United States of America

Confidence Building Measure Return covering 2015

Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction

Submitted to the United Nations on
April 15, 2016
Declaration form on Nothing to Declare or Nothing New to Declare for use in the information exchange

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Date: April 15, 2016

State Party to the Convention: United States of America

Date of ratification/accession to the Convention: March 26, 1975

National point of contact: Mr. Christopher Park, Department of State

Inquiries may be directed to BWC_USCBM@state.gov.
Report of the United States of America to the United Nations Department for Disarmament Affairs

Pursuant to the procedural modalities agreed upon in April 1987 at the "Ad Hoc Meeting of Scientific and Technical Experts for States Parties to the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction," the United States of America submits the following information under Article V of the Convention:

**Confidence Building Measure A, Part 1**
Exchange of data on research centres and laboratories page 4

**Confidence Building Measure A, Part 2**
Exchanges of information on national biological defence research and development programmes

(i) Declaration page 13
(ii) Description page 15
(iii) Facilities page 32

**Confidence Building Measure B**
Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins page 133

**Confidence Building Measure C**
Encouragement of publication of results and promotion of use of knowledge page 145

**Confidence Building Measure E**
Declaration of legislature, regulations, and other measures page 148

**Confidence Building Measure F**
Declaration of past activities in offensive and/or defensive biological research and development programmes page 152

**Confidence Building Measure G**
Declaration of vaccine production facilities Page 154

**Appendix A**
List of the Biological Select Agents and Toxins, and NIAID Category A, B and C Priority Pathogens page 159

**Appendix B**
Compiled list of microorganisms and toxins used for biodefense research Page 163
Form A, Part 1

BWC - Confidence Building Measure

Exchange of data on research centres and laboratories

United States of America

April 15, 2016
Exchange of data on research centres and laboratories

1. Name(s) of facility.
National Biodefense Analysis and Countermeasures Center (NBACC)
[Declared in accordance with Form A, Part 2 (iii)]

2. Responsible public or private organization or company.
U.S. Department of Homeland Security Science and Technology Directorate
Operated by Battelle National Biodefense Institute LLC

3. Location and postal address.
8300 Research Plaza, Fort Detrick, Maryland 21702

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.
U.S. Department of Homeland Security (DHS)
U.S. Department of Defense (DOD) - partly
U.S. Department of Justice (DOJ)

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m²).
BSL 4 Laboratory 980 m²

6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.
NBACC conducts studies to better understand current and future biological threats; to assess vulnerabilities; and to determine potential impacts to guide the development of biological countermeasures such as detectors, drugs, vaccines, and decontamination technologies. When needed, NBACC conducts experimental programs to better characterize the benefits and risks of changes in U.S. biodefense preparations. NBACC also develops bioforensic assays and provides operational bioforensic analysis to support the attribution of biocrime and bioterrorism.
(http://bnbi.org/)

The types of agents registered for use at NBACC are BSL-2 toxins, BSL-2 gram positive and gram negative bacterial agents, BSL-2 viral agents, BSL-3 gram positive and gram negative bacterial agents, BSL-3 viral agents, and BSL-4 viral agents.
Exchange of data on research centres and laboratories

1. Name(s) of facility.
U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)
[Declared in accordance with Form A, Part 2 (iii)]

2. Responsible public or private organization or company.
U.S. Army Medical Research and Materiel Command

3. Location and postal address.
1425 Porter Street, Fort Detrick, Frederick, Maryland 21702-5011

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.
U.S. Department of Defense (DoD) – partly
U.S. Department of Homeland Security (DHS)
U.S. Department of Health and Human Services (DHHS)
U.S. Department of Agriculture (USDA)
Universities
Private sector companies

5. Number of maximum containment units\(^3\) within the research centre and/or laboratory, with an indication of their respective size (m\(^2\)).
BSL 4 Laboratory =1186 m\(^2\)

6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.
USAMRIID conducts research to develop strategies, products, information, procedures, and training programs for medical defense against biological warfare threats and infectious diseases. Medical products developed to protect military personnel against biological agents include vaccines, drugs, diagnostic capabilities, and various medical management procedures.

Additional information can be found at: http://www.usamriid.army.mil/
Exchange of data on research centres and laboratories

1. Name(s) of facility.
Centers for Disease Control (CDC), Office of Infectious Diseases (OID)
[Declared in accordance with Form A, Part 2 (iii)]

2. Responsible public or private organization or company.
Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

3. Location and postal address.
1600 Clifton Road N.E., Atlanta, Georgia, 30333

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.
U.S. Agency for International Development (USAID)
U.S. Department of Defense (DOD) – partly
U.S. Department of Health and Human Services (HHS)
U.S. Department of Homeland Security (DHS)
U.S. Department of State (DOS)

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m²).
BSL-4 Laboratory = 136 m²
BSL-4 Laboratory = 271 m²
BSL-4 Laboratory = 136 m²

6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.
Activities include developing diagnostic assays for public health, developing and validating methods to differentiate and characterize organisms and the toxins that they produce, developing environmental sampling methods for recovery of agents from porous and nonporous surfaces for public health, routine reference antimicrobial susceptibility testing of clinical isolates, conducting molecular and antigenic characterization of organisms, determining pathogenicity and virulence of infectious agents, development of culture-independent point of care diagnostics, maintaining emergency response laboratory expertise and capacity, evaluating vaccines and medical countermeasures, determining the natural history of infectious organisms, assessing immune correlates of protection, and conducting epidemiologic studies and surveillance for diseases. Additional information can be found at: http://www.cdc.gov/oid/.

Biodefense activities include those with select agents (the select agents list is available at: http://www.selectagents.gov/SelectAgentsandToxinsList.html).
Exchange of data on research centres and laboratories

1. Name(s) of facility
Integrated Research Facility at Fort Detrick (IRF – Frederick)
[Declared in Accordance with Form A, Part 2 (iii)]

2. Responsible public or private organization or company
National Institutes of Health, Department of Health and Human Services
Operated by Battelle Memorial Institute

3. Location and postal address
8200 Research Plaza, Frederick, Maryland 21702

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence
Department of Health and Human Services (HHS)

5. Number of maximum containment units³ within the research centre and/or laboratory, with an indication of their respective size (m²)
BSL 4 Laboratory = 1305 m²

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate
The Integrated Research Facility at Fort Detrick in Frederick, Maryland (IRF-Frederick) is a component of the Division of Clinical Research of the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH). The mission of the IRF-Frederick is to manage, coordinate, and facilitate the conduct of emerging infectious disease and biodefense research to develop vaccines, countermeasures, and improved medical outcomes for patients. Research emphasis is placed on elucidating the nature of high consequence pathogens. Additional information can be found at:
http://www.niaid.nih.gov/about/organization/dir/irf/Pages/default.aspx.
Exchange of data on research centres and laboratories

1. **Name(s) of facility**
   Integrated Research Facility at Rocky Mountain Laboratories (IRF-RML)
   [Declared in Accordance with Form A, Part 2 (iii)]

2. **Responsible public or private organization or company**
   National Institutes of Health (NIH), Department of Health and Human Services (HHS)

3. **Location and postal address**
   903 South 4th Street, Hamilton, Montana 59840 United States

4. **Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence**
   Department of Health and Human Services (HHS)

5. **Number of maximum containment units** within the research centre and/or laboratory, with an indication of their respective size (m²)
   BSL-4 Laboratory = 1145 m²

6. **Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate**
   Rocky Mountain Laboratories (RML) is a component of the Division of Intramural Research of the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH). The RML mission is to play a leading role in the nation’s efforts to develop diagnostics, vaccines, and therapeutics to combat emerging and re-emerging infectious diseases. Research at the Integrated Research Facility at Rocky Mountain Laboratories (IRF-RML) is dedicated to understanding the mechanisms of pathogenesis of microbial agents associated with or likely to cause serious or lethal human diseases using molecular methods and animal model systems. Additional information can be found at:
Exchange of data on research centres and laboratories

1. Name(s) of facility
Galveston National Laboratory (GNL) Complex including Robert E. Shope Laboratory

2. Responsible public or private organization or company
The University of Texas Medical Branch

3. Location and postal address
301 University Boulevard, Galveston, Texas 77555

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence
Universities
U.S. Department of Agriculture (USDA)
Private Foundations
Pharmaceutical Industry
U.S. Department of Energy (DOE)
U.S. Department of Defense (DOD) - partly
U.S. Department of Homeland Security (DHS)
National Institutes of Health (NIH)

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m²)
BSL-4 Laboratory = 186 m² (Shope Laboratory)
BSL-4 Laboratory = 1022 m² (GNL Laboratory)

6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate
The mission of the Galveston National Laboratory is to assist the National Institute of Allergy and Infectious Diseases and the nation in the development of an improved means for the prevention, diagnosis and treatment of potentially life-threatening diseases caused by naturally emerging and purposefully disseminated infectious agents. To accomplish this goal GNL conducts multidisciplinary research into the causes, modes of transmission, and mechanisms of infectious diseases. Studies focus on a number of pathogens requiring BSL-4 containment, primarily those that cause viral hemorrhagic fevers, as well as some zoonotic viruses requiring enhanced BSL-3 containment. Products likely to emerge from research and investigations within the GNL include novel diagnostic assays, improved therapeutics and treatment models, and preventative measures such as vaccines. Additional information can be found at: http://www.utmb.edu/gnl/.
Exchange of data on research centres and laboratories

1. Name(s) of facility
The Betty Slick and Lewis J. Moorman, Jr. Laboratory Complex, Department of Virology and Immunology

2. Responsible public or private organization or company
Texas Biomedical Research Institute

3. Location and postal address
P.O. Box 760549, San Antonio, Texas 78245-0549

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence
Department of Health and Human Services
Department of Defense (DOD) - partly
Department of Homeland Security (DHS)
Private Sector Companies
Private Donors

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m²)
BSL 4 Laboratory = 114 m²

6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.
The mission of the Laboratory is to develop vaccines and therapeutics against viral pathogens, and to determine how viruses replicate and spread. Scientists are studying new and emerging disease threats, possible bioterrorism agents, and as-yet uncharacterized agents for biodefense. TXBiomed (formerly Southwest Foundation for Biomedical Research) has permits from the U.S. Department of Agriculture and the Centers for Disease Control to work on select agents. Additional information can be found at: http://www.txbiomed.org/about/extraordinary-resources/biosafety-level-4-laboratory.
Exchange of data on research centres and laboratories

1. Name(s) of facility
Viral Immunology Center - National B Virus Resource Laboratory

2. Responsible public or private organization or company
Georgia State University

3. Location and postal address
P. O. Box 4118, Atlanta, Georgia 30302-4118

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence
Department of Health and Human Services
Georgia Research Alliance
Immunology Core Support
Elizabeth R. Griffin Research Foundation

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m²)
BSL 4 Laboratory = 60 m²

6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate
The Viral Immunology Center provides a global resource to assist in the identification of zoonotic disease transmissions and to develop enhanced strategies to detect viral infections in macaques. Current projects in the National B Virus Resource Laboratory are focused on the molecular biology of human and non-human primate alphaherpesviruses and the diseases they cause. Studies focus on the mechanisms by which virus kills the host and how that process can be circumvented with:

- **Early identification** - research focuses on the design and development of new approaches to more effectively identify these agents in both natural and foreign hosts;
- **Appropriate antiviral drugs** - researchers continually screen the efficacy of existing as well as novel antiviral agents to inhibit the growth of viruses that can potentially cross into the human population, either through occupational exposure or through more subtle contact; and
- **In the future, effective vaccines.**

Additional information can be found at [http://www2.gsu.edu/~wwwvir/Research/Index.html](http://www2.gsu.edu/~wwwvir/Research/Index.html)
National biological defence research and development programmes - Declaration

United States of America

April 15, 2016
Form A, Part 2 (i)

National biological defence research and development programme: Declaration

Are there any national programmes to conduct biological defence research and development within the territory of the State Party, under its jurisdiction or control anywhere? Activities of such programmes would include prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

Yes 🆒
No   

If the answer is Yes, complete Form A, part 2 (ii) which will provide a description of each programme.
Form A, Part 2 (ii)

BWC - Confidence Building Measure

National biological defence research and development programmes - Description

United States of America

April 15, 2016
National biological defence research and development programmes

The United States Government conducts a broad effort to reduce the risks presented by the deliberate or accidental release of biological agents and to defend against those threats in the event they occur. As called for by the National Strategy for Countering Biological Threats, this encompasses a range of initiatives, including improving global access to the life sciences to combat infectious disease regardless of its cause; establishing and reinforcing norms of safe and responsible conduct within the life sciences; improving capacity to detect and respond to outbreaks as they occur; and instituting a suite of coordinated activities that collectively help to influence, identify, inhibit, and/or interdict those who seek to misuse the life sciences.

One key element of this effort is the U.S. biodefense enterprise, which itself includes a variety of research and development programs aimed at protecting against the deliberate use of biological materials to cause harm. These programs focus on the identification of harmful pathogens and outbreaks of infectious diseases and their containment, treatment, and elimination from the environment. These programs are managed by several agencies with direct stakes in national security, environmental protection, and human and animal health and safety, including the Departments of Agriculture, Defense, Energy, Health and Human Services, Homeland Security, and the Environmental Protection Agency.

Historically, certain pathogens were selected for use as biological weapons because of their pathogenicity. Research on these pathogens, including study of molecular mechanisms and related diagnostic, vaccine and therapeutic development work, not only increases U.S. biodefense preparedness, but also offers inherent benefits for broader public health needs. Efforts to improve medical product stability, potency and ease-of-use that cut across disease targets could yield significant benefits for public health systems that cannot support existing treatments that require refrigeration, multiple doses or sophisticated diagnostic techniques. Similarly, biodefense initiatives to improve human and animal host defenses, to monitor emerging infectious diseases and drug-resistant microbes, and to clean up the site of a biological weapons attack have civilian applications that benefit public health services, such as epidemiological disease surveillance and environmental remediation.

To promote the benefits gained by these programs and to ensure that the research is available to the scientific community both domestically and internationally, the United States Government encourages the publication of research funded by its biodefense programs.

For more information on U.S. Government strategies related to biodefense, including biological threat preparedness and response, please consult:

- Presidential Policy Directive 8: National Preparedness (PPD-8);
- National Strategy for Defense of United States Agriculture and Food (HSPD-9);
- National Biodefense Strategy (HSPD-10/National Security Presidential Directive-33 [NSPD-33]);
- Medical Countermeasures against Weapons of Mass Destruction (HSPD-18);
- Public Health and Medical Preparedness (HSPD-21);
- National Strategy to Combat Weapons of Mass Destruction (NSPD-17/HSPD-4);
- Executive Order 13527 (“Establishing Federal Capabilities for the Timely Provision of Medical Countermeasures following a Biological Attack”); and National Strategy for Countering Biological Threats.
National biological defence research and development programmes: Description

1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

The Department of Defense Chemical and Biological Defense Program develops capabilities to enable the U.S. Armed Forces to deter, prevent, protect from, mitigate, respond to, and recover from the effects of chemical, biological, and radiological (CBR-) threats as part of a layered, integrated defense. The Program is an integral contributor to a global and systems approach for Countering Weapons of Mass Destruction (CWMD), Global Health Security, and other pertinent mission areas.

The Program works to counter biological threats by providing complementary sets of sensors, protective equipment, and medical countermeasures to counter known and unknown threats, including novel and naturally occurring emerging infectious diseases that may also pose a biological weapons threat. Current research focuses on signaling mechanisms between host and bacterial cells; expanding capabilities for pre- and post-exposure therapeutics for bacterial biological select agents and novel threats; testing battlefield detection and identification methods, protective systems, and decontamination systems; and developing rapid and deployable detection assays for force protection as well as medical defenses against neurotoxins.

The Program also works on producing self-disinfecting and/or self-decontaminating materials as well as developing, producing, and fielding capabilities for sampling, detecting, and identifying biological agents.

Biological defense related work conducted by the Department of Defense is carried out by the military services and biological defense program-focused agencies. These include funding agencies and service laboratories within the Departments of the Air Force, Army, and Navy, and the Defense Threat Reduction Agency/Joint Science and Technology Office, the Joint Program Executive Office for Chemical and Biological Defense, and the Defense Advanced Research Projects Agency.

2. State the total funding for each programme and its source.

$593,425,000  U.S. Department of Defense (DoD)

3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?

Yes

4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?

57%

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.

- Provide support and capabilities to protect the U.S. Armed Forces against biological warfare threats and emerging infectious diseases.
- Development and testing of vaccines, therapeutics, and diagnostic systems
- Development of self-disinfecting and/or self-decontaminating materials
- Development and testing of detection and identification methods, protective equipment, and decontamination systems
6. Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).

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7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

In accordance with Form A part 2 (iii):
- Naval Medical Research Center (NMRC)
- Naval Research Laboratory (NRL)
- Naval Surface Warfare Center-Dahlgren Division Chemical, Biological, Radiological (CBR) Defense Laboratory
- Lothar Salomon Test Facility (LSTF)
- U.S. Army Edgewood Chemical and Biological Center
- U.S. Army Medical Research Institute of Chemical Defense (USAMRICD)
- U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)
National biological defense research and development programme: Description

1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.

