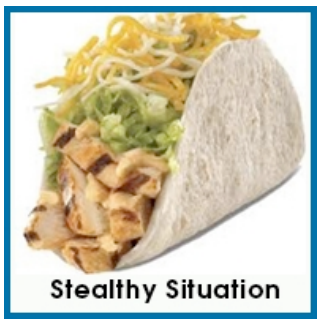

Food Related Emergency Exercise Boxed-set

(FREE-B)

How Sweet It Is(n't)

Situation Manual

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Introduction

Purpose

To protect the health of the American public, it is crucial that we ensure that food products are safe for consumption. Everyone involved in the food chain, from farmer to consumer, has a responsibility to keep the food supply safe.

At any point during production or distribution, food can be contaminated either accidentally from employee error or on purpose from sabotage, fraud or terrorist activities. Regardless of the circumstances, the Food and Drug Administration (FDA) and United States Department of Agriculture Food Safety and Inspection Service (USDA FSIS), collaborating with State and local agencies, work closely to safeguard the American food supply.

Through this working relationship, FDA, USDA FSIS, and Centers for Disease Control and Prevention (CDC) continuously seek new ideas and strategies to reduce the incidence of human health emergencies and to support food defense-related innovation. In light of food defense concerns, it is incumbent that Federal, State and local governments and industry partners understand the roles and responsibilities of all participating entities.

This scenario focuses attention on the regulatory traceback investigation that occurs after standard product testing shows that a food product contains excessive levels of a contaminant, as well as a recall of contaminated food from commerce. Like typical foodborne outbreaks, the response will initially be at the local and State levels; however, this scenario will also introduce participants, to a minor extent, to the unique aspects of an international investigation.

Participants

This scenario should include participants from State, local and Tribal agriculture and health departments, the food production and processing industry, food product distributors, and the FDA (Federal and/or regional). Ideally, participants would also include representatives from foreign embassies/consulates (attachés), Foreign Ag Service, Customs and Border Protection (CBP), and brokers/importer organizations — however, recognizing that this group may be difficult for a State employee to identify and coordinate with, discussion questions will be used to prompt State and local officials to consider the need for input from and their potential interaction with these authorities.

Goal

This tabletop exercise provides participants with an overview of actions taken at the Federal, Tribal, State, territorial and local levels when a food-related incident occurs. It will focus on the role that key personnel play in containing the problem and protecting consumers. A large amount of information in this tabletop exercise will be generated from discussions among participants as they go through a hypothetical scenario. During the tabletop exercise, participants will assess plans, policies and procedures and think about how they would realistically apply them in the event of an incident. This tabletop exercise will help to facilitate discussion among various participating entities, such as State and local entities and the private sector within the State.

Exercise Objectives

At the conclusion of this tabletop exercise, participants will be able to:

- Explain their specific roles and responsibilities in reacting to an unintentional contamination
- Describe the specific risks and consequences of not adhering to the guidelines and procedures for collecting product samples, maintaining chain of

custody and conducting analytical product testing in accordance with recognized standards

- Catalog critical information related to the upstream flow of food products from distribution to the source
- Analyze the flow of food products through the upstream distribution system and identify linkages and commonalities that may reveal the root source of contamination
- List the unique challenges inherent in the traceback of food through an international distribution system
- Understand the importance of internal and external communications and dialogue and have ideas about how to improve both in their organization

Exercise Structure

This exercise is designed to be an interactive, facilitated tabletop exercise. Participants are encouraged to ask questions of each other and learn from one another. It has been designed by a group of subject matter and instructional design experts to provide participants with a real-life, plausible food safety scenario. While this scenario has been simplified in order to present the information in an effective way, the scenario itself and the discussion questions have been designed to encourage participant dialogue and surface topics that are critically important to reacting to such incidents. The exercise has also been developed to provide participants with an opportunity to explore important topics like interagency collaboration, jurisdictional issues and risk communication. The information in this scenario reflects the policies and procedures currently in use and is accurate as of May 2011. If there has been an update to the procedure in your jurisdiction, please be sure to make the group aware of the change and work with the facilitator to ensure that all participants understand the update.

