FDA BOVINE SPONGIFORM ENCEPHALOPATHY RESPONSE PLAN SUMMARY

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U.S. FOOD AND DRUG ADMINISTRATION
BOVINE SPONGIFORM ENCEPHALOPATHY EMERGENCY RESPONSE PLAN

I. INTRODUCTION

A finding of a Bovine Spongiform Encephalopathy (BSE) emergency in the animal population could undermine consumer confidence in the food supply and have a severe adverse effect to large segments of the animal population. The threat of BSE entering the food chain could have long-term health consequences for the human population. In order to mitigate these consequences, the FDA is preparing to respond to a BSE emergency and provide the necessary resources to address the myriad of issues that could arise.

I.A MISSION

The mission of the FDA is to—

- Protect the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.
- Advance the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable.
- Help the public get accurate, science-based information needed to use medicines and foods to improve health.

I.B PURPOSE

The purpose of the *FDA BSE Emergency Response Plan* is to provide a coordinated response to BSE emergencies involving FDA-regulated products. To accomplish this, the plan:

- Describes the essential steps to take in response to any emergency related to BSE.
- Defines procedures for the use of FDA resources to augment and support local and state governments and other federal agencies.
- Describes specific actions FDA components and personnel take when responding to emergencies involving BSE.
- Enhances the Agency's emergency preparedness and response capabilities.

I.C SCOPE

The *FDA BSE Emergency Response Plan* guides FDA personnel and provides top government officials outside the FDA with a comprehensive resource that explains FDA emergency responsibilities and procedures during a potential or actual BSE emergency.

This plan outlines responsibilities and establishes procedures to act immediately in cases involving a possible BSE emergency. These procedures cover FDA-regulated products or ingredients possibly introduced into the U.S. market.

Prompt emergency actions depend upon the expeditious reporting and investigation of significant incidents and complaints relating to FDA-regulated products. Subsequent to a suspected or confirmed BSE emergency, FDA Headquarters and Regional/District staff follow these response procedures.

This plan does not address long-term response or recovery. Additionally, the plan does not cover every conceivable situation; however, it does supply the basic guidelines regarding most BSE emergencies that the FDA may encounter.

II. PLANNING ASSUMPTIONS

- BSE emergencies affecting FDA-regulated products require an immediate response by the FDA. Protection of the affected or potentially affected population is the highest priority during response operations.
- It is unlikely that any single entity possesses the authority and expertise to act unilaterally on the many difficult issues that may arise in response to a BSE emergency affecting a multijurisdictional area.
- A BSE emergency may overwhelm the capabilities of a state and its local governments, requiring the FDA and other federal agencies to assist the state in meeting the needs of the emergency situation. Local resources perform the emergency response for the first 24 to 48 hours with requested federal help arriving thereafter. FDA assets will supplement the local response, as needed, when the emergency affects an FDA-regulated product or requires the use of countermeasures involving FDA-approved products (investigational new drug [IND], investigational new animal drug [INAD], or investigational device exemption [IDE]).
- In the event of an emergency, FDA continues to be responsible for its regulated products. FDA will coordinate with the states and other federal agencies, but FDA must be responsible for products under its jurisdiction.
- Agency response will be a phased process, dependent on available information.
- Congress designated the United States Department of Agriculture (USDA)/ Animal and Plant Health Inspection Service (APHIS) as the lead agency in responding to foreign animal diseases. To effectively protect the public, the FDA and USDA are continuously working to strengthen communication and the working relationship between the agencies. Increasing diligence in sharing information and the exchange of contact liaisons results in reducing the duplicative efforts in inspection and investigation of cases that may have cross-jurisdictional implications. The BSE response plans for both organizations will increasingly incorporate and reflect appropriate inter-agency protocols and procedures.
- Extensive coordination with local, state, and foreign governments may be necessary in conjunction with other federal agencies.
- All agencies involved in a response use the following terms:
  - **BSE Alert:** A formal notification issued by the FDA or other organization to the FDA EOC when situations or incidents involve reports (confirmed or unconfirmed) regarding:
    - Any imported animal feed or animal feed ingredient from a BSE restricted country that may contain animal tissue or protein, as Import Alerts #99-25 and 71-04 address.

- Any domestic animal feed or animal feed ingredient that contains prohibited materials obtained either from a BSE restricted country or from an unknown source.
- Any food, dietary supplement, cosmetic, drug, device, or biologic that contains or may contain material contaminated with prohibited materials, that may have become contaminated with prohibited materials, or that was imported in violation of a relevant import alert or regulation.
- A suspected or confirmed case of variant Creutzfeldt-Jakob Disease (vCJD) by the Centers for Disease Control and Prevention (CDC) or MedWatch, or a Biological Product Deviation (BPD) report in a person who has not been in a BSE restricted country.

– **BSE Emergency:** 1) Situations involving a presumptive or confirmed diagnosis of infection by the alleged BSE agent in any bovine or product derived from a bovine (domestic or imported) in the U.S. 2) Any report of a confirmed case of disease caused by the BSE agent in other mammalian species in the U.S.

– **BSE Restricted Country:** A country listed in Title 9, Part 94.18 of the Code of Federal Regulations (CFR). For a full listing of these countries, please refer to http://www.aphis.usda.gov/vs/ncie/country.html.

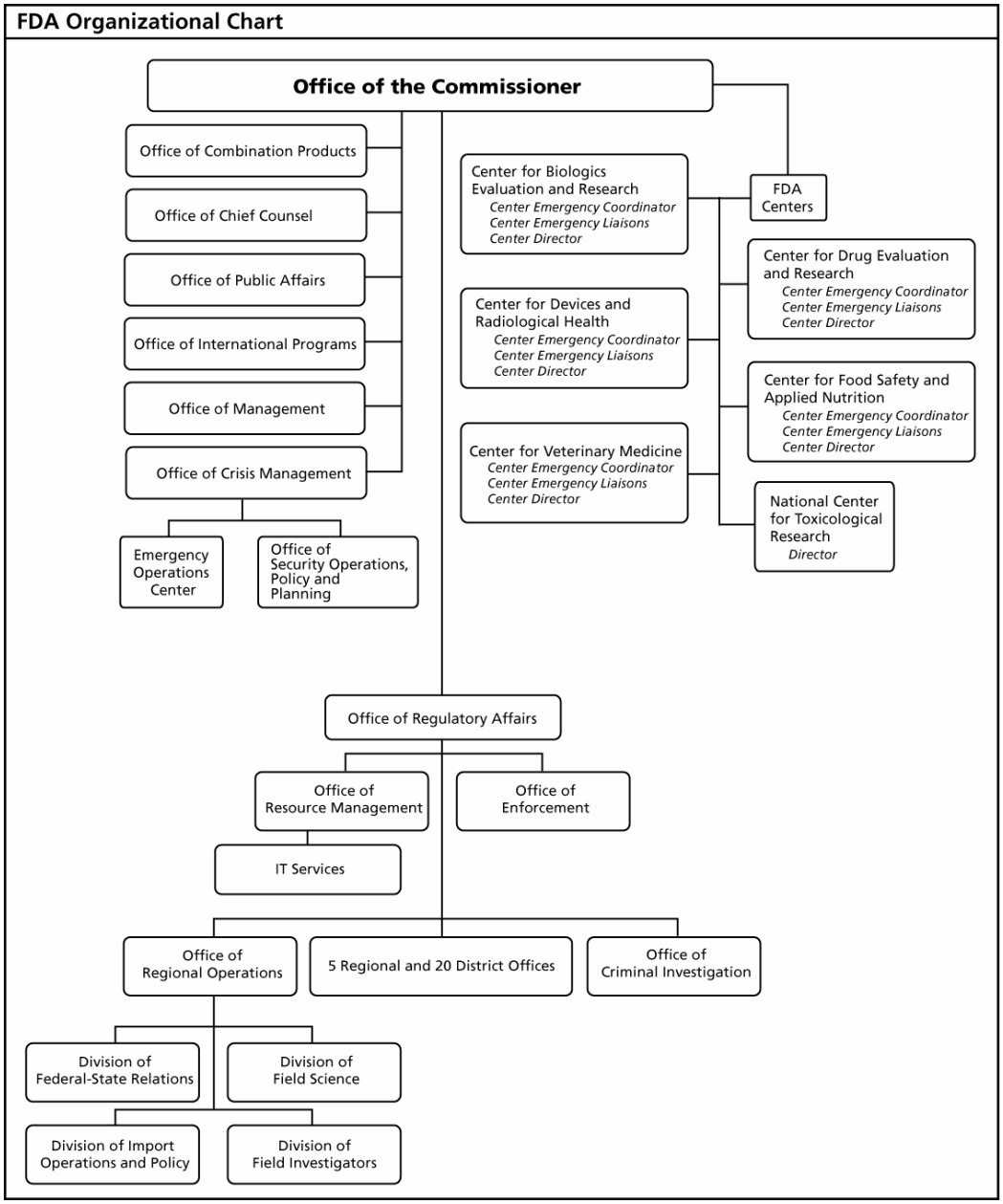
– **Confirmed Positive BSE Case:** A BSE presumptive positive case confirmed by the United Kingdom's Central Veterinary Laboratory.