The Environmental Protection Agency (EPA)’s mission is to protect public health and the environment. The National Homeland Security Research Center (NHSRC), part of the EPA's Office of Research and Development, conducts and reports on research to improve capacity to respond to and recover from environmental contamination of water infrastructure, buildings and outdoor areas by chemical, biological, radiological and nuclear (CBRN) agents. The NHSRC biodefense program focuses on EPA's two biodefense responsibilities: 1) assistance in the protection of the American water supply, and 2) decontamination of indoor and outdoor areas should the U.S. suffer a contamination incident.

EPA is designated as the government's lead sector-specific agency for water, and is responsible for protecting water systems and detecting and recovering from terrorist attacks affecting them. EPA's homeland security research is responsible for developing products and providing expertise to protect, detect, respond to, and recover from terrorist attacks on the nation's water and wastewater infrastructure.

EPA is also the lead federal agency for the remediation of areas contaminated by terrorist events involving the release of biological organisms, biotoxins, chemical warfare agents, toxic industrial chemicals, and radiological materials. Terrorist acts may involve biological, chemical, and radiological agents not previously encountered as environmental pollutants. EPA's homeland security research is responsible for providing procedures and methods that will assist EPA’s responders in the characterization and containment of contamination, and in the remediation of sites following terrorist attacks.

2. State the total funding for the programme and its source.
$8,500,000 U.S. Environmental Protection Agency (EPA)

3. Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defense facilities?
Yes

4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?
35%

5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.

To address capabilities related to EPA’s indoor/outdoor remediation mission, NHSRC, through intramural and extramural avenues, conducts research related to characterization methods, risk assessment, decontamination methods, and waste management. Specifically the program develops and evaluates 1) sampling and analytical methods for environmental matrices, 2) decontamination methods for complex environments, and 3) treatment methods for solid and liquid waste. Supporting such capabilities, NHSRC has been addressing the fate and transport of biological agents and developing exposure assessment information and methods to support risk assessment decisions.
6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)

7. Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defense research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

Not Applicable
National biological defence research and development programmes: Description

1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.

The Department of Health and Human Services (HHS) supports activities to improve local and state public health systems, to expand existing biosurveillance efforts, and to fund research on medical countermeasures against potential bioterror agents.

The National Institutes of Health (NIH) biodefense program is supported by funding from HHS. The NIH, and specifically the National Institute of Allergy and Infectious Diseases (NIAID), has the primary responsibility within the U.S. Government for civilian biodefense research. The intent of the program is to provide countermeasures to be used to protect the U.S. civilian population through the development of vaccines, therapeutic agents and rapid, agent-specific assays.

2. State the total funding for each programme and its source.
$76,068,526  Department of Health and Human Services (HHS)

3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?
Yes

4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?
25%

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.
Battelle Memorial Institute facilitates scientific research at the Integrated Research Facility at Fort Detrick (IRF-Frederick), including refinement of animal models to facilitate countermeasure development, with direction from the IRF Scientific Steering Committee.
6. Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).

7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases
Dale and Betty Bumpers Vaccine Research Center
Integrated Research Facility at Fort Detrick (IRF - Frederick)
Integrated Research Facility at Rocky Mountain Laboratories (IRF - RML)
National biological defence research and development programmes: Description

1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.

The objective of the Mass Spectrometry Toxin Laboratory and the Chemical Threats Method Development Laboratory within CDC’s National Center for Environmental Health, Division of Laboratory Sciences is to develop toxin assays that are critical for better detection and diagnosis during a public health response to biological toxins.

2. State the total funding for each programme and its source.
$2,407,816  Department of Health and Human Services (HHS)

3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?
No

4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?
N/A

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.
N/A
6. Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).

7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

CDC, National Center for Environmental Health (NCEH), Division of Laboratory Sciences (DLS)
National biological defence research and development programmes: Description

1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

The activities of the CDC Office of Infectious Disease (OID) include developing diagnostic assays for public health, conducting molecular and antigenic characterization of microorganisms, evaluating decontamination methods, determining pathogenicity and virulence of infectious agents, determining the natural history of infectious organisms, and conducting epidemiologic studies and surveillance for diseases. Biodefense activities include those with select agents. OID includes the National Center for Emerging Zoonotic Infectious Diseases (NCEZID) and the National Center for Immunization and Respiratory Diseases (NCIRD).

The select agents list is available at: [http://www.selectagents.gov/SelectAgentsandToxinsList.html](http://www.selectagents.gov/SelectAgentsandToxinsList.html)

2. State the total funding for each programme and its source.
$30,868,649 Department of Health and Human Services (HHS)

3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?
Yes

4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?
5%

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.
Vaccine efficacy trials, reagent development, bioterrorism preparedness and response activities, avian influenza preparedness, and disease surveillance in CDC field locations.
6. Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).

7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

- CDC, OID, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Vector Borne Diseases (DVBD) - Ft. Collins
- CDC, Office of Infectious Diseases (OID)
National biological defence research and development programmes: Description

1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.

Background

Foreign diseases of plants and animals represent a major threat to U.S. agriculture. Introduction of these agents, either accidental or deliberate, has devastating social and economic effects -- not only in the country's agricultural systems but also in a wide range of economic activities. Diseases of concern include but are not limited to wheat rust, Foot-and-Mouth Disease, Avian Influenza, Rift Valley Fever, Classical Swine Fever, African Swine Fever, Exotic Newcastle disease, Vesicular stomatitis, and Exotic Bluetongue.

Plant and Animal health officials define an exotic or foreign plant or animal disease as important infectious diseases of crops, livestock or poultry believed to be absent from the U.S. and its territories that has a potential significant health or economic impact. In addition, foreign animal diseases (FAD) are considered a threat to the U.S. when they significantly affect human health or animal production and when there is an appreciable cost associated with disease control and eradication efforts. To protect the long-term health and profitability of U.S. animal agriculture, incursions of a FAD must be rapidly controlled.

In the U.S., control usually means disease eradication. Disease eradication is currently accomplished by eliminating crops or animals, resulting in loss of foods, loss of income to the farm community, public opposition and environmental disruption. In addition to control costs, one of the most immediate and severe consequences of a FAD occurrence in the U.S. will be the loss of export markets. As we move into the 21st century, many new issues and factors are affecting prevention, control, management, and recovery from foreign disease outbreaks. These factors include free trade agreements, free trade blocks, regionalization, increased international passenger travel, intensification of plant and animal production, the constant evolution of infectious agents, and the uncertain impact of biotechnology and bioterrorism.

Current methods for prevention and control of high consequence diseases, including prevention, detection, control and eradication, are not socially or economically acceptable. Rapid detection and characterization tools for prevention, control and eradication of foreign plant and animal diseases are inadequate or not currently available. Our understanding of pathogenesis, transmission, and host responses is insufficient to rapidly control and eradicate disease outbreaks resulting from foreign plant and animal diseases incursions. Effective countermeasures to prevent, control and eradicate foreign plant and animal diseases are lacking or inadequate.

Strategic Objectives

- Establish Agriculture Research Service (ARS) laboratories into a fluid, highly effective research network, to maximize use of core competencies and resources
- Access to specialized high containment facilities to study zoonotic and emerging diseases
- Develop an integrated animal and microbial genomics research program
- Establish centers of excellence in animal immunology
- Launch a biotherapeutic discovery program providing alternatives to animal drugs
- Build a technology-driven vaccine and diagnostic discovery research program
- Develop core competencies in field epidemiology and predictive biology
- Develop internationally recognized OIE expert collaborative research laboratories
- Establish a best-in-class training center for our nation's veterinarians and scientists
• Develop a model technology transfer program to achieve the full impact of our research discoveries
• Determine basic knowledge of the biology, pathology, and epidemiology of selected Oomycete pathogens as the basis for development of improved control/management strategies

Research Needs

In order to control foreign animal disease, a wide variety of agent detection platforms needs to be developed and validated. Information for design of these platforms will come in part from further knowledge of pathogen genomics and proteomics and in part from understanding the evolution and genetic variability of disease agents. Although many of the foreign animal diseases have existed for many years in many countries, there is still much more fundamental knowledge of these agents that is required. There is still a lack of understanding in host range and tissue tropism, carrier state, duration and routes of shedding, transmission mechanisms, (e.g. vectors, fomites, aerosols), ecology and epidemiology (e.g., wildlife reservoirs). Effective prevention and control tools need to be developed in order to prepare for the possibility of a foreign animal disease outbreak in the U.S. These could include tools for identifying suitable control strategies which take into account the short amount of time available and the cost of recovery from disease outbreaks. There is a need for development of vaccines and biotherapeutics suitable for strategic stockpiles and for integrated methods of disease control (including vector control and animal management), which lead to a better capability to regain country disease-free status and retain economic sustainability.

Expected Outputs:

• Better anticipation of introduction of foreign animal diseases
• Capability to advise regulatory officials on scientific procedures for the prevention of introduction of FADs
• Better capability to produce effective products to control and eliminate foreign animal diseases
• Real-time detection of agents in a wide range of farm matrices
• Searchable databases of genome and proteome information for major known FAD agents
• Improved ability to predict or anticipate emergence or introduction FAD agents
• Discovery of effective candidate biotherapeutics
• Discovery of effective candidate vaccines that allow differentiation of infected animals from vaccinated animals (DIVA)
• Viable integrated vector control strategies that minimize losses
• In-depth knowledge of pathogen biology, taxonomy, genetics, ecology, and pathology of emerging Oomycete pathogens that can be used to develop novel and effective exclusion, control and management strategies

The USDA-ARS biodefense research program is intramural and implemented in ARS high containment facilities in the following locations: Ames, Iowa; Orient Point, New York; Athens, Georgia; and Frederick, Maryland.

2. State the total funding for the programme and its source.
   $17,600,000 U.S. Department of Agriculture (USDA)

3. Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?
   No

4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?
   Not Applicable

5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.
   Not Applicable
6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)

![Organizational Structure Diagram]

7. Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

In accordance with Form A part 2 (iii):
Foreign Disease-Weed Science Research Unit
Plum Island Animal Disease Center (PIADC)
Southeast Poultry Research Laboratory
National Animal Disease Center (NADC)
National biological defence research and development programmes: Description

1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.

Preventing terrorism and enhancing security, including protection against biological terrorism, is one of the five key Department of Homeland Security (DHS) mission areas. This includes efforts to: prevent terrorist attacks, including biological attacks; prevent the unauthorized acquisition, importation, movement, or use of, *inter alia*, biological materials and capabilities within the United States; and reduce the vulnerability of critical infrastructure to terrorist attacks and other hazards. These efforts are further guided by the Homeland Security Presidential Directive – 10, “Biodefense for the 21st Century,” which outlines the four guiding pillars of the DHS Biodefense program: Threat Awareness, Prevention and Protection, Surveillance and Detection, and Response and Recovery.

The goal of the DHS biodefense program is to leverage emerging technologies to protect against biological attacks targeting the U.S. population, agriculture, or infrastructure. The DHS Biodefense program focuses on scenario modeling, agent release detection, training in responding to biological events, biological countermeasures research, development, testing, and evaluation (RDT&E) efforts, and on the transition of resultant technologies to operational use. The five main areas of study are: 1) systems studies and decision support tools, 2) threat awareness, 3) surveillance and detection research and development (R&D), 4) forensics, and 5) response and restoration. The program supports other U.S. federal agencies in overall coordination of national biodefense efforts.

Efforts conducted during 2015 include comprehensive threat and risk assessments to guide prioritization of the Nation's biodefense investments, biodefense knowledge management, the development of next-generation detectors for biological threat agents for critical infrastructure and urban areas, decontamination of transit systems, and bioforensics research in support of criminal investigations and attribution. Efforts at the National Biodefense Analysis and Countermeasures Center included biological threat characterization, development of response plans and risk communication and at the Plum Island Animal Disease Center, development of vaccines and diagnostics for foreign animal diseases.

The DHS Compliance Review Group, chaired by the DHS Deputy Secretary, met in 2015 to review all relevant DHS-funded biological defense projects for compliance with the provisions of the Biological Weapons Convention and associated U.S. domestic laws and policies.

2. State the total funding for the programme and its source.
$95,400,000 U.S. Department of Homeland Security (DHS)

3. Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?
Yes. The program funds work contracted to collaborating federal agencies (including defense agencies), national laboratories, private sector institutions and universities.

4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?
100 %
5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4. Identical to answer provided in question 1.

6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme).

7. Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

In accordance with Form A Part 2(iii):
National Biodefense Analysis and Countermeasures Center (NBACC)
Plum Island Animal Disease Center (PIADC)
Form A, Part 2 (iii)

BWC - Confidence Building Measure

National biological defence research and development programmes - Facilities

United States of America

April 15, 2016
National biological defence research and development programme

The U.S. Government identified potential concerns associated with public release of information regarding highly pathogenic microorganisms and toxins at specific facilities. To balance these concerns with a desire to promote transparency, the U.S. public CBM return characterizes microorganisms and toxins studied at each facility on Form A, Part 2 (iii) as Select Agents and/or NIAID Category A pathogens. Furthermore, Appendix B lists the specific microorganisms and toxins studied for biodefense research and development at all facilities reported on Form A, part 2 (iii) below.

To maintain a high level of transparency to States Parties, the U.S. makes available, via the restricted-access portion of the ISU website, a Supplement containing information on microorganisms and toxins studied at each individual facility reported on Form A, part 2 (iii).

As stated in the U.S. working paper for the 2013 Meeting of Experts (BWC/MSP/2013/MX/WP.9), “the United States will report microorganisms and toxins that appear on either the Select Agent or the National Institute of Allergy and Infectious Diseases (NIAID) Category A pathogen lists, beginning in 2014.” These lists are reproduced in Appendix A for reference.

Biological Select Agents and Toxins (Select Agents) are biological agents or toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products. Possession, use and transfer of Select Agents are regulated by the Select Agent Rules. Detailed information on Select Agents and their regulation can be found at: [http://www.selectagents.gov](http://www.selectagents.gov).

The NIAID designated Category A pathogens as priorities for additional research efforts as part of the NIAID biodefense research agenda. Detailed information about NIAID Category A pathogens can be found at: [http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/Pages/CatA.aspx](http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/Pages/CatA.aspx).
National biological defence research and development programmes: Facilities

1. What is the name of the facility?
   National Biodefense Analysis and Countermeasures Center (NBACC)

2. Where is it located (provide both address and geographical location)?
   8300 Research Plaza, Fort Detrick, Maryland 21702

3. Floor area of laboratory areas by containment level (m²):
   - BSL-2: 1,282 m²
   - BSL-3: 2,564 m²
   - BSL-4: 980 m²
   Total laboratory floor area: 4,826 m²

4. The organizational structure of each facility:
   (i) Total number of personnel: 173
   (ii) Division of personnel:
        - Military: 0
        - Civilian: 173
   (iii) Division of personnel by category:
        - Scientists: 33
        - Engineers: 42
        - Technicians: 57
        - Administrative and support staff: 41
   (iv) List the scientific disciplines represented in the scientific/engineering staff:
        Aerobiology, Bacteriology, Biochemistry, Bioinformatics, Biological Science, Biomedical Science, Biophysics, Biotechnology, Cell Biology, Chemistry, Computer Science, Genetics, Immunology, Molecular Biology, Toxicology, Veterinary Medicine, Virology
   (v) Are contractor staff working in the facility? If so, provide an approximate number:
        Yes: Number: 173
   (vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
        U.S. Department of Homeland Security (DHS)
        U.S. Department of Defense (DoD) – partly
        U.S. Department of Justice (DoJ)
   (vii) What are the funding levels for the following program areas:
        Research: $7,049,860
        Development: $13,947,786
        Test and evaluation: $0
        Total: $20,997,646
   (viii) Briefly describe the publication policy of the facility:
        The NBACC publication policy is to present research results to the greater scientific community as widely as possible. As a Federally Funded Research and Development Center (FFRDC) engaged in research with select agents/regulated pathogens, NBACC has established a formal, multi-tiered review system to ensure compliance and conformance with U.S. Government laws, regulations and policies including: export control regulations under Export Administration Regulations (EAR) and International Traffic in Arms Regulations (ITAR); the Biological Weapons Convention (BWC), and internal U.S. Department of Homeland Security (DHS) policies. Prior to submittal to journals or release, all

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references:)


11. Miller S, Cronin H. Developing a positive reinforcement training program for research sheep. Lab Animal Sci Prof. 2015 Jun 1; (3): 43-4. [https://www.aalas.org/articles/2015/06/01/developing-a-positive-reinforcement-training-program-for-research-sheep](https://www.aalas.org/articles/2015/06/01/developing-a-positive-reinforcement-training-program-for-research-sheep)


5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: The NBACC mission is to provide the nation with the scientific basis for characterization of biological threats and bioforensic analysis to support attribution investigations. NBACC conducts studies to fill in information gaps to better understand current and future biological threats; to assess vulnerabilities; and to determine potential impacts to guide the development of biological countermeasures such as detectors, drugs, vaccines, and decontamination technologies. When needed, NBACC conducts experimental programs to better characterize the benefits and risks of changes in U.S. biodefense preparations. NBACC also develops bioforensic assays and provides operational bioforensic analysis to support the attribution of biocrime and bioterrorism.

Microorganisms and/or Toxins Studied: Select Agents (HHS, Overlap), Select Toxins (HHS), simulants, NIAID Category A pathogens.

