

Coordinating Agency:

Department of Health and Human Services

Cooperating Agencies:

Department of Agriculture
Department of Commerce
Department of Defense
Department of Energy
Department of Homeland Security
Department of the Interior
Department of Justice
Department of Labor
Department of State
Department of Transportation
Department of Veterans Affairs
Environmental Protection Agency
General Services Administration
U.S. Agency for International Development
U.S. Postal Service
American Red Cross

INTRODUCTION

Purpose

The purpose of the Biological Incident Annex is to outline the actions, roles, and responsibilities associated with response to a human disease outbreak of known or unknown origin requiring Federal assistance. In this document, a biological incident includes naturally occurring biological diseases (communicable and noncommunicable) in humans as well as terrorist events. This definition also includes those biological agents found in the environment, or diagnosed in animals, that have the potential for transmission to humans (zoonosis). Incidents that are restricted to animal, plant, or food health or safety are reviewed in other annexes. Actions described in this annex take place with or without a Presidential Stafford Act declaration or a public health emergency declaration by the Secretary of Health and Human Services (HHS). This annex outlines biological incident response actions including threat assessment notification procedures, laboratory testing, joint investigative/response procedures, and activities related to recovery.

Scope

The objectives of the Federal Government's response to a biological terrorism event or to a naturally occurring disease outbreak with a known or novel pathogen are to:

- Detect the event through disease surveillance and environmental monitoring.
- Identify and protect the population(s) at risk.
- Determine the source of the disease.
- Assess the public health, law enforcement, and international implications.
- Control and contain any possible epidemic (including providing guidance to State, tribal, territorial, and local public health authorities).
- Augment and surge public health and medical services.

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- Identify the cause and prevent the recurrence of any potential resurgence, additional outbreaks, or further spread of disease.
- Assess the extent of residual biological contamination and conduct response, restoration, and recovery actions as necessary.

The unique attributes of this response require separate planning considerations that are tailored to specific health concerns and effects of the disease (e.g., terrorism versus natural outbreaks, communicable versus noncommunicable, etc.).

Specific operational guidelines, developed by respective organizations to address the unique aspects of a particular biological agent or planning consideration, will supplement this annex and are intended as guidance to assist Federal, State, tribal, territorial, and local public health and medical planners.

Special Considerations

Detection of a bioterrorism act against the civilian population may occur in several different ways and involve several different modalities:

- An attack may be surreptitious, in which case the first evidence of dissemination of an agent may be the presentation of disease in humans or animals. This could manifest either in clinical case reports to domestic or international public health authorities or in unusual patterns of symptoms or encounters within domestic or international health surveillance systems.
- A terrorist-induced infectious disease outbreak initially may be indistinguishable from a naturally occurring outbreak; moreover, depending upon the particular agent and associated symptoms, several days could pass before public health and medical authorities even suspect that terrorism may be the cause. In such a case, criminal intent may not be apparent until some time after illnesses are recognized.
- Environmental surveillance systems, such as the BioWatch system, may detect the presence of a biological agent in the environment and trigger directed environmental sampling and intensified clinical surveillance to rule out or confirm an incident. If confirmed, the utilization of environmental surveillance systems may allow for mobilization of a public health, medical, and law enforcement response in advance of the appearance of the first clinical cases or a rapid response after the first clinical cases are identified.
- Other cooperating departments and agencies listed in this annex may detect acts of bioterrorism or biological incidents through their normal operations and surveillance efforts. Should this occur, notifications should be made according to approved interagency response protocols, consistent with the health and law enforcement assessment process described in this annex.

Policies

This annex supports policies and procedures outlined in the *National Response Framework*, Emergency Support Function (ESF) #8 – Public Health and Medical Services Annex, ESF #10 – Oil and Hazardous Materials Response Annex, ESF #11 – Agriculture and Natural Resources Annex, ESF #15 – External Affairs Annex, the Terrorism Incident Law Enforcement and Investigation Annex, and the International Coordination Support Annex.

HHS serves as the Federal Government's primary agency for the public health and medical preparation and planning for and response to a biological terrorism attack or naturally occurring

outbreak that results from either a known or novel pathogen, including an emerging infectious disease.