– **Presumptive Positive BSE:** A bovine designated by APHIS as a laboratory test positive for BSE, with signs of central nervous system (CNS) disease and the observation of histopathological lesions of BSE in the brain and/or a positive test for immunohistochemical staining for the BSE agent.

III. RESPONSIBILITIES AND ORGANIZATION

Section III identifies the roles and responsibilities of FDA Centers and Offices responding to a BSE emergency. FDA Centers and Offices work closely with the Office of the Commissioner and with industry and government partners to ensure the safety of FDA-regulated products in the United States and worldwide using novel and expeditious approaches to product regulation for optimized availability and use in all populations. Note that in many emergencies, issues might arise that involve more than one Center or Office. A brief description of each Center or Office listed in Figure III-1 follows.

Figure III-1. FDA Organizational Chart



III.A OFFICE OF THE COMMISSIONER

A number of the Office of the Commissioner (OC) offices play a significant role in supporting the response to a BSE emergency, such as the Office of Crisis Management, the Office of International Programs, and the Office of Public Affairs. In addition, other OC offices, such as the Office of Combination Products, the Office of Chief Counsel, and the Office of Management /Office of Shared Services, can provide valuable assistance during the FDA's response to a BSE emergency.

III.A.1 Office of Combination Products

The Office of Combination Products (OCP) assigns an FDA Center to have primary jurisdiction for review of combination products (drug-device, drug-biologic, and device-biologic products). OCP works with FDA Centers to develop guidance to clarify the regulation of combination products and serves as a focal point for combination product issues, within and outside the FDA. If a BSE emergency involves a combination product, OCP can assist in coordinating emergency responses from each Center with jurisdiction of a given combination product.

III.A.2 Office of Chief Counsel

The Office of Chief Counsel (OCC) provides legal services involving the agency's regulatory activities. FDA lawyers support the Agency's public health and consumer protection missions in two primary ways: handling litigation and providing counseling advice.

III.A.3 Office of Public Affairs

The Office of Public Affairs (OPA) serves as the FDA's primary liaison with the news media and develops much of the material the FDA uses to communicate its public health and consumer protection messages to the public. OPA issues press releases, talk papers, and other public statements; responds to media requests; and arranges and supports media interviews. For example, OPA can coordinate with FDA Centers to rapidly provide consumer education materials explaining steps consumers can take to protect themselves after a BSE emergency.

III.A.4 Office of International Programs

The Office of International Programs (OIP) is responsible for communicating appropriate emergency-related information with foreign governments and organizations, such as the World Health Organization (WHO). OIP also receives information and requests for information from foreign governments.

III.A.5 Office of Management/Office of Shared Services

The Office of Management (OM)/Office of Shared Services (OSS) has the capability to provide information technology (IT) support to the FDA Centers and Offices during an emergency.

III.A.6 Office of Crisis Management

The Office of Crisis Management (OCM) consists of the OCM Director (and staff); FDA EOC staff; and Office of Security Operations, Policy, and Planning staff. OCM is responsible for developing crisis management policies and managing Agency emergencies when they occur. OCM's responsibilities include coordination of FDA participation in internal and external counter-terrorism (CT) and emergency exercises; planning, developing, and directing all activities relating to the Agency's physical and personnel security program; coordinating Agency evaluation of BSE emergencies to determine response actions; and coordinating intra-agency and interagency emergency preparedness and response activities.

III.A.6.a Emergency Operations Center

The FDA Emergency Operations Center (EOC), a branch of the OCM, is the single point of coordination for the FDA's response to any BSE emergency. The FDA EOC is the physical facility that serves as the central point for the Agency's response activity. During a BSE emergency, the FDA EOC will coordinate and report on all response activity and interagency communication. The FDA EOC monitors BSE emergencies; triages complaints and alerts; issues assignments to the field; coordinates responses; and communicates with other federal, state, and local agencies as they request technical and material support from the FDA.

The FDA EOC maintains contact with the Department of Health and Human Services (HHS) Secretary's Command Center (SCC), CDC EOC, USDA/FSIS Office of Food Security and Emergency Preparedness, and other EOCs, as appropriate. The FDA EOC will continue to direct and monitor all FDA response activities throughout the life cycle of an emergency.

III.A.6.b Office of Security Operations, Policy, and Planning

The Office of Security Operations, Policy, and Planning (OSOPP) can provide support during the FDA's response to a BSE emergency in several ways. For example, in the event of a requirement to verify security clearances for FDA liaisons responding to EOCs at other government agencies, at the FDA EOC, or at the Joint Operations Center (JOC) located near the site of a BSE emergency, OSOPP maintains a list of all cleared FDA personnel and processes security clearances. OSOPP can also assist with providing guidance on the proper handling, marking, processing, and storage of classified materials.

III.B OFFICE OF REGULATORY AFFAIRS

The Office of Regulatory Affairs (ORA), which the Associate Commissioner for Regulatory Affairs (ACRA) leads, serves as the lead office for all regulatory activities of the FDA. ORA consists of four headquarters offices: Office of Regional Operations, Office of Criminal Investigation, Office of Resource Management, and Office of Enforcement, as well as five Regional and 20 District Offices. In addition, ORA maintains a database of FDA-regulated establishments. The database can enable the FDA to rapidly identify affected establishments.

III.B.1 Office of Resource Management

Within the Office of Resource Management (ORM), the Division of Planning, Evaluation, and Management (DPEM) generates a field workforce work plan every fiscal year. The field workforce work plan adjusts as required in the event that emergencies arise. The field workforce, via the ACRA, is able to divert resources in response to an emergency. DPEM is also responsible for generating after action reports (AAR) pertaining to resources used in emergency response. NOTE: Evaluation of resources used to respond to any emergency is possible via the FDA Field Accomplishments and Compliance Tracking System (FACTS). Predefined Program Assignment Codes exist in the reporting system that enable DPEM to track accomplishments and resources expended during a brief or extended response period.

III.B.2 Office of Enforcement

The Office of Enforcement (OE) handles enforcement actions against individuals and companies that violate the FFDCA. When appropriate, OE monitors the extent of product removal. OE notifies the Department of Defense (DoD) Defense Supply Center of any food contamination situation.

III.B.3 Office of Regional Operations

The Office of Regional Operations (ORO) Headquarters consists of four divisions:

- The Division of Federal-State Relations (DFSR) maintains the FDA's rapid communication system to state governments, major municipalities, and poison control centers during an emergency.
- The Division of Field Science (DFS) prepares the ORA laboratory response and monitors surveillance databases.
- The Division of Import Operations and Policy (DIOP) monitors and controls import and export activity associated with implicated product, countries, foreign manufacturers and shippers, filers, importers, and/or consignees. DIOP can also coordinate targeted surveillance of imported products with the U.S. Bureau of Customs and Border Protection (CBP), as DIOP is part of a multi-agency work group with CBP and USDA for joint operations related to BSE preventative measures and emergencies originating from foreign sources.

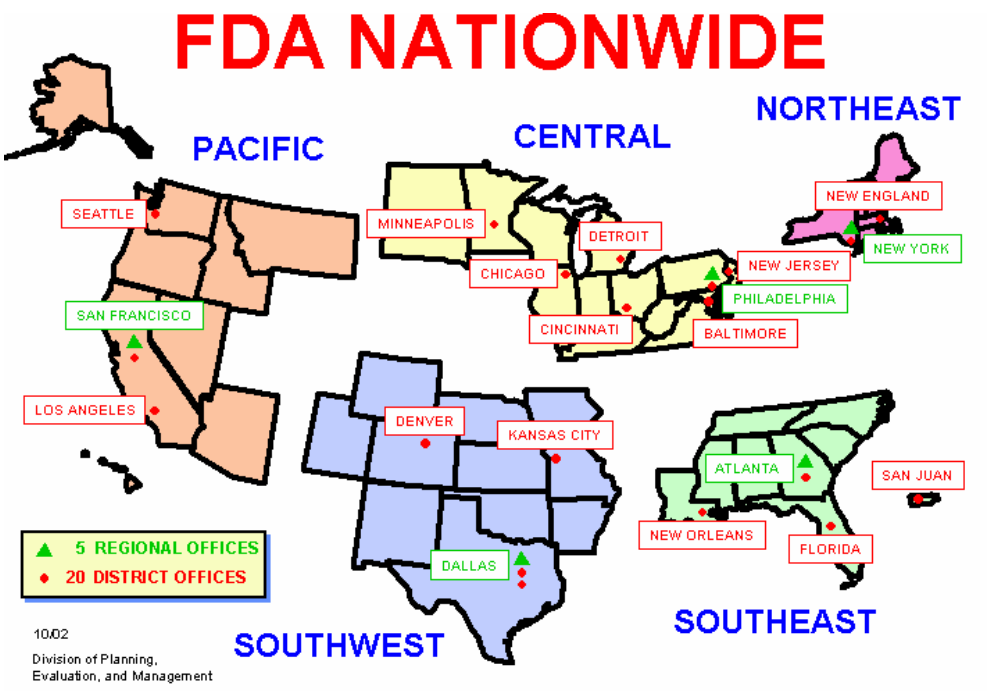
- The Division of Field Investigations (DFI) provides guidance and assistance in coordinating emergency field investigations.