Outdoor Studies: No outdoor studies performed

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1 Including viruses and prions.
National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Plum Island Animal Disease Center (PIADC)

2. Where is it located (provide both address and geographical location)?
40550 Route 25, Orient Point, New York 11957

3. Floor area of laboratory areas by containment level (m²):
   - BSL-2: 292 m²
   - BSL-3: 18,046 m²
   - BSL-4: 0 m²
   - Total laboratory floor area: 18,338 m²

4. The organizational structure of each facility:
   (i) Total number of personnel: 403
   
   (ii) Division of personnel:
       - Military: 0
       - Civilian: 403

   (iii) Division of personnel by category:
       - Scientists: 88
       - Engineers: 6
       - Technicians: 47
       - Administrative and support staff: 262

   (iv) List the scientific disciplines represented in the scientific/engineering staff:
       Biological Science, Chemistry, Engineering, Microbiology, Molecular Biology, Computational Biology, Pathology, Veterinary Medicine

   (v) Are contractor staff working in the facility? If so, provide an approximate number:
       Yes
       Number: 287

   (vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
       U.S. Department of Agriculture (USDA)
       U.S. Department of Homeland Security (DHS)

   (vii) What are the funding levels for the following program areas:
       - Research: $6,000,000
       - Development: $10,500,000
       - Test and evaluation: $4,953,257
       - Total: $21,453,257

   (viii) Briefly describe the publication policy of the facility:
       DHS scientific research staffs are expected to publish papers in open literature. Papers are peer reviewed and approved by PIADC and DHS for security, clarity, and accuracy with regard to the description of work prior to submittal to journals or release. USDA Agricultural Research Service (ARS) has several publication policies: 1) Policy Number 150.1 "Dissemination of Public Information by ARS," http://www.afm.ars.usda.gov/ppweb/PDF/150-01.pdf; 2) Number 113.1 "Publishing (Print and Electronic), www.afm.ars.usda.gov/ppweb/2010/113-1-ARS.pdf; and 3) Number 152.1 "Procedures for
(ix) **Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):**


   [http://jvi.asm.org/content/90/3/1298.abstract](http://jvi.asm.org/content/90/3/1298.abstract)

   [http://dx.doi.org/10.1016/j.virol.2015.04.024](http://dx.doi.org/10.1016/j.virol.2015.04.024)

   [http://vdi.sagepub.com/content/27/2/140.abstract](http://vdi.sagepub.com/content/27/2/140.abstract)

   [http://jvi.asm.org/content/89/4/2324.full](http://jvi.asm.org/content/89/4/2324.full)

   [http://jcm.asm.org/content/53/2/755.full.pdf+html](http://jcm.asm.org/content/53/2/755.full.pdf+html)

   [http://cvi.asm.org/content/early/2015/11/20/CVL00426-15.abstract](http://cvi.asm.org/content/early/2015/11/20/CVL00426-15.abstract)

   [http://jgv.microbiologyresearch.org/content/journal/jgv/10.1099/vir.0.071597-0](http://jgv.microbiologyresearch.org/content/journal/jgv/10.1099/vir.0.071597-0)

    [http://jvi.asm.org/content/89/11/6048.full.pdf+html](http://jvi.asm.org/content/89/11/6048.full.pdf+html)


Http://online.liebertpub.com/doi/full/10.1089/vbz.2014.1702

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms\(^2\) and/or toxins studied, as well as outdoor studies of biological aerosols:

**Objectives:** PIADC provides the only research and development and confirmatory diagnostic capability for specific high-consequence, contagious, foreign animal diseases of livestock, including foot-and-mouth disease, in the U.S. Technologies researched and developed are vaccines, antivirals, and diagnostic methods.

**Microorganisms and/or Toxins Studied:** Select Agents (USDA).

**Outdoor Studies:** No outdoor studies performed

\(^2\) Including viruses and prions.
**National biological defence research and development programmes: Facilities**

1. **What is the name of the facility?**
   Lothar Salomon Test Facility (LSTF)

2. **Where is it located (provide both address and geographical location)?**
   2029 Burns Road, TEDT-DPW-LS MS#6, Dugway, Utah 84022-5006

3. **Floor area of laboratory areas by containment level (m²):**
   - BSL-2: 710 m²
   - BSL-3: 336 m²
   - BSL-4: 0 m²
   Total laboratory floor area: 1,046 m²

4. **The organizational structure of each facility:**
   (i) **Total number of personnel:** 38

   (ii) **Division of personnel:**
       - Military: 0
       - Civilian: 38

   (iii) **Division of personnel by category:**
       - Scientists: 31
       - Engineers: 1
       - Technicians: 4
       - Administrative and support staff: 2

   (iv) **List the scientific disciplines represented in the scientific/engineering staff:**
       Aerobiology, Bacteriology, Biochemistry, Engineering, Immunology, Microbiology, Molecular Biology, Toxicology, Virology

   (v) **Are contractor staff working in the facility? If so, provide an approximate number:**
       Yes. Number: 9

   (vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**
       - U.S. Department of Defense (DoD) – partly
       - U.S. Department of Homeland Security (DHS)
       - U.S. Department of Justice (DOJ)

   (vii) **What are the funding levels for the following program areas:**
       - Research: $0
       - Development: $0
       - Test and evaluation: $1,582,000
       Total: $1,582,000

   (viii) **Briefly describe the publication policy of the facility:**
       Lothar Salomon’s unique facilities and experienced staff of scientists, test officers, engineers, and technicians provide a full range of chemical and biological testing services, including the development of one-of-a-kind test capabilities, to meet customer requirements for new or developmental products. The
results from testing are documented in government publications, and their distribution is controlled by the test customer or sponsor. These results are not generally suitable for publication in peer-refereed journals.


(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):
None (see above response to question 4.viii)

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms\(^3\) and/or toxins studied, as well as outdoor studies of biological aerosols:
Objectives: Test battlefield detection and identification methods, protective equipment, and decontamination systems, including interferent testing of biological detectors, and develop/validate aerosol particle dispersion models to enhance countermeasure response. Additional information can be found at: http://www.dugway.army.mil

Microorganisms and/or Toxins Studied: Select Agents (HHS, Overlap), NIAID Category A pathogens, Simulants

Outdoor Studies: Yes - using simulants

\(^3\) Including viruses and prions.
1. What is the name of the facility?
Naval Medical Research Center (NMRC)

2. Where is it located (provide both address and geographical location)?
8400 Research Plaza, Fort Detrick, Maryland 21702

3. Floor area of laboratory areas by containment level (m²):
- BSL-2: 2,000 m²
- BSL-3: 0 m²
- BSL-4: 0 m²
Total laboratory floor area: 2,000 m²

4. The organizational structure of each facility:
   (i) Total number of personnel: 61
   (ii) Division of personnel:
      - Military: 13
      - Civilian: 48
   (iii) Division of personnel by category:
      - Scientists: 19
      - Engineers: 0
      - Technicians: 35
      - Administrative and support staff: 7
   (iv) List the scientific disciplines represented in the scientific/engineering staff:
      Biochemistry, Computational Biology, Immunology, Microbiology, Molecular Biology
   (v) Are contractor staff working in the facility? If so, provide an approximate number:
      Yes, Number: 43
   (vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
      U.S. Department of Defense – wholly
   (vii) What are the funding levels for the following program areas:
      - Research: $4,725,008
      - Development: $0
      - Test and evaluation: $0
      - Total: $4,725,008
   (viii) Briefly describe the publication policy of the facility:
      Professional scientists are encouraged to publish papers in peer reviewed journals. All publications must obtain the necessary command and public affairs permission before submission.
      Release of DoD publications is guided by DoD Directive 5230.09, Clearance of DoD Information for Public Release (http://www.dtic.mil/whs/esd/osr/docs/523009p.pdf) and DoD Instruction 5320.29,
Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references):

   [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4368569](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4368569)


   [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4591134](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4591134)

   [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4412822/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4412822/)

   [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4417685/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4417685/)

   [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4417688/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4417688/)

   [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4417686/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4417686/)

   [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC45931591](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC45931591)


5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

**Objectives:** The goal of the program is the development of rapid and deployable detection assays to protect deployed forces. During 2015 we continued studying clinical cases of sepsis in austere environments with the ultimate goal of understanding host-pathogen interactions, development of new diagnostic assays and better treatment strategies against relevant infectious diseases. Additional information is available at [http://www.med.navy.mil/sites/nmrc/Pages/bd_main.htm](http://www.med.navy.mil/sites/nmrc/Pages/bd_main.htm).

**Microorganisms and/or Toxins Studied:** Select Agents (HHS, Overlap), Select Toxins (HHS), NIAID Category A pathogens

**Outdoor Studies:** None

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4 Including viruses and prions.
National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Naval Research Laboratory (NRL)

2. Where is it located (provide both address and geographical location)?
4555 Overlook Ave., SW, Washington, D.C. 20375

3. Floor area of laboratory areas by containment level (m²):
BSL-2:  520 m²
BSL-3:  0 m²
BSL-4:  0 m²
Total laboratory floor area:  520 m²

4. The organizational structure of each facility:
(i)  Total number of personnel:  33

(ii)  Division of personnel:
  Military  1
  Civilian  32

(iii)  Division of personnel by category:
  Scientists  28
  Engineers  1
  Technicians  4
  Administrative and support staff  0

(iv) List the scientific disciplines represented in the scientific/engineering staff:
  Biochemistry, Biophysics, Chemical Engineering, Chemistry, Immunology, Mechanical Engineering, 
  Microbiology, Molecular Biology, Physics

(v)  Are contractor staff working in the facility? If so, provide an approximate number:
  Yes  Number:  4

(vi)  What is (are) the source(s) of funding for the work conducted in the facility, including indication if 
  activity is wholly or partly financed by the Ministry of Defence?
  U.S. Department of Defense – Wholly

(vii) What are the funding levels for the following program areas:
  Research  $ 3,959,000
  Development  $ 1,742,000
  Test and evaluation  $ 0
  Total  $ 5,701,000

(viii) Briefly describe the publication policy of the facility:
  Professional scientists are encouraged to publish papers in peer reviewed journals. All publications must 
  obtain the necessary command and public affairs permission before submission. 
  Employees are encouraged to publish. Release of DoD publications is guided by DoD Directive 
  5230.09 (Clearance of DoD Information for Public Release,
http://www.dtic.mil/whs/esd/osr/docs/523009p.pdf) and DoD Instruction 5320.29 (Security and Policy
publishing information related to biological defense efforts. Public release of unclassified technical
information is subject to sponsor approval.

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous
12 months. (To include authors, titles, and full references.):

1. Daniele MA, Boyd DA, Mott DR, Ligler FS. 3D hydrodynamic focusing microfluidics for emerging
2. Gaylord ST, Dinh TL, Goldman ER, Anderson GP, Ngan KC, Walt DR. Ultrasensitive detection of ricin
toxin in multiple sample matrixes using single-domain antibodies. Anal Chem. 2015 May 22;
3. Hart MB, Sivaprasasam V, Eversole JD, Johnson LJ, Czege J. Optical measurements from single
hydrodynamically focused particle stream enabled by a three-dimensional microfluidic nozzle.
Characterization of the Effect of Growth Phase and Culture Medium on Bacteria. Appl Spectrosc. 2015
production of a single domain antibody with an engineered stabilizing extra disulfide bond. Microb Cell
015-0340-3
7. Olson MA, Zabetakis D, Legler PM, Turner KB, Anderson GP, Goldman ER. Can template-based protein
models guide the design of sequence fitness for enhanced thermal stability of single domain antibodies?
JB. Optimizing nanoplasmonic biosensor sensitivity with orientated single domain antibodies.
9969-3

5. Briefly describe the biological defence work carried out at the facility, including type(s) of
microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: The objectives of research at NRL are to develop and test reliable systems for the detection of
chemical and biological (CB) warfare agents in order to provide early warning and contamination avoidance
information. Additional information is available at http://www.nrl.navy.mil/research/.
Microorganisms and/or Toxins Studied: Simulants
Outdoor Studies: None

5 Including viruses and prions.
National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Naval Surface Warfare Center-Dahlgren Division, Chemical, Biological, Radiological (CBR) Defense Laboratory

2. Where is it located (provide both address and geographical location)?
6149 Welsh Road, Dahlgren, Virginia 22448

3. Floor area of laboratory areas by containment level (m²):
BSL-2: 190 m²
BSL-3: 26 m²
BSL-4: 0 m²
Total laboratory floor area: 216 m²

4. The organizational structure of each facility:
   (i) Total number of personnel: 184
   (ii) Division of personnel:
        Military 0
        Civilian 184
   (iii) Division of personnel by category:
        Scientists 64
        Engineers 46
        Technicians 16
        Administrative and support staff 58
   (iv) List the scientific disciplines represented in the scientific/engineering staff:
        Aerospace Engineering, Chemical Engineering, Chemistry, Computer Engineering, Computer Science, Electronic Engineering, Industrial Engineering, Mathematics, Mechanical Engineering, Microbiology, Molecular Biology, Operations Research Analysis, Physics, Toxicology
   (v) Are contractor staff working in the facility? If so, provide an approximate number:
        Yes Number: 30
   (vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
        U.S. Department of Defense (DoD) – partly
        Private Sector Companies
        Internal (Laboratory Directed Research and Development [LDRD])
        Other Governmental Agencies
   (vii) What are the funding levels for the following program areas:
        Research $ 1,331,000
        Development $ 6,161,940
        Test and evaluation $ 3,553,636
        Total $ 11,046,576
Briefly describe the publication policy of the facility:
Professional scientists are encouraged to publish papers in peer reviewed journals. All publications must obtain the necessary command and public affairs permission before submission.


Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references):

Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:
Objectives: Efforts at this defense laboratory are focused on biological detection systems, collective and individual protection systems, hazard mitigation technologies, risk assessment tools, and consequence management planning. http://www.navsea.navy.mil/Home/WarfareCenters/NSWCDahlgren.aspx
Microorganisms and/or Toxins Studied: Select Agents (Overlap), NIAID Category A pathogens, Simulants
Outdoor Studies: None

6 Including viruses and prions.
National biological defence research and development programmes: Facilities

1. What is the name of the facility?
U.S. Army Edgewood Chemical and Biological Center (ECBC)

2. Where is it located (provide both address and geographical location)?
5183 Blackhawk Road, Aberdeen Proving Ground, Maryland 21010-5424

3. Floor area of laboratory areas by containment level (m²):
   - BSL-2: 532 m²
   - BSL-3: 177 m²
   - BSL-4: 0 m²
   Total laboratory floor area: 709 m²

4. The organizational structure of each facility:
   (i) Total number of personnel: 105
   (ii) Division of personnel:
       - Military: 0
       - Civilian: 105
   (iii) Division of personnel by category:
       - Scientists: 44
       - Engineers: 0
       - Technicians: 42
       - Administrative and support staff: 19
   (iv) List the scientific disciplines represented in the scientific/engineering staff.
       Aerobiology, Aerospace Engineering, Biochemistry, Biomedical Engineering, Biotechnology, Chemical Engineering, Chemistry, Computer Engineering, Electronic Engineering, Immunology, Mathematics, Mechanical Engineering, Microbiology, Molecular Biology, Operations Research Analysis, Physics, Physiology, Toxicology, Toxinology, Virology.
   (v) Are contractor staff working in the facility? If so, provide an approximate number.
       Yes. Number: 37
   (vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
       U.S. Department of Defense (DoD) – Wholly
   (vii) What are the funding levels for the following programme areas:
       - Research: $763,000
       - Development: $21,341,000
       - Test and evaluation: $0
       Total: $22,104,000
   (viii) Briefly describe the publication policy of the facility:
       It is Army policy to encourage scientific and technical personnel to publish research procedures and results in recognized professional journals as well as present their work at national and international
professional meetings. Such publication is an important part of the Army’s research and development program.

Publications are prepared and published in accordance with Army regulations. The regulations governing the publication of research findings include:


(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months (include authors, titles and full references.)


5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms (including viruses and prions) and/or toxins studied, as well as outdoor studies of biological aerosols.  

**Objectives:** Development of non-medical defensive material against biological agents through research, development, and engineering of rapid detection, identification, decontamination methods as well as physical protection from biological threat agents. Additional information is available at [http://www.ecbc.army.mil/research/index.html](http://www.ecbc.army.mil/research/index.html).

**Microorganisms and/or Toxins Studied:** Select Agents (HHS, Overlap) and Toxins, NIAID Category A pathogens, Simulants

**Outdoor Studies:** None
National biological defence research and development programmes: Facilities

1. What is the name of the facility?
U.S. Army Medical Research Institute of Chemical Defense (USAMRICD)

2. Where is it located (provide both address and geographical location)?
2900 Ricketts Point Road, Aberdeen Proving Ground, Maryland 21010
(Main office for facility moved into new headquarters.)

