20,000 pounds of nuggets. Ice is an ingredient in the mixing process. The plant makes its own ice in a two story building. An auger through a chute is used to transport the ice from the ice room to the processing floor. Today for the 08S14 procedure you are looking at ice use in the plant. You observed the water intake area, the second floor ice room, the auger and the chute. The chute is mostly hidden from the view of plant workers by plastic curtains; you made an extra effort to inspect this area. On the stainless steel chute you observed some yellowish-white powder, with a long streak running the entire length of the chute.

Did a vulnerability occur? What action, if any, do you take?

Because yellowish- white powder is not a normal ingredient used in ice making, you informed the Plant Manager of your finding. Some ice had already been used for the processing of the chicken nuggets; therefore the Plant Manager voluntarily stopped production. He also asked his Maintenance Chief and Security Chief to take a look at the powder and determine the next course of action.

You continued your inspection and found that a paper sac of an unknown chemical was hanging from a make-shift hook attachment above the chute. The sac had a small slit cut open, and a small quantity of powder was continuously being poured on the chute. You did not notice any other abnormal findings in the ice house, nor at the water intake valve. After you showed your observations to the plant management, you called your Front Line Supervisor (FLS) and District Office. After your conference with the District Office you saw that the local Fire Department's HAZMAT team was already on the scene. You continued your secondary role because you knew from your Incident Command System (ICS) 100 and 200 training to let the first responders take on the primary role in these situations.

In your role of ensuring that the food supply remains safe, you retained the day's production of chicken nuggets and all products in the mixing vats. You also retained the previous day's entire production lot. You recorded trend indicator "T" on the results section of PBIS for the 08S procedure and wrote an NR. You also checked "T" on Question 3a of FSIS Form 5420-1 and filled out the rest of the form. You observed that the HAZMAT team had sent a pound of ice from the ice chute, a pound of raw chicken

mix from the mixing-vat, and a pound of finished chicken nuggets from the previous day's production to a specialty lab. FSIS laboratories do not test for unknown, potentially hazardous chemicals, so you did not collect a sample, but you did offer the guidance of FSIS laboratory personnel for discussions of the analysis of food samples.

A few days later the plant received the lab sample results which indicated the presence of ricin in some samples. The lab result for the previous day's finished chicken nuggets came back negative. You immediately notified your Frontline Supervisor and District Office about the ricin. Because ricin is a very lethal chemical, the establishment condemned the entire batch of product produced on the date of your finding.

What additional action, if any, would be taken?

You released the finished chicken nuggets produced the day before your finding of the powder on the chute. The establishment followed its own food safety and defense protocols, and hired a decontamination company to do a thorough cleaning of the entire facility, making sure any remaining dry ingredients or other products were not contaminated. The decontamination company gave the establishment a clean bill of health. The District Office sent an Enforcement Investigation and Analysis Officer (EIAO) to go over the records review process, and you assisted him in the investigation.

It is worthy of note that this facility makes products that enter the National School Lunch Program. Many of those products are subject to more rigorous food defense controls during processing as stipulated in purchasing contracts with the Agricultural Marketing Services.

<u>Discussion:</u> Ricin is a very potent chemical that causes death. While not readily available to the general public, it can be made by a person with some training in chemistry. Although it may lose some potency after cooking, there is enough toxicity left that one should be very careful handling this chemical.

Scenario 11-2007 Import Alert

You are an OPEER CID Investigator. The current Department of Homeland Security threat condition is YELLOW (Elevated) with no specific threat to the food and agricultural sector. As instructed in FSIS Directive 5420.3, Revision 4 dated 10-31-06, you perform certain food defense surveillance procedures in public warehouses and other related firms in commerce.

Today you are reviewing a large commercial warehouse. Your random food defense procedure turned out to be "Receiving /Shipping". While observing meat and poultry product in containers in the freezer, you observed a pallet of product in boxes shrink-wrapped in clear plastic labeled "Beef Ground Patties and stamped resembling the mark of Federal inspection stating "USDA Inspected and Passed for Wholesomeness". You are suspicious because the "US Inspected and Passed for Wholesomeness" label only applies to poultry not meat products. Meat products should be marked "USDA Inspected and Passed".

Did a potential food defense vulnerability occur? What action, if any, do you take?

Discussion: You asked the warehouse supervisor about the order and he tried to avoid the discussion. Using the authorities provided under Section 202 of the Federal Meat Inspection Act (FMIA) you ask the warehouse supervisor to open a box so that you can examine the inventory.

You found that the boxes contained duck feet. You ask the warehouse supervisor for records on the product, including all shipping records (bills of lading), account records (showing ownership of the product), warehouse records (sorting/loting inventory records) and any other related records.