This exercise was developed by the Institute of Food Technologists (IFT) on behalf of the Food and Drug Administration CFSAN Food Defense Oversight Team. The entire series of modules includes the following: This exercise is a multimedia, facilitated tabletop exercise (TTX). Participants will respond to three different modules:

- **Module 1 –** Identification of Violative Food
- **Module 2 –** Traceback Investigation
- **Module 3 –** Traceforward Investigation and Recall

This scenario was also produced in cooperation with the Centers for Disease Control and Prevention.

Exercise Guidelines

As with any learning experience, it is important that this exercise is conducted in a safe learning environment so that all participants can share and explore concepts with one another, while discussing multiple solutions and options for a given issue. This exercise will operate under the following guidelines:

- This will be an open, low-stress and non-public learning environment and is not intended to set precedents.
- Participants will listen to and respect the varying viewpoints of all of the other participants.
- The scenario we will discuss is plausible, and the events occurred as presented. Suspend your disbelief, and feel free to discuss differing policies and procedures during the breakout discussion.
- Today's facilitator is not necessarily a subject matter expert, and participants are expected to provide the expertise needed to ensure that our discussion is accurate and thorough.
- We will apply our findings from today's activities to our jobs/functions and share key findings with colleagues.

Roles and Responsibilities

Lead Planner – The person who has overall responsibility for the tabletop exercise, including convening the Planning Team and all pre- and post-exercise needs

Participants – Respond to the scenario based on their first-hand, experiential knowledge; current plans and procedures of their individual entity, agency or jurisdiction; and insights from training and experience.

Evaluator(s) – Record the highlights of the discussion at each breakout table. These people do not participate in the exercise but capture the essence of the dialog for use in the After Action Report. They are chosen based on their expertise in the areas they are to observe.

Facilitator – Generally leads the exercise, provides situation updates and moderates discussions. They also provide additional information and resolve questions as needed. Key officials may also assist with the facilitation as subject matter experts during the exercise.

Group Leader – Representative from each table (volunteered by the group) who will lead the group as it explores discussion questions and the breakout activities.

Group Recorder/Reporter – Representative from each table (volunteered by the group) who will ensure that the group discussions are kept on time, record the key themes discussed at the table, and will be responsible for reporting out during the large group dialogue.

MODULE 1 – Identification of Violative Product

Lead is a heavy metal that can accumulate in the body. High levels of lead in the blood, especially of children, cause developmental delays and other adverse health consequences. The Food and Drug Administration issued a Guidance Document in November 2006 indicating that levels of lead in candy above 0.10 ppm could indicate a lack of compliance with Good Manufacturing Practices.

High levels of lead have been associated with ingredients found in candy, such as chili powder. These candies are generally imported into the United States. Several states have programs to test for lead in candy and take legal action when lead levels above an established limit are detected.

May 16

On the morning of May 16, a State health inspector, operating under state authority, visited a distribution center that provided many local grocery stores with candy. The inspector observed 25 cases of an imported chili-containing candy, Yenny's Chili Dulces, and collected five 1-pound packages of the candy from multiple cases in inventory at the distribution center. This particular brand had not previously been tested for lead by the State, but the inspector recognized this type of candy as one that had been associated with elevated lead levels in the past.

The health inspector was careful to establish the chain of custody of the samples by sending them to the State food and drug laboratory through an approved carrier via second-day shipping. The samples were analyzed a week after receipt, given that the product was suspect.

Notes: About Sample Preparation and ICP-MS Analysis

There is high variability in lead levels within candy, including piece-to-piece variation. By doing "pulls," there is a greater likelihood of having a sample that is representative of the make-up of the lot.

ICP-MS stands for "inductively coupled plasma mass spectrometry," and is used as a tool to determine the concentration of metals (and several non-metals) in a sample with a very high degree of sensitivity. For example, metals can be detected at concentrations less than one part per trillion.