3. Floor area of laboratory areas by containment level (m²):
   - BSL-2: 300 m²
   - BSL-3: 0 m²
   - BSL-4: 0 m²
   Total laboratory floor area: 300 m²

4. The organizational structure of each facility:
   (i) Total number of personnel: 17
   (ii) Division of personnel:
       - Military: 0
       - Civilian: 17
   (iii) Division of personnel by category:
       - Scientists: 7
       - Engineers: 0
       - Technicians: 10
       - Administrative and support staff: 0
   (iv) List the scientific disciplines represented in the scientific/engineering staff:
       Biochemistry, Molecular Biology, Pharmacology, Physiology
   (v) Are contractor staff working in the facility? If so, provide an approximate number:
       Yes. Number: 12
   (vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
       U.S. Department of Defense (DoD) – wholly
   (vii) What are the funding levels for the following program areas:
       - Research: $2,017,755
       - Development: $0
       - Test and evaluation: $0
       Total: $2,017,755
   (viii) Briefly describe the publication policy of the facility:
       It is Army policy to encourage scientific and technical personnel to publish research procedures and results in recognized professional journals as well as present their work at national and international professional meetings. Such publication is an important part of the Army’s research and development program.


(i) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references):


5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

**Objectives:** Discover and develop medical products and knowledge solutions against chemical and toxin threats through research, education and training, and consultation. USAMRICD performs comprehensive, basic scientific research using established and emerging technologies that support the transition of products to advanced development; develops education and training capabilities for military, interagency, domestic, and international personnel in the medical management of chemical casualties; and provides a venue for mutually beneficial collaboration with external investigators and interagency partners to conduct medical chemical defense research against chemical warfare agents and toxins. [https://usamricd.apgea.army.mil/]

**Microorganisms and/or Toxins Studied:** HHS Select Toxins

**Outdoor Studies:** None

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7 Including viruses and prions.
National biological defence research and development programmes: Facilities

1. What is the name of the facility?
   U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)

2. Where is it located (provide both address and geographical location)?
   1425 Porter Street, Fort Detrick, Fredrick, Maryland 21702

3. Floor area of laboratory areas by containment level (m²):
   - BSL-2: 26,026 m²
   - BSL-3: 3,139 m²
   - BSL-4: 1,186 m²
   Total laboratory floor area: 30,351 m²

4. The organizational structure of each facility:
   (i) Total number of personnel 919
   (ii) Division of personnel:
        Military 206
        Civilian 713
   (iii) Division of personnel by category:
        Scientists 275
        Engineers 8
        Technicians 352
        Administrative and support staff 284
   (iv) List the scientific disciplines represented in the scientific/engineering staff.
        Aerobiology, Biochemistry, Chemistry, Clinical Immunology, Entomology, Genetics, Immunology, Microbiology, Molecular Biology, Toxicology, Veterinary Medicine, Virology.
   (v) Are contractor staff working in the facility? If so, provide an approximate number.
        Yes. Number: 453
   (vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
        - U.S. Department of Defense (DoD) – Partly
        - U.S. Department of Homeland Security (DHS)
        - U.S. Department of Health and Human Services (DHHS)
        - U.S. Department of Agriculture (USDA)
        - Universities
        - Private sector companies
   (vii) What are the funding levels for the following programme areas:
        - Research $3,365,277
        - Development $51,409,181*
        - Test and evaluation $5,322,071
        - Total $60,096,529
*Includes reimbursables from Cooperative Research and Development Agreements and other Departments

(viii) Briefly describe the publication policy of the facility:
It is Army policy to encourage scientific and technical personnel to publish research procedures and results in recognized professional journals as well as present their work at national and international professional meetings. Such publication is an important part of the Army’s research and development program.

Publications are prepared and published in accordance with Army regulations. The regulations governing the publication of research findings include:


(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months (include authors, titles and full references.)


   http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4575071/


43. Amemiya K, Dankmeyer JL, Fetterer DP, Worsham PL, Welkos SL, Cote CK. Comparison of the early host immune response to two widely diverse virulent strains of Burkholderia pseudomallei that cause


Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: Develop medical countermeasures, including candidate vaccines, undergo diagnostic tests and drug or immunological therapies for biological agents, and perform exploratory studies and advanced development of protective and therapeutic countermeasures and agent identification technologies. Additional information is available at [http://www.usamriid.army.mil/](http://www.usamriid.army.mil/).

Agents Microorganisms and/or Toxins: Select Agents (HHS, Overlap), Select Toxins (HHS), NIAID Category A pathogens

Outdoor Studies: None

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8 Including viruses and prions.
National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Brookhaven National Laboratory

2. Where is it located (provide both address and geographical location)?
Brookhaven National Laboratory, Biology Department, Upton, New York 11973
(Located on William Floyd Parkway, County Road 46, 1.5 miles north of Long Island Expressway Exit 68)

3. Floor area of laboratory areas by containment level (m²):
   - BSL-2: 18 m²
   - BSL-3: 0 m²
   - BSL-4: 0 m²
   Total laboratory floor area: 18 m²

4. The organizational structure of each facility:
   (i) Total number of personnel: 3
   (ii) Division of personnel:
        Military: 0
        Civilian: 3
   (iii) Division of personnel by category:
        Scientists: 3
        Engineers: 0
        Technicians: 0
        Administrative and support staff: 0
   (iv) List the scientific disciplines represented in the scientific/engineering staff:
        Biochemistry, Structural Biology
   (v) Are contractor staff working in the facility? If so, provide an approximate number:
        No
   (vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
        Department of Defense (DoD) – partly
        Department of Health and Human Services (HHS)
   (vii) What are the funding levels for the following program areas:
        Research: $689,000
        Development: $0
        Test and evaluation: $0
        Total: $689,000
   (viii) Briefly describe the publication policy of the facility:
        As a Department of Energy/Office of Science (DOE-SC) facility, BNL is required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory
dissemination requirements, and ensure a fair return on Departmental and taxpayer investment. BNL has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related endeavors. BNL also has procedures in place to manage and protect classified, sensitive controlled unclassified, and export-controlled scientific and technical information, yet make it accessible for appropriate access by the Department, its contractors, and others. Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following: 1) classification/declassification, 2) copyrighted materials or other intellectual property, 3) export controls or distribution restrictions, and 4) sensitive content that limits access. [US Department of Energy, Scientific and Technical Information Management: https://www.directives.doe.gov/directives/0241.1-BOrder-b/view](https://www.directives.doe.gov/directives/0241.1-BOrder-b/view)

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):

   http://www.nature.com/articles/srep17795


5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: The overall objective of the work is to develop countermeasures for biowarfare agents. The specific aims of the projects are to determine the three-dimensional structures of the agents. The purified agents are crystallized using standard crystallization techniques and brought to the National Synchrotron Light Source (also located at Brookhaven National Laboratory) for x-ray diffraction studies. These results can lead to vaccine development, treatment, and/or diagnosis and detection. Additional information is available at https://www.bnl.gov/biosciences/.

Microorganisms and/or Toxins Studied: HHS Select Toxin.

Outdoor Studies: None.
National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Lawrence Livermore National Laboratory (LLNL)

2. Where is it located (provide both address and geographical location)?
7000 East Avenue, Livermore, California 94550 (62 km east-southeast of San Francisco, California)

3. Floor area of laboratory areas by containment level (m²):
   BSL-2: 1,685 m²
   BSL-3: 59.5 m²
   BSL-4: 0 m²
   Total laboratory floor area: 1,744.5 m²

4. The organizational structure of each facility:
   (i) Total number of personnel: 65
   (ii) Division of personnel:
        Military: 0
        Civilian: 65
   (iii) Division of personnel by category:
        Scientists: 26
        Engineers: 11
        Technicians: 15
        Administrative and support staff: 13
   (iv) List the scientific disciplines represented in the scientific/engineering staff:
        Aerosol Science, Analytical Biochemistry, Analytical Mass Spectrometry, Bacteriology, Biochemistry,
        Bioinformatics, Biomedical Engineering, Biomedical Science, Biotechnology, Computational Biology,
        Computer Science, Environmental Science, Epidemiology, Genomics, Immunology, Mass Spectrometry,
        Microbial Forensics, Microbiology, Molecular Biology, Molecular Diagnostics, Nanotechnology,
        Proteomics, Toxinology, Virology.
   (v) Are contractor staff working in the facility? If so, provide an approximate number:
        No
   (vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if
        activity is wholly or partly financed by the Ministry of Defence?
        Department of Defense-partially
        Department of Energy
        Department of Health & Human Services (HHS)
        Department of Homeland Security
   (vii) What are the funding levels for the following program areas:
        Research: $4,474,000
        Development: $3,189,000
        Test and evaluation: $1,718,000
        Total: $9,381,000
Briefly describe the publication policy of the facility:
As a DOE/NNSA facility, LLNL is required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory dissemination requirements, and ensure a fair return on Departmental and taxpayer investment. LLNL has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related endeavors. LLNL also has procedures in place to manage and protect classified, sensitive controlled unclassified, and export-controlled scientific and technical information, yet make it accessible for appropriate access by the Department, its contractors, and others. Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following: 1) classification/declassification, 2) copyrighted materials or other intellectual property, 3) export controls or distribution restrictions, and 4) sensitive content that limits access. [US Department of Energy, Scientific and Technical Information Management: https://www.directives.doe.gov/directives/0241.1-BOrder-b/view]

Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references):

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:
Objectives: Biological agent detection, therapeutics development, virulence mechanism elucidation, structural characterization, agent viability testing, response planning, assay development for monitoring for biological decontamination/response, and bioforensics. Development of diagnostic platforms that use a variety of techniques, such as PCR, immunoassay, microarray, mass spectrometry and genomic sequencing to gather useful information about the species present in the sampling environment. Development of microbial forensic assays to help determine geographic origin and attribution. Beyond detection, response, recovery, and attribution, LLNL also has ongoing research projects to elucidate mechanisms of host-pathogen interactions. Additional information is available at https://missions.llnl.gov/biosecurity.
Microorganisms and/or Toxins Studied: Select Agents (HHS, Overlap), NIAID Category A pathogens, simulants.
Outdoor Studies: There were no outdoor studies.
National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Los Alamos National Laboratory (LANL)

2. Where is it located (provide both address and geographical location)?
Bikini Atoll Road SM-30, Los Alamos, NM 87545
(Approximately 45 miles west of Santa Fe, New Mexico)

3. Floor area of laboratory areas by containment level (m²):
- BSL-2: 320 m²
- BSL-3: 0 m²
- BSL-4: 0 m²
Total laboratory floor area: 320 m²

4. The organizational structure of each facility:
   (i) Total number of personnel: 47
   (ii) Division of personnel:
        Military 0
        Civilian 47
   (iii) Division of personnel by category:
        Scientists 22
        Engineers 1
        Technicians 21
        Administrative and support staff 3
   (iv) List the scientific disciplines represented in the scientific/engineering staff:
        Bacteriology, Biological Science, Chemistry, Cell Biology, Microbiology, Molecular Biology,
        Bioinformatics, Genomics, Environmental Science, Plant Pathology, Analytical Biochemistry, Molecular
        Diagnostics, Public Health, Biotechnology, Biochemistry, Genetics, Virology.
   (v) Are contractor staff working in the facility? If so, provide an approximate number:
        Yes, 1.
   (vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if
        activity is wholly or partly financed by the Ministry of Defence?
        Department of Defense (DoD) – partly
        Department of Health & Human Services (HHS)
        Department of Homeland Security (DHS)
        Internal (Laboratory Directed Research and Development)
        U.S. Agency for International Development (USAID)
   (vii) What are the funding levels for the following program areas:
        Research $9,642,000
        Development $1,900,000
        Test and evaluation $1,300,000
        Total $12,842,000
Briefly describe the publication policy of the facility:
As a DOE/NNSA facility, LANL is required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory dissemination requirements, and ensure a fair return on Departmental and taxpayer investment. LANL has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related endeavors. LANL also has procedures in place to manage and protect classified, sensitive controlled unclassified, and export-controlled scientific and technical information, yet make it accessible for appropriate access by the Department, its contractors, and others. Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following: 1) classification/declassification, 2) copyrighted materials or other intellectual property, 3) export controls or distribution restrictions, and 4) sensitive content that limits access. [US Department of Energy, Scientific and Technical Information Management: https://www.directives.doe.gov/directives/0241.1-BOrder-b/view]

Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):
   Rosovitz (2015). Whole-Genome Sequences of 80 Environmental and Clinical Isolates of Burkholderia
   pseudomallei. Genome Announcements 3(1). http://genomea.asm.org/content/3/1/e01282-14.full
    A. Bishop-Lilly, D. C. Bruce and S. R. Coyne (2015). Thirty-two complete genome assemblies of nine
    Yersinia species, including Y. pestis, Y. pseudotuberculosis, and Y. enterocolitica. Genome
    A. Bishop-Lilly, D. C. Bruce and H. S. Gibbons (2015). Complete genome sequences for 35 biothreat
    Broomall, K. A. Bishop-Lilly, D. C. Bruce and O. Chertkov (2015). Genome sequencing of 18 Francisella
    strains to aid in assay development and testing. Genome announcements 3(2): e00147-00115.
    isolates, both pathogenic and near neighbor. Genome Announcements 3(2): e00159-00115.
    http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4417668/
    Francisella novicida DPG 3A-IS. Genome Announcements 3(5).
    http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4574370/
    Davenport, J. G. Jaissle and P. S. Chain (2015). Finished Genome Assembly of Yersinia pestis EV76D
    and KIM 10v. Genome Announcements 3(5). http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4574367/
    and P. S. G. Chain (2015). Finished Genome Sequence of Bacillus cereus Strain 03BB87, a Clinical
    Isolate with B. anthracis Virulence Genes. Genome Announcements 3(1).
    Bruce and C. Han (2015). Complete genome assemblies for two single-chromosome Vibrio cholerae
    isolates, strains 1154-74 (serogroup O49) and 10432-62 (serogroup O27). Genome Announcements 3(3):
    H. An optical biosensor for detection of pathogen biomarkers from Shiga toxin-producing Escherichia
    coli in ground beef samples Proc. SPIE 9310, Frontiers in Biological Detection: From Nanosensors to
    Systems VII, 931004 (2 March 2015); doi: 10.1117/12.2079658
    sequences of six botulinum neurotoxin-producing strains representing three clostridial species illustrate
    the mobility and diversity of botulinum neurotoxin genes. Infection, Genetics and Evolution 30: 102-113.
20. Stromberg LR, Stromberg ZE, Banisadr A, Graves SW, Moxley RA and Mukundan H, Purification and
    characterization of lipopolysaccharides from six strains of non-O157 Shiga toxin-producing Escherichia
    recordings, radio and television interviews and slides are also available online.
5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

**Objectives:** The biological defense research and development activities at the Los Alamos National Laboratory include pathogen characterization, host-pathogen interaction studies, pathogen detection, integrative biosurveillance and analysis technology development. The main objectives for the studies are to: understand molecular mechanisms of host-pathogen interaction; study molecular, chemical, and physical characteristics of biothreat agents, including bacteria, viruses and toxins, for detection, characterization, assay design and improvement; evaluate detection assay and platform performance; assess commercial techniques for pathogen detection and biosurveillance on environmental monitoring procedures; develop DNA, RNA and protein based bioforensics assays; develop next generation high throughput microbial sequencing, finishing and analysis capabilities; perform viral and bacterial pathogen sequencing for characterization, comparative genomic analysis, and metagenomic analysis; develop high throughput assays for host-pathogen protein interactions screening; develop and validate assays to improve the ability to identify and characterize bioterrorism incident; and identify host molecular targets as potential therapeutic candidates. Additional information is available at http://www.lanl.gov/science-innovation/capabilities/bioscience-biosecurity-health/biosecurity-health/index.php.

**Microorganisms and/or Toxins Studied:** Select Agents (HHS, Overlap), NIAID Category A

**Outdoor Studies:** There were no outdoor studies.
National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Pacific Northwest National Laboratory (PNNL)

2. Where is it located (provide both address and geographical location)?
902 Battelle Boulevard, Richland, Washington 99352 (The Pacific Northwest National Laboratory is located in north Richland, Washington, and is served by the Tri-Cities Airport in Pasco. Richland, Pasco and Kennewick make up the Tri-Cities where the Columbia, Snake and Yakima Rivers meet before heading to the Pacific Ocean.)

3. Floor area of laboratory areas by containment level (m²):
   Richland campus:          BSL-2    769 m²
                              BSL-3    0 m²
                              BSL-4    0 m²
                              Total laboratory floor area: 769 m²
   Sequim campus:            BSL-2    81 m²
                              BSL-3    0 m²
                              BSL-4    0 m²
                              Total laboratory floor area 81 m²

4. The organizational structure of each facility:
   (i) Total number of personnel: 94
   (ii) Division of personnel:
         Military          0
         Civilian         94
   (iii) Division of personnel by category:
         Scientists       80
         Engineers        2
         Technicians     0
         Admin and Support Staff 12
   (iv) List the scientific disciplines represented in the scientific/engineering staff:
         Analytical Mass Spectrometry, Bacteriology, Biochemistry, Biological Science, Cell Biology, Chemistry, Computational Biology, Genetics, Genomics, Mass Spectrometry, Microbial Forensics, Microbiology, Molecular Biology, Nanotechnology, Pathology, Proteomics, Structural Biology, Systems Biology, Virology.
   (v) Are contractor staff working in the facility? If so, provide an approximate number:
         Yes, 1.
   (vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
         Department of Defense (DoD)-partially
         Department of Energy (DOE)
         Department of Health & Human Services (HHS)
Department of Homeland Security (DHS)
Internal (Laboratory Directed Research and Development)
Other Government Agencies

(vii) What are the funding levels for the following program areas:

- Research: $10,483,000
- Development: $314,000
- Test and evaluation: $1,391,000
- Total: $12,188,000

(viii) Briefly describe the publication policy of the facility:

As a DOE Office of Science facility, PNNL is required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory dissemination requirements, and ensure a fair return on Departmental and taxpayer investment. PNNL has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related endeavors. PNNL also has procedures in place to manage and protect classified, controlled unclassified, and export-controlled scientific and technical information, yet make it accessible for appropriate access by the Department, its contractors, and others. Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following: 1) classification/declassification, 2) copyrighted materials or other intellectual property, 3) export controls or distribution restrictions, and 4) sensitive content that limits access. [US Department of Energy, Scientific and Technical Information Management: https://www.directives.doe.gov/directives/0241.1-BOrder-b/view] For this location, a searchable database of materials published since 1988 is available at http://www.pnnl.gov/publications/.