The Department of Agriculture (USDA) serves as the Government's primary agency for outbreaks and/or attacks that may occur in animals used in the commercial production of food. USDA may also serve as the Government's primary agency for attacks on food processing/slaughtering facilities under its regulatory purview. In the event of a food or animal event, HHS may provide additional public health and veterinary epidemiological assistance to USDA. Wildlife events will be placed under the purview of the Department of the Interior (DOI), while those involving marine animals will be managed and monitored by the Department of Commerce.

The Secretary of Homeland Security is the principal Federal official for domestic incident management. Pursuant to the Homeland Security Act of 2002, the Secretary is responsible for coordinating Federal operations within the United States to prepare for, respond to, and recover from terrorist attacks, major disasters, and other emergencies, including biological incidents.

State, tribal, territorial, and local governments are primarily responsible for detecting and responding to disease outbreaks and implementing measures to minimize the health, social, and economic consequences of such an outbreak.

The Attorney General has lead responsibility for criminal investigations of terrorist acts or terrorist threats by individuals or groups inside the United States, or directed at U.S. citizens or institutions abroad. Generally acting through the Federal Bureau of Investigation (FBI), the Attorney General, in cooperation with other Federal departments and agencies engaged in activities to protect our national security, shall also coordinate the activities of the other members of the law enforcement community to detect, prevent, preempt, and disrupt terrorist attacks against the United States. If any agency or government entity becomes aware of an overt threat involving biological agents or indications that instances of disease may not be the result of natural causes, the Department of Justice (DOJ) must be notified through the FBI's Weapons of Mass Destruction Operations Unit (WMDOU).

If the threat is deemed credible by the FBI in coordination with HHS or USDA, the FBI, in turn, immediately notifies the National Operations Center (NOC) and the National Counterterrorism Center (NCTC). The Laboratory Response Network (LRN) is used to test samples for the presence of biological threat agents. Any agency or organization that identifies an unusual or suspicious test result should contact the FBI to ensure coordination of appropriate testing at an LRN laboratory. Decisions on where to perform additional tests on samples are made by the FBI, in coordination with HHS or USDA. All relevant threat and public health assessments should be provided to the NOC. Test results on human samples from non-LRN facilities are considered a "first pass" or "screening" test.

Once notified of a credible threat or disease outbreak, HHS convenes a meeting of ESF #8 partners to assess the situation and determine appropriate public health and medical actions. The Department of Homeland Security (DHS) coordinates overall nonmedical support and response actions across all Federal departments and agencies. HHS leads public health and medical emergency response efforts across all Federal departments and agencies.

The FBI coordinates the investigation of criminal activities if such activities are suspected.

HHS provides guidance to State, tribal, territorial, and local authorities and collaborates closely with the FBI in the proper handling of any materials that may have evidentiary implications (e.g., LRN samples, etc.) associated with disease outbreaks suspected of being terrorist or criminal in nature. If evidentiary materials are shared with or procured from foreign

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governments, HHS and the FBI will coordinate and share information with the Department of State (DOS) as appropriate.

HHS will be supported by other Federal agencies as appropriate during the various states of a biological incident response in the preparation, planning, and/or response processes and will perform the roles described in this annex in coordination with DHS and State partners. If the incident response progresses such that it requires multiagency participation, DHS will serve as the Incident Coordinator. HHS will serve as the coordinating agency for public health issues as will other agencies for their area of technical expertise.

If there is potential for environmental contamination, HHS collaborates with the Environmental Protection Agency (EPA) in developing and implementing sampling strategies and sharing results.

In the event of an outbreak of an agriculturally significant zoonotic disease or human foodborne pathogen, HHS collaborates with USDA during the preparation, planning, and/or response processes.

Given the dynamic nature of a biological incident, HHS, in collaboration with other departments and agencies, determines the thresholds for a comprehensive Federal Government public health and medical response. These thresholds are based on specific event information rather than predetermined risk levels.

Federal public announcements, statements, or press releases related to a threat or actual bioterrorism event will be coordinated with the DHS Office of Public Affairs consistent with ESF #15, if activated.