(End notes)

The laboratorian carefully opened each bag of candy and removed several pieces from each bag to generate a composite sample. A representative analytical sample was prepared for digestion and ICP-MS analysis. Test results showed that the composite sample contained 0.18 ppm of lead and was above the legal limit in the State, as well as the limit set by FDA guidance for lead in candy for small children. Given that this type of candy (imported candy containing chili) had previously been associated with elevated

lead levels and that positive samples often had lead levels in this range, it was assumed that the candy had been unintentionally contaminated at some point in production.

Notes: About Signals that May Prompt Sample Collection

Within this jurisdiction, there is a legal limit for the level of lead in candy, and the State supports a program to test candy samples. In other jurisdictions, it may be more likely that a child exhibits an elevated blood lead level and that after the elimination of other possible sources of lead (e.g., paint dust), a consumer product such as candy emerges as the likely source of lead.

(End notes)

Once the positive sample was detected, another individual performed the analysis from the same composite sample. The second test confirmed an elevated level of lead in the candy, and the results of both tests were sent to the supervisor at the health department.

May 26

On May 26, the supervisor at the health department telephoned the health inspector in the field who had originally taken the samples. The inspector returned to the distribution center, provided the results of the laboratory analysis and told the manager of the center that the candy was in violation of state law and could not be sold.

The inspector was able to obtain copies of invoices from the distribution center that showed that the candy had been purchased from two importers. Although the candy did not have lot numbers on the bags or on the outer cases, the manager at the distribution center assured the inspector that the cases in inventory had been received on or after May 5, as the distribution center was out of stock of that candy prior to the Cinco de Mayo celebration. The distributor received two shipments of candy from importer A: 15 cases on May 5 and 20 cases on May 12. Because of the temporary shortage, the distributor had also ordered seven cases from importer B, which were received on May 10. Both importers were located in the same state as the distributor.

The manager stated that there were seven “regular” customers for this candy: two larger retailers who generally ordered two cases per week and four smaller stores who ordered an average of a case per week. However, the manager also said that there were occasionally other types of individuals (such as ice cream trucks, concession stands, etc.) that wanted less than a case of candy, and that the distributor would split cases for these customers. All customers were located in the same state as the distributor.

The distribution center reluctantly volunteered to issue a recall and limited the recall to product shipped on and after May 5. The distributor also had to create a record in the Reportable Food Registry.

Notes: About the Reportable Food Registry

From http://www.fda.gov/food/foodsafety/foodsafetyprograms/rfr/default.htm#about:

> **"The Reportable Food Registry (RFR or the Registry) is an electronic portal for Industry to report when there is reasonable probability that an article of food will cause serious adverse health consequences. The Registry helps the FDA better protect public health by tracking patterns and targeting inspections. The Food and Drug Administration Amendments Act of 2007 (Pub. L.110-085), section 1005 directs the FDA to establish a Reportable Food Registry for Industry.**
>
> **The RFR applies to all FDA-regulated categories of food and feed, except dietary supplements and infant formula.**
>
> **Registered Food Facilities that manufacture, process, pack or hold food for human or animal consumption in the United States under section 415(a) of the FD&C Act (21 U.S.C. 350d) are required to report when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals.**
>
> **Federal, State and local government officials may voluntarily use the RFR portal to report information that may come to them about reportable foods."**

(End notes)

Table 1 shows when the distributor received cases of candy from the importers and when and to whom the cases were sold. Because the cases looked identical and did not have lot numbers or dates applied to them, the distributor could not be certain which customers received candy from which importer.

Table 1. Records from the Distribution Center showing dates of receipt and shipment of candy

Date	Received	Shipped	Remaining
Th, May 5	15 cases – importer A	2 cases- cust M	13 cases A(1)*
Fr, May 6		1 case- cust N 1 case- cust O ½ case- cust P	10 ½ cases A(1)
Sa, May 7		2 cases- cust Q	8 ½ cases A(1)
Mo, May 9		½ case- cust R	8 cases A(1)
Tu, May 10	7 cases – importer B	2 cases- cust S	13 cases A(1)+B**
We, May 11		1 case- cust T 1 case- cust U	11 cases A(1)+B
Th, May 12	20 cases – importer A	2 cases- cust M	29 cases A(1)+B+A(2)
Fr, May 13		1 case- cust N 1 case- cust O	27 cases A(1)+B+A(2)
Sa, May 14		2 cases- cust Q	25 cases A(1)+B+A(2)
Mo, May 15			25 cases A(1)+B+A(2)

*A(1) indicates the first shipment received from importer A; A(2) indicates the second delivery made by importer A to the distributor.