Records reveal that the Importer of Record (IoR) is located within your area of assignment. On contacting the IoR you discover that the poultry product is part of a larger shipment of product imported from Vietnam and destined for a retail market in a large city in the eastern United States.

Did a potential food defense vulnerability occur? What action, if any, do you take?

- 1. You detain and control the product as set out in FSIS Directive 8410.1, Revision 2, Detentions and Seizures.
- 2. Notify the appropriate Area Veterinarian-in-Charge (AVIC) or Smuggling Interdiction Trade Compliance (SITC) officer, Animal and Plant Health Inspection Service (APHIS), and
- 3. Issue an Import Alert via normal channels and send a copy to both the OPEER Regional Manager and the OIA Regional Import Field Supervisor. You will also fill out FSIS form 5420-3 (Memorandum of Interview), give a copy to the operator, and electronically mail a copy to FSIS Share Point site.

Do you need to take any further action? Why?

Further discussion: Duck feet imported from Vietnam to USA are prohibited items. Highly pathogenic avian influenza (HPAI) H5N1 virus has been isolated several times in Vietnam and many other Pacific Ocean nations. Any poultry product from such countries are prohibited.

Investigators should make special efforts in trying to locate these products in commerce, such as at retail markets, warehouses and restaurants.

A situation like this typically involves a conference call with the Hazard Evaluation Committee (HEC), initiated by the OPEER Regional Manager.

Hydraulic Fluid in Chicken Nuggets SIKE Scenario 12-07 Food Defense Verification Procedures

You are a consumer Safety Inspector (CSI), assigned to a large poultry ready-to-eat (RTE) processing establishment. The current Department of Homeland Security threat condition is YELLOW (Elevated) with no specific threat to the food and agriculture sector. As instructed in FSIS Directive 5420.1 rev 3, after performing all your food safety procedures, you performed a food defense procedure. To determine which procedure to perform, you drew a random number from the computer that corresponded to 08S15 (Processing/Manufacturing).

The plant receives raw poultry meat, processes it with other ingredients, and makes nuggets for the school lunch program. On this day the plant is producing a batch of 20, 000 pounds of nuggets. Guar gum is an ingredient used as a binder. The plant receives all its ingredients from vendors and stores them in the ingredient room. It brings all its ingredients and places them close to the large chopper/mixer. Today for the 08S15 procedure you are to look at grinding/emulsification as your operational task. However, by the time you finished all your food safety procedures most of the mixing and emulsification is finished. At the emulsification area, you noticed a container with some liquid. From your experience you recognized the liquid as guar gum. And also from your experience at this establishment you know that all ingredients are precisely weighed and calculated before they leave the ingredient room; and once they leave the ingredient room into the processing floor, they never go back to the ingredient room for quality control reasons. So finding a container with liquid in it in the emulsification

area baffled you, and you conducted a thorough investigation. You requested and received the help of the processing supervisor; and you jointly tried to find out if guar gum or some other liquid was mixed in the nugget mix.

The processing supervisor informed you that during clean up that morning a hydraulic hose was accidentally ruptured, and the maintenance personnel were working on repairing the hydraulic system. You continued your joint investigation by asking the maintenance foreman if any hydraulic fluid was ever brought to the processing floor that morning. The maintenance foreman informed you that a container of hydraulic fluid was brought into the emulsification area to fix the broken hydraulic system used to raise the hydraulic lift to dump the poultry meat and ingredients to the chopper/mixer. From your experience you knew that guar gum and hydraulic fluid are almost identical in color and consistency. You and the processing supervisor agreed that most probably the hydraulic fluid, instead of guar gum, had been mistakenly added to the nugget mix.

Did vulnerability occur? What action, if any, do you take?

You looked at the MSDS (Material Safety Data Sheet) for the hydraulic fluid, and found that it could cause death if ingested. You called your Front Line Supervisor (FLS) and sought guidance and direction. You were directed to retain the day's production of nuggets and all products in the mixing vats. You collected a sample of the emulsified nugget mix and sent it to an FSIS lab requesting to look for hydraulic oil components.

In a few days the lab results confirmed the presence of hydraulic oil components in the sample. You took the following course of action:

- You immediately notified your Frontline Supervisor and District Office about the test results so that an NRIR (Non Routine Incident Report) could be initiated at the District Office.
- You recorded a "T" for the 08S15 procedure.
- Immediately notified the establishment management and discussed the findings.
- Completed an NR for the product adulteration and cited the appropriate ISP code and regulations.
- Completed FSIS Form 5420-1.
- Provided a copy of the NR and FSIS Form 5420-1 to the plant management.
- Sent a copy electronically to the district analyst and the IF-OFDER mailbox in Outlook. You also maintained a copy in the file.

Because hydraulic fluid is a harmful chemical, the establishment condemned the entire batch of product produced on the date of your finding.

