Partnership for Food Protection's

Surveillance, Response and Post Response Workgroup presents

Best Practices for Use of FoodSHIELD During Food and Feed Incidents

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Executive Summary

The Best Practices for use of FoodSHIELD during food and feed incidents document was created by the Partnership for Food Protection's (PFP) Surveillance, Response, and Post Response Workgroup as a guide to facilitate information sharing and communication for FDA, state and local food safety officials responding to a food or feed safety incident. FoodSHIELD is a secure, web-based communication, coordination, education, and training platform for food safety and defense. FDA and state and local agencies use FoodSHIELD during incident response efforts to share information. This document provides instructions for utilizing the FoodSHIELD web-based system to share response information in real time among food and feed safety stakeholders. It provides instructions for building and managing a workgroup and recommends using a consistent nomenclature for naming files and documents while sharing information within the system.

Best Practices for using FoodSHIELD to Share Information During Incidents

Purpose Statement:

Provide best practices for using the FoodSHIELD web-based system to food and feed regulatory stakeholders and promote integration of food, feed, cosmetic, and all-hazards incident response to enhance mutual coordination, communication, and collaboration. This document is meant to provide best practices for using FoodSHIELD as a tool to improve real time communication among stakeholders during food and feed incidents.

Scope:

The FoodSHIELD Best Practices outlines FoodSHIELD functionalities and stakeholder roles during an incident, and provides expectations and benefits for organizations involved. This document is intended for those who have basic knowledge of FoodSHIELD. This document will not focus on routine projects, routine inspections, or other activities outside of an incident.

Background:

FoodSHIELD is a secure, web-based system for communication, coordination, education, and training for food safety and defense officials. FDA, state, and local agencies use FoodSHIELD during incident response efforts to share information, increase collaboration and communication, and provide training and education. FoodSHIELD has 11,461 total users and 140 workgroups, consisting of public health and food regulatory officials from federal, state, and local government agencies. Information sharing via FoodSHIELD has become an integral part of outbreak investigations. By inviting state commissioned officials to the FoodSHIELD workgroups, FDA is able to share both trade secret and Confidential Commercial Information (CCI) that pertains to the workgroup topic. Only state officials that hold an FDA commission are able to view both trade secret information and CCI.

In order for all regulatory and investigative partners to take full advantage of the FoodSHIELD system, best practices are established to set roles, responsibilities, and procedures for officials who use the system during incidents.

To help determine best practices, representatives in MN, TX, IA, and various FDA offices participated in an online exercise to test FoodSHIELD's capabilities in a mock outbreak response scenario. Each stakeholder received a specified task list and timetable to work from during the exercise. The task list contained several communication and collaboration functionalities to be tested. The outcome of the pilot set expectations for what the system should be used for during outbreak investigations and which best practices should be followed by all agencies during incident response efforts. This Best Practice document is the result of outcomes from this exercise.

When using this Best Practices document, it is helpful for participants to have prior knowledge of FoodSHIELD and to have taken the FoodSHIELD training (see references).

User Benefits of FoodSHIELD for Incident Response Efforts:

FoodSHIELD allows computer access for all users, is free to join and easy to use. It allows for real-time communication, information sharing, coordination, and collaboration between users from all levels of government. FoodSHIELD meets the federal government National Institute of Standards and Technology (NIST)/ Federal Information Security Management Act (FISMA) Standards so it provides a secure environment that agencies can use to collaborate and communicate with each other.

Best Practices for Federal/State/Local Organizational Roles & Responsibilities in FoodSHIELD

FDA Users:

FDA FoodSHIELD users may include participants such as the Center for Veterinary Medicine (CVM), the Center for Food Safety and Applied Nutrition (CFSAN), the Coordinated Outbreak Response and Evaluation Network (CORE), the Office of the Commissioner (OC), and the Office of Regulatory Affairs (ORA).