**The manager indicated that "first in, first out" inventory control should have been in place. However, because the origins of the cases of candy could not be determined, it couldn't be guaranteed that all cases originating from the May 5 shipment from importer A were depleted before cases from importer B were used to fill orders.

Notes: About International Health Regulations (IHR)

From http://www.who.int/ihr/about/en/:

The International Health Regulations organization is usually informed about any potential intentional contamination event. According to the World Health Organization, "this legally-binding agreement significantly contributes to global public health security by providing a new framework for the coordination of the management of events that may constitute a public health emergency of international concern, and will improve the capacity of all countries to detect, assess, notify and respond to public health threats."(End notes)

Developments

- Collection of candy samples at distributor for lead analysis
- Analysis of samples and identification of violative product
- Distribution center informed of results
- Voluntary recall of defective product and identification of importer(s)

Task

Use your allotted time to consider the developments and questions assigned to your group for Module 1.

- Identify a group leader and group recorder/reporter at your table.
- Identify any additional requirements, critical issues, decisions and questions you think should be addressed at this time.
- Unanswered questions should be recorded for discussion with the entire group.

Questions for Participant Groups

State, Local, Tribal, Territorial Regulatory Agency

1. What authority do you have to collect samples? How do you establish and demonstrate the chain of custody of the samples from the distribution center to the lab?
    a. If you do not have the authority to collect samples, as in this scenario, are there other ways you might be alerted to a potential issue with this type or brand of candy that would prompt an investigation? Does your state have a Childhood Lead Poisoning Prevention Program (CLPPP)?
2. How do you determine how many cases to open to take samples? Do you communicate lot numbers or other case identifiers, case location in a pallet, etc. to the laboratory?
3. What could you do if the distribution center refused to issue a voluntary recall of the candy? Who would need to make these decisions and take these actions? What authorities do you have in your jurisdiction to control violative product in commerce?

4. How is the scope of a recall determined? Who participates in this discussion? How is the public health threat weighed against the economic loss to the industry or firm? Was the recall being limited by distribution date reasonable in this case?
5. If the lead level had been much higher, posing an imminent health threat, would the actions have been different? How?
6. If the lead level had been much higher, for example, 0.8 ppm, would you still have assumed that the contamination was accidental? What other signals would you look for if you suspected contamination might be intentional?
7. In this scenario, the State has a limit on the level of lead and candy that is consistent with FDA guidance. What if an elevated level of lead was found for which no limit had been established (e.g., in a different food product)?
8. When collecting records from the distributor, which records are requested? Based on your experience in collecting records, how long would it take to generate a table similar to Table 1 in an "average" investigation? What could be done to accelerate this process? If these records were not available, what action would you have taken?
9. If some of the distributor's customers were in other states, how would your actions change? Would you contact your counterparts in the other states? If so, who, and what information would you provide?
10. Do you verify that the firm is registered with the FDA? How familiar are health inspectors, local regulators, food manufacturers, distributors and retailers with the Reportable Food Registry? Do you alert them to the Federal requirement to use this system when a recall is issued? If the firm requests assistance with this process, what do you recommend to them?
11. At this point would the FDA be contacted? Who within your chain of command would make that decision and initiate that contact?

Laboratorians

1. Are resources available to translate invoices or other documents that are not in English? What if individuals at the distribution center did not speak English?
2. In this scenario, how quickly would a sample like this be analyzed? Who determines the prioritization of testing samples, and how do you communicate with those who may receive delayed results?
3. How long are samples kept after the initial analysis is done?
4. If the two tests yielded different results, what would be done? How could this difference be explained?