What additional action, if any, would be taken?

The establishment followed its own food safety and defense protocols, and hired a decontamination company to do a thorough cleaning of the emulsification area. The decontamination company gave the establishment a clean bill of health after a complete assessment and decontamination procedures of the emulsification equipment and all other pieces of equipment after the emulsifier. The District Office sent an Enforcement Investigation and Analysis Officer (EIAO) to go over the records review process, and you assisted him in the investigation. The establishment modified its food defense plan to include an additional column to its daily

production log with a statement that all hazardous material brought into the processing floor must be removed from the processing floor before production resumes. An additional precautionary step the plant initiated was to have the daily production log initialed by a supervisor verifying the removal of any hazardous chemical that was ever brought into the processing floor.

<u>SIKE Scenario 13-2007 Food Defense Verification Procedure -</u> Storage Areas – 08S16

You are a Consumer Safety Inspector (CSI), assigned to a small ground beef processing establishment. The current Department of Homeland Security threat condition is YELLOW (Elevated) with no specific threat to the food and agricultural sector. As instructed in FSIS Directive 5420.1 rev. 3 after performing all your food safety procedures, you performed a food defense procedure instead of a scheduled 04C01 procedure. To perform an unbiased procedure, you drew a random number from the computer. That number corresponded to 08S16 (Storage Areas).

The plant receives raw beef in combo bins from several suppliers, and produces ground beef patties for several major nationwide restaurant chains. While monitoring the storage coolers, you observed that the plastic covers of several combo bins had rips and sharp cuts in them. Based on your professional judgment the damage to the combo covers appeared to be intentional. You called in the cooler foreman to let him know that you were intending to perform a closer inspection of those combos. Wearing a rubber glove you lifted several plastic covers. You observed that the meat under the cuts in the covers was much more wet than the surrounding product, as if someone had poured a liquid on it. This proved to be the case of all of four combo bins with torn tops. You wrote down the lot numbers of those combos and headed to consult with your Frontline supervisor.

Did a breach occur? What action, if any, do you take?

You informed your Frontline supervisor with a suspicion of intentional tampering who agreed with your line of thinking. She informed you that she would further consult with the District Office and OPHS and get back to you. The Frontline Supervisor called you back with the information that OFO, HQ has contacted OPHS and Eastern lab was sending four sample boxes, supplies and FSIS Forms 10,210-3 by FEDEX to arrive the next day. She authorized you to collect four samples to be sent to the Eastern laboratory the moment the supplies arrive.

You are very familiar with raw ground beef components from your past experience with FSIS Directive 10,010.1, Rev 1, attachment 2. You informed the plant management that you were collecting four samples from the four suspicious combos. You collected 1.5 pounds of beef chunks from each affected combo per sample using sterile procedure, and placed them into individual sterile sample bags. The plant also collected four companion samples for their own lab analysis. The plant voluntarily retained those combos, and you wrote down the retained tag numbers, and lot numbers. You again followed the sampling procedure as outlined in Directive 10,010.1, and sent four samples to the Eastern lab overnight by FEDEX.

While you were waiting to hear from FSIS Eastern lab, the plant informed you that the plant's in-house lab found three of the four samples positive for E. coli 0157:H7. The plant notified the local Sheriff's department and the regional FBI to launch an investigation. The plant also notified you that they were sending the entire affected lots to another federal establishment under company seal for cooking labeled with the instructional statement, "for cooking only".

Do you need to take any further action? Why?

The next day you received the FSIS lab results. Two of the four samples were positive for E. coli 0157:H7. The lab results did not indicate the presence of any other threat agents.

- You record a "T" for the 08S16 procedure.
- Immediately notify the establishment management and discuss the findings.
- Complete an NR for the product adulteration and cite the appropriate ISP code and regulations.
- Complete FSIS Form 5420-1.
- Provide a copy of the forms to the plant management: and
- Send a copy electronically to the district analyst and the IF-OFDER mailbox in Outlook. Maintain a copy in the file.

Discussion

The plant has voluntarily suspended operations until the Police and FBI finish their preliminary investigation. You provided all the pertinent information as enumerated on page 6 of FSIS Directive 5500.2, rev 1 to your District Office (DO) so that an FSIS Form 5500-8 can be completed. You also update the DO periodically with further information about changes in the facility's operational status, so that the 5500-8 can be updated over time.

If you have any question about this SIKE please email to ASKFSIS for a response.

<u>SIKE Scenario 14-2007 Food Defense Verification Procedure - Storage Areas – 08S16</u>

You are a Consumer Safety Inspector (CSI), assigned to a small ground beef processing establishment. The current Department of Homeland Security threat condition is Elevated (YELLOW). As instructed in FSIS Directive 5420.1 rev. 3, after performing all your food safety procedures, you performed an unscheduled food defense procedure instead of the scheduled 04 procedure. To ensure an unbiased selection of a 08 procedure, you drew a random number from the computer. That number corresponded to 08S16 (Storage Areas).