Planning Assumptions

In a biological incident, Federal, State, tribal, territorial, and local officials require a highly coordinated response to public health and medical emergencies. The biological incident also may affect other countries, or be of international concern, and therefore involve extensive coordination with DOS and the international health community (e.g., notification to the World Health Organization (WHO) and other international health organizations under the International Health Regulations (IHR)).

Disease transmission may occur from direct contact with an infected individual or animal, an environmental reservoir (includes contaminated surface or atmospheric dispersion), an insect vector, or contaminated food and water. Indirect contact transmission may also occur where contaminated inanimate objects (fomites) serve as the vehicle for transmission of the agent. Hands may also play a role in indirect transmission.

A biological incident may be distributed across multiple jurisdictions simultaneously. This could require the simultaneous management of multiple "incident sites" from national and regional headquarters locations in coordination with multiple State, tribal, territorial, and local jurisdictions.

A response to contagious and noncontagious public health emergencies may require different planning assumptions or factors.

The introduction of biological agents, both natural and deliberate, is often first detected through clinical or hospital presentation. However, there are other methods of detection, including environmental surveillance technologies such as BioWatch, and medical and syndromic surveillance systems. Early detection of biological agents offers an opportunity to take proactive measures to mitigate the consequences of disease outbreak.

Routine fish and wildlife health and disease surveillance, including investigation of wildlife mortality events conducted on public lands and in public laboratories, provides the opportunity for early detection of biological agents and acts of bioterrorism. Animal health surveillance in the agriculture sector provides similar opportunities.

No single entity possesses the authority, expertise, and resources to act unilaterally on the many complex issues that may arise in response to a nonroutine disease outbreak and loss of containment affecting a multijurisdictional area. The national response requires close coordination between numerous agencies at all levels of government and with the private sector.

The Federal Government supports affected State, tribal, territorial, and local health jurisdictions as requested or required. The response by HHS and other Federal agencies is flexible and adapts as necessary as the outbreak evolves.

The LRN provides analytical support to inform public health assessment of the potential for human illness associated with exposure and the scope of this kind of risk. The LRN also provides for definitive testing of both environmental and clinical samples, as well as limited supporting analysis of food samples that may be implicated as part of epidemiological investigations associated with incident response to cases of human illness. Early HHS, FBI, USDA, EPA, and DHS coordination enhances the likelihood of successful preventative and investigative activities necessary to neutralize threats and attribute the source of the outbreak. (The Food Emergency Response Network (FERN) is a complementary system that integrates the Nation's food-testing laboratories at the local, State, and Federal levels into a network that is able to respond to emergencies involving biological, chemical, or radiological contamination of food. The FERN structure is organized to ensure Federal and State interagency participation and cooperation in the formation, development, and operation of the network.)

Response to disease outbreaks suspected of being deliberate in origin requires consideration of special law enforcement and homeland security requirements as well as international legal obligations and requirements.

An investigation into intentional biological threats or incidents will likely require the initiation of a joint criminal and epidemiological investigation. The FBI would coordinate criminal investigative activities with appropriate State/local and Federal partner agencies, such as DHS, HHS, and USDA.

CONCEPT OF OPERATIONS

Biological Agent Response

The key elements of an effective biological response include (in nonsequential order):

- Rapid detection of the outbreak or introduction of a biological agent into the environment.
- Rapid dissemination of key safety information, appropriate personal protective equipment, and necessary medical precautions.
- Swift agent identification and confirmation.
- Identification of the population at risk (to include animals, marine life, and plants).
- Determination of how the agent is transmitted, including an assessment of the efficiency of transmission.

- Determination of susceptibility to prophylaxis and treatment.
- Definition of the public health and medical services, human services, and mental health implications.
- Control and containment of the epidemic when possible, and use of mitigation strategies when containment is not possible (e.g., in the event of an influenza pandemic).
- Identification of the law enforcement implications/assessment of the threat.
- Augmentation and surging of local health and medical resources.
- Protection of the population through appropriate public health and medical actions.
- Dissemination of information to enlist public support and provide risk communication assistance to responsible authorities.
- Assessment of environmental contamination and cleanup/decontamination/proper disposal of bioagents that persist in the environment, and provision of consultation on the safety of drinking water and food products that may be derived from directly or environmentally exposed animals, crops, plants and trees, or marine life.
- Tracking and preventing secondary or additional disease outbreak.
- Administration of countermeasures when appropriate.