Food Industry

1. If samples are collected for testing by a government authority, do you "hold" the lots or cases until test results are communicated? Do you expect to hear if the result is "OK" or only if there is a problem?
2. Do you require any documentation from suppliers regarding the safety of products (e.g., certificate of analysis, etc.)? Do you conduct testing of products you receive? If so, how do you determine the frequency and scope of testing?
3. If you possessed a contaminated product, how long would it take you to determine the previous source and immediate recipient of the product and develop a table similar to Table 1? What kinds of documents would have the information to develop such a table? Are they only in paper form or are records electronic?
4. Have you ever had to use the Reportable Food Registry? If so, would you expect to use it in this instance? If not, what is your familiarity level with it, and where would you go to find more information about the requirements?

FDA

1. As presented, this is currently an issue within a single state, but is a product that is imported. At what point would you expect to become involved?
    a. How would the scenario change if the product was made by a U.S.-headquartered company with manufacturing operations that were outside the U.S.?
2. Are entries into the Reportable Food Registry monitored? Who is responsible for following up with immediate providers and recipients to ensure that the proper action is taken and that the action is documented?

MODULE 2 – Traceback Investigation

May 27

On May 27, a State inspector visited importer A, who indicated that only one firm from the country of Ablagon provided him with the candy. The importer provided invoices and customs documents that showed that 55 cases of candy were imported weekly.

Later that day, the same inspector also visited importer B, who stated that only one firm (the same one that provided importer A) sold this particular candy. Importer B's invoice and customs records showed that 100 cases were imported every other week.

Both importers voluntarily recalled all of Yenny's Chili Dulces that they had handled within the past six months and used the Reportable Food Registry to associate these recalls with the one initiated by the distributor.

May 28

Next, the State contacted the district office of the FDA so that future shipments of this brand of candy would be detained for evaluation, preventing future contaminated candy from entering commerce in the United States. The FDA sent its own team of investigators to obtain samples of the candy and performed its own analyses, which confirmed elevated levels of lead.

The FDA/State agency issued a letter to the manufacturer in Ablagon, advising that the candy was considered adulterated within that state because of the level of lead contamination and it could no longer be sold within the state. The manufacturer was advised that if they wanted to sell the product in the state, the candy would have to be reformulated or conditions would otherwise have to be improved to control lead levels, and that the firm would need to pay the State to test future lots of the product to ensure that lead was within legal limits. The letter also requested that the firm reimburse the State for the cost of the initial tests that showed that the candy contained excessive levels of lead. The State subsequently started to look for similar products from the manufacturer and increased their sampling and analysis of other confection products from Ablagon.

FDA issued an import bulletin to detain product from this firm at the border. By contacting the prior notice center (FDA/CBP), FDA was able to see what information was provided before this product arrived in the United States and confirmed that the two importers of record matched the paperwork on file. FDA began inspecting additional import records to see how much of this type of candy from this country was entering the United States.

FDA contacted the comparable authorities in Ablagon to inform them of the issue. FDA also began to sample similar types of candy imported from Ablagon, including candy from multiple manufacturers.

MODULE 2 – Traceback Investigation

Developments

- State investigation of importers, brokers and review of customs documents implicates one overseas manufacturer.
- State issues letter to the overseas manufacturer about contaminated product(s).
- FDA district office contacted and FDA sends investigator to obtain samples for analysis.
- FDA issues import bulletin to detain products at border.
- FDA contacts manufacturer to address issues and samples similar manufacturers.

Task

Use your allotted time to consider the developments and questions assigned to your group for Module 1.

- Identify a group leader and group recorder/reporter at your table.
- Identify any additional requirements, critical issues, decisions and questions you think should be addressed at this time.
- Unanswered questions should be recorded for discussion with the entire group.