The plant receives raw beef in combo bins from several suppliers, and produces ground beef chubs for several local retailers.

While monitoring the storage coolers, you observed white powder sprinkled over meat trimmings in four combo bins. You immediately notified the cooler foreman to let him know of your finding. The cooler foreman retained the four combo bins with company tags. Upon further investigation you determined that a few combos of trimmings had already been ground that day. Lot numbers of affected combos of beef trimmings with the white powder and ground beef that were already ground that day were obtained and recorded. With all the information collected, you determined it was time to consult with your Frontline supervisor.

Did a breach occur? Was there intentional product tampering or sabotage? What immediate action, if any, do you take?

You informed your Frontline supervisor about your suspicion of intentional tampering who agreed with your suspicion. You informed her that you are in the process of sending the District Office (DO) data that are pertinent to initiate an FSIS Form 5500-4 (NRIR), and you are going to do that as soon as you finish your phone call with the Frontline supervisor. You also informed her that the establishment management has notified the FBI and local law enforcement authorities.

Local law enforcement officials arrived at the establishment and began their investigation. The FBI forensic team collected five samples for analysis. The plant voluntarily retained the ground beef produced that day in addition to the already retained combo bins. Retained tag numbers and lot numbers were recorded.

While you were waiting to hear the results of the tests from the FBI, local and national news media began reporting an increase in illnesses with customers who consumed beef purchased locally. The symptoms associated with the illnesses included fatigue, loss of feeling in their extremities, irritation of stomach and throat, nausea, vomiting, and rapid dehydration. A few older patients displayed cardiac arrhythmias in addition to many of the above symptoms as reported by the news media.

The next day you found out about the FBI lab results. All five samples were positive for Arsenic trioxide. The lab results did not indicate the presence of any other threat agents.

Do you need to take any further action? Why?

- Record a "T" in PBIS for the reported 08S16 procedure.
- Immediately notify the establishment management and discuss the findings.
- Complete an NR for the product adulteration and cite the appropriate ISP code and regulations.
- Complete FSIS Form 5420-1.
- Provide a copy of the forms to the plant management; and
- Send a copy electronically to the district analyst and the IF-OFDER mailbox in Outlook. Maintain a copy in the file.

Discussion and Actions

The plant has voluntarily condemned the combo trimmings with the visible powder and all ground beef produced on the day that the powder was observed. They have voluntarily retained all existing ground beef produced

the day before, and sent samples for further testing. The plant has voluntarily suspended operations until the local law enforcement and FBI finished their investigation. You are aware that FSIS personnel only play a supportive role in a crime scene as described here. The primary role belongs to the first responders (FBI, local law enforcement). The establishment has made arrangements with a private contractor to destroy the contaminated product.

Arsenic trioxide is a white powder used in the manufacture of pesticides and chemicals. If you have any question about this SIKE please email to askFSIS for a response.

SCENARIO 01-2012: WATER SYSTEMS FOOD DEFENSE VERIFICATION PROCEDURE (08S14) – OUTSIDE WELL

Situation

You are a Consumer Safety Inspector (CSI) assigned to a large chicken slaughter and processing establishment performing Food Defense Verification Procedure 08S14 (Water Systems).

The plant is supplied primarily by the municipal water system, but also frequently uses two wells on its premises as secondary sources of water to save costs. You check the inside water systems and do not identify any potential food defense vulnerabilities. You then check the two wells and see that although one of the wells is locked, it appears that someone has tampered with the other well; the lock is intact, but the hasp has been pried open from the door jamb. You evaluate the plant operations further, and you discover that the well that might have been tampered with was online at the time of your inspection.

Actions and Conclusions

You discuss your findings with the maintenance supervisor, who informs you that he was not aware of any potential tampering with the well, and that the broken door hasp must be a very recent occurrence. Because a person could deliberately introduce contaminants or adulterants through the well, you inform the Inspector in Charge (IIC) of the situation.

The IIC holds a teleconference with the district manager (DM) and FSIS' Eastern Laboratory in Athens, on which the DM and laboratory staff ask the IIC to collected a water sample from both wells—a sample from the well that someone potentially tampered with, and a sample from the intact well for comparison—and to send both samples to the Eastern laboratory for testing. (The DM instructs the IIC to collect these samples despite the fact that FSIS does not routinely test potable water samples.) When collecting the water samples the IIC notices that the samples show no visible signs or smells that suggest that they are contaminated. The establishment voluntarily retains the product that used the well—water pending the water-test results.