Primary Federal functions include supporting State, tribal, territorial, and local public health and medical capacities according to the policies and procedures detailed in the *National Response Framework* and its annexes (e.g., ESF #8).

Outbreak Detection

Determination of a Disease Outbreak

The initial indication of a biological incident may be the recognition by public health and medical authorities that a significantly increased number of people are becoming ill and presenting to local healthcare providers.

One tool to support this process is the National Biosurveillance Integration System (NBIS). NBIS leverages the individual capabilities of multiple surveillance systems by integrating and analyzing domestic and international surveillance and monitoring data collected from human health, animal health, plant health, and food and water monitoring systems. This integrated cross-domain analysis allows for enhanced situational awareness and potentially reduced detection time, thus enabling more rapid and effective biological incident response decisionmaking.

As a result of the nature in which a disease outbreak may be recognized, critical decisionmaking support requires integrated surveillance information, identification of the causative biological agent, a determination of whether the observations are related to a naturally occurring or deliberate outbreak, and identification of the population(s) at risk.

Laboratory Confirmation

During the evaluation of a suspected disease outbreak, laboratory samples are distributed to appropriate laboratories. During a suspected terrorist incident, sample information is provided

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to the FBI for investigative use and to public health and emergency response authorities for epidemiological use and agent characterization to facilitate and ensure timely public health and medical interventions, as well as environmental cleanup. If the incident begins as an epidemic of unknown origin detected through Federal, State, tribal, territorial, or local health surveillance systems or networks, laboratory analysis is initiated through the routine public health or animal health laboratory systems.

Identification (Analysis and Confirmation)

The samples collected and the analyses conducted must be sufficient to characterize the causative agent of the outbreak. LRN and FERN laboratories fulfill the Federal responsibility for rapid analysis of biological agents. In a suspected terrorism incident, sample collection activities and testing are coordinated with the FBI and LRN member(s).

Suspicious Substances

Since there is no definitive/reliable field test for biological agents of concern, all potential bioterrorism samples are transported to an LRN laboratory, where expert analysis is conducted using established Federal protocols/reagents. A major component of this process is to establish and maintain the law enforcement chain of custody and arrange for transport.

The following actions occur if a positive result is obtained by an LRN on an environmental sample submitted by the FBI or other designated law enforcement personnel:

- The LRN immediately notifies the local FBI of the positive test result and informs the appropriate public health officials.
- The local FBI Field Office makes local notifications and contacts the FBI Headquarters WMDOU.
- FBI Headquarters convenes an initial threat assessment conference call with the local FBI, HHS, and appropriate Federal, State, tribal, territorial, and local response officials to review the results, assess the preliminary information and test results, and arrange for additional testing.
- FBI Headquarters immediately notifies DHS of the situation. Situational updates will be provided, as appropriate.
- Original samples may be sent to HHS/Centers for Disease Control and Prevention for confirmation of LRN analyses. As appropriate, the FBI will direct additional forensic examination of biological materials and/or evidence.
- HHS provides guidance on protective measures such as prophylaxis, treatment, continued facility operation, and use of personal protective equipment.
- HHS, EPA, and cooperating agencies support the determination of the contaminated area. EPA will provide data to support the determination of the contaminated area and to assist with decisions regarding whether to shelter-in-place. EPA will also play a role in the decontamination of facilities and outdoor areas.

Notification

Any disease outbreak suspected or identified by an agency within HHS or through a Federal, State, tribal, territorial, or local public health partner as having public health implications is

brought to the immediate attention of HHS (as detailed in the ESF #8 Annex), in addition to the notification requirements contained in the *National Response Framework*.

Any potentially significant biological agent, disease outbreak, or suspected bioterrorism act affecting or involving animals, plant health, or wildlife should involve notifications to USDA (animals and plant health) and DOI (wildlife).