Questions for Participant Groups

State, Local, Tribal, Territorial Regulatory Agency

1. At what point would the FDA be contacted, and who within your chain of command would initiate that contact?
2. If the lead level had been much higher, posing an imminent health threat, would the actions have been different?
3. Would you assist the importers in determining the scope of the recall? For a product without a lot number, how do you determine the breadth of product that should be recalled?
4. Who generates the letter to the manufacturer? Is it a form letter? Is it in English only? How do you ensure that the letter is received? Does FDA receive a copy of this letter, and is communication with the manufacturer coordinated between FDA and the State? Is a letter generated to the importer of record as well?
5. What other actions might you take? Would you sample other products? If so, what products might you sample? How is the reimbursement of testing costs handled?
6. How would your actions have differed if the product was made by an American company whose manufacturing operations were outside the United States?
7. How would you follow up on a voluntary recall at point of purchase and with the consumer? Who is responsible for notifying the consumer? How do you reach the consumer in a culturally and linguistically acceptable manner?

Laboratorian

1. If, due to this incident, the number of samples submitted for analysis increases, who determines the prioritization of testing? What policies are in place if the demand for testing exceeds the throughput (number of tests that can be conducted at any given time) capabilities of the lab? What arrangements are in place with other laboratories?
2. If the candy manufacturer wants to show that newly produced product contains acceptable levels of lead, how many samples do you test? How many different lots of candy must be tested?

3. If the manufacturer submits results of independent laboratory testing to show that the product is acceptable, are you asked to evaluate these results? What criteria do you use to ensure that the independent laboratory is qualified to perform the test and that the results are accurate?
4. Does the FDA contact you for information regarding initial test results? Does the FDA ever ask you to test samples that they previously obtained?

FDA

1. When contacted by the State with laboratory results showing high lead levels, do you wait to perform an independent analysis before taking action? Are there circumstances under which you would accept the State lab results and proceed with regulatory action? Why or why not?
2. Upon learning of elevated lead levels, who would be responsible for monitoring imports for this candy? What systems are in place to ensure that future shipments of candy are not accepted into the United States without examination? Are any other agencies such as Customs and Border Protection engaged?
3. If the FDA had an office in the country of origin of the candy, would this office be alerted to the issue? What actions would they be expected to take?
4. What determines if an import alert versus an import bulletin should be issued?
5. In this scenario, the State issued a letter to the manufacturer in Ablagon. Is this a State or Federal responsibility? Would the FDA also issue a letter? How would communication with the manufacturer be coordinated between the State and the FDA? Who is responsible for notifying the consumer? How do you reach the consumer in a culturally and linguistically acceptable manner?

Food Industry

1. As the importer, if a product does not have a lot number associated with it, how would you determine the scope of the recall? How would you communicate to your customers which product was affected and which product was not?
2. If you were the manufacturer and received the letter from the State health department, would you attempt to determine the cause of lead contamination? How? How would you prevent the issue from recurring?
3. If you were the manufacturer, how would you know when the problem began? How much product could potentially be affected?
4. If you were the manufacturer, how would you go about identifying and notifying customers, if at all? To what extent would the Reportable Food Registry be used?
5. Who is responsible for notifying the consumer? How do you reach the consumer in a culturally and linguistically acceptable manner?

MODULE 3 – Traceforward Investigation and Recall

Once the investigators knew the country of origin for the contaminated candy, it was important to determine where it had been offered for sale so that it could be removed from the marketplace.

Because the distribution center voluntarily issued a recall and had contact information for regular customers, the distributor contacted those customers to advise them of the recall. The State required the distributor to document the date, time and specific person who was called; confirm that the individual understood that the candy was recalled and could not be sold; and indicate how much product the retail customer had in stock and how that product would be discarded.

The State worked with the distributor to generate a press release that was submitted to the Associated Press. Additionally, the State issued a health alert, including pictures of the contaminated product and information regarding the effects of lead on children and circulated it to the local media and local health departments. Since FDA tests confirmed the State findings, they also issued a public statement warning consumers not to consume this candy.