The IIC asks you to verify whether or not the company had noted the potential vulnerability at the well in any of their daily records. Your records-review produced no evidence of any such documentation.

You document the 08S14 procedure in the Public Health Information System (PHIS) with an "S". The IIC schedules a meeting with the establishment, and you accompany the IIC to the meeting. At the meeting, you and the IIC inform the establishment that if the test results for the water sample show that it is non-potable, you will enter a Noncompliance Record (NR) in PHIS, and change the results of the 08S14 from an "S" to a "T". You refer the establishment to FSIS' website related to food defense and emergency preparedness

(http://www.fsis.usda.gov/Food Defense & Emergency Response/index.asp) for

additional information on countermeasures the establishment could adopt to protect water systems.

After your meeting with the establishment, you document a Memorandum of Interview in PHIS (MOI; FSIS Form 5420.1). You also attach a USDA Retain/Reject tag to the valve which connects the water from the potentially tampers-with well to the plant water supply to stop further use of the well water, and advise plant management accordingly.

Once test results are available, the Eastern Laboratory notifies the district office that the water sample from the well that appeared to have been tampered with had an unacceptable level of arsenic (200 ppb or 200 microgram/liter; the Environmental Protection Agency's acceptable level for arsenic is 10 ppb). The concentration of arsenic in the water sample from the intact well is 5 ppb and, therefore, is considered acceptable. The district office informs the IIC of the test results, and that an Enforcement Investigation and Analysis Officer (EIAO) is on her way to the establishment to review and document the event, and to collect data for a Non Routine Incident Report (NRIR). The district office also instructs the IIC to share the test results with plant management, and to ask the establishment to have records available for the Emergency Management Committee (EMC; refer to Directive 6500.1) through the district office as soon as possible. The establishment voluntarily retains the product suspected to be contaminated with arsenic.

Because there was evidence that product could be adulterated, you enter an NR in PHIS. You attach the NR to the MOI and give it to the establishment. You send electronic copies of the MOI via PHIS to: 1) your Frontline Supervisor; 2) the district office through the IIC; and 3) to the EIAO to assist her in her investigation. (**Note**: An NR does not take the place of an MOI. If contamination of product is discovered during the performance of a food defense procedure, both an NR and an MOI should be written. CSIs and other inplant personnel should follow Directive 5000.1 if an enforcement action is necessary.)

The establishment decides to hire a night watchman to patrol the outside premises, and has stopped using water from the well that was tampered with.

SCENARIO 02-2012: SHIPPING AND RECEIVING FOOD DEFENSE VERIFICATION PROCEDURE (08S17) – UNLOCKED EGG TANKER

Scenario

You are a Consumer Safety Inspector (CSI) and the Inspector in Charge (IIC) at a one-shift egg breaking and processing plant. Earlier in the day, the foreman had notified you that a tanker truck of unpasteurized "liquid egg yolk" was scheduled to arrive at about 2:00 pm and you decided to perform Food Defense Verification Procedure 08S17 (Shipping and Receiving) on that tanker truck. When the tanker arrives, you notice that it has an unlocked/unsealed hatch.

Actions and Conclusions

You review Directive 5420.1 rev 7 and determine that there is a potential food defense vulnerability. In addition, as per CFR 590.504(o) (2), tanker trucks with unpasteurized liquid egg product are to move under seal and certificate between official establishments for pasteurization, re-pasteurization or heat treatment. You, therefore, have discovered a potential food defense vulnerability, and a food safety violation. You document this in the Public Health Information System (PHIS), and retain the product with a USDA Retain/Reject tag until pasteurization.

You then meet with the establishment management to discuss the potential food defense vulnerability. You refer the establishment to FSIS' website related to food defense and emergency preparedness

(http://www.fsis.usda.gov/Food Defense & Emergency Response/index.asp) for additional food defense resources, including food defense plans. After your meeting, you: 1) write a Memorandum of Interview (MOI) on Form 5420.1 in PHIS to document your meeting with the establishment operator; and 2) send via PHIS an electronic copy of the MOI to the frontline supervisor, the district office and IFOFDER (e-mail address of OFDER).

SCENARIO 03-2012: PROCESSING/MANUFACTURING FOOD DEFENSE VERIFICATION PROCEDURE (08S15) – POWDER ADDED TO GRINDER FOR HAMBURGER

Situation

You are a Consumer Safety Inspector (CSI), assigned to a small ground beef processing establishment performing Food Defense Verification Procedure 08S15 (Processing/Manufacturing).

The plant receives raw materials (combo beef) from several suppliers, and produces hamburger patties for several major chains of restaurants nation wide. The plant plans to make two large batches of hamburger patties today. You decide to view the meat grinding area as part of performing 08S15. When you enter the grinding room, you notice an unsupervised, contract pest control employee near the grinder. After the pest control employee left the area, an hourly worker tells you that he observed the pest control employee dump white powder from a plastic bag into the grinder.