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):


5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

**Objectives:** PNNL is involved in biodefense-related activities, such as agent characterization (e.g., knock out experiments and investigation of infectious properties of agents) and the development of detection methods (e.g., nucleic acid, toxin, and proteomic signatures), testing and evaluation of commercial off the shelf equipment for agent detection as well as investigation of next generation biodetection equipment, biological and chemical forensics, investigation of natural history of agents, pathogenesis studies, and interrogating DNA sequencing data and related analysis tools. No outdoor studies of biological aerosols were collected. Additional information is available at [http://www.pnnl.gov/nationalsecurity/technical/capabilities/cbps/chem_biological_science.stm](http://www.pnnl.gov/nationalsecurity/technical/capabilities/cbps/chem_biological_science.stm).

**Microorganisms and/or toxins studied:** Select Agents (HHS, Overlap), NIAID Category A, Simulants

**Outdoor Studies:** No outdoor studies of biological aerosols were conducted.
National biological defence research and development programmes: Facilities

1. Name of the facility:
   Sandia National Laboratories (SNL)

2. Where is it located?
   New Mexico Campus: P. O. Box 5800, Albuquerque, NM 87185 (located on Kirtland Air Force Base, in southeastern Albuquerque)
   California Campus: 7011 East Avenue, Livermore, California (located in Livermore, CA.)
   (Note: Personnel and budget are shared between New Mexico and California campuses.)

3. Floor area of laboratory areas by containment level (m²):

   New Mexico campus:  
   - BSL-2: 652.58 m²  
   - BSL-3: 0 m²  
   - BSL-4: 0 m²  
   Total laboratory floor area: 652.58 m²

   California campus:  
   - BSL-2: 230 m²  
   - BSL-3: 0 m²  
   - BSL-4: 0 m²  
   Total laboratory floor area: 230 m²

4. Organizational structure of each facility:
   (i) Total number of personnel:
       New Mexico campus: 157  
       California campus: 43

   (ii) Division of personnel:  
        - Military: 0  
        - Civilian: 200

   (iii) Division of personnel by category:  
         - Scientists: 113  
         - Engineers: 29  
         - Technicians: 48  
         - Admin and Support Staff: 10

   (iv) Scientific discipline(s) that best describes field of work:  
        Aerosol Science, Biochemistry, Biomedical Engineering, Biotechnology, Chemical Engineering,  
        Materials Science, Medicine, Nanotechnology, Aerobiology, Bioinformatics, Biological Science, Cell  
        Biology, Immunology, Molecular Biology, Virology, Molecular Diagnostics, Biophysics, Chemistry,  
        Physics, Analytical Biochemistry, Analytical Chemistry, Analytical Mass Spectrometry, Bacteriology,  
        Bioinorganic Chemistry, Biomedical Science, Computational Biology, Computer Engineering, Computer  
        Science, Electrical Engineering, Environmental Engineering, Environmental Science, Genetics,  
        Genomics, Mass Spectrometry, Mathematics, Mechanical Engineering, Microbial Forensics,  
        Microbiology, Neuroscience, Operations Research Analysis, Optical Spectroscopy, Pathology,  
        Physiology, Polymer Science, Protein Engineering, Proteomics, Structural Biology, Toxicology

   (v) Are Contractor staff working in the facility?  
        Yes  Number: 10 (9 New Mexico campus; 1 California campus)
(vi) What is (are) the source(s) of funding for the work conducted in the facility?
- Department of Defense (DoD)
- Department of Health and Human Services (HHS)
- Department of Homeland Security (DHS)
- Internal (Laboratory Directed Research & Development, LDRD)
- Private sector

(vii) What are the funding levels for Research and Development and Testing and Evaluation as of the most recent calendar year?

<table>
<thead>
<tr>
<th>Type</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research</td>
<td>$12,543,979.28</td>
</tr>
<tr>
<td>Development</td>
<td>$2,738,717.75</td>
</tr>
<tr>
<td>Test and Evaluation</td>
<td>$796,106.75</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$16,078,803.78</strong></td>
</tr>
</tbody>
</table>

(viii) Briefly describe the publication policy of the facility:
As a Department of Energy/National Nuclear Security Administration (DOE/NNSA) facility, Sandia National Laboratories is required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory dissemination requirements, and ensure a fair return on Departmental and taxpayer investment. SNL has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related endeavors. SNL also has procedures in place to manage and protect classified, sensitive controlled unclassified, and export-controlled scientific and technical information, yet make it accessible for appropriate access by the Department, its contractors, and others. Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following: 1) classification/declassification, 2) copyrighted materials or other intellectual property, 3) export controls or distribution restrictions, and 4) sensitive content that limits access. [Department of Energy, Scientific and Technical Information Management: https://www.directives.doe.gov/directives/0241.1-BOrder-b/view]

(ix) Provide a list of publicly available papers and reports resulting from work during the previous 12 months (To include authors, titles, and full references.):
5. Briefly describe the biological defense work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols.

**Objectives:** To improve our nation’s ability to anticipate and defend against biological threats, our multidisciplinary research team is applying Sandia’s traditional strengths in engineering and technology development to achieve the following goals: 1) Gain basic knowledge regarding the fundamental molecular processes of pathogenesis, including the dynamic interactions between microbial pathogens and their hosts; 2) Develop assays, novel materials, and platforms to detect and diagnose traditional and unknown pathogens, as well as to discover novel therapeutic targets; and 3) Obtain an understanding of the microbiome’s effects on human health in the absence or in the presence of an infectious disease. Additional information is available at [http://www.sandia.gov/research/research_foundations/bioscience/index.html](http://www.sandia.gov/research/research_foundations/bioscience/index.html).

**Microorganisms and/or toxins studied:** No select agents, select toxins or NIAID Category A pathogens were studied at the facility.

**Outdoor studies:** There were no outdoor studies.
National biological defence research and development programmes

1. What is the name of the facility?
Centers for Disease Control and Prevention (CDC), National Center for Environmental Health (NCEH), Division of Laboratory Services (DLS)

2. Where is it located (include both address and geographical location)?
4770 Buford Highway, Atlanta, Georgia 30341

3. Floor area of laboratory areas by containment level:
BL2 568 m²
BL3 0 m²
BL4 0 m²
Total laboratory floor area 568 m²

4. The organizational structure of each facility.
(i) Total number of personnel 21
(ii) Division of personnel:
  Military 0
  Civilian 21
(iii) Division of personnel by category:
  Scientists 21
  Engineers 0
  Technicians 0
  Administrative and support staff 0
(iv) List the scientific disciplines represented in the scientific/engineering staff.
Analytical Biochemistry, Analytical Chemistry, Analytical Mass Spectrometry, Biochemistry, Biology, Chemistry, Mass Spectrometry, Proteomics
(v) Are contractor staff working in the facility? If so, provide an approximate number.
Yes  Contractor staff = 6
(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
Centers for Disease Control and Prevention, Department of Health and Human Services (HHS)
(vii) What are the funding levels for the following programme areas:
  Research $1,302,354
  Development $363,375
  Test and evaluation $742,086
  Total $2,407,816
(viii) Briefly describe the publication policy of the facility:
Scientists are encouraged to publish their results in the peer reviewed scientific literature as well as present their work at national and international professional meetings. The clearance policy for information products disseminated outside CDC for public use is available online at:
(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.)


5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols.

**Objectives:** The Division of Laboratory Sciences develops methods for measuring selected toxins to help improve detection and diagnosis during a public health response to biological toxins. More information can be found at http://www.cdc.gov/nceh/dls/.

**Agents Microorganisms and/or toxins studied:** HHS Select Toxins

**Outdoor studies:** Outdoor studies of biological aerosols were not conducted at the facility or off-site by facility personnel.
National biological defence research and development programmes

1. What is the name of the facility?
Centers for Disease Control and Prevention (CDC), Office of Infectious Diseases (OID)

2. Where is it located (provide both address and geographical location)?
1600 Clifton Road N.E., Atlanta, Georgia 30333

3. Floor area of laboratory areas by containment level:
BL2  294 m²  
BL3  2143 m²  
BL4  543 m²  
Total laboratory floor area  2980 m²  

4. The organizational structure of each facility.

(i) Total number of personnel  236  
(ii) Division of personnel:  
   Military  3  
   Civilian  233  
(iii) Division of personnel by category:  
   Scientists  199  
   Engineers  0  
   Technicians  23  
   Administrative and support staff  14  
(iv) List the scientific disciplines represented in the scientific/engineering staff.
Animal Science, Biochemistry, Bioinformatics, Biology, Biological Science, Cell Biology, Chemistry, Clinical Immunology, Ecology, Entomology, Epidemiology, Genetics, Genomics, Immunology, Medicine, Microbiology, Molecular Biology, Molecular Diagnostics, Public Health, Statistics, Veterinary Medicine, Virology  
(v) Are contractor staff working in the facility? If so, provide an approximate number.
Yes  Contractor staff = 59  
(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
U.S. Agency for International Development (USAID)  
Department of Defense (DOD)  
Department of Health and Human Services (HHS)  
Department of Homeland Security (DHS)  
Department of State (DOS)  
(vii) What are the funding levels for the following program areas:
Research  $ 13,833,850  
Development  $ 7,633,607  
Test and evaluation  $ 9,401,192  
Total  $ 30,868,649
Briefly describe the publication policy of the facility:
Publication is encouraged and managed by editorial and clearance policies conducted at all levels of the Agency. The clearance policy for information products disseminated outside CDC for public use is available online at: [http://www.cdc.gov/od/science/policies](http://www.cdc.gov/od/science/policies). CDC Policy on "Oversight and clearance of dual use research of concern" is available online at: [http://aops-masis.cdc.gov/Policy/Doc/policy516.pdf](http://aops-masis.cdc.gov/Policy/Doc/policy516.pdf)

Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)


5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms* and/or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: Activities at this facility include developing diagnostic assays for public health, developing and validating methods to differentiate and characterize organisms and the toxins that they produce, developing environmental sampling methods for recovery of agents from porous and nonporous surfaces for public health, routine reference antimicrobial susceptibility testing of clinical isolates, conducting molecular and antigenic characterization of organisms, determining pathogenicity and virulence of infectious agents, development of culture-independent point of care diagnostics, maintaining emergency response laboratory expertise and capacity, vaccine evaluation, medical countermeasure evaluation, determining the natural history of infectious organisms and assessing immune correlates of protection, and conducting epidemiologic studies and surveillance for diseases. More information can be found at: http://www.cdc.gov/oid/.

Microorganisms and/or toxins studied: Select Agents (HHS, USDA, Overlap), Select Toxins (HHS), NIAID Category A pathogens

Outdoor Studies: Outdoor studies of biological aerosols were NOT conducted at the facility or off-site by facility personnel.
National biological defence research and development programmes

1. What is the name of the facility?
CDC, OID, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Vector Borne Diseases (DVBD) - Ft. Collins

2. Where is it located (include both address and geographical location)?
3156 Rampart Road, Fort Collins, Colorado 80521

3. Floor area of laboratory areas by containment level:
BL2  66 m²
BL3  1142 m²
BL4  0 m²
Total laboratory floor area  1208 m²

4. The organizational structure of each facility.
(i) Total number of personnel  60
(ii) Division of personnel: Military  0
Civilian  60
(iii) Division of personnel by category:
Scientists  27
Engineers  0
Technicians  16
Administrative and support staff  17
(iv) List the scientific disciplines represented in the scientific/engineering staff.
Animal Science, Bacteriology, Bioinformatics, Biological Science, Cell Biology, Ecology, Entomology, Environmental Science, Epidemiology, Genomics, Immunology, Medicine, Microbiology, Molecular Biology, Molecular Diagnostics, Pathology, Public Health, Structural Biology, Veterinary Medicine, Virology

(v) Are contractor staff working in the facility? If so, provide an approximate number.
Yes  Contractor staff = 5

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
U.S. Department of Health & Human Services
Department of Defense (DoD)
Department of State (DoS)
Department of Homeland Security (DHS)

(vii) What are the funding levels for the following programme areas:
Research  $1,436,889
Development  $279,893
Test and evaluation  $401,091
Total  $2,117,873
(viii) Briefly describe the publication policy of the facility:
Publication is encouraged and managed by editorial and clearance policies conducted at all levels of the Agency. The clearance policy for information products disseminated outside CDC for public use is available online at: http://www.cdc.gov/od/science/policies
CDC Policy on "Oversight and clearance of dual use research of concern," is available online at: http://aops-masis.cdc.gov/Policy/Doc/policy516.pdf

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.)

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: CDC's Division of Vector Borne Diseases (DVBD) possesses many of the select agents that are on the Department of Health and Human Services (HHS) and HHS/U.S. Department of Agriculture overlap lists. Within CDC, DVBD has the primary responsibility for research on tularemia, plague and alphaviruses. This research involves development of assays for surveillance and detection of each agent and molecular and antigenic characterization. More information can be found at: http://www.cdc.gov/nczeid/dvbd/

Microorganisms and/or toxins studied: Select Agents (HHS, Overlap), NIAID Category A pathogens

Outdoor Studies: No outdoor studies of biological aerosols were conducted at the facility or off-site by facility personnel.
National biological defence research and development programmes

1. What is the name of the facility?
Integrated Research Facility at Rocky Mountain Laboratories (IRF-RML)

2. Where is it located (include both address and geographical location)?
903 South 4th Street, Hamilton, Montana 59840

3. Floor area of laboratory areas by containment level:
   BL2 1361 m²
   BL3 407 m²
   BL4 1145 m²
   Total laboratory floor area 2913 m²

4. The organizational structure of each facility.
   (i) Total number of personnel = 109
   (ii) Division of personnel: 
        Military = 0
        Civilian = 109
   (iii) Division of personnel by category:
        Scientists = 47
        Engineers = 0
        Technicians = 57
        Administrative and support staff = 5
   (iv) List the scientific disciplines represented in the scientific/engineering staff.
        Aerobiology, Animal Science, Bacteriology, Biochemistry, Biological Science, Cell Biology, Entomology,
        Genetics, Genomics, Immunology, Microbiology, Microscopy, Molecular Biology, Pathology, Proteomics,
        Veterinary Medicine, Virology
   (v) Are contractor staff working in the facility? If so, provide an approximate number.
        Yes  Contractor staff = 5
   (vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if
        activity is wholly or partly financed by the Ministry of Defence?
        Department of Health and Human Services (HHS)
   (vii) What are the funding levels for the following programme areas:
        Research $19,842,451
        Development $0
        Test and evaluation $0
   (viii) Briefly describe the publication policy of the facility:
        All researchers are encouraged to publish results in peer-reviewed open literature. The NIH Public Access Policy
        (http://publicaccess.nih.gov/) ensures that the public has access to the published results of NIH funded research. It
        requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the National
        Library of Medicine’s PubMed Central digital archive upon acceptance for publication. To help advance science
        and improve human health, the policy requires that these papers are accessible to the public on PubMed Central
        no later than 12 months after publication.
Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.)


5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: The Integrated Research Facility at Rocky Mountain Laboratories hosts research dedicated to understanding the mechanisms of pathogenesis of microbial agents associated with or likely to cause serious or lethal human diseases using molecular methods and animal model systems. Research activities include pathogenesis studies, vaccinology, and the development of therapeutic countermeasures and rapid diagnostic assays in support of the civilian biodefense program. More information is available at http://www.niaid.nih.gov/about/organization/dir/rml/Pages/default.aspx.

Microorganisms and/or toxins studied: Select Agents (HHS, Overlap, USDA), NIAID Category A pathogens

Outdoor studies: No outdoor studies of biological aerosols were conducted.
National biological defence research and development programmes

1. What is the name of the facility?
Integrated Research Facility at Fort Detrick (IRF-Frederick)

2. Where is it located (include both address and geographical location)?
8200 Research Plaza, Frederick, Maryland 21702

3. Floor area of laboratory areas by containment level:
   - BL-2: 878 m²
   - BL-3: 0 m²
   - BL-4: 1305 m²
   - Total laboratory floor area: 2183 m²

4. The organizational structure of each facility.
   (i) Total number of personnel: 91
   (ii) Division of personnel:
       - Military: 0
       - Civilian: 91
   (iii) Division of personnel by category:
       - Scientists: 29
       - Engineers: 2
       - Technicians: 53
       - Administrative and support staff: 7
   (iv) List the scientific disciplines represented in the scientific/engineering staff.
       Aerobiology, Aerosol Science, Analytical Biochemistry, Biochemistry, Biological Science, Cell Biology,
       Immunology, Medicine, Microbiology, Microscopy, Molecular Biology, Molecular Diagnostics, Pathology,
       Public Health, Veterinary Medicine
   (v) Are contractor staff working in the facility? If so, provide an approximate number.
       Contractor staff = 80
   (vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if
       activity is wholly or partly financed by the Ministry of Defence?
       Department of Health and Human Services (HHS)
   (vii) What are the funding levels for the following programme areas:
       - Research: $19,261,144
       - Development: $0
       - Test and evaluation: $0
   (viii) Briefly describe the publication policy of the facility:
       All researchers are encouraged to publish results in peer-reviewed open literature. The NIH Public Access Policy
       (http://publicaccess.nih.gov/) ensures that the public has access to the published results of NIH funded research. It
       requires scientists to submit final peer-reviewed journal manuscripts that arise form NIH funds to the National
       Library of Medicine’s PubMed Central digital archive upon acceptance for publication. To help advance science
and improve human health, the policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.)