Notes: About Lead Poisoning

From http://www.epa.gov/region2/lead/, http://www.cdc.gov/nceh/lead/tips.htm

Lead and Lead Poisoning:

Lead is a toxic metal that can cause a range of health effects. Children six years old and younger have the greatest risk of developing lead poisoning. Adults exposed to high levels of lead, usually in the workplace, are also at risk. The frequency and severity of medical symptoms increase with the concentration of lead in the blood. Children's blood lead levels tend to increase rapidly from 6 to 12 months of age and tend to peak at 18 to 24 months because they tend to put their hands or other objects, which may be contaminated with lead dust, into their mouths as part of normal development.

Health Effects:

Lead may enter the body by accidental ingestion of lead-contaminated items or by the inhalation or ingestion of lead dust. Lead is more dangerous for children because their growing bodies absorb more lead. Their brains and nervous systems are more sensitive to the damaging effects of lead. If undetected, children with high levels of lead in their bodies can suffer from: damage to the brain and nervous system, behavior and learning problems, slowed growth, hearing problems, headaches, and even death. The only way to know if your child has been poisoned by lead is to get a blood test. Adults who are poisoned may experience reproductive problems, high blood pressure and hypertension, nerve disorders, memory problems, and muscle and joint pain.

Notes: Where Lead is Found

Lead-based paint is the main source of lead in homes. Many homes built before 1978 were painted with lead-based paint. When this paint peels, chips, chalks or cracks, the lead can become

airborne, forming lead-contaminated household dust or soil.. Lead-based paint may also be a hazard when found on surfaces that children can chew or that get a lot of wear. In addition to paint, lead may also be found in soil, drinking water, old toys and furniture, and food and liquids stored in lead-contaminated containers.

(End notes)

When State investigators reviewed records from importers A and B, they found that both importers sold the candy to distributors in two neighboring states. One of those states had a regulatory limit on lead levels in candy, but the other did not. Given that adulterated food was shipped into interstate commerce, the State provided the FDA with its traceback and traceforward information so that they could coordinate follow-up with the other impacted states. The FDA and the affected states conducted recall audit checks to make sure the product was removed from the commercial shelves after the recall.

Developments

- Press releases issued by the distributor.
- State and FDA communicate the recall to consumers and advise them to avoid eating the candy.
- Distributor to confirm customers are notified and inventory is destroyed.
- State provides FDA with traceback and traceforward information to coordinate follow-up with impacted states.
- The FDA and the affected states conduct recall audit checks to ensure the product is removed from commercial shelves.

Task

- Use your allotted time to consider the developments and questions assigned to your group for Module 1.
- Identify a group leader and group recorder/reporter at your table.
- Identify any additional requirements, critical issues, decisions and questions you think should be addressed at this time.
- Unanswered questions should be recorded for discussion with the entire group.

Questions for Participant Groups

State, Local, Tribal, Territorial Regulatory Agencies

1. Without access to the manufacturers' production and distribution records, what steps would you take to ensure that the violative candy was not offered for sale in your jurisdiction?
2. What kind of documentation do you require to show that the violative product has been appropriately destroyed? How is the contaminated product destroyed, disposed and/or discarded? How do you follow up to ensure that these actions are actually taken?
3. If the issue was detected in another state and you received notification from FDA that this product may be offered for sale in your state, what would you do? Who would receive this notification, and who would be responsible for carrying out any action? How is this dependent on the laws in your state?
4. If an investigation of this candy resulted from a child exhibiting Elevated Blood Lead Levels (EBLL), what other agencies would be involved?

5. Once the violative product is found, is this information communicated to programs whose served communities would be at risk for having consumed the product in question (e.g., WIC, CLPPP, etc.)? If so, how?
6. Who is responsible for developing the health alert and communicating with the media about the recall? What is the frequency and timeliness of this communication? Is there a standard template that is followed, or is information customized depending on the situation? Is there a risk communication plan? (Refer to Food Emergency Response Plan in the Resources section.) How is conflicting information in the media handled?
7. Who within the organization works with the distributor to generate the press release? Who decides if the release should be in English only or in multiple languages? What is the communication vehicle (print, radio, etc.)?
8. Would your state conduct a recall audit check? How is this done? Do you use third-party providers to check stores to ensure product has been removed?
9. When would the investigation be considered complete?