- FDA users may utilize FoodSHIELD for information sharing
    - The webinar function is routinely used by FDA
    - The activities feed (for incident requests/updates) and email functions will not be routinely used due to the need to capture similar information into the existing FDA Emergency Operations Network (EON) system
- FDA members may accept invitations to join state/local workgroups when invited during incidents
- For incidents, FDA may create a workgroup and add members
    - When FDA CORE is leading an outbreak for FDA, a CORE representative will usually set up and be the owner of the workgroup
    - CORE and district personnel will be assigned as administrators of the FDA workgroup while other personnel in the workgroup will serve as members
    - CORE may change user access to the workgroup after an incident is concluded
    - FDA workgroup owners may invite other federal partners (i.e. CDC, USDA, DOD) to their workgroup if FDA has determined that it is permissible to share the specific non-public information under 21 CFR 20.85
- FDA ORA District office personnel are requested by the workgroup owner or designee to add state commissioned officials to the FDA workgroup as appropriate providing one avenue for FDA to share information with state commissioned officials
    - Once state commissioned officials are invited to join the FDA workgroup, response information will be shared through the workgroup.
    - To avoid duplicative efforts FDA will no longer upload documents into, or share folders with, state owned workgroups created to manage information for the same response.

- Types of documents to be shared under identified folders:
    - trackback documents
    - major laboratory information
    - Incident Command System forms
    - Other documents as appropriate (e.g. inspectional documents)
- When CORE is managing an outbreak, they will upload relevant documents received/created into the workgroup

State/Local Users:

State and local users include regulatory officials, environmental health specialists/sanitarians, epidemiologists, and laboratorians.

- State/local lead investigator may set up a FoodSHIELD workgroup for the incident and invite strategic partners (e.g. state, local and FDA partners)
- State/local users should have two administrators in their workgroup to invite their agency's participants allowing for continued administrative management if one of the administrators is away from the office
- State/local administrators should designate a Point of Contact (POC) to upload documents to streamline the process and avoid duplication of work
- Examples of documents state/local users might upload are:
    - traceback documents
    - epidemiology-related
    - inspectional reports
    - laboratory results
- State/local users can utilize the activity feed email and webinar features in FoodSHIELD as needed
- State/local users may share folders, import workgroups, and create associations with external partners
- State/local users may join workgroups when invited
- State/local workgroup owner can either close a workgroup or change user roles within the workgroup after the investigation is finished for long-term access to the workgroup documents
- State/local officials that are commissioned by the FDA may be invited to join FDA FoodSHIELD workgroups
- Given that both trade secret and CCI may be shared in these workgroups, state/local officials with 20.88 agreements only and state/local officials with no confidentiality agreements are not able to be FDA workgroup members in outbreak scenarios
    - Trade secret information shared may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Examples of trade secret information include product formulation and manufacturing processes. CCI information shared consists of information which is used in a business and is of

such type that it is customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the entity to which it belongs. Examples of CCI would include business documents related to production, distribution, and quality assurance.

Workgroup Best Practices

Initiation of a Workgroup

Nomenclature for Incident Files:

Consistency in presenting information is important in order to enhance communication and coordination among government officials. Best practices for naming conventions, are outlined below for incident files.

Incident Workgroup Title:

Best Practices include at minimum your Agency, the Pathogen, and Year in your workgroup title so other members can search for your workgroup in FoodSHIELD. Workgroup titles may be altered due to other outbreaks simultaneously occurring. When creating the incident workgroup title, consider including the following templates and examples:

- Gold standard template for titling : "Agency creating the workgroup /pathogen (more specific with Pulsed-field Gel Electrophoresis (PFGE), if needed)/vehicle (with status, if known)/states involved/month/year"
    - Example: MDA/Salmonella Newport 166/lettuce (suspect)/ML/May/2012
    - Standard FDA CORE Workgroup Title: CORE/E. coli O121/lettuce/ML/November 2014

    Note: ML stands for multiple states
    - Additional examples: MDA/Salmonella Newport/tomatoes(suspect)/2014; 2014/Salmonella Newport/MN/MDA; Salmonella Newport/tomatoes (suspect)/April/2014

- If your Agency decides to include a date in the Workgroup Title, take these findings into consideration:
    - Ability to calculate the length of time between identification of the cluster via surveillance and onset of 1st case's illness
    - Ability to measure the time between onset and surveillance will aid in defining the average time your agency takes to identify it as an outbreak
    - FDA CORE's date in the incident title is the date that CORE Signals and Surveillance is notified of the incident

Folder Titles:

When creating the incident folders within your workgroup, there are four categories that should be created. Of course, other folders can be added (as well as subfolders) as needed.