5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: The Integrated Research Facility at Fort Detrick in Frederick, Maryland manages, coordinates, and facilitates the conduct of emerging infectious disease and biodefense research to develop vaccines, countermeasures, and improved medical outcomes for patients. Batelle Memorial Institute facilitates research performed at the IRF-Frederick with direction from the IRF Scientific Steering Committee.

Microorganisms and/or Toxins Studied: Select Agents (HHS, USDA, Overlap), NIAID Category A pathogens

Outdoor studies: No outdoor studies of biological aerosols were conducted.
National biological defence research and development programmes

1. What is the name of the facility?
C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases

2. Where is it located (include both address and geographical location)?
9000 Rockville Pike, Bethesda, Maryland 20892

3. Floor area of laboratory areas by containment level:
   - BL2: 2725 m²
   - BL3: 1356 m²
   - BL4: 0 m²
   - Total laboratory floor area: 4081 m²

4. The organizational structure of each facility.
   (i) Total number of personnel = 162
   (ii) Division of personnel: Military = 0
        Civilian = 162
   (iii) Division of personnel by category:
        Scientists = 87
        Engineers = 0
        Technicians = 70
        Administrative and support staff = 5
   (iv) List the scientific disciplines represented in the scientific/engineering staff.
        Bacteriology, Biological Science, Chemistry, Immunology, Medicine, Microbiology, Molecular Biology, Parasitology, Pathogenesis, Toxicology, Vaccine Evaluation, Virology
   (v) Are contractor staff working in the facility? If so, provide an approximate number.
        Yes Contractor staff = 18
   (vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
        Department of Health and Human Services (HHS)
   (vii) What are the funding levels for the following programme areas:
        Research $35,883,213
        Development $0
        Test and evaluation $0
   (viii) Briefly describe the publication policy of the facility:
        All researchers are encouraged to publish results in peer-reviewed open literature. The NIH Public Access Policy (http://publicaccess.nih.gov) ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the National Library of Medicine’s PubMed Central digital archive upon acceptance for publication. To help advance science and improve human health, the policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.
(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.)


Page 113 of 164


5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols.

**Objectives:** At the C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases, the Laboratory of Infectious Diseases (LID) focuses on vaccine development, host immune response to viruses, and viral molecular biology and genetics. The Laboratory of Parasitic Diseases (LPD) conducts basic and applied research on the prevention, control, and treatment of a variety of parasitic and bacterial diseases of global importance. The Laboratory of Viral Diseases (LVD) carries out investigations on the molecular biology of viruses, the interactions of viruses with host cells, the pathogens of viral diseases, and host defense mechanisms. The Laboratory of Clinical Infectious Diseases (LCID) conducts clinical and basic studies of important human infections and immunological diseases. The Laboratory of Bacteriology (LB) studies bacteria that cause important human infections to identify novel or improved strategies to control bacterial diseases, including development of diagnostics, vaccines, and therapeutics. More information can be found at [http://www.nih.gov/news-events/news-releases/nih-dedicates-cw-bill-young-center-biodefense-emerging-infectious-diseases](http://www.nih.gov/news-events/news-releases/nih-dedicates-cw-bill-young-center-biodefense-emerging-infectious-diseases).

**Microorganisms and/or toxins studied:** Select Agents (HHS, USDA), NIAID Category A pathogen

**Outdoor studies:** No outdoor studies of biological aerosols were conducted.
National biological defence research and development programmes

1. What is the name of the facility?
Dale and Betty Bumpers Vaccine Research Center (VRC)

2. Where is it located (include both address and geographical location)?
National Institutes of Health, Department of Health and Human Services
9000 Rockville Pike, Bethesda, Maryland 20892

3. Floor area of laboratory areas by containment level:
- BL2: 89 m²
- BL3: 0 m²
- BL4: 0 m²
Total laboratory floor area: 89 m²

4. The organizational structure of each facility.
   (i) Total number of personnel = 8
   (ii) Division of personnel:
        Military = 0
        Civilian = 8
   (iii) Division of personnel by category:
        Scientists = 8
        Engineers = 0
        Technicians = 0
        Administrative and support staff = 0
   (iv) List the scientific disciplines represented in the scientific/engineering staff.
        Biological Science
   (v) Are contractor staff working in the facility? If so, provide an approximate number.
        Contractor staff = 1
   (vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
        Department of Health and Human Services (HHS)
   (vii) What are the funding levels for the following programme areas:
        Research: $1,081,718
        Development: 0
        Test and evaluation: 0
   (viii) Briefly describe the publication policy of the facility:
        All researchers are encouraged to publish results in peer-reviewed open literature. The NIH Public Access Policy (http://publicaccess.nih.gov/) ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise form NIH funds to the National Library of Medicine’s PubMed Central digital archive upon acceptance for publication. To help advance science and improve human health, the policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.
(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.)


5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: The mission of the Vaccine Research Center (VRC) is to conduct research that facilitates the development of effective vaccines for human disease. The research focus of the Biodefense Research Section comprises three areas: development of vaccines and antivirals against hemorrhagic fever viruses such as Ebola, Marburg, and Lassa; studies of the mechanism of vaccine-induced immune protection and host immunity to natural infection; basic research to understand the mechanism of virus replication (entry) and neutralization. More information can be found at http://www.niaid.nih.gov/about/organization/vrc/pages/default.aspx/Pages/default.aspx.

Microorganisms and/or toxins studied: No U.S. Select Agents, NIAID Category A pathogens, or applicable simulants were used.

Outdoor studies: No outdoor studies of biological aerosols were conducted.
Form A, Part 2 (iii)

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Foreign Disease-Weed Science Research Unit

2. Where is it located (provide both address and geographical location)?
1301 Ditto Avenue, Fort Detrick, Maryland 21702

3. Floor area of laboratory areas by containment level (m²):
   - BSL-2: 105 m²
   - BSL-3: 950 m²
   - BSL-4: 0 m²
   Total laboratory floor area: 1,055 m²

4. The organizational structure of each facility:
   (i) Total number of personnel: 28
   (ii) Division of personnel:
       - Military: 0
       - Civilian: 28
   (iii) Division of personnel by category:
       - Scientists: 10
       - Engineers: 0
       - Technicians: 13
       - Administrative and support staff: 5
   (iv) List the scientific disciplines represented in the scientific/engineering staff:
       Agronomy, Biological Science, Genomics, Horticulture, Bacteriology, Microbial Forensics, Molecular Diagnostics, Plant Biochemistry, Plant Molecular Biology, Plant Pathology, Plant Physiology, Proteomics, Virology, Weed Science
   (v) Are contractor staff working in the facility? If so, provide an approximate number:
       No.
   (vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
       U.S. Department of Agriculture (USDA)
   (vii) What are the funding levels for the following program areas:
       - Research: $4,000,000
       - Development: $0
       - Test and evaluation: $0
       - Total: $4,000,000
   (viii) Briefly describe the publication policy of the facility:
       All scientific research data is available for publication in peer-reviewed publications after review for dual use determination. All scientists are required to have a minimum of two peer-reviewed publications per year. They are encouraged to present research at scientific conferences and to publish in books and proceedings. The USDA
Agricultural Research Service (ARS) maintains a searchable online database of publications by scientists at this location (available at http://www.ars.usda.gov/services/services.htm?modecode=80-44-05-00&locpubs=yes).

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):


5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

**Objectives:** The Foreign Disease-Weed Science Research Unit has two distinct missions united by a common relationship to plant pathology and the unit's unique BL-3 plant pathogen laboratory and greenhouse containment facilities. 1) The mission of the foreign disease program is to develop techniques for the rapid detection and identification of new and emerging crop pathogens, and to provide fundamental information on emerging pathogens for risk assessment and the development of practical phytosanitary regulations for the import and export of agricultural commodities and germplasm. 2) The mission of the weed biological control program is to collect foreign pathogens overseas from weeds in their native habitat, and to evaluate, characterize and release the pathogens in the U.S. for biological control of introduced weeds, leading to improved, sustainable weed control practices in agricultural systems with reduced dependence on chemical herbicides. Additional information about research projects conducted at this location is available at [http://www.ars.usda.gov/research/projects_programs.htm?modecode=80-44-05-00](http://www.ars.usda.gov/research/projects_programs.htm?modecode=80-44-05-00).

**Microorganisms and/or Toxins Studied:** Select Agents (Plant Protection and Quarantine, PPQ)

**Outdoor Studies:** No research work is done outdoors with infectious organisms.
National biological defence research and development programmes: Facilities

1. What is the name of the facility?
National Animal Disease Center (NADC)

2. Where is it located (provide both address and geographical location)?
1920 Dayton Avenue, Ames, Iowa 50010

3. Floor area of laboratory areas by containment level (m²):

<table>
<thead>
<tr>
<th>Containment Level</th>
<th>Floor Area (m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BSL-2</td>
<td>4,410</td>
</tr>
<tr>
<td>BSL-3</td>
<td>2,489</td>
</tr>
<tr>
<td>BSL-4</td>
<td>0</td>
</tr>
<tr>
<td>Total laboratory floor area</td>
<td>6,899</td>
</tr>
</tbody>
</table>

In addition NADC has unique animal biocontainment facilities ranging from ABSL-2 to ABSL-3Ag (highest biocontainment level that can accommodate food producing animals and various wildlife species). Biocontainment enhancements include HEPA-filtered supply air; dual HEPA filtered exhaust; air-tight doors; shower-in/out of each animal room; heat-treated waste; steam-treated rendering for carcasses; stainless steel penning and gating systems; epoxy-coated floors; and epoxy-covered surfaces. NADC also has two large biocontainment buildings that are considered ABSL-2-enhanced.

<table>
<thead>
<tr>
<th>Biocontainment Level</th>
<th>Floor Area (m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABSL-2</td>
<td>3,467.7</td>
</tr>
<tr>
<td>ABSL-3</td>
<td>160.5</td>
</tr>
<tr>
<td>ABSL-3Ag</td>
<td>1,581.6</td>
</tr>
<tr>
<td>Total biocontainment facility floor area</td>
<td>5209.8</td>
</tr>
</tbody>
</table>

4. The organizational structure of each facility:

   (i) Total number of personnel: 48

   (ii) Division of personnel:

   - Military: 0
   - Civilian: 48

   (iii) Division of personnel by category:

   - Scientists: 8
   - Engineers: 1
   - Technicians: 10
   - Administrative and support staff: 29

   (iv) List the scientific disciplines represented in the scientific/engineering staff:

   - Agricultural Engineering, Animal Science, Biochemistry, Bioinformatics, Biology, Biotechnology, Cell Biology, Clinical Immunology, Computational Biology, Ecology, Genetics, Genomics, Immunology, Infectious Disease, Mass Spectrometry, Microbiology, Molecular Biology, Pathogenesis, Pathology, Physiology, Prionology, Proteomics, Statistics, Structural Biology, Vaccine Evaluation, Veterinarian, Veterinary Clinical Research, Veterinary Medicine, Virology

   (v) Are contractor staff working in the facility? If so, provide an approximate number:

   - No

   (vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
U.S. Department of Agriculture (USDA)  
Department of Defense (DoD) – partly  
Department of Health and Human Services (HHS)  
Universities  
Private Sector Companies

(vii) **What are the funding levels for the following program areas:**

<table>
<thead>
<tr>
<th>Program Area</th>
<th>Funding Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research</td>
<td>$5,800,000</td>
</tr>
<tr>
<td>Development</td>
<td>$0</td>
</tr>
<tr>
<td>Test and evaluation</td>
<td>$0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$5,800,000</strong></td>
</tr>
</tbody>
</table>

(viii) **Briefly describe the publication policy of the facility:**

All scientific research data is available for publication in peer-reviewed publications after review for dual use determination. All scientists are required to have a minimum of two peer-reviewed publications per year. They are encouraged to present research at scientific conferences and to publish in books and proceedings. The USDA Agricultural Research Service (ARS) maintains a searchable online database of publications by scientists at this location (available at [http://www.ars.usda.gov/services/services.htm?modecode=50-30-20-00&locpubs=yes](http://www.ars.usda.gov/services/services.htm?modecode=50-30-20-00&locpubs=yes)).

(ix) **Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references):**


http://www.veterinaryresearch.org/content/46/1/69.

http://link.springer.com/article/10.1007/s10344-014-0890-4#/page-1


29. Neill JD, Dubovi EJ, Ridpath JF. 2015. Identification of amino acid changes in the envelope glycoproteins of bovine viral diarrhea viruses isolated from alpaca that may be involved in host adaptation. Veterinary Microbiology. 
http://dx.doi.org/10.1016/j.vetmic.2015.06.007.


http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4375345/

http://search.proquest.com/openview/1db3bf2d7bce0f12a3a857bfce6ca4fe/1?pq-origsite=gscholar


   http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=9760206&fileId=S1466252315000067

   http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=9760264&fileId=S1466252315000134


   http://europepmc.org/abstract/med/26198210


5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

**Objectives:** Support the control and eradication of national and international exotic, emerging, zoonotic, and endemic infectious diseases of animals through a comprehensive research program emphasizing basic and applied research in diagnostics, prevention, and control strategies, prediction of disease outbreaks, molecular epidemiology, and understanding disease pathogenesis. Specifically, the research programs aim to produce new research knowledge and technology to: prevent, reduce or eliminate losses from impaired performance and increased deaths and condemnations; develop more sensitive, specific and faster diagnostic tests; develop vaccines designed for the control and, when feasible, the eradication of disease; improve our understanding of the ecology and epidemiology of pathogens at the domestic animal-wildlife interface; and improve our understanding of the genetic and pathophysiologic basis of disease and pathogen virulence. This research provides government regulatory agencies and the livestock industries with improved intervention strategies against priority diseases. Additional information about research projects conducted at this location is available at http://www.ars.usda.gov/research/projects_programs.htm?modecode=50-30-20-00.

**Microorganisms and/or Toxins Studied:** Select Agents (Overlap, USDA)

**Outdoor Studies:** No research work is done outdoors with infectious organisms.
National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Southeast Poultry Research Laboratory

2. Where is it located (provide both address and geographical location)?
934 College Station Road, Athens, Georgia 30605

3. Floor area of laboratory areas by containment level (m²):
   - BSL-2: 1,138 m²
   - BSL-3: 624 m²
   - BSL-4: 0 m²
   Total laboratory floor area: 1,762 m²

4. The organizational structure of each facility:
   (i) Total number of personnel: 37
   (ii) Division of personnel:
       - Military
       - Civilian
       Total: 37
   (iii) Division of personnel by category:
       - Scientists: 10
       - Engineers: 0
       - Technicians: 18
       - Administrative and support staff: 9
   (iv) List the scientific disciplines represented in the scientific/engineering staff:
       Animal Science, Bioinformatics, Biological Science, Biotechnology, Cell Biology, Computational Biology, Epidemiology, Genetics, Genomics, Immunology, Microbiology, Molecular Biology, Molecular Diagnostics, Pathology, Public Health, Veterinary Medicine, Virology
   (v) Are contractor staff working in the facility? If so, provide an approximate number:
       No
   (vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
       U.S. Department of Agriculture (USDA)
       Department of Health and Human Services (HHS)
       Department of Defense (DoD) – partly
       Non-Profit Associations
       Private Sector Companies
       Department of State
   (vii) What are the funding levels for the following program areas:
       - Research: $3,700,000
       - Development: $0
       - Test and evaluation: $0
       Total: $3,700,000
(viii) Briefly describe the publication policy of the facility:
All scientific research data is available for publication in peer-reviewed publications after review for dual use determination. All scientists are required to have a minimum of two peer-reviewed publications per year. They are encouraged to present research at scientific conferences and to publish in books and proceedings. The USDA Agricultural Research Service (ARS) maintains a searchable online database of publications by scientists at this location (available at http://www.ars.usda.gov/services/services.htm?modecode=60-40-10-00&locpubs=yes).

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):


5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: Provide scientific solutions to national and international exotic, emerging and endemic poultry viral diseases through a comprehensive research program emphasizing basic and applied research in diagnostics, prevention, and control strategies; prediction of disease outbreaks; molecular epidemiology; and understanding of disease pathogenesis. Produce new research knowledge and technology to: prevent, reduce or eliminate losses from impaired performance and increased deaths and condemnations; develop more sensitive, specific and faster diagnostic tests; develop vaccines designed for the control and, when feasible, the eradication of disease; improve our understanding of the ecology and epidemiology of viruses at the wild bird-domestic poultry interface; and improve our understanding of the genetic and pathobiological basis of virulence. This research provides government regulatory agencies and the poultry industries with improved intervention strategies against poultry viral diseases. The Laboratory has one research unit that conducts biological defense work: Exotic and Emerging Avian Viral Diseases Research Unit. Additional information about research projects conducted at this location is available at http://www.ars.usda.gov/main/site_main.htm?modecode=60-40-10-00.