Actions and Conclusions

You and the worker tell the plant manager about the potential food defense vulnerability.

The plant manager voluntarily retains the product and begins an investigation. You inform your district office of the situation, who, in consultation with FSIS' laboratories, decide that testing should be conducted. You inform the plant manager that FSIS would like to collect a one pound sample of the ground beef for special analysis. The district office provides you with the address of a specialty lab and special instructions for sampling and shipping procedures. You collect and send the sample as instructed.

Two days later, the results of the laboratory test indicate that strychnine is present. The plant launches a police case against the pest control company.

You meet with plant management and discuss the importance of supervising outside contractors in production areas, and refer the establishment to FSIS' website related to food defense and emergency preparedness

(http://www.fsis.usda.gov/Food_Defense & Emergency Response/index.asp) for more information on food defense. After the interview you document it in PHIS in a Memorandum of Interview (MOI) and check trend indicator "T" for your food defense verification task.

Because there was evidence that product could be adulterated, you enter a Noncompliance Record (NR) in PHIS. You attach the NR to the MOI and give it to the establishment via PHIS. You send electronic copies of the MOI via PHIS to: 1) your frontline supervisor; 2) the District Office through the IIC; and 3) to the EIAO to assist her in her investigation. (Note: An NR does not take the place of an MOI. If contamination of product is discovered during the performance of a food defense procedure, both an NR and an MOI should be written. CSIs and other in-plant personnel should follow Directive 5000.1 if an enforcement action is necessary.)

The district office informs you that an Enforcement Investigation and Analysis Officer (EIAO) is on her way to the establishment to review and document the event, and to collect data for a Non Routine Incident Report (NRIR). The district office also instructs the IIC to share the test results with plant management, and to ask the establishment to have records available for the Emergency Management Committee (EMC; refer to Directive 6500.1) through the district office as soon as possible.

SCENARIO 04-2012: PROCESSING/MANUFACTURING FOOD DEFENSE VERIFICATION PROCEDURE (08S15) – WHITE POWDER IN COMBO BINS FOR SAUSAGES

Situation

You are a Consumer Safety Inspector (CSI) in a processing plant performing Food Defense Verification Procedure 08S15 (Processing/Manufacturing).

The plant makes several types of sausages, including German, Thuringer (Cervalet) and blood sausage. Today the plant is making a 500 pound batch of Thuringer sausage. As part of performing the 08S15 procedure, you visit the ingredient mixing area and notice that the door to the dry ingredient room is open, but that nobody is in the area. You also notice a plastic bag labeled *Compound 1080* lying on top of the trash can; the bag is empty except for a bit of flour-like powder that is in the bottom of the bag. You are not aware of Compound 1080 being an ingredient in Thuringer sausage.

Actions and Conclusions

You find the foreman in charge of the sausage production, bring him to the ingredient room, and show him the bag. The foreman does not know what Compound 1080 is, but does tell you that he had just added the dry ingredients to the meat in the chopper.

You called the Technical Service Center in Omaha to gather additional information about the nature of the chemical. A Staff Officer tells you that Compound 1080 is a very poisonous rodenticide that is only available to licensed pest control operators. He also tells you that FSIS laboratories do not have the capability to detect Compound 1080.

You call your Front Line Supervisor (FLS), who tells you that he will come to the plant, and tells you to remain in the plant and try to find out where the bag came from. He also tells you to check the combo bins in the cooler for any white powder. Two of the combo bins had their plastic coverings partially removed and appeared to have been sprinkled with a white powder substance. You apply a USDA Retain/Reject tag to those two combo bins. You called the district office (DO) to let them know your findings and inform the office of your conversation with the Technical Service Center. The district manager (DM) tells you that arrangements are being made with a specialty lab for a sample to be analyzed.

The plant does not know how the empty bag of Compound 1080 got in the ingredient room, and decides to voluntarily retain the product until the lab results are available. The plant tells you that Thuringer sausage had not been produced for many months and, therefore, there are no earlier batches to be concerned about.

After conversations with FSIS' laboratories, the DO provides you with sampling instructions. As per its instructions—after informing the establishment and putting on a pair of gloves—you collect a one pound sample of the raw ground product, and a one pound sample from the two combo bins which the plastic removed. You ship the samples overnight to the specialty lab as arranged by the DO, writing "Compound 1080 Suspected" on the sample form as directed by the DO. Your FLS asks you to call him

after receiving the lab result. The plant management has called the police to investigate the potential contamination incident.

[Note: Under some circumstances, if it is suspected that a hazardous substance is present, a HAZMAT team might be dispatched to the scene to collect samples and conduct an investigation. The DO would you inform you if that is the case.]