Working together with the field, these divisions handle the FDA's day-to-day field operations at 5 regional offices, 20 district offices, and more than 165 resident posts.

III.B.4 Regional and District Offices

The 5 Regional and 20 District Offices develop and maintain cooperative relationships with state, local, and other federal agencies in support of coordinated emergency response activities. The Regional and District Offices work with these other agencies to verify product information and secure the suspect product. They obtain additional information by reviewing records and examining products to focus follow-up actions. Field investigators may collect samples for laboratory analysis; detain, seize, and/or embargo product in support of public health protection and state and local government; request state officials to hold suspect product; issue requests for voluntary holds or suspension of operations of industry; request and monitor industry recalls; conduct necessary inspections, detentions, and sampling of domestic and imported products; and conduct traceback investigation work. Figure III-2 illustrates the FDA across the nation.

Figure III-2. FDA Nationwide



III.B.5 Office of Criminal Investigation

The Office of Criminal Investigation (OCI) has special agents at Headquarters and in offices nationwide. OCI is responsible for the criminal casework of the FDA, including serving as the FDA partner and liaison to law enforcement and intelligence agencies. OCI works closely with the Federal Bureau of Investigation (FBI) during the investigative process.

III.C FOOD AND DRUG ADMINISTRATION CENTERS

The FDA product centers are responsible for the regulation of a defined set of products. Their professional staff includes both clinical and scientific experts. This expertise (analytical, laboratory, sampling procedures, subject matter expertise, and industry knowledge) is available for critical consultation should a BSE emergency occur. The National Center for Toxicological Research (NCTR) primarily conducts regulatory and applied research based on Agency needs.

Centers are responsible for scientific evaluations and policy decisions (in cooperation with the FDA EOC and the ACRA) in their respective program areas. Each Center has a BSE committee that provides scientific, compliance, and policy decision function. FDA product centers participate in an emergency response when the response includes, or may include, regulatory activities or products under their jurisdiction.

III.C.1 Center for Biologics Evaluation and Research

The Center for Biologics Evaluation and Research (CBER) ensures the safety, efficacy, and quality of biological products potentially threatened by a BSE emergency. Specific activities regarding BSE responses include:

- Regulating the safety, purity, and potency of biological products (e.g., blood, blood products, vaccines, allergenics, in vitro diagnostics, and devices) using bovine ingredients as part of the manufacturing process.
- Providing information regarding manufacturers' compliance with Good Manufacturing Practices (GMP) and other relevant product quality issues, including guidance on stability protocols to evaluate whether a manufacturer can extend an expiration date.

III.C.2 Center for Drug Evaluation and Research

The Center for Drug Evaluation and Research (CDER) ensures the safety, efficacy, and quality of drugs with bovine ingredients. Specific activities regarding BSE response include providing information regarding manufacturers' compliance with GMP and other relevant product quality issues, including shelf life extension guidance and sources of critical medical countermeasures in shortage situations.

III.C.3 Center for Devices and Radiological Health

The Center for Devices and Radiological Health (CDRH) ensures the safety, efficacy, and quality of medical devices potentially threatened by a BSE emergency. The Center provides technical liaisons to other federal and international agencies with BSE responsibilities. Specific activities for BSE responses include:

- Regulation of medical devices containing bovine material. Medical devices that may contain bovine material include cardiac, dental, ophthalmic, orthopedic, plastic, and restorative devices.
- Providing information on the current data and guidance on the use and reuse of medical devices contaminated via surgery.

III.C.4 Center for Food Safety and Applied Nutrition

The Center for Food Safety and Applied Nutrition (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 have proper labeling. CFSAN has the authority to regulate food producers and distributors involved in interstate commerce, and to issue recommendations on food safety issues, including foods and cosmetics using bovine ingredients. CFSAN also determines whether data collected by another agency or organization (e.g., USDA) are adequate for FDA decisions in an emergency.

III.C.5 Center for Veterinary Medicine

The Center for Veterinary Medicine (CVM) ensures the safety, efficacy, and quality of drugs used in animals, including animal feed and companion animals, animal food and feed, and medical devices used on animals potentially threatened by a BSE emergency. Specific activities regarding BSE response include:

- Collaborating with public health agencies (such as CDC, HHS, and USDA) and with states, through DFSR, regarding feed contaminant, tissue residue programs, and other monitoring programs for meat and poultry involving a BSE emergency.
- Providing information regarding manufacturers' compliance with GMP and other relevant animal drug product quality issues.
- Providing advice in the assessment of animal drug or feed product involving a BSE emergency.

III.C.6 National Center for Toxicological Research

NCTR conducts scientific research to support and anticipate the FDA's current and future regulatory needs. This research includes fundamental and applied research on biological mechanisms of action underlying the toxicity of regulated products that could have utility in responding to a BSE emergency.

IV. OPERATING PROCEDURES

IV.A OPERATING PROCEDURE—NOTIFICATION

IV.A.1 Information Flow into the FDA EOC

The FDA EOC may receive notification of a BSE emergency through a variety of means, including from FDA Headquarters, APHIS, FSIS, CDC, USDA, FDA District Offices, FDA Centers, other federal and state agencies, consumers, and other sources outside the FDA, such as through monitoring of the media.

The FDA EOC expects immediate notification of any actual or potential BSE emergency via phone (primary notification method) with a secondary notification by fax or e-mail referencing the initial notification. An FDA EOC Emergency Coordinator will record all information about the initial call and subsequent follow-up information. When possible, the person making and receiving the report documents the following information:

- Description of the emergency situation and status (presumptive or confirmed)
- Description and number of animals affected/dead, location, number in herd, number of herd mates slaughtered and their date and location
- Description of product utilizing the affected bovine derived material (brand name, size, lot number, etc.)
- Responsible firm (manufacturer, supplier, distributor) and contact person at the firm (phone number)
- Information related to the history of the individual regarding blood or tissue donation (or receipt) in the case of CJD cases, which will occur in the population
- Any history related to foreign exposure for these cases
- Press coverage, if any or anticipated, or any other pertinent information
- Description of imported products in domestic commerce subject to BSE prohibitions
- If available, traceback information on products to their source, to include domestic distribution chain, and where relevant, customs entry data, responsible importer of record, and foreign shipper/manufacturer data.

Report any actual or potential BSE emergency promptly by phone to the FDA EOC with follow-up by fax or e-mail referencing the initial notification. Figure IV-1 lists FDA EOC contact information.

Figure IV-1. Contacting the FDA EOC

FDA Emergency Operations
5600 Fishers Lane
Room 12A-55, HFA-615
Rockville, MD 20857
301-443-1240 (24-hour line)
301-827-3333 (Main fax)

The FDA's EOC serves as the Agency's focal point for all emergency response activities 7 days a week, 24 hours a day. After regular duty hours (8:00 a.m. to 4:30 p.m. Eastern Time, Monday through Friday, excluding federal holidays), and when the FDA EOC is not operating, an answering service refers all emergency calls via pager to the EOC Late Duty Officer. The Late Duty Officer follows guidelines set forth in the *EOC Procedures Manual*, including notification procedures.

If the FDA EOC receives information regarding a BSE emergency, the FDA EOC transmits such information to the HHS SCC, appropriate FDA Centers, District Office(s) involved, the FDA OCI, and the USDA. OCI notifies the FBI and/or local law enforcement officials, if required. Notification of state officials occurs at the direction of the FDA EOC or OCI via the DFSR.

An initial notification may include reports of contamination relating to animal-derived or animal-containing product from a BSE Restricted Country in any FDA regulated product, including foods with less than three percent meat content, dietary supplements, cosmetics, biologics, drugs, devices, or veterinary products. Alerts may be reports of suspect CJD cases or cases of vCJD.