Following these initial notifications, the procedures detailed in the ESF #8 Annex are followed. Instances of disease that raise the "index of suspicion" of terrorist or criminal involvement, as determined by HHS or USDA (for animal and plant diseases), are reported to FBI Headquarters. In these instances, FBI Headquarters, in conjunction with HHS and/or USDA, examines available law enforcement and intelligence information, as well as the technical characteristics and epidemiology of the disease, to determine if there is a possibility of criminal intent. If the FBI, in conjunction with HHS or USDA, determines that the information represents a potential credible terrorist threat, the FBI communicates the situation immediately to the NCTC and NOC, which notifies the White House, as appropriate. If warranted, the FBI, HHS, and/or USDA and respective State, tribal, territorial, and/or local health officials will conduct a joint law enforcement and epidemiological investigation to determine the causative agent of the disease outbreak, the extent of the threat to public health and public safety, and the individual(s) responsible.

In the event of an environmental detection of a biological threat agent above established agency-specific thresholds, the responsible agency should contact HHS, the FBI, and the NOC within 2 hours of laboratory confirmation. The FBI and HHS, in conjunction with DHS, will convene an initial threat assessment conference call with appropriate Federal, State, tribal, territorial, and local officials to examine the potential threat and public health risk posed by the detection. Coordination of assessment and response activities will involve officials from the impacted State, tribal, territorial, and local jurisdiction(s).

Activation

Once notified of a threat or disease outbreak that requires or potentially requires significant Federal public health and medical assistance, HHS requests activation of ESF #8 from FEMA and convenes a meeting of its internal components and the ESF #8 partner organizations to assess the situation and determine the appropriate public health and medical actions. DHS coordinates all nonmedical support, discussions, and response actions.

The immediate task following any notification is to identify the affected and vulnerable population and the geographic scope of the incident. The initial public health and medical response includes some or all of the following actions:

- Targeted epidemiological investigation (e.g., contact tracing).
- Dissemination of key safety information and necessary medical precautions.
- Intensified surveillance within healthcare settings for patients with certain clinical signs and symptoms.
- Intensified collection and review of potentially related information (e.g., contacts with nurse call lines, laboratory test orders, school absences, over-the-counter pharmacy sales, unusual increase in sick animals, wildlife deaths, decreased commercial fish yields).
- Organization and potential deployment of Federal public health and medical response assets (in conjunction with State, tribal, territorial, and local officials) to include personnel, medical

and veterinary supplies, and materiel (e.g., the Strategic National Stockpile (SNS) and the National Veterinary Stockpile (NVS)).

If there is suspicion that the outbreak may be deliberate, the FBI may establish a Joint Operations Center (JOC), which may be integrated into the Joint Field Office structure, if established, to coordinate investigative and intelligence activities among Federal, State, tribal, territorial, and local authorities. Within the JOC structure locally, and the FBI's Strategic Information and Operations Center in Washington, DC, responsible public health officials would be integrated into the established structures to coordinate the interaction between law enforcement and public health investigations.

ACTIONS

Controlling the Epidemic

The following steps are required to contain and control an epidemic affecting large populations:

- HHS assists State, tribal, territorial, and local public health and medical authorities with epidemic surveillance and coordination.
- HHS assesses the need for increased surveillance in State, tribal, territorial, and local entities not initially involved in the outbreak and notifies the appropriate State, tribal, territorial, and local public health officials with surveillance recommendations should increased surveillance in these localities be needed.
- DHS coordinates with HHS and State, tribal, territorial, and local officials on the messages released to the public to ensure that communications are timely, consistent, accurate, and actionable. Messages should address anxieties, alleviate any unwarranted concerns or distress, and enlist cooperation with necessary control measures. Public health and medical messages to the public should be communicated by a recognized health authority (e.g., the U.S. Surgeon General). (See the Public Affairs Support Annex.)
- Consistent with the IHR, if the outbreak first arises within the United States, HHS, in coordination with DOS, immediately notifies and coordinates with appropriate international health agencies. Given the nature of many disease outbreaks, this notification and coordination may have occurred earlier in the process according to internal operating procedures. HHS advises the NOC when notifications are made to international health agencies.
- The public health system, starting at the local level, is required to initiate appropriate protective and responsive measures for the affected population, including first responders and other workers engaged in incident-related activities. These measures may include mass vaccination or prophylaxis for populations at risk and populations not already exposed, but who are at risk of exposure from secondary transmission or the environment.
- HHS evaluates the incident with its partner organizations and makes recommendations to the appropriate public health and medical authorities regarding the need for isolation, quarantine, or shelter-in-place to prevent the spread of disease.
- The Governor of an affected State or territory implements isolation and/or social-distancing requirements using State/local legal authorities. The tribal leader of a recognized tribe may also order a curfew, isolation, social distancing, and quarantine under tribal legal authorities. In order to prevent the import or interstate spread of disease, HHS may take appropriate Federal actions using the authorities granted by title 42 of the U.S. Code, 42 CFR parts 70 and 71, and 21 CFR part 1240. These measures may include State, tribal,

territorial, and local assistance with the implementation and enforcement of isolation and/or quarantine actions if Federal authorities are invoked.

- Where the source of the disease outbreak has been identified as originating outside the United States, whether the result of terrorism or a natural outbreak, HHS works in a coordinated effort with DHS and other supporting agencies to identify and isolate persons, cargo, mail, or conveyances entering the United States that may be contaminated.
- The scope of the disease outbreak may require mass isolation or quarantine of affected or potentially affected persons. Depending on the type of event, food, animals, and other agricultural products may need to be quarantined to prevent further spread of disease. In addition, livestock or poultry may need to be vaccinated or depopulated, and the movement of animals and equipment on and off affected premises may be restricted. In this instance HHS and USDA will work with State, tribal, territorial, and local health and legal authorities to recommend the most feasible, effective, and legally enforceable methods of isolation and quarantine. If interstate travel restrictions, including restrictions on arriving international travelers, are determined to be necessary, HHS will work closely with DOS, DHS, the Department of Transportation, and State, tribal, territorial, and local authorities to implement any recommended measures. In the event that foreign nationals are subject to isolation and/or quarantine, HHS will work through DOS to notify affected foreign governments.

Decontamination

For certain types of biological incidents (e.g., anthrax), it may be necessary to assess the extent of contamination and decontaminate victims, responders, animals, equipment, transportation conveyances, buildings, critical infrastructure, and large outdoor areas. Such decontamination and related activities take place consistent with the roles and responsibilities, resources and capabilities, and procedures contained in the ESF #8, ESF #10, ESF #11, and ESF #14 – Long-Term Community Recovery Annexes, the Terrorism Incident Law Enforcement and Investigation Annex, and the Catastrophic Incident Annex. (Note: Chemicals used for biological decontamination (e.g., for inactivating highly infectious biological agents such as *Bacillus anthracis* spores) must be registered for that purpose by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act. If, during an emergency, a response entity wants to use a chemical that has not been registered for inactivating the specific biological agent(s) of concern, a request for an emergency exemption from registration must be submitted to and granted by EPA.)

Special Issues

International Notification/Implications

A biological incident may involve internationally prescribed reportable diseases. In addition to case reporting, biological incidents with global public health significance must also be reported to international public health authorities. A biological incident may also have implications under the Biological Weapons Convention if it can be attributed to actions of a foreign party; DOS would manage the diplomatic aspects of any such case.

Per the IHR, once a positive determination is made of a biological incident determined to be of sufficient concern and to be a “public health event of international consequence,” HHS, working with DOS and DHS, notifies WHO through the appropriate regional office, the Pan American Health Organization. HHS, in coordination with DOS, notifies other international health agencies as appropriate.

Allocation and Rationing

If critical resources for protecting human life are insufficient to meet all domestic needs, the Secretary of Health and Human Services makes recommendations to the Secretary of Homeland Security regarding the allocation of scarce Federal public health and medical resources.

RESPONSIBILITIES

The procedures in this annex are built on the core coordinating structures of the *National Response Framework*. The specific responsibilities of each department and agency are described in the respective ESF and Incident Annexes.

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