You perform a record review of the last two days' production to check whether any other product is likely to have been adulterated with the compound.

In reviewing the plants records in the Public Health Information System (PHIS), you note that you had previously written a Memorandum of Interview (MOI) for Food Defense Verification Task 08S16 a month earlier because the dry ingredient room was not secured. You had also written an MOI for task 08S15 (Processing/Manufacturing) because you saw unauthorized personnel in the production area two months before that. The plant had responded to both MOI's stating that they would further study the incidents and get back to you. The plant does not have a written food defense plan.

You record the 08S15 procedure in PHIS with the trend indicator "S". You meet with establishment management to discuss the situation and tell them that, if the lab sample comes back positive for the rodenticide, you will change the "S" to a "T". Y After your meeting with the establishment, you complete a Memorandum of Interview (MOI; FSIS Form 5420.1) in PHIS.

Two days later, the DO calls with the laboratory results, which indicate that the Thuringer sausage, and the two combo bins contain Compound 1080, and that all products produced in the last two days should be retained for further inspection and investigation by an FSIS team and other Federal and local officials. The DO also informs you that an EIAO is coming to the plant to conduct a records review.

You enter a Noncompliance Record (NR; 5400-4) in PHIS under Task Code 03I01 (Product with Secondary Inhibitors-Not Shelf Stable) for a monitoring violation because the plant's HACCP plan states that all ingredients, including raw material, will be checked visually for any extraneous material before grinding. You retained the entire batch of the affected product in the cooler until the plant can comply with 417.3 (a) and 417.4 (a) (3). You also changed the trend indicator for the 08S15 procedure from "S" to "T" in PHIS.

You attach the NR to the MOI in PHIS and send it to the establishment. You send electronic copies of the MOI via PHIS to: 1) your Frontline Supervisor; 2) the district office through the IIC; and 3) to the EIAO to assist her in her investigation.

[Note: An NR does not take the place of an MOI. If contamination of product is discovered during the performance of a food defense procedure, both an NR and an MOI should be written. CSIs and other in-plant personnel should follow Directive 5000.1 if an enforcement action is necessary.]

SCENARIO 05-2012: WATER SYSTEMS FOOD DEFENSE VERIFICATION PROCEDURE (08S14) – POWDER IN THE ICE ROOM

Situation

You are a consumer Safety Inspector (CSI), at a large ready-to-eat (RTE) chicken processing establishment performing Food Defense Verification Procedure 08S14 (Water Systems).

The plant receives raw chicken breasts, and processes them with other ingredients to make chicken nuggets for the school lunch program. On this day the plant is producing a batch of 20,000 pounds of nuggets. Ice is an ingredient in the mixing process. The plant makes its own ice in a two story building, and transports that ice to the processing flow via a chute with an auger. As part of your 08S14 procedure you are looking at ice use in the plant. You observe the water intake area, the second floor ice room, the auger and the chute, which is mostly hidden from the view of plant workers by plastic curtains. You see a streak of yellowish-white powder running down the stainless steel chute, and a paper sac hanging from a make-shift hook attached above the chute. The sac has a small slit cut in the bottom, allowing a small stream of powder to pour on the ice chute. Yellowish-white powder is not a normal ingredient used in ice making. You did not see any other potential vulnerabilities in the ice house, or at the water intake valve.

Actions and Conclusions

You immediately inform the plant manager of your finding. Because ice had already been used for the processing of the chicken nuggets, the plant manager voluntarily stops production. He also asks his maintenance chief and security chief to look at the powder, and determine the next course of action.

After showing plant management the chute with the powder and the bag, you call your front line supervisor (FLS) and district office to inform them of the developments. On the call, you make sure they know that products for the National School Lunch Program are involved. After your call, you see that the local fire department's HAZMAT team is already on the scene. You continue in a secondary role because you know from your Incident Command System (ICS) 100 and 200 training to let the first responders take the primary role in these situations.

In your role of ensuring that the food supply remains safe, you retain the day's production of chicken nuggets and all products in the mixing vats. You also retain the previous day's entire production lot. You record trend indicator "T" for the 08S procedure in PHIS, and record an NR. You also checked "T" on Question 3a of FSIS Form 5420-1 and fill out the rest of the form. You note that the HAZMAT team has sent a pound of ice from the ice chute, a pound of raw chicken mix from the mixing-vat, and a pound of finished chicken nuggets from the previous day's production to a specialty lab. FSIS laboratories do not necessarily test for unknown, potentially hazardous chemicals, so you did not collect a sample, but you did offer the guidance of FSIS laboratory personnel for discussions of the analysis of food samples.