Table IV-1. Initial Notification Listing for a BSE Alert

Office	Personnel/Designate
Office of Regional Operations	Deputy Director/Director
Office of Regulatory Affairs	Associate Commissioner
Office of the Commissioner	Associate Deputy Commissioner
Center for Veterinary Medicine	BSE Emergency Coordinator
Center for Food Safety and Applied Nutrition	BSE Emergency Coordinator
Division of Federal-State Relations	Director, DFSR
Division of Import Operations and Policy	Director, DIOP
Division of Field Science	Director, DFS
Division of Field Investigations	Director, DFI
Office of Enforcement	Deputy Director
Office of Corporate Counsel	Chief Counsel
Office of Public Affairs	Assistant Commissioner
Appropriate FDA Field Offices	DIB or DD
USDA/Animal Plant Health and Inspection Service	Chief, TSE Response Team
USDA/Food Safety and Inspection Service	Associate Administrator
Center for Biological Evaluation and Research	BSE Emergency Coordinator
Center for Drug Evaluation and Research	BSE Emergency Coordinator
Center for Devices and Radiological Health	BSE Emergency Coordinator
U.S. Customs and Border Protection	Other Government Agencies Liaison
Department of Defense	VSA Deputy Director
Trade and Industry Associations	Contacted by respective Centers

Table IV-2. Notification Listing For a BSE Emergency

Office	Personnel/Designate
Office of Regional Operations	Deputy Director/Director
Office of Regulatory Affairs	Associate Commissioner
Office of the Commissioner	Associate Deputy Commissioner
Center for Veterinary Medicine	BSE Emergency Coordinator
Center for Food Safety and Applied Nutrition	BSE Emergency Coordinator
Center for Biological Evaluation and Research	BSE Emergency Coordinator
Center for Drug Evaluation and Research	BSE Emergency Coordinator
Center for Devices and Radiological Health	BSE Emergency Coordinator
Division of Federal-State Relations	Director, DFSR
Division of Import Operations and Policy	Director, DIOP
Division of Field Science	Director, DFS
Division of Field Investigations	Director, DFI
Office of Enforcement	Deputy Director
Office of Public Affairs	Assistant Commissioner
Appropriate Field Offices	
USDA/Animal Plant Health and Inspection Service	Chief, TSE Response Team
USDA/Food Safety and Inspection Service	Associate Administrator
Office of Chief Counsel	Chief Counsel
Office of International Programs	Director, International Relations Staff
Office of Legislative Affairs	Associate Commissioner
Office of Emergency Preparedness	Director, OEP
Center for Disease Control	TSE Representative
National Institutes of Health	TSE Expert
U.S. Customs and Border Protection	Other Government Agencies Liaison
Department of Defense	VSA Deputy Director
Trade and Industry Associations	Contacted by Respective Centers

IV.A.2 Risk Assessment/Situation Analysis

The following cases represent anticipated potential BSE emergencies. The FDA included the USDA BSE Response Plan in the analysis. In most cases, the BSE causative agent is likely to be of foreign origin. Consequently, all emergency procedures incorporate both domestic and import/international operations. The FDA EOC receives notification of all cases except Case A, Central Nervous System (CNS) Suspect Bovine. In Case A, the suspect animal is not part of the food chain.

CASE A: Central Nervous System (CNS) Suspect Bovine

Definition

Any bovine that has CNS signs (such as lack of coordination, aggression, seizures, fine head tremors, etc.) the USDA/APHIS designates.

USDA Response Plan

- Inspection procedures include identifying animals with CNS conditions.
- The USDA considers animals with such conditions suspect for BSE. They prohibit the animals from slaughter and refer them to APHIS for examination.

Actions

- USDA does not notify the FDA in suspect bovine cases; however, if the FDA receives a report of such an animal, the FDA notifies USDA/APHIS.
- Pathologists at APHIS' National Veterinary Services Laboratories (NVSL) histopathologically examine the brains from these condemned animals. In addition, they test samples using a technique called immunohistochemistry (IHC), which tests for the presence of the protease-resistant prion protein (PrP-res, a marker for BSE). If the examination or testing show no evidence of BSE, the USDA takes no further action.

CASE B: Presumptive Positive BSE Case

Definition

A case involving APHIS's laboratory tests diagnosing a bovine as a BSE presumptive positive. Pathological observations for a BSE presumptive positive are:

- Presence of histopathological lesions consistent with BSE in the brain.
- Positive for IHC staining for BSE agent.

USDA Response Plan

According to the USDA/APHIS BSE Response Plan, a pathologist from USDA/NVSL hand carries the sample to the United Kingdom for confirmation. The international animal health community recognizes the United Kingdom's Central Veterinary Laboratory (CVL) as the world's reference laboratory for diagnosing BSE.

Actions

USDA/APHIS notifies the FDA EOC 24-hour phone number (301-443-1240) in the case of a presumptive positive BSE in an animal. Once the FDA receives notification, the EOC and CVM work with USDA/APHIS to cooperatively determine the status and disposition of the animal and herd mates.

The following scenarios may be a rare occurrence; however, they are possible:

1. Animal-derived material used in any FDA-regulated product or its manufacture:
   - Determine feed history and origin of presumptive positive bovine looking for source of potentially BSE-contaminated feed and animals.
   - Determine feed history and origin of herd mates of presumptive positive bovine to traceback sources of potential BSE-contaminated feed and animals.
   - Determine feed history and origin of geographically close herds to presumptive positive premises for source of potentially BSE-contaminated feed, animals, and bovine-derived material. Expand the investigation to other herds as investigational information indicates.
   - Prepare draft press releases in coordination with USDA/APHIS in anticipation of positive confirmation of a BSE case.
   - If determination shows the case is negative for BSE, the agencies close the case.

CASE B: Presumptive Positive BSE Case (cont.)

2. Animal rendered to animal feed:

   - The FDA identifies the renderer and trace meat and bone meal forward. The FDA may use state resources in the investigation. The FDA works with the involved state to isolate and secure animals consuming contaminated feed.

3. Animal isolated without processing to feed (frozen, refrigerated, and incinerated):

   - Arrange for secure disposal of the animal that the plant separated and isolated from other carcasses while waiting laboratory analysis.

4. Animal parts as ingredients for FDA-regulated products:

   - Determine the plant's use, collection, and storage of edible bovine parts (e.g., fetal calf serum, lungs, pericardia, meat used in FDA-regulated products, collagen, and meat and bone meal).
   - Determine to whom and where products are going and their intended use.
   - Determine if any FDA products or FDA-regulated products contain animal part products and if distribution occurred.
   - Determine if FDA foods contains meat from animal and herd mates.
   - Determine if pet foods and animal feeds use meat by-products.

CASE C: Confirmed Positive BSE Case

Definition

A case of a BSE presumptive positive bovine that the United Kingdom's CVL confirms as positive.

Actions

- Continue FDA investigation, data collection, feed history and controls, and information on disposition of derived materials.
- Continue communicating with USDA and other agencies regarding case activities.
- Finalize and distribute press releases.

1. BSE animal(s) originating within the U.S.:

   - FDA Centers involved provide immediate and long-term health hazard assessment and action recommendations to Center Directors and the FDA EOC.

2. BSE animal(s) originating outside the U.S.:

   - Determine whether bovine ingredients from the case entered into the U.S. manufacturing processes for regulated products.
     - NO → The FDA closes the case.
     - YES → The FDA takes the following actions:
       - Appropriate FDA Centers provide an immediate health hazard assessment and action recommendations to the Center Directors and the FDA EOC.
       - The FDA, working with USDA/APHIS, attempts to determine the origin of the animal, including whether it was from a known BSE country.

CASE D: Imported Product (Containing Meat or Animal By-Product) Originating from a BSE Restricted Country Identified as Not Refused by USDA/APHIS or FDA

Actions

- Appropriate FDA Center(s) determine the existence of a health hazard. If an immediate health hazard exists, the FDA EOC notifies DIOP to add the product, country, and firm to the import alert for detention without physical examination of future entries. The FDA evaluates any distribution of product to determine the need for further FDA action, such as recall.
- DIOP contacts the headquarters office of CBP, Office of Field and Trade Programs, Other Government Agencies Branch to report imported product (meat containing or animal by-product) from a BSE Restricted Country that bypassed safety screening procedures put in place by USDA and the FDA, and to request placement of the product and manufacturer on alert status to hold future entries.
- If there is no immediate health hazard, the FDA EOC notifies DIOP for further appropriate action.

IV.B OPERATING PROCEDURE—ACTIVATION

IV.B.1 Activation of the FDA EOC

The FDA EOC Director and/or the FDA EOC team leaders receive briefings on reports of an alert or emergency, to include emergency preparedness exercises involving BSE emergencies. The FDA EOC's response to this notification may include partial or full activation of the FDA EOC. The authority to activate the FDA EOC resides with the FDA EOC Director. The OCM Director may also order the activation of the EOC. The ACRA, the Commissioner, and/or the Secretary of HHS may also request the activation of the FDA EOC.