Microorganisms and/or Toxins Studied: Select Agents (USDA)

Outdoor Studies: No research work is done outdoors with infectious organisms.
Form B

BWC - Confidence Building Measure

Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins

United States of America
April 15, 2016
Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern

Human Infection with Novel Influenza A(H1N1)v:
On May 12, 2015, the U.S. National Focal Point was notified of a case of human infection with a novel influenza A(H1N1) variant virus.

On April 15, 2015, a 27 year-old male with medical history significant for tobacco use and obesity developed an acute respiratory illness in Ohio. He first sought healthcare on April 18, and was eventually hospitalized on April 20, 2015. While hospitalized, his clinical course was notable for pneumonia, respiratory failure, and cardiac arrest. He did not have evidence of bacterial infection secondary to his primary viral pneumonia. His condition continued to worsen over the course of his hospitalization and he died on April 27, 2015.

A lower respiratory tract specimen obtained on April 21, 2015, yielded initial results positive for influenza A(H1N1)pdm09 virus (a seasonal influenza virus) on multiplex testing done on April 21, 2015, but subsequent RT-PCR testing at the state public health laboratory on April 30, 2015 was suggestive of a novel influenza A virus. Additional RT-PCR testing conducted at CDC on May 2, 2015, confirmed infection with an H1N1v virus of classical swine origin. Subsequent partial genetic sequencing conducted at CDC on May 3, 2015, indicated infection with an A(H1N1)v virus similar to influenza A(H1N1) viruses currently circulating in swine.

This was the first variant influenza virus infection reported in the United States in 2015. Since reporting of novel influenza viruses became nationally notifiable in 2005, 20 cases of H1N1v, including this one, have been reported to CDC. This is the first H1N1v-associated fatality.

The patient worked at a livestock facility that housed cattle and swine but did not have direct contact with swine in the week prior to his illness onset, according to his employer. No illness was reported in the patient’s household or close contacts, his co-workers, or the healthcare workers who cared for him during his illness. An investigation into the source of the patient’s infection and to determine if there were other epidemiologically-linked cases of H1N1v virus infection was conducted. Further genetic sequencing of the virus was also conducted at CDC.

Swine-origin influenza A viruses currently circulate among North American swine herds. Human infections with these viruses (i.e., variant virus infections) are rarely detected, and cases usually occur following direct or close contact with pigs. Since 2005, a total of 379 variant virus infections have been identified in the United States; the current case was only the second variant influenza fatality reported. There has been limited, non-sustained human-to-human transmission of variant influenza viruses, but no ongoing community transmission has been identified.

Human Infection with Novel Influenza A (H3N2v):
On July 29, 2015, the U.S. National Focal Point was notified of a case of human infection with influenza A (H3N2) variant (H3N2v) virus.

On July 3, 2015, a 10 year-old male with medical history significant for cancer (and immune compromise subsequent to chemotherapy) developed an acute respiratory illness in Minnesota. He was hospitalized for his illness on July 3, and on July 6, treatment with oseltamivir was initiated. An upper respiratory tract specimen obtained on July 6, 2015, yielded results consistent with an H3N2v virus on RT-PCR testing conducted at the state public health laboratory on July 16, 2015. Additional RT-PCR testing conducted at CDC on July 20, 2015, confirmed infection with an H3N2v virus. This was the first H3N2v virus infection reported in the United States in 2015.

The patient’s family resides on a farm with swine, and the patient reported direct contact with swine in the week prior to his illness onset. No illness was reported in the patient’s household or close contacts or in healthcare workers caring for him during his illness. An investigation into the source of the patient’s infection and to determine if there are other epidemiologically-linked cases of H3N2v virus infection was conducted. Additional laboratory testing, including genetic sequencing of the virus, was conducted at CDC.

Swine influenza is a respiratory disease of pigs caused by influenza A viruses that regularly cause outbreaks of influenza in pigs. Human infections with these viruses (i.e., variant virus infections) are rarely detected and usually only occur in people with exposure to infected pigs. There has been limited, non-sustained, human-to-human transmission of variant influenza viruses, and no ongoing community transmission has been identified. General information about variant and swine influenza is available [http://www.cdc.gov/flu/swineflu/index.htm](http://www.cdc.gov/flu/swineflu/index.htm).
Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern

Inadverted Shipment of Live *Bacillus anthracis* to Laboratories in Multiple U.S. and Overseas Locations:
On May 31, 2015, the U.S. IHR National Focal Point officially reported an inadvertent shipment of live *Bacillus anthracis* (anthrax) to laboratories in multiple U.S. and overseas locations. Although this event did not meet at least two criteria for an IHR Article 6 notification and did not constitute a public health emergency of international concern, the United States shared this information under Article 7, regarding an unexpected event for the information of member Nations.

The U.S. Department of Defense (DoD) collaborated with the U.S. Centers for Disease Control and Prevention (CDC) to investigate an inadvertent shipment of live anthrax samples from a DoD laboratory to laboratories in multiple U.S. states and overseas locations. The DoD Chemical and Biological Defense Program (CBDP) develops medical and physical countermeasures to protect the warfighter and the nation from chemical and biological threats. As part of this mission, DoD regularly ships inactivated or “killed” biological materials for countermeasure development by industry, academia, and other federal laboratories.

On May 22, 2015, CDC was notified by a biotechnology company in Maryland, reporting that it had been able to culture small amounts of live anthrax bacteria from samples sent to them as part of a DoD test, although all samples were supposed to have been inactivated. CDC, as the nation’s public health lead and regulatory authority for biological select agents and toxins, began working with DoD, private laboratories, state officials, and the Federal Bureau of Investigation (FBI) to investigate all laboratories known to have received this suspect sample. Ultimately, laboratory samples of anthrax that were thought to have been killed, but were later found to contain a small amount of live anthrax, were sent by a DoD laboratory to 194 laboratories and 9 countries.

As part of CDC’s response, CDC
- Ensured that people were safe, by working with state health departments to identify potentially exposed workers, assess their health risk, and offer treatment when appropriate;
- Developed recommendations for effective decontamination of laboratories, in collaboration with the Environmental Protection Agency (EPA); and
- Secured the samples of live anthrax inadvertently sent to places not approved to have live anthrax or any select agent, to prevent any further potential exposures.

CDC does not suspect any risk to the general public. There are no suspected or confirmed cases of anthrax infection in potentially exposed laboratory workers.

The Federal Select Agent Program (FSAP), jointly comprised of CDC’s Division of Select Agents and Toxins (DSAT) and the United States Department of Agriculture’s (USDA) Animal and Plant Health Inspection Service (APHIS), Agriculture Select Agent Services (AgSAS), issued a moratorium on the use and transfer of inactivated *B. anthracis* to prevent inadvertent exposure until safer and more effective procedures regarding inactivated *B. anthracis* can be developed based on the interagency scientific discussion and research into the matter.

FSAP also developed a policy regarding the “Inactivation of *Bacillus anthracis*” (http://www.selectagents.gov/policystatement_bacillus.html). The policy states that all vegetative cell and spore preparations of *Bacillus anthracis* strains will be regulated as select agents. HHS and USDA plan to publish Notices of Proposed Rulemaking (NPRM) in the Federal Register in 2016 requesting public comment on proposed biosafety requirements, including specific provisions for the inactivation of select agents. Until consistently safe and effective procedures for inactivation and sterility testing can be established, select agent strains of *Bacillus anthracis* that have been through inactivation procedures will remain select agents as stated in the FSAP policy.
As a result of this incident, DoD conducted its own investigation concerning performance and accountability. DoD took this matter very seriously and acted with urgency to address this matter within Deputy Secretary of Defense Work’s 30-day timeline. DoD will update this notification with timely, accurate, and sufficiently detailed information as appropriate, including after the CDC and internal DoD investigations are complete or if the Department determines that the status regarding Article 7 changes.

More information regarding this matter is available at:
Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern

Measles Outbreak:
On February 10, 2015, the IHR Program was notified of a potential public health emergency of international concern (PHEIC) involving a large multi-state measles outbreak that started in California in December 2014 and spread to at least 6 additional states, including Arizona, Colorado, Nebraska, Oregon, Washington, and Utah.

A provisional total of 147 cases, reported between December 28, 2014 and March 2, 2015, were linked to the outbreak associated with these Disney parks in seven states: (CA 131, AZ 7, CO 1, NE 2, OR 1, UT 3, WA 2). The confirmed cases include Disneyland employees. In addition, other cases visited these Disney parks while infectious in early January. No source case for the outbreak was identified.

Genotyping of patient samples indicated measles virus strain B3, which has also been detected in at least 14 countries and at least 6 U.S. states. Other genotypes reported from U.S. outbreaks in 2015 were D8, and D9; genotypes H1 and D4 were detected in isolated importations.

CDC Division of Viral Diseases provided technical expertise and assisted states with active case investigation, including laboratory confirmation and genotyping, and contact tracing. In addition, the DVD team served as subject matter experts for media interviews, clinician outreach calls, and inquiries from HHS and the general public. CDC’s Division of Global Migration and Quarantine (DGMQ) worked with local, state, and international partners, as well as with the airlines to obtain the passenger manifests from the flights to help identify, locate, and interview contacts.

http://www.cdc.gov/measles/cases-outbreaks.html
**Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern**

**Lassa Fever:**
On May 25, 2015, the U.S. IHR National Focal Point became aware of a fatal case of Lassa Fever.

On May 25, 2015, PAHO/WHO was informed that the United States Center for Disease Control and Prevention (CDC) and the New Jersey Department of Health had diagnosed and confirmed a fatal case of Lassa fever in a person returning to the United States from Liberia. The patient traveled from Liberia to Morocco to JFK International Airport on May 17, 2015. The patient did not have a fever on departure from Liberia, did not report symptoms such as diarrhea, vomiting, or bleeding during the flight, and when his temperature was taken on arrival in the United States, he did not have a fever at that time. On May 18, 2015, the patient went to a hospital in New Jersey with symptoms of a sore throat, fever, and tiredness. According to the hospital, he was asked about his travel history and he did not indicate travel to West Africa. The patient was sent home the same day, and on May 21, he returned to the hospital when his symptoms worsened. On May 23, the travel history was revealed and the patient was transferred to a treatment center prepared to treat viral hemorrhagic fevers.

Samples submitted to CDC tested positive for Lassa fever on May 25, 2015. Tests for Ebola and other viral hemorrhagic fevers were negative. The patient was in appropriate isolation when he died on May 25, 2015. During the deployment in Newark, New Jersey, CDC worked with public health officials to communicate with the health workers and other personnel from the hospitals, advise on procedures and personal protective equipment, procedures for dealing with the body and the remaining specimens, to generate a list of patient contacts. Those identified as close contacts were monitored for 21 days for symptoms.

[http://www.cdc.gov/media/releases/2015/p0525-lassa.html](http://www.cdc.gov/media/releases/2015/p0525-lassa.html)
Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern

Listeria monocytogenes infections linked to pre-packaged caramel apples made from whole apples:

On January 16, 2015, the U.S. National Focal Point was notified of 32 human cases of *Listeria monocytogenes* infection linked to whole apples from Bidart Bros. used in commercially produced, pre-packaged caramel apples.

By February 12, 2015, a total of 35 people infected with the outbreak strains of *Listeria monocytogenes* had been reported from 12 states. Thirty-four ill people were hospitalized, and seven deaths were reported. Listeriosis contributed to at least three of these deaths. A total of 11 (31%) illnesses were pregnancy-related (occurred in a pregnant woman or her newborn infant), with one illness resulting in a fetal loss. Three invasive illnesses (meningitis) were among otherwise healthy children aged 5–15 years. A total of 28 (90%) of the 31 ill people interviewed reported eating commercially produced, prepackaged caramel apples before becoming ill.

CDC and the FDA recommended that consumers not eat commercially produced, prepackaged caramel apples that were recalled or made with Bidart Bros. apples, and retailers should not sell or serve them. CDC and FDA also recommend that consumers not eat any recalled Granny Smith and Gala apples produced by Bidart Bros. This investigation is now closed, and the shelf life of recalled products has passed.

[http://www.cdc.gov/listeria/outbreaks/caramel-apples-12-14/](http://www.cdc.gov/listeria/outbreaks/caramel-apples-12-14/)
Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern

Listeria monocytogenes infections linked to Blue Bell Creameries:
On April 23, 2015, the U.S. National Focal Point was notified of 10 cases of Listeria monocytogenes infection linked to ice cream and other frozen products from Blue Bell Creameries.

In March 2015, Blue Bell Creameries of Brenham, Texas, voluntarily recalled certain ice cream products potentially contaminated with Listeria monocytogenes. On April 20, 2015, the firm expanded its recall to include all of its products that were currently on the market because they also had the potential to be contaminated with Listeria monocytogenes. This recall included ice cream, frozen yogurt, sherbet and frozen snacks made at all Blue Bell facilities.

A total of ten people with listeriosis related to this outbreak were reported in the United States. Illness onset dates ranged from January 2010 to January 2015. Five cases were identified at a single hospital and the other five cases were identified through a retrospective review of the PulseNet database for DNA fingerprints that were similar to isolates collected from Blue Bell ice cream samples. All ten (100%) patients were hospitalized, and three deaths were reported. Several strains of Listeria monocytogenes were involved in this outbreak.

The U.S. Food and Drug Administration (FDA) received information regarding international distribution of the recalled products and notified government authorities of all of the following affected countries:

Belize, British Overseas Territories (Anguilla, Bermuda, Montserrat, Tortola, and Turks and Caicos), Chile, China, Dominica, Dominican Republic, Egypt, Haiti, Jordan, Kuwait, Mexico, Oman, Panama, Peru, Philippines, Qatar, St. Kitts and Nevis, Saudi Arabia, Trinidad and Tobago, United Arab Emirates, and Yemen.

FDA and the CDC recommended that consumers not eat recalled Blue Bell brand ice cream or frozen products and institutions and retailers should not sell or serve them. This investigation is now closed. However, people could continue to get sick because recalled products may still be in consumer freezers and consumers unaware of the recalls could eat them. Institutions should not serve and retailers should not sell recalled products.

From the U.S. FDA: http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm438104.htm

From the U.S. CDC: http://www.cdc.gov/listeria/outbreaks/ice-cream-03-15/index.html
Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern

Zika virus:
The U.S. National Focal Point was notified of a case of Zika virus on December 16, 2015.

On December 16, 2015, the Territorial Epidemiologist of the Puerto Rico Department of Health (PRDH) received a report of a laboratory-confirmed case of Zika virus disease in the Commonwealth of Puerto Rico.

The patient was an 80 year-old male resident of Humacao, Puerto Rico, who was hospitalized in the Veterans Administration (VA) Hospital in San Juan, Puerto Rico, in early December 2015. He reported lethargy, diarrhea, anorexia, headache, and body pain that began on November 25. The patient was found to have thrombocytopenia and renal failure in the hospital but recovered and was discharged. Per VA staff, the patient reported no travel history outside of Puerto Rico in the two weeks prior to his illness onset and testing for other etiologies was negative. A blood sample obtained on December 2 was positive for Zika viral RNA by RT-PCR at the Public Health Reference Laboratory for the Department of Veterans Affairs. Subsequent sequencing of the envelope gene was 98-99% homologous with the Asian strain. Sequencing of the patient sample at the CDC confirmed Zika virus.

The Puerto Rico Department of Health interviewed the patient and confirmed no history of travel outside the island in the prior 3 months. Epidemiological investigations were conducted to determine the source of exposure and to identify possible additional cases. Vector control efforts that were initiated, and are still underway, included inspections to identify mosquito breeding sites. The public was also urged to take preventive measures to avoid mosquito bites.

Background:
In May 2015, the World Health Organization reported the first local transmission of Zika virus in the Western Hemisphere, with autochthonous cases identified in Brazil. Since then, local transmission has been identified in 21 additional countries and territories in the Americas including the U.S. Virgin Islands. Further expansion of these outbreaks and spread to other countries in the region is likely.

Zika virus is a mosquito-borne flavivirus transmitted primarily by *Aedes aegypti* mosquitoes. This vector also transmits dengue and chikungunya viruses and is found throughout much of the Americas, including parts of the United States. Humans are the primary amplifying host for Zika virus and approximately 20% of infected persons develop symptomatic disease. The most common clinical findings are acute onset of rash and fever. Additional symptoms can include arthralgia, myalgia, and headaches. Mortality and severe disease is rare.

No specific treatment, vaccine, or preventive drug is available. Treatment is palliative and can include rest, fluids, and use of analgesics and antipyretics. Most patients’ symptoms improve within one week. Guillain-Barre Syndrome has been reported following Zika virus infections and a possible association between maternal infection with Zika virus and subsequent microcephaly in infants is being investigated. The best way to prevent Zika virus infection is to avoid mosquito bites: use air conditioning or screens when indoors, use insect repellents, and wear long sleeves and pants when outdoors. Persons infected with Zika virus should be protected from mosquito exposure during the first week of illness to prevent further spread of the virus.