- Folder categories:
    - Agency creating workgroup/Epidemiology
    - Agency creating workgroup/Traceback Flow Diagrams & Timelines
    - Agency creating workgroup/Laboratory
    - Agency creating workgroup/Incident summary documents

- Additional folders/subfolders categories:
    - Traceback Records (Invoices, Bill of Lading, and receipts)
    - Environmental/Investigation/Inspection (for inspection reports or investigation summaries)
    - Public Media Response/Public Information

    Note: Although the agency name is listed at the beginning of the folder title, this doesn't necessarily mean this agency produced the document within the folder. For example, CORE may have a "CORE/Epidemiology" folder which contains epidemiological documents provided by state partners and/or CDC. Designating the agency at the beginning of the folder name just designates which agency is housing the material. Subfolders and/or document titles can convey who actually created the documents.

Document Titles:

Be clear and descriptive when naming the type of document being uploaded. For example, don't include a line list and label it as "epi info." It could be more appropriately labeled as: "MN Draft line list updated 4/12/14."

- Webinar and Email subject lines:
    - Be descriptive to convey the purpose of the webinar and email
    - For a webinar include meeting subject, date, and time occurring (with the time zone)

- Roles when inviting participants to a workgroup:
    - The owner will invite each participant to be either an administrator or member of the workgroup. It is noted that owners have three asterisks (***) after their administrator title in FoodSHIELD.

Document/Email/Activity Feed/Discussion Board

Document Disclaimers/Version controls:

Consider the need to add disclaimers and version control within documents depending on your agency protocols.

- Example of disclaimer: "This document is an internal FDA document and should not be distributed beyond its intended audience without express permission from FDA."

- Standard statement about distribution of documents should be on each document per your agency requirements (restricted access, publicly accessible)
- Example of a document title with date and version control: "MN diagram for Distributor A_traceback leg_Created 4/14/14, Version 1"
- FoodSHIELD has the capability of automatic version control which should be tested by agencies

Email:

There are three ways to use email in FoodSHIELD (see the user guide). The appropriate email type should be used based on the type and size of information being sent. Certain agencies may choose not to use the email feature, based on existing protocols.

- Secure send – Can be used to send very large files
- Communications Application – Can be used to send regular correspondence to the whole group or selected members
- Document email – Can be used to send document(s) without downloading them to your desktop.

Activity Feeds:

There are limitations when directly typing information into the activity feed.

- It will not send the message in an email to workgroup members; it will only appear in the FoodSHIELD system
- Information posted to the feed is listed according to the date/time it was posted and it is not a threaded discussion, meaning a user can't directly respond to a particular post in the feed
- It is not captured for downloading outside the FoodSHIELD system
- Important information could be easily overlooked due to the long chain of some activity feeds

Webinars:

During complex investigations when explanations of documents and materials need to be understood by multiple workgroup participants, a webinar is very helpful. Desktop sharing for viewing/editing of documents can be used during webinars.

- Webinar capacity is 70 separate connections across the entire system at one time
- If several webinars are scheduled at one time that prevent your webinar from taking place, please contact the FoodSHIELD helpdesk (helpdesk@foodshield.org) to request a seminar room that allows more than 70 connections

Sharing between Workgroups

Sharing Folders:

Before folders are shared, they should be named appropriately so the agency name (the agency that created the folder) is at the beginning, right before the folder name.