Activation requires the FDA EOC Director to formally announce the activation of the FDA EOC and notify appropriate Centers/Offices and the HHS SCC. This activation announcement may include a status report explaining the decision to activate and a description of operating hours and staffing level (see Figure IV-2). Circumstances, including an actual/potential national emergency, disaster, or exercise, will dictate operating hours and staffing levels for the FDA EOC.

Figure IV-2. Activation/Deactivation Checklist

Activation

- Determine operating level and shifts needed:

  _____

- Prepare notice of activation (Example: The FDA EOC activated on [date] beginning at [time]. This activation is due to [emergency].).
- Issue notice of activation.
- Notify EOC staff to report to the EOC.
- Notify ORA IT for necessary support.

Deactivation

- Prepare notice of deactivation. (Example: The FDA EOC is returning to normal operations effective on [date and time]. Please provide Lessons Learned Report Input to the Planning Section no later than [date and time].)
- Issue notice of deactivation.
- Collect documents applicable to the emergency response and submit them to the Planning Section for archiving, as required.

After the activation procedures commence, the FDA EOC requests additional resources necessary to support the FDA EOC. The FDA EOC will request a technical support representative from ORA IT to work in the FDA EOC during the initial FDA EOC activation and to remain on call for the duration of the FDA EOC activation if operating on a 24-hour shift. The FDA EOC also alerts ORM of the potential need for additional administrative support personnel, such as secretaries.

When activation occurs and 24-hour operations commence, the FDA staffs the EOC for either two or three shifts. NOTE: The FDA EOC maintains a reserve roster of the FDA staff from Headquarters Offices with pre-training to work in the FDA EOC for additional staffing support during 24/7 FDA EOC operations.

IV.B.2 Additional Notifications

The FDA EOC, working with the appropriate Center Emergency Coordinator, coordinates the response to a BSE emergency affecting an FDA-regulated product. The FDA EOC has primary responsibility for coordinating with other FDA entities (Centers and ORA) to ensure necessary investigations and actions are occurring in response to a BSE emergency. The FDA EOC prepares periodic updates or status reports on investigations and actions for the participating districts, FDA Headquarter units, and other agencies as appropriate. The FDA EOC will coordinate information concerning emergencies with headquarters offices of other federal agencies.

The FDA EOC notifies OIP of the following:

- BSE emergencies originating from foreign sources.
- BSE emergencies originating in the United States with the potential to impact other countries.
- Products identified with mammalian protein or BSE exported from the United States to foreign sources.
- Any real or potential imported products identified with mammalian protein.

The FDA EOC notifies OPA of the following:

- All BSE emergencies so that OPA can monitor ongoing or imminent press coverage and begin to prepare public educational materials for FDA statements to respond to inquiries.

The FDA EOC provides DFSR with the following:

- Copies of any press releases issued.

The FDA EOC notifies DIOP of the following:

- BSE emergencies originating from foreign sources. The FDA EOC also provides DIOP with any traceback information derived from the FDA EOC Emergency Coordinator or Late Duty Officer's initial report.

IV.B.3 Mobilization and Deployment of FDA Resources

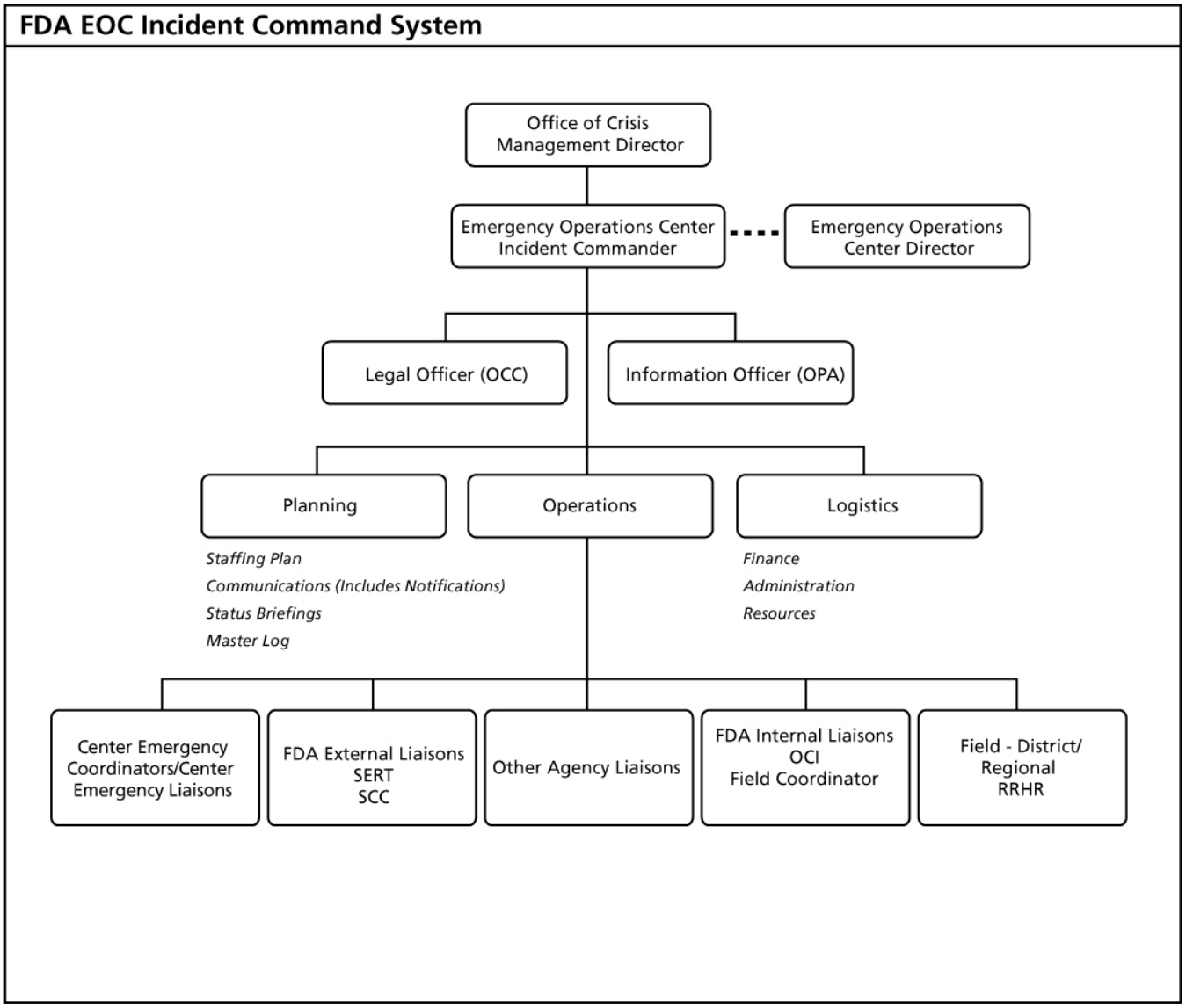
The FDA EOC assesses resource requirements on an ongoing basis during a BSE emergency. The FDA EOC works with HHS and/or the HHS Secretary's Emergency Response Team (SERT) to coordinate the provision of required resources. The FDA EOC distributes mobilization and deployment timelines. If requested, HHS and/or the HHS SERT support the FDA in fulfilling or meeting its deployment requirements.

IV.C OPERATING PROCEDURE—RESPONSE OPERATIONS

IV.C.1 Introduction

The FDA conducts response operations under the Incident Command System (ICS). The command function and subordinate functions of planning, operations, and logistics act as the foundation of the ICS (finance and administrative functions fall under logistics in the FDA EOC ICS structure). The design of the system enables the rapid expansion of support to emergency operations. The FDA EOC follows the ICS, illustrated in Figure IV-3.

Figure IV-3. FDA EOC Incident Command System



IV.C.2 Overview of ICS Positions

IV.C.2.a Office of Crisis Management Director

The OCM Director provides strategic leadership and guidance for the FDA EOC's response to a BSE emergency. The OCM Director coordinates with the FDA EOC Director to ensure the FDA EOC is fulfilling its role in the response. The OCM Director is the FDA EOC's point of contact for communicating with the FDA OC.

IV.C.2.b FDA EOC Incident Commander

During the response to an emergency, the Incident Commander (IC) for the FDA EOC for that response serves as the leader for the FDA EOC. The FDA EOC IC coordinates the dissemination of information to the FDA EOC staff responding to the BSE emergency. The FDA EOC IC ensures information review for appropriate action, including referral to the field for any necessary follow-up. In addition, the FDA EOC IC is the coordination point for consultation regarding command and operations decisions involving appropriate agency, departmental, and interagency issues. The OCM Director may select the FDA EOC IC for each particular emergency from an appropriate Center or Office senior manager and may consult with Center and Office Directors in making that decision.