Laboratorian

1. Do you currently have the technology to perform this type of testing, and does your method have a limit of detection low enough to identify a product containing a violative level of lead? If not, how would you handle this situation?
2. If the method used was appropriate to test dust, but not food, would the results of an analysis of food still be valid?
3. What do you do if someone questions the accuracy of your test findings?

Food Industry

1. If you had received product that was subsequently recalled, what would you do with it? How is product disposition dependent on the type of contaminant?
2. What sort of financial compensation would you expect if you had to return or destroy a product that had been recalled? Who would provide this compensation?
3. How would you protect yourself from distributing contaminated product in the future? Would you review your supplier specifications? Do you ask for Certificates of Analysis?

FDA

1. Who crafts the public statement notifying consumers of the issue? How do you ensure that the message reaches the intended population? Is there a risk communication plan?
2. When contacting the competent authority in Ablagon, what actions would they be expected to take?
3. What would prompt you to contact the U.S. Trade Representative to Ablagon, the World Trade Organization, etc.?
4. When would the investigation be considered complete?

Wrap Up Activities

We will spend the remaining time synthesizing what we discussed today, identifying important action steps to include in the After-Action Report and Improvement Plan (AAR/IP) and obtaining your feedback on the overall exercise. An AAR/IP is an important tool used to evaluate the exercise addressing outcomes, strengths, weaknesses and lessons learned. The facilitator will let you know when to expect to receive the final AAR/IP. The AAR/IP should be treated as a "For Official Use Only" document and only shared with those having a need to know.

At your table, please take a few minutes to discuss the questions below as directed by the facilitator. We will then take some time as a large group to identify common themes and takeaways. At the conclusion of this discussion, we ask that you complete the feedback form that will be provided by your facilitator.

Wrap-up questions

1. What is the most important thing you learned today in terms of managing an outbreak that impacts multiple jurisdictions?
2. What information do you need make informed decisions during such an event? If you don't have that information, how do you get it or what needs to be done to make a decision without it?
3. How will your organization evaluate your protocols, policies and procedures based on your participation in this exercise?
4. What top three actions should be taken to ensure proper event management based upon what you have learned from this exercise?
5. What went right, and what can you improve on at each stage of the outbreak investigation?
6. What are the roles and responsibilities of the various clinical, public health, regulatory and laboratory communities engaged in this investigation?
7. What could be done through all phases to reduce the time from the first signal to implementation of effective controls to final resolution in order to protect public health and reduce the economic impact on the entire industry?
8. What are some key lessons related to risk communication that you discussed today? What can you commit to doing to ensure that your organization supports a consistent, multi-jurisdictional, science-based message in the event of a foodborne illness outbreak?
9. What would differ if, unlike candy, neither the State nor FDA (or any other Federal agency for that matter) had explicit guidance for when a product is considered to have "too much" lead?
10. Who has the responsibility and authority to follow up when contaminated products are found to have been imported?

Appendix A: Resources

FDA lead information:
http://www.fda.gov/Food/FoodSafety/FoodContaminantsAdulteration/Metals/Lead/default.htm

California Department of Public Health lead information:
http://www.cdph.ca.gov/programs/Pages/FDB%20Lead%20In%20Candy%20Program.aspx

CDC lead information: http://www.cdc.gov/nceh/lead/

EPA lead information: http://www.epa.gov/region2/lead/

Appendix B: Acronyms Used

AAR	After-Action Report
AAR/IP	After-Action Report and Improvement Plan
CBP	Customs and Border Protection
CDC	Centers for Disease Control and Prevention
CLPPP	Childhood Lead Poisoning Prevention Program
EBLL	Elevated Blood Lead Levels
FDA	Food and Drug Administration
HSEEP	Homeland Security Exercise and Evaluation Program
ICP-MS	Inductively Coupled Plasma Mass Spectrometry
IFT	Institute of Food Technologists
WIC	Women Infants and Children
TTX	Tabletop Exercise
USDA FSIS	United States Department of Agriculture Food Safety and Inspection Service