On February 1, 2016, the World Health Organization declared a Public Health Emergency of International Concern (PHEIC) because of clusters of microcephaly and other neurological disorders in some areas affected by Zika. As of Feb, 16, 2016, CDC remains actively engaged in response to outbreaks of Zika occurring in the Americas and increased reports of birth defects and Guillain-Barré syndrome in areas affected by Zika.

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern

Summary of Reports: In 2015, the United States submitted two World Organization for Animal Health (OIE) immediate reports for animal disease events that deviated from the normal pattern. These included one low pathogenic notifiable avian influenza report and one highly pathogenic avian influenza (HPAI) report. Event summaries can be found on the OIE website: http://web.oie.int/wahis/public.php. Summaries are organized by the year of their occurrence. Even though the OIE removed vesicular stomatitis virus from its OIE-listed diseases for 2015, a significant event occurred in the United States in 2015 and is reported here.

2015 immediate reports:

Notifiable Avian Influenza
Avian influenza (AI) is caused by influenza type A viruses which can infect poultry (such as chickens, turkeys, pheasants, quail, domestic ducks, geese, and guinea fowl) and are carried by free-flying waterfowl such as ducks, geese, and shorebirds. AI viruses are classified by a combination of two groups of proteins: hemagglutinin or “H” proteins, of which there are 16 (H1-H16), and neuraminidase or “N” proteins, of which there are 9 (N1-N9). Many different combinations of “H” and “N” proteins are possible. Each combination is considered a different subtype, and each subtype can be further sub-classified as different strains. AI viruses are identified by their pathogenicity (low or high)—the ability of a particular virus strain to produce disease in domestic chickens. Any influenza A virus (including H5 and H7 avian influenza viruses) in its high pathogenic form is reportable in birds, but only H5 and H7 low pathogenic avian influenza viral infections in poultry are notifiable as per Chapter 10.4 on avian influenza of the OIE Terrestrial Animal Health Code (2015): http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_avian_influenza_viruses.htm.

Low Pathogenic Avian Influenza (LPAI), H7N3
OIE Immediate Report March 17, 2015 –Resolved August 18, 2015
Low pathogenic notifiable avian influenza H7N3 was detected in a commercial tom (male) turkey flock located in Merced County, California. The USDA Animal and Plant Health Inspection Service (APHIS) and the California Department of Food and Agriculture (CDFA) completed a comprehensive epidemiological investigation of the event. The turkey flock was depopulated and appropriate cleaning and disinfection (C&D) of the premises completed. All follow-up surveillance and testing for influenza A virus was negative.

Highly Pathogenic Avian Influenza (HPAI), H5N1
HPAI H5N1 was detected in hunter-harvested wild birds in Whatcom County, Washington. The HPAI H5N1 wild bird event (reported to OIE in 2015) was identified as part of the increased avian influenza surveillance of wild birds, and related to the 2014 ongoing H5N8 and H5N2 HPAI events. Required enhanced AI surveillance throughout the United States did not identify any other detections of this novel HPAI EA/AM H5N1-reassortant virus. This novel HPAI EA/AM H5N1-reassortant virus was not found in any poultry, commercial or backyard, anywhere in the United States.

2014 OIE immediate reports resolved in 2015:

Highly Pathogenic Avian Influenza (HPAI), H5N8
USDA APHIS, in conjunction with state departments of agriculture and wildlife, conducted a comprehensive epidemiological investigation and enhanced surveillance (including wild bird surveillance of hunter-harvested birds) in response to the HPAI H5N8 and H5N2 wild bird related events. Novel avian influenza virus of Eurasian
origin (EA-H5N8 clade 2.3.4.4) spread rapidly along wild bird migratory pathways during 2014 -2015. Introduction of this EA-H5N8 virus into the Pacific Flyway sometime during 2014 has allowed mixing with North American (AM) lineage viruses and generated new combinations with genes from both EA and AM origin (or “reassortant” viruses) such as the EA/AM H5N2-reassortant detected in Canada and the United States. These findings are not unexpected as the EA-H5N8 virus continues to circulate. The EA H5 clade 2.3.4.4 viruses are highly pathogenic for poultry.

All control areas have been released and outbreaks concluded the HPAI H5N8 event. The required surveillance in the state and control areas has been completed with negative results for HPAI; the depopulation of infected premises has been completed and appropriate disposal was completed; cleaning and disinfecting of the infected premises has been completed (including, but not limited to, outside areas of premises, equipment, trucks, and other fomites); and no recent HPAI detections through wild bird surveillance have been made.

**Highly Pathogenic Avian Influenza (HPAI), H5N2**

OIE Immediate Report December 16, 2014—Resolved November 18, 2015

USDA APHIS, in conjunction with state departments of agriculture and wildlife, conducted a comprehensive epidemiological investigation and enhanced surveillance (including wild bird surveillance of hunter-harvested birds) in response to the HPAI H5N8 and H5N2 wild bird related events. Novel avian influenza virus of Eurasian origin (EA-H5N8 clade 2.3.4.4) spread rapidly along wild bird migratory pathways during 2014 -2015. Introduction of this EA-H5N8 virus into the Pacific Flyway sometime during 2014 has allowed mixing with North American (AM) lineage viruses and generated new combinations with genes from both EA and AM origin (or “reassortant” viruses) such as the EA/AM H5N2-reassortant detected in Canada and the United States. These findings are not unexpected as the EA-H5N8 virus continues to circulate. The EA H5 clade 2.3.4.4 viruses are highly pathogenic for poultry.

All control areas have been released and outbreaks closed in the HPAI H5N2 event. The required surveillance in the state and control areas has been completed with negative results for HPAI; the depopulation of infected premises has been completed and appropriate disposal was completed; cleaning and disinfection of the infected premises has been completed (including, but not limited to, outside areas of premises, equipment, trucks, and other fomites); and no recent HPAI detections through wild bird surveillance have been made.

**Other outbreaks:**

**Vesicular stomatitis virus**

Vesicular stomatitis is an insect-transmitted acute disease, primarily of horses, cattle, and pigs, with less frequent infections of sheep and goats, and characterized by the formation of vesicles on the snout, mouth, udder, and feet. The causative agent is vesicular stomatitis virus (VSV), a member of the genus *Vesiculovirus* in the family *Rhabdoviridae*. The OIE removed VSV from its OIE-listed diseases for 2015. Vesicular stomatitis will continue to be a reportable disease in the United States because of its clinical similarity with foot-and-mouth disease (FMD) in cloven-hoofed animals.

The 2015 VSV outbreak in the United States began April 29, 2015, and the last VSV-affected premises was identified in January 2016. To date, a total of 823 VSV-affected premises (New Jersey serotype) have been confirmed or suspected in 8 U.S. states; Arizona (36 premises in 3 counties), Colorado (441 premises in 36 counties), Nebraska (38 premises in 10 counties), New Mexico (52 premises in 13 counties), South Dakota (50 premises in 7 counties), Texas (4 premises in 4 counties), Utah (56 premises in 8 counties), and Wyoming (146 premises in 10 counties). Currently, there is one premises remaining under quarantine in one state (Colorado).
Form C

BWC - Confidence Building Measure

Encouragement of Publication of Results and Promotion of Use of Knowledge

United States of America

April 15, 2016
| Department of Health and Human Services (HHS) Open Government Plan  
http://www.hhs.gov/open/plan | The key principles of Open Government are transparency, collaboration, and participation. |
|-------------------------------|----------------------------------------------------------------------------------------------------------|
| HHS Strategic Plan 2014-2018  
http://www.hhs.gov/secretary/about/priorities/priorities.html | The plan describes HHS' work to address complex, multifaceted, and ever-evolving health and human service issues. Goal 4 of this plan is to Increase Efficiency, Transparency, Accountability, and Effectiveness of HHS Programs. |
| National Institutes of Health (NIH) Data Sharing Policy and Implementation Guide  
http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm | This guidance provides the National Institutes of Health (NIH) policy statement on data sharing and additional information on the implementation of this policy. |
| Centers for Disease Control and Prevention (CDC) Policy on Releasing and Sharing Data  
http://www.cdc.gov/maso/Policy/ReleasingData.pdf | Public health and scientific advancement are best served when data are shared with public health agencies and academic researchers in an open, timely, and appropriate way. |
| The Journal Emerging Infectious Diseases  
http://wwwnc.cdc.gov/eid/ | Emerging Infectious Diseases is an open access, peer-reviewed journal published by the Centers for Disease Control and Prevention (CDC). |
| The Morbidity and Mortality Weekly Report (MMWR)  
http://www.cdc.gov/mmwr/ | CDC’s primary vehicle for scientific publication of reliable, authoritative, objective, and useful public health information and recommendations; open access. |
| The Excellence in Science Committee (EISC) at the CDC  
http://www.cdc.gov/od/science/excellence/ | The EISC fosters, supports, and protects an environment for the promotion of scientific integrity, quality assurance, and the rapid dissemination of scientific innovations, technology, and information with the ultimate goal of improving public health. |
| CDC Office of Science Quality (OSQ)  
http://www.cdc.gov/od/science/quality/ | The OSQ is responsible for increasing the impact of CDC research and science by promoting standards and recommended practices for scientific quality, relevance, credibility, transparency, and utility within the agency and throughout the public health community (e.g., authorship, scientific clearance, peer review, and extramural research policies). |
| Advancing Excellence and Integrity of CDC Science  
http://www.cdc.gov/od/science/ | The Office of the Associate Director for Science's mission is to strengthen the quality, integrity, and relevance of CDC's science and health impact |
| Office of Scientific Integrity (OSI)  
http://www.cdc.gov/od/science/integrity/ | OSI ensures that CDC science and research activities comply with various federal laws, regulations, and policies; coordinates the agency’s 301(d) and 308(d) confidentiality protections; ensures leadership in public health ethics; and provides trainings to promote a well-educated and |
<table>
<thead>
<tr>
<th>Resource</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Public Health Image Library (PHIL)</strong></td>
<td>The PHIL offers an organized, electronic gateway to CDC images for reference, teaching, presentation, and public health messages; open access.</td>
</tr>
<tr>
<td><strong>U.S. Food and Drug Administration (FDA) Publications Database</strong></td>
<td>An actively updated and searchable research publications database for all FDA publications.</td>
</tr>
<tr>
<td><strong>FDA Office of Science and Engineering Laboratories (OSEL) Annual Report</strong></td>
<td>The OSEL Annual Report provides current information about the Office's organization and intramural science activities; provides a summary of the Office's direct laboratory support for pre-market review and compliance cases; and provides a bibliography of scientific publications, presentations, and research seminars for the fiscal year.</td>
</tr>
<tr>
<td><a href="http://www.fda.gov/AboutFDA/Offices/OfficeofMedicalProductsandTobacco/CDRH/CDRHHistoricalReports/ucm109778.htm">http://www.fda.gov/AboutFDA/Offices/OfficeofMedicalProductsandTobacco/CDRH/CDRHHistoricalReports/ucm109778.htm</a></td>
<td></td>
</tr>
<tr>
<td><strong>FDA Center for Biologics Evaluation and Research (CBER)</strong></td>
<td>This CBER website provides links to the strategic plan for regulatory science and research, general information about research programs, as well as highlights from selected research publications.</td>
</tr>
<tr>
<td><a href="http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/default.htm">http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/default.htm</a></td>
<td></td>
</tr>
<tr>
<td><strong>PubMed Central (PMC)</strong></td>
<td>PMC is the National Library of Medicine’s digital archive. Final peer-reviewed manuscripts that arise from NIH funds are accessible to the public on PMC no later than twelve months after publication; open access.</td>
</tr>
<tr>
<td><strong>The National Institutes of Health (NIH) Public Access Policy</strong></td>
<td>The NIH Public Access Policy ensures that the public has access to the published results of NIH funded research.</td>
</tr>
<tr>
<td><strong>Agricultural Research Magazine</strong></td>
<td>The Agricultural Research Magazine is the USDA’s science magazine published by the Agricultural Research Service (ARS); open access.</td>
</tr>
<tr>
<td><a href="http://www.ars.usda.gov/is/AR/">http://www.ars.usda.gov/is/AR/</a></td>
<td></td>
</tr>
</tbody>
</table>
Declaration of legislation, regulations and other measures

United States of America

April 15, 2016
Form E

<table>
<thead>
<tr>
<th>Relating to</th>
<th>Legislation</th>
<th>Regulations</th>
<th>Other measures</th>
<th>Amended since last year</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Development, production stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>(b) Exports of micro-organisms\textsuperscript{10} and toxins</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes [1]</td>
</tr>
<tr>
<td>(c) Imports of micro-organisms\textsuperscript{11} and toxins</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes [2]</td>
</tr>
<tr>
<td>(d) Biosafety\textsuperscript{11} and biosecurity\textsuperscript{12}</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes [3]</td>
</tr>
</tbody>
</table>

[1] Amendments re: (b) Exports of micro-organisms and toxins:

**Implementation of the Australia Group (AG) November 2013 Intersessional Decisions**

This regulation was published in the June 16, 2015 Federal Register (80 FR 34266) and amends the Commerce Control List (CCL) entry in the Export Administration Regulations (EAR) that controls certain human and zoonotic pathogens and toxins, and removes the CCL entry that controls certain animal pathogens to reflect the merger of two AG common control lists based on recommendations presented at the Australia Group (AG) Intersessional meeting in 2013, and adopted in 2014. As a result, the AG “List of Animal Pathogens for Export Control” was merged with the AG “List of Biological Agents for Export Control,” creating a single AG common control list for these items (i.e., the AG “List of Human and Animal Pathogens and Toxins for Export Control”). The scope of the controls on these human and animal pathogens and toxins was not affected by the merger of the two lists into a single AG common control list. This rule also makes conforming amendments to other provisions in the EAR to reflect these changes. This rule does not contain changes based on the understandings reached at the June 2014 AG Plenary meeting, because no amendments to the EAR were required as a result of these understandings.


**Implementation of the Australia Group (AG) November 2013 Intersessional Decisions; Correction**

This technical corrections rule was published in the September 18, 2015 Federal Register (80 FR 34266) to amend the Export Administration Regulations (EAR) to correct typographical errors contained in a final rule published in the Federal Register on June 16, 2015 (80 FR 34266). The Note to ECCN 1C351.a.4 in that final rule incorrectly referenced ECCN 1C352.a.4, instead of ECCN 1C351.a.4. This rule corrects the Note to ECCN 1C351.a.4 to read as follows: “Avian influenza (AI) viruses of the H5 or H7 subtype that do not have either of the characteristics described in 1C351.a.4 (specifically, 1C351.a.4.a or a.4.b) should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0). If the amino acid motif is similar to that observed for other HPAI isolates, then the isolate being tested should be considered as HPAI and the virus is controlled under 1C351.a.4.” The corrections to this Note do not affect the

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\textsuperscript{9} Including guidelines.

\textsuperscript{10} Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

\textsuperscript{11} In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.

\textsuperscript{12} In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.
scope of the controls described in ECCN 1C351.a.4.

[2] Amendments re: (c) Imports of micro-organisms and toxins

Federal Select Agency Program Policy Statement: When APHIS and CDC Import Permits Not Required for the Importation or Interstate Transportation of Select Agents
http://www.selectagents.gov/regpermits.html

[3] Amendments re: (d) Biosafety and biosecurity

Federal Select Agent Program (FSAP) Policy Statement: Inactivated Bacillus anthracis
Although non-viable select agents are excluded from the select agent regulations, it has been observed that some inactivation protocols previously used may not inactivate Bacillus anthracis spores completely, necessitating issuance of this policy statement. Unless waived by the Animal and Plant Health Inspection Service (APHIS) Administrator or Department of Health and Human Services (HHS) Secretary, it is the policy of the FSAP that all vegetative cell and spore preparations of Bacillus anthracis strains regulated as select agents that were subject to an inactivation procedure on or after June 2, 2015 are considered a select agent and the storage, transfer, or work with this material must comply with regulations found at 42 CFR 73 and 9 CFR 121 until a more comprehensive protocol for inactivation of B. anthracis can be established and validated. This time period was selected based on the date the Federal Select Agent Program (FSAP) issued a moratorium to entities that produces and ships inactivated B. anthracis to other laboratories. Possession of such material by an entity not registered to possess the regulated strain of B. anthracis or located in a room not listed on a registered entity’s registration must be reported within 24 hours of discovery to the FSAP. Additional information is available at http://www.selectagents.gov/policystatement_bacillus.html.

New White House Memorandum on Biosafety and Biosecurity Measures
On October 29, 2015, the White House released a memorandum from Assistants to the President John Holdren and Lisa Monaco on the next steps to enhance biosafety and biosecurity in the United States. The memo highlights the conduct of parallel federal and broad stakeholder reviews to generate specific recommendations to strengthen the U.S. government's biosafety and biosecurity practices and oversight system (https://www.whitehouse.gov/sites/default/files/docs/10-2015_biosafety_and_biosecurity_memo.pdf)

Federal Experts Security Advisory Panel and Fast Track Action Committee on the Select Agent Regulations
On October 29, 2015, the United States government released two sets of recommendations and implementation plans from the Federal Experts Security Advisory Panel (FESAP, which conducted an internal U.S. Government review of biosafety and biosecurity practices) and from the Fast Track Action Committee on Select Agent Regulations