IV.C.2.c FDA EOC Director

The FDA EOC Director directs the daily functions for the FDA EOC. The FDA EOC Director may also serve as the FDA EOC IC. When the FDA EOC Director serves as the IC, then responsibility for daily EOC functions transfers to an FDA EOC Team Leader.

IV.C.2.d Legal Officer

OCC provides a Legal Officer to work as a member of the FDA EOC, as required. The Legal Officer provides legal advice to the FDA EOC IC and responds to requests for information and assistance from Centers and Offices regarding legal issues.

IV.C.2.e Information Officer

OPA provides an Information Officer to work as a member of the FDA EOC. The Information Officer handles all media inquiries and coordinates the release of information to the media with other agencies' public affairs officers.

IV.C.2.f Planning Section

The Planning Section's function includes the collection, evaluation, dissemination, and utilization of information regarding the development of the emergency and the status of resources. This section's responsibilities can also include creation of the Incident Action Plan (IAP), which defines the response activities and resource utilization for a specified time period during the FDA EOC's response to an emergency.

IV.C.2.g Operations Section

The Operations Section is responsible for carrying out the response activities described in the IAP. The Operations Section Chief coordinates the activities of the Operations Section and has primary responsibility for receiving and implementing the IAP. The Operations Section Chief reports to the FDA EOC IC and determines the required resources and organizational structure needed within the Operations Section.

IV.C.2.h Logistics Section

The Logistics Section is responsible for coordinating support for facilities, services, and materials. This section takes on a greater role in long-term or extended operations. In addition to logistics, this section is responsible for financial and administrative issues that are critical for tracking emergency costs and reimbursement accounting.

IV.C.2.i Center Emergency Coordinators

Each FDA Center has a designated CEC who serves as the conduit of emergency information between his/her Center and the FDA EOC. Throughout the emergency, CECs are proactive and keep direct contact with the FDA EOC to facilitate efficient communication of relevant emergency updates. CECs maintain a current knowledge of the evolving situation and ongoing FDA EOC activities and ensure the appropriate relay of information to and from their Centers.

IV.C.2.j Center BSE Coordinators

Each FDA Center has a designated BSE Coordinator that serves as initial contact point between the EOC and the Center. If the FDA EOC notifies the Center of a BSE emergency, the Center BSE Coordinator contacts all appropriate Center staff. If notified by any other source, the Center BSE coordinators notify the FDA EOC.

The Center BSE Coordinators are as follows:

- CBER – Emergency Coordinator, Office of Compliance and Biologics Quality.
- CDER – Emergency Operations Officer.
- CDRH – Senior Associate Center Director.
- CVM – Director of the Division of Compliance.
- CFSAN – Head of the Emergency Coordination and Response Staff (ECR), CFSAN/Office of Compliance (OC).

IV.C.2.k Center Emergency Liaisons

Each FDA Center has a designated CEL who deploys, as requested, to the FDA EOC during the response to emergencies requiring the activation of the FDA EOC. CELs maintain a current knowledge of the evolving situation and ongoing FDA EOC activities and communicate such activity to and from their CECs. CELs operate a Center desk within the FDA EOC and act as members of the FDA EOC staff while present.

IV.C.2.l FDA External Liaisons

FDA external liaisons report to external agencies' EOCs and represent the FDA during an emergency. These outside agencies might include the HHS, USDA, and Department of State (DOS). These liaisons not only serve as direct links between the FDA EOC IC and their assigned agencies, but also work as members of the external agencies' EOCs. FDA External Liaisons maintain an awareness of the situation and external agency activities and communicate these activities to the FDA EOC. Further, FDA External Liaisons inform the external agencies' EOCs of activities, concerns, and information requests from the FDA.

IV.C.2.m Other Agency Liaisons

During a BSE emergency, other agencies (USDA, CDC, and others) may send a representative to the FDA EOC. These agency liaisons provide assistance to the FDA EOC IC regarding decisions involving their respective outside agencies. Other Agency Liaisons maintain communication between the other agency and the FDA EOC and will work as members of the FDA EOC team. Further, Other Agency Liaisons inform the FDA EOC of activities, concerns, and information requests from their own agencies.

IV.C.2.n Field—District/Regional

FDA Districts will be the lead response organization when an emergency occurs within their district boundaries. The FDA EOC maintains contact with the Districts and Regions to ensure that they are aware of any events that would necessitate their involvement in the response.

Each Regional and District Office maintains a means by which headquarters can communicate emergency situations 24 hours a day, 7 days a week. Each region/district will establish and maintain procedures for internal communications and provide for appropriate liaison and notification systems to city, county, and state governments, and local offices of federal agencies.

All reports of a BSE emergency, a BSE alert, or actual adverse effects associated with FDA-regulated products require immediate investigation and immediate reporting to the EOC by phone, e-mail, or fax (see Figure IV-1, Contacting the FDA EOC). Report the nature and effect of the emergency, including the following information:

- Probable or actual distribution pattern, if known, for suspect product(s).
- Steps taken to coordinate FDA actions with state, local, and other federal officials, and any independent actions the state and/or local officials take.
- Actions firms take, corrective actions, recalls, etc.

The district in which the emergency is occurring will assume the lead investigative role in determining the cause of the emergency and obtaining necessary information for the Agency to confirm the health hazard. If it becomes apparent during the course of the investigation that a firm in another district is responsible for the product involved in the emergency, the “lead district” designation transfers to the home district of the responsible firm. Any change in the designation of "lead district" should occur in concurrence with the FDA EOC. In certain widespread emergencies involving more than one responsible firm, the FDA EOC may assume the lead role without designation of a “lead district.”

The "lead district" will identify an ad hoc emergency management team headed by the District Director or a designated district person and a coordinator. The district will determine the exact number and mix of persons on the team. Districts should direct any recommendations for reallocation of field staff between or among districts during emergencies to ORO.

The district should promptly name a senior staff employee as coordinator of the emergency response activities. Generally, this person’s location is at the lead district office in order to facilitate communication and record review. In a widespread emergency, the involved districts may name additional coordinators, as necessary. The coordinator is responsible for advising management of necessary follow-up actions and channeling all necessary communications. This includes any or all of the following steps:

- Investigation/analysis:
  - Issuing assignments to district personnel to obtain the information necessary for Agency personnel to evaluate the health hazard of the situation.
  - Monitoring assignments to assure timely completion.
  - Arranging for continuing contact with investigators for flow of information.
  - Seeking technical guidance through the FDA EOC relating to the investigation, samples needed, etc.

- Determining, in consultation with DFS and FDA EOC, the appropriate laboratory to which to submit samples and alerting that laboratory as soon as possible to allow for necessary preparations.

- Maintaining communications:
  - Keeping appropriate center, district, and regional officials informed of investigational and analytical progress.
  - Preparing daily status reports.
  - Contacting appropriate state and local authorities involved with the investigation.
  - Serving as local the FDA press contact concerning the emergency. The coordinator or other designated official will work with headquarters in preparing statements to the press.
  - FDA field and headquarters employees may receive requests to respond to media inquiries about ongoing investigations when not in a position to first seek guidance from OPA. Personnel should refer all media inquiries on emergency-related subject matter to OPA. This ensures the issuance of only accurate, complete, timely, authorized, and coordinated information, allowing for a full perspective of the situation.
    - Notify OPA, either directly or through the FDA EOC, as soon as possible after such media contacts.
    - Report significant press coverage of the emergency as soon as possible to the FDA EOC so that OPA, DFSR, and other offices stay informed.
    - Obtain copies of state, company, or other press releases and fax them to the FDA EOC in a timely manner.

The FDA lead district office (or a large resident post) facility should generally serve as FDA's field command post because of the available communications equipment. If the emergency is in a state without a well-equipped FDA office, the FDA's field command post may co-locate with the cooperating lead state agency.

IV.D OPERATING PROCEDURE—RESPONSE DEACTIVATION

The FDA discontinues emergency response operations upon fulfillment of their statutory responsibilities, or when other agencies, such as the USDA, no longer require its assistance.

Actions the FDA EOC takes upon deactivation include the following:

- Notification of all FDA Centers/Offices.
- Notification of supporting agencies/personnel.

- Notification of staff on other EOC shifts.
- Compilation of records detailing personnel and resources used to support response operations.
- Confirmation that all FDA personnel returned from any deployments in support of emergency operations.
- Development of FDA internal lessons learned report.

IV.E OPERATING PROCEDURE—RECOVERY

The FDA EOC IC continually assesses the emergency and determines whether to continue operating the FDA EOC or modify or terminate the FDA EOC's response operations. This decision includes determining whether the FDA achieved its objectives for protecting public health and containing the BSE emergency. In making this decision, the FDA EOC IC coordinates with and seeks input from appropriate experts and stakeholders. The FDA will participate in recovery activity, as required. The FDA EOC may resume operating during normal business hours during the recovery stage. The FDA EOC IC determines when the FDA EOC should return to normal operating procedures in coordination with the OCM Director, and he/she issues a corresponding agencywide announcement.