- Ensure that folders are shared only with parties deemed appropriate by your agency
- If you want to share a folder, send an email to the party you want to share with through your agency email system, and ensure the party agrees to the folder being shared.
- If sharing a folder, the party receiving the folder should not edit/delete/add documents to this folder.
- There is no way in the documents view to determine which folders have been shared with whom. Therefore, adding a copy of the email exchange requesting folder sharing to the document folder that is being shared is helpful.
- Shared folders are color coded by, one way sharing (green) vs. two way sharing (red).
- When a folder is shared, the folder automatically updates so the same documents are available to all partners.
- Certain agencies may choose to not share folders, based on agency protocols

Importing Workgroup Members:

This can be valuable if there is more than one workgroup created by different agencies or even within the same agency for an incident. It is an easy way to add people from one workgroup to another.

Deactivation

Deactivation Procedure:

If you are an owner of a workgroup, you should create a deactivation procedure for your workgroup ahead of time. There are several mechanisms to further secure/archive information within a workgroup, once your agency deems it is appropriate to do so.

- Closing a workgroup so only the owner retains access to it
- Changing user roles so workgroup members can only view the documents and can't edit/upload new documents
- Completely removing the workgroup by emailing the FoodSHIELD administrators at helpdesk@foodshield.org
- Based on your agency's decision, email the workgroup members of the incident to inform them regarding further securing of your workgroup information
- Some information in these workgroups may help assist with prevention activities in the future
- Ensure that final incident documents are uploaded into the workgroup prior to taking steps to deactivate the workgroup

References

1. FoodSHIELD
    a. User Guide/Knowledgebase
        i. The user guide can be downloaded from the FoodSHIELD Knowledgebase located under the Support Materials Section. The Knowledgebase can be found by clicking the Helpdesk/Support icon on the menu bar.
    b. Hour Long Webinar Training and recording
        i. https://www.foodshield.org/index.cfm/about-learn-more/training/
    c. How to gain membership to FoodSHIELD
        i. https://www.foodshield.org/member/register/index.cfm
    d. Live Helpdesk: 1-877-960-2007, live chat feature, helpdesk@foodshield.org
        i. Hours 7am -7pm CST
        ii. http://support.foodshield.org/support/home

2. Commissioning Process & Information Sharing Procedures
    a. Overview of Commissioning
        i. http://www.fda.gov/ForFederalStateandLocalOfficials/CommunicationbetweenFDAStateLocalandTribalOfficials/default.htm
    b. Regulatory Procedures Manual - Ch. 3
        i. http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176712.htm

Glossary

Centers for Disease Control and Prevention (CDC) – CDC works 24/7 to protect America from health, safety, and security threats, both foreign and domestic. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, human error or deliberate attack, CDC fights disease and supports communities and citizens to do the same. CDC increases the health security of our nation. As the nation's health protection agency, CDC saves lives and protects people from health threats. To accomplish our mission, CDC conducts critical science and provides health information that protects our nation against expensive and dangerous health threats, and responds when these arise. CDC is involved in:

- Detecting and responding to new and emerging health threats
- Tackling the biggest health problems causing death and disability for Americans
- Putting science and advanced technology into action to prevent disease
- Promoting healthy and safe behaviors, communities and environment
- Developing leaders and training the public health workforce, including disease detectives
- Taking the health pulse of our nation

http://www.cdc.gov/about/organization/mission.htm

Department of Defense (DOD) – The Department of Defense is America's oldest and largest government agency. The mission of the Department of Defense is to provide the military forces needed to deter war and to protect the security of our country.
http://www.defense.gov/about/

Epidemiology – The study of the occurrence of disease or other health-related conditions or events in defined populations. The control of disease in populations is also often considered to be a task for epidemiology. Epidemiologists conduct surveillance and carry out investigations using hypothesis testing and analytic research to identify the causes of diseases, including the physical, biological, social, cultural, and behavioral factors that influence health. *(Based on the definition identified in the Council to Improve Foodborne Outbreak Response (CIFOR) Guidelines for Foodborne Disease Outbreak Response. Appendix 1: Glossary)*
http://www.cifor.us/documents/CIFORGuidelinesAppendices.pdf