A few days later the plant receives the sample test results, which detect the presence of ricin in some of the samples. The lab results for the previous day's finished chicken nuggets are negative. You immediately notify your FLS and district office about the results. Because ricin is a very lethal chemical, the establishment condemned the entire batch of product produced on the date of your finding. You release the chicken nuggets produced the day before you found the powder on the chute that had tested negative for ricin.

(**Note:** Ricin is a very toxic chemical, and exposure to even small amounts can cause death. While not readily available to the general public, it can be made by a person with some training in chemistry. Although it may lose some potency after cooking, there is enough toxicity left that one should be very careful handling this chemical.)

The establishment—consistent with its own food safety and defense protocols—hires a decontamination company to do a thorough inspection and cleaning of the facility, making sure that remaining dry ingredients and other products are not contaminated. The decontamination company verifies that there is no more ricin present in ingredients, equipment or elsewhere in the facility. The district office sends an Enforcement Investigation and Analysis Officer (EIAO) to go over the records review process, and you assist him in the investigation.

It is important to note that, because this facility makes products that enter the National School Lunch Program, products might be subject to more rigorous food defense controls during processing that are stipulated in purchasing contracts with the Agricultural Marketing Services (AMS). AMS representatives would work with the establishment to ensure that those requirements are met.

SCENARIO 06-2012: STORAGE AREA FOOD DEFENSE VERIFICATION PROCEDURE - STORAGE AREAS (08S16) – ARSENIC IN COMBO BINS WITH CONSUMERS GETTING ILL

Situation

You are a Consumer Safety Inspector (CSI), assigned to a small ground beef processing establishment performing Food Defense Verification Procedure 08S16 (Storage Areas).

The plant receives raw beef in combo bins from several suppliers, and produces ground beef chubs for several local retailers. While monitoring the storage coolers you observe white powder sprinkled over meat trimmings in four combo bins.

Actions and Conclusions

You immediately notify the cooler foreman to let him know of your finding. The cooler foreman retains the four combo bins with company tags. Upon further investigation you determine that a few combo bins of trimmings had already been ground that day. You obtain and record the lot numbers of the combo bins of beef trimmings containing the white powder, and the lot numbers of ground beef that were already ground that day. With all the information collected, you telephone your Frontline Supervisor (FLS) to inform her about the situation and your suspicion that intentional contamination occurred, and consult with her about your next steps. Your FLS is also concerned about the potential that intentional contamination has occurred. You tell her that you collected the information that is relevant to FSIS Form 5500-4 (NRIR) so the DO can initiate the form, and that you will send that information as soon as the phone call is finished. You also inform her that the establishment management has notified the FBI and local law enforcement authorities.

Local law enforcement officials and the FBI forensic team arrive at the establishment and began their investigation; the FBI collects five samples for analysis. The plant voluntarily retains the ground beef produced that day, in addition to the already retained combo bins. You record the retained tag numbers and lot numbers.

While you are waiting to hear the sample test results from the FBI, local and national news media are reporting an increase in illnesses in customers who consumed locally purchased beef. The symptoms associated with the illnesses include fatigue, loss of feeling in their extremities, irritation of stomach and throat, nausea, vomiting, and rapid dehydration. According to the news reports, a few older patients displayed cardiac arrhythmias in addition to many of the above symptoms. The plant voluntarily condemns the combo trimmings with the visible powder and all ground beef produced on the day that the powder was observed, and they voluntarily retain all existing ground beef produced the day before and send samples for further testing. The plant also voluntarily suspends operations until the local law enforcement and FBI finish their investigation.

The next day, the FBI's test results arrive indicating that all five samples are positive for arsenic trioxide; the lab results do not indicate the presence of any other threat agents.

You are aware that FSIS personnel only play a supportive role in a crime scene as described here. The primary role belongs to the first responders (FBI, local law enforcement). The establishment has made arrangements with a private contractor to destroy the contaminated product.

(**Note**: arsenic trioxide is a white powder used in the manufacture of pesticides and other chemicals.)

You meet with plant management, and refer them to FSIS' website related to food defense and emergency preparedness

(http://www.fsis.usda.gov/Food_Defense_&_Emergency_Response/index.asp) for more information on food defense. After the interview you enter a Memorandum of Interview (MOI; Form 5420-1) and check trend indicator "T" for your food defense verification task in the Public Health Information System (PHIS).

Because there was evidence that product could be adulterated, you write a Noncompliance Record (NR) in PHIS. You attach the NR to the MOI and send it to the establishment. You send electronic copies of the MOI to: 1) your FLS; and 2) the district office via PHIS.

(**Note**: An NR does not take the place of an MOI. If contamination of product is discovered during the performance of a food defense procedure, both an NR and an MOI should be written. CSIs and other in-plant personnel should follow Directive 5000.1 if an enforcement action is necessary.)