Recovery activities may begin before the response phase is complete. Primary recovery activities include—

- Working with HHS to issue press releases clarifying the safety of affected products.
- Completing investigational findings, laboratory analysis, and reports.
- Initiating compliance actions and/or recommendations.
- Completing all emergency communications.
- Destroying, disposing, and reconditioning of products.
- Implementing appropriate security measures.
- Assessing similar products for potential contamination.
- Developing a follow-up monitoring program to determine the safety of unrestricted products.
- Obtaining input from stakeholders on the effectiveness of the FDA's emergency response.

During the recovery period, the FDA EOC Planning Section works with stakeholders to conduct a lessons learned analysis that identifies the following:

- Improvements to emergency response plans and procedures.
- Interventions to better protect public health.
- Improvements for communications.
- Recommendations to modify regulatory policy, laboratory and field operations, and research activities.
- Improvements for preparedness.

A final lessons learned report draws conclusions from data collected and relevant parties within the FDA receive the report. All FDA Centers and Offices should submit their input to the FDA EOC Director no later than 2 weeks following the emergency using the Lessons Learned Report input form.

V. AUTHORITIES

The FDA conducts activities pursuant to the following authorities:

- Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA), as amended (USC Title 21) (http://www.access.gpo.gov/uscode/title21/chapter9_.html).
- The Public Health Service Act (USC Title 42) (http://www.fda.gov/opacom/laws/phsvcact/phsvcact.htm).
- The Federal Anti-Tampering Act (USC Title 18, Section 1356) (http://www.fda.gov/opacom/laws/fedatact.htm).
- Relevant U.S. Government operating plans (see specific agencies' web sites).
- Federal Response Plan, January 2003 (http://www.fema.gov/pdf/rrr/frp/frp2003.pdf).
- U.S. Department of Health and Human Services Counter-Terrorism Concept of Operations Plan (Version IXb).

V. ANNEXES

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ANNEX A—ACRONYMS

AAFCO	Association of American Feed Control Officials
AAR	After Action Report
ACPA	Assistant Commissioner for Public Affairs
ACRA	Associate Commissioner for Regulatory Affairs
ACS	Automated Commercial System
AERS	Adverse Event Reporting System
ASPHEP	Assistant Secretary for Public Health Emergency Preparedness
BIA	Bureau of Indian Affairs
BPD	Biological Product Deviation
BSE	Bovine Spongiform Encephalopathy
CAERS	CFSAN Adverse Event Reporting System
CBER	Center for Biologics Evaluation and Research
CBP	U.S. Bureau of Customs and Border Protection
CCRF	Commissioned Corps Readiness Force
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CEC	Center Emergency Coordinator
CEL	Center Emergency Liaison
CFO	Chief of Field Operations
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
CFSAN/OC	Center for Food Safety and Applied Nutrition/Office of Compliance (formerly Office of
CMS	Center for Medicare and Medicaid Services
CNS	Central Nervous System
CONPLAN	Concept of Operations Plan
COOP	Continuity of Operations Plan
CT	Counter-terrorism
CVL	Central Veterinary Laboratory
CVM	Center for Veterinary Medicine
DEST	Domestic Emergency Support Team
DFI	Division of Field Investigations
DFO	District Field Office
DFS	Division of Field Science
DFSR	Division of Federal-State Relations
DHS	Department of Homeland Security
DIL	Derived Intervention Levels
DIOP	Division of Import Operations and Policy
DMAT	Disaster Medical Assistance Team
DMORT	Disaster Mortuary Operational Response Team
DoD	Department of Defense
DOE	Department of Energy

DOS	Department of State
DOT	Department of Transportation
DPEM	Division of Planning, Evaluation, and Management
ECR	Emergency Coordination and Response Staff
ECRS	Electronic Correspondence Referral System
eLEXNET	Electronic Laboratory Exchange Network
EOC	Emergency Operations Center
EPA	Environmental Protection Agency
Epi-X	Epidemic Information Exchange
ERD	Emergency Response Division
ERT	Emergency Response Team
ESF	Emergency Support Function
FACTS	Field Accomplishments and Compliance Tracking System
FBI	Federal Bureau of Investigation
FCO	Federal Coordinating Officer
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
FERN	Food Emergency Response Network
FFDCA	Federal Food, Drug and Cosmetic Act of 1938
FFI	Fatal Familial Insomnia
FOIA	Freedom of Information Act
FRP	Federal Response Plan
FRPCC	Federal Radiological Preparedness Coordinating Committee
FSIS	Food Safety and Inspection Service
GETS	Government Emergency Telecommunications Service
GIS	Geographical Information System
GMP	Good Manufacturing Practices
HazMat	Hazardous Materials
HHS	Health and Human Services
HRSA	Health Resources and Services Administration
HSPD	Homeland Security Presidential Directive
IAP	Incident Action Plan
IATA	International Air Transport Association
IC	Incident Commander
ICS	Incident Command System
IDE	Investigational Device Exemption
IHC	Immunohistochemistry
IHS	Indian Health Service
INAD	Investigational New Animal Drug
IND	Investigational New Drug
IOM	Investigations Operations Manual
IT	Information Technology

JIC	Joint Information Center
JOC	Joint Operations Center
LRN	Laboratory Response Network
MAFF	Ministry of Agriculture, Fisheries, and Foods
MOU	Memorandum of Understanding
MRI	Magnetic Resonance Imaging
MST	Management Support Team
NASA	National Aeronautics and Space Administration
NCS	National Communications System
NCTR	National Center for Toxicological Research
NIH	National Institutes of Health
NIMS	National Incident Management System
NRP	National Response Plan
NSC	National Security Council
nvCJD	New Variant Creutzfeldt-Jakob Disease
NVSL	National Veterinary Services Laboratories
OASIS	Operational and Administrative System for Input Support
OC	Office of the Commissioner
OCC	Office of the Chief Counsel
OCI	Office of Criminal Investigation
OCM	Office of Crisis Management
OCP	Office of Combination Products
OE	Office of Enforcement
OEO	Office of Emergency Operations (former name of the FDA's Emergency Operations Center)
OEP	Office of Emergency Preparedness
OIP	Office of International Programs
OIT	Office of Information Technology
OLA	Office of Legislative Affairs
OLAP	On-Line Analytical Processing
OM	Office of Management
OPA	Office of Public Affairs
OPDIV	Operational Division
ORA	Office of Regulatory Affairs
ORM	Office of Resource Management
ORO	Office of Regional Operations
OSC	On-Scene Coordinator
OSOPP	Officer of Security Operations, Policy, and Planning
OSS	Office of Shared Services
OTC	Over the Counter
PHS	Public Health Service
POC	Point of Contact
PPE	Personal Protective Equipment

REOC	Regional Emergency Operations Center
RFA	Request for Assistance
RFI	Request for Information
RHA	Regional Health Administrator
RPM	Regulatory Procedures Manual
SAMHSA	Substance Abuse and Mental Health Services Administration
SCC	Secretary's Command Center
SERT	Secretary's Emergency Response Team
SOP	Standard Operating Procedures
TSE	Transmissible Spongiform Encephalopathy
UCS	Unified Command System
USC	United States Code
USCG	United States Coast Guard
USDA	United States Department of Agriculture
USTR	U.S. Trade Representative
VA	Department of Veterans Affairs
VAERS	Vaccine Adverse Event Reporting System
vCJD	Variant Creutzfeldt-Jakob Disease
VMAT	Veterinary Medical Assistance Team
WEAC	Winchester Engineering and Analytical Center
WHO	World Health Organization
WMD	Weapons of Mass Destruction

ANNEX B—DEFINITIONS

Items in this section are as follows:

Tab 1 General Definitions
Tab 2 BSE Specific Definitions

Tab 1 General Definitions

Disaster Medical Assistance Teams (DMAT): A group of healthcare practitioners and providers that provide emergency medical care during a disaster or other unusual event. They may provide primary healthcare and/or augment overloaded local healthcare staff. The design of DMATs allows a rapid-response element to supplement local medical care until the mobilization of other federal or contract resources or the resolution of the situation. DMATs fall under the overarching National Disaster Medical System, and as such, receive the medical authority, training, and standards to practice throughout the nation from HHS. However, in the event of an emergency requiring activation of the FRP, the NDMS and all the assets it encompasses fall under the ultimate jurisdiction of DHS. Once finalization of the NRP is complete, this may change.

Disaster Field Office (DFO): The office established in or near the disaster area to support federal and state response and recovery operations. The Disaster Field Office houses the Federal Coordinating Officer (FCO), the Emergency Response Team, and, where possible, the State Coordinating Officer and support staff.