Food and Drug Administration (FDA) – FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, food and feed, cosmetics, and products that emit radiation. FDA is responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable, and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health. FDA also has responsibility for regulating the manufacturing, marketing and distribution of tobacco products, to protect the public health, and to reduce tobacco use by minors. FDA plays a significant role in the Nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the

food supply and by fostering the development of medical products to respond to deliberate and naturally emerging public health threats.
http://www.fda.gov/aboutfda/whatwedo/default.htm

FDA Commissioned Official – Commissioning is a process that permits State and local officials to conduct examinations and investigations under the authority of the FD&C Act. In other words, state and local officials who are commissioned can conduct examinations, inspections, and investigations, as well as collect and obtain samples, and copy and verify records under the FD&C Act even when state and municipal laws do not give them this authority. Because they are acting under FDA's authority, commissioned officials may have access to non-public information, including deliberative documents, Commercial Confidential Information (CCI), and trade secret information when acting in their capacity as commissioned officials. Commissioned officials may not further share non-public information obtained in this capacity.
http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/UCM358066.pdf

FDA 20.88 Agreement – A 20.88 agreement permits FDA to share certain non-public information with various state and local officials who have signed a written agreement in accordance with 21 CFR 20.88. In the agreement, the state or local government agency confirms it has the authority to protect non-public information from public disclosure and it promises to not further disclose such information without written permission from FDA. Unlike Commissioning, FDA cannot share trade secret information under 20.88 agreements.
http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/UCM358066.pdf

FDA's Center for Food Safety and Applied Nutrition (CFSAN) – The Center for Food Safety and Applied Nutrition, (CFSAN), is one of six product-oriented centers, in addition to a nationwide field force, that carry out the mission of the Food and Drug Administration (FDA). CFSAN, in conjunction with the Agency's field staff, is responsible for promoting and protecting the public's health by ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled.
http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/default.htm

FDA's Center for Veterinary Medicine (CVM) – The mission of the Center for Veterinary Medicine (CVM) is: "Protecting Human and Animal Health." To achieve this broad mission, CVM:

- Makes sure an animal drug is safe and effective before approving it. The center approves animal drugs for companion (pet) animals, such as dogs, cats, and horses; and for food-producing animals, such as cattle, pigs, and chickens. If the drug is for a food-producing animal, before approving it, the center also makes sure that food products made from treated animals (meat, milk, and eggs) are safe for people to eat;
- Monitors the safety and effectiveness of animal drugs on the market;
- Makes sure food for animals(which includes animal feed, pet food, and pet treats)is safe, made under sanitary conditions, and properly labeled;

- Makes sure a food additive for use in food for animals is safe and effective before approving it;
- Conducts research that helps FDA ensure the safety of animal drugs, food for animals, and food products made from animals; and
- Helps make more animal drugs legally available for minor species, such as fish, hamsters, and parrots; and for minor (infrequent and limited) uses in a major species, such as cattle, turkeys, and dogs.

http://www.fda.gov/aboutfda/centersoffices/officeoffoods/cvm/default.htm

FDA's Coordinated Outbreak Response and Evaluation (CORE) – CORE was created to manage not just outbreak response, but surveillance and post-response activities related to incidents involving multiple illnesses linked to FDA-regulated human and animal food and cosmetic products. The goal of the CORE Network is to build upon the *best* of what we currently do across FDA in incident response, and not only to streamline, but to strengthen FDA's efforts to prevent, detect, investigate, respond to, and learn from incidents and outbreaks.
http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm272347.htm

FDA's Office of the Commissioner (OC) – The Food and Drug Administration (FDA) is headed by the Commissioner of Food and Drugs. Organizations within the Office of the Commissioner (OC) report to the Commissioner. The Office of the Commissioner provides centralized agency-wide program direction and management services to support effective administration and FDA's consumer protection efforts within its regulatory framework and to put available resources to the most efficient use. This office reports to the FDA Commissioner.
http://www.fda.gov/AboutFDA/CentersOffices/oc/default.htm