Emergency: An unforeseen combination of circumstances or the resulting state that calls for immediate action.

Emergency Response Team (ERT): A team composed of federal program and support personnel, which FEMA activates and deploys into an area affected by a major disaster or emergency. This team assists the FCO in carrying out his/her responsibilities under the Stafford Act, an emergency declaration, applicable laws, regulations, and the FEMA-State agreement. The team is an interagency team, consisting of the lead representative from each federal department or agency assigned primary responsibility for an Emergency Support Function (ESF) and key members of the FCO's staff, formed to assist the FCO in carrying out his/her responsibilities. The team provides a forum for coordinating the overall federal consequence management response requirements.

Federal Coordinating Officer: Federal official who represents the President and coordinates overall response and recovery activities. The FCO represents the President as provided by Section 303 of the Stafford Act for the purpose of coordinating the administration of federal relief activities in the designated area.

Federal Response Plan: Plan for federal disaster assistance under the Stafford Act.

Incident Command System: A model for the command, control, and coordination of resources at the scene of an emergency and at emergency operations centers.

National Disaster Medical System: An asset sharing partnership designed to provide emergency medical assistance to states following a catastrophic disaster or other major emergency. The design of the system enables it to care for victims of any emergency that exceeds the medical care capability of the affected local and state resources. The NDMS receives the medical authority, training, and standards to practice throughout the nation from HHS. However, in the event of an emergency requiring activation of the

FRP, the NDMS and all the assets it encompasses fall under the ultimate jurisdiction of DHS. Once the finalization of the NRP is complete, this may change.

The NDMS has three primary objectives:

- Provide health, medical, and related social service response to a disaster area in the form of medical response units or teams and medical supplies and equipment.
- Evacuate patients who cannot receive care in the affected area to designated locations elsewhere in the nation.
- Provide hospitalization in federal hospitals and a voluntary network of non-federal acute care hospitals that agree to accept patients during a national emergency.

Public Information Officer: Headquarters or field official responsible for preparing and disseminating public information in cooperation with responding federal, state, and local agencies. Under the FDA EOC Incident Command System during an emergency response, the Information Officer performs this role within the FDA EOC.

Regional Emergency Operations Center: Temporary facility, established at the FEMA Regional Office or FEMA Regional Center, for coordination of federal response until the DFO becomes operational.

Senior FEMA Official: Official appointed by the FEMA Director to direct initial FEMA response on-scene and as a team leader for the advance element of the ERT.

State Coordinating Officer: Official designated by the governor of the affected state to work with the on-scene coordinator (OSC) and FCO in coordinating response efforts.

Traceback Investigation: The method used to identify the sources of the products implicated in a BSE emergency. The purpose is to determine and document the distribution and production chain for a product back to its source.

Traceforward Investigation: The method used to identify the distribution of the product downstream from its source. The purpose is to determine and document the distribution and production chain and identify additional persons at risk for exposure to a product implicated during a BSE emergency.

Traceout: Epidemiological investigation procedure that traces movement of products and/or animals possibly exposed to infection.

Tab 2 BSE Specific Definitions

Bovine: Cattle or relating to cattle.

Bovine Spongiform Encephalopathy: A disease (also known as mad-cow disease), which is a progressive, lethal central nervous system (CNS) disease, strictly targeting cattle. The appearance of vacuoles, or round clear spaces in neurons in the brains of affected cattle that give the brain a "sponge-like" appearance (spongiform) characterize BSE.

BSE Alert: A formal notification issued by the FDA or other organization to the Emergency Operations Center when situations or incidents involve reports (confirmed or unconfirmed) regarding:

- Any imported animal feed or animal feed ingredient from a BSE restricted country that may contain animal tissue or protein, as Import Alerts #99-25 and 71-04 address.
- Any domestic animal feed or animal feed ingredient that contains prohibited materials obtained either from a BSE restricted country or from an unknown source.
- Any food, dietary supplement, cosmetic, drug, device, or biologic that contains or may contain material contaminated with prohibited materials or that may have become contaminated with prohibited materials or that was imported in violation of a relevant import alert or regulation.
- A suspected or confirmed case of variant Creutzfeldt-Jakob Disease (vCJD) by the Centers for Disease Control and Prevention (CDC) or MedWatch, or a Biological Product Deviation (BPD) report in a person who has not been in a BSE restricted country.

BSE Emergency: (1) Situations involving a presumptive or confirmed diagnosis of infection by the alleged BSE agent in any bovine or product derived from a bovine (domestic or imported) in the U.S. (2) Any report of a confirmed case of disease caused by the BSE agent in other mammalian species in the U.S.

BSE Restricted Country: A country listed in Title 9, Part 94.18 of the Code of Federal Regulations (CFR). For a listing of these countries, please refer to the following website: http://www.aphis.usda.gov/vs/ncie/country.html.

Central Nervous System Suspect Bovine: A bovine showing signs of a CNS disease as designated by the United States Department of Agriculture (USDA)/Animal and Plant Health Inspection Service (APHIS). The signs of suspected CNS disease in cattle may include the animal's lack of coordination, aggression, seizures, and fine head tremors.

Creutzfeldt-Jakob Disease: A rare neurological disease that usually afflicts persons over 55 years of age. The first CJD identification was in the 1920s, and it occurs at a rate of about one person per million each year worldwide. It is important to note that

this incidence rate represents an average over time. Because age is a key factor in evaluating CJD distribution, and because the disease tends to strike people over the age of 55, the actual rate is higher for people in this age range. German physicians Hans Gerhard Creutzfeldt and Alfons Jakob first defined CJD in its natural form in the 1920s.

Confirmed Positive BSE Case: A BSE presumptive positive case confirmed by the United Kingdom's Central Veterinary Laboratory.

Presumptive Positive BSE: A bovine that APHIS has designated as a laboratory test positive for BSE, with signs of CNS disease and the observation of histopathological lesions of BSE in the brain and/or a positive test for immunohistochemical staining for the BSE agent.

Prions: Infectious proteins that are the leading hypothetical causative agents of spongiform encephalopathy. Prions consist of a single molecule containing about 250 amino acids. There is a normal form PrP, which has mostly an alpha helix structure. There is also an abnormal form PrP^{Sc}, which has mostly a beta sheet structure and which most believe to be the infectious agent in Transmissible Spongiform Encephalopathy.

Ruminant: Member of the mammalian suborder Ruminatia; an animal that has a stomach with four complete cavities and that characteristically regurgitates undigested food from the rumen and masticates it when at rest. Such animals include cattle, deer, and oxen.

Transmissible Spongiform Encephalopathy (TSE): Name for a group of brain diseases that causes sponge-like abnormalities in brain cells. The accumulation of abnormal prion protein in the brain is an association of TSE diseases.

Variant CJD (vCJD) or new variant CJD (nvCJD): Name given to a newly identified human TSE which is significantly different from other forms of CJD in that it occurs in younger patients. Most believe the transmissible agent responsible for BSE causes vCJD. Signs and symptoms vary but may include loss of coordination, personality changes, mania, and dementia. (Both vCJD and nvCJD refer to the same entity.)

NOTE: Additional terms specific to BSE are available in APHIS's "Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States," http://www.aphis.usda.gov/lpa/issues/bse/bsecan_risk_anal.pdf.

ANNEX C—USDA BSE RESPONSE PLAN

(Source: USDA Bovine Encephalopathy (BSE) Response Plan, July 2001)

USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for ensuring the health and care of animals and plants. APHIS improves agricultural productivity and competitiveness and contributes to the national economy and the public health. USDA's Food Safety and Inspection Service (FSIS) is responsible for protecting the nation's meat and poultry supply – making sure it is safe, wholesome, unadulterated, and properly labeled and packaged. These two agencies have come together to lead USDA's actions in prevention, monitoring, and control of BSE in the U.S. livestock and food supply.

APHIS and FSIS determined that the BSE Red Book, which details laboratory and field activities carried out in an emergency, needed another component – a notification plan. APHIS and FSIS developed the BSE Response Plan, which gives instructions to USDA staff concerning who is to do what, when, where, and how in the event of BSE diagnosis in the United States.

The FDA plays a role in the USDA's BSE Response Plan. In the event of a confirmed or presumptive diagnosis of BSE, USDA will notify the FDA if carcasses moved to rendering or animal feed manufacturing and will provide the FDA with information regarding disposal of the carcass and its parts, including the use of non-food items. The FDA will accompany the USDA epidemiologist in contacting feed manufacturers or brokers to establish the ingredients used in each feed. Additionally, the FDA will provide representation on a recall committee to respond to potential or real health hazard emergencies reported to the Emergency Response Division (ERD).

The website http://cofcs66.aphis.usda.gov/lpa/issues/bse/bsesum.pdf contains a complete summary of the USDA BSE Response Plan.