FDA's Office of Regulatory Affairs (ORA) – The U.S. Food and Drug Administration's Office of Regulatory Affairs (ORA) is the lead office for all agency field activities. ORA inspects regulated products and manufacturers, conducts sample analyses of regulated products and reviews imported products offered for entry into the United States. Besides executing its mission through its federal workforce, ORA also works with its state, local, tribal, territorial and foreign counterparts to further the agency's mission.
http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/default.htm

Incident – An occurrence or event, natural or human-caused that requires an emergency response to protect life or property. Incidents can include major disasters, emergencies (like foodborne outbreaks), terrorist attacks, terrorist threats, wild land and urban fires, floods, hazardous materials spills, nuclear accidents, aircraft accidents, earthquakes, hurricanes, tornadoes, tropical storms, war-related disasters, public health and medical emergencies (i.e. outbreak), and other occurrences requiring an emergency response.

Incident Command System (ICS) – According to FEMA, Incident Command System (ICS) is a standardized management tool for meeting the demands of small or large emergency or nonemergency situations. ICS

represents "best practices" and has become the standard for emergency management across the country. It may be used for planned events, natural disasters, and acts of terrorism and is a key feature of the National Incident Management System (NIMS). The ICS is a management system designed to enable effective and efficient domestic incident management by integrating a combination of facilities, equipment, personnel, procedures, and communications operating within a common organizational structure, designed to enable effective and efficient domestic incident management. A basic premise of ICS is that it is widely applicable. It is used to organize both near and long-term field-level operations for a broad spectrum of emergencies, from small to complex incidents, both natural and manmade. ICS is used by all levels of government—federal, state, local, and tribal—as well as by many private-sector and nongovernmental organizations. ICS is also applicable across disciplines. It is normally structured to facilitate activities in five major functional areas: command, operations, planning, logistics, and finance and administration.
http://training.fema.gov/EMIWeb/IS/ICSResource/assets/reviewMaterials.pdf

Rapid Response Team (RRT) – The Food Protection Rapid Response Teams (RRTs) conduct integrated, multiagency responses to all hazards food and feed emergencies in various states across the nation. RRTs are developed through a multiyear cooperative agreement between FDA and state food regulatory partners. There are currently eighteen (18) RRTs within the Program. This cooperative agreement requires that these teams engage partners across disciplines and jurisdictions to build core capabilities and explore innovative approaches to response. The RRTs vary from each other in accordance with differences in government structures, geographies, laws, resources, etc. The RRTs activate in response to food emergencies in their states, drawing on the resources and partnerships developed through this project to accomplish responses characterized by improvements in areas such as interagency communication, established plans and procedures, and jointly trained and exercised staff.
http://www.fda.gov/ForFederalStateandLocalOfficials/CooperativeAgreementsCRADAsGrants/ucm297407.htm

Status (of vehicle) – When a vehicle is not confirmed, agencies may use the word “suspect” in the incident title after the vehicle name.

Traceback – The method used to determine the source and scope of the product/processes associated with an outbreak, and document the distribution and production chain of the product that has been implicated in a foodborne illness or outbreak. *(Multistate Foodborne Outbreak Investigations Guidelines for Improving Coordination and Communications. Glossary)*
http://www.cifor.us/clearinghouse/tooldetail.cfm?id=212

Trade Secret – Trade secret information shared may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Examples of trade secret information include product formulation and manufacturing processes.

Confidential Commercial Information – CCI information shared consists of information which is used in a business and is of such type that it is customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the entity to which it belongs. Examples of CCI would include business documents related to production, distribution, and quality assurance.

United States Department of Agriculture (USDA) – The United States Department of Agriculture (USDA) provides leadership on food, agriculture, natural resources, rural development, nutrition, and related issues based on sound public policy, the best available science, and efficient management. http://www.usda.gov/wps/portal/usda/usdahome?navid=MISSION_STATEMENT

Vehicle – This term is used to refer to an item that is known to have been the source of infection or intoxication, and caused an illness. In foodborne outbreaks, this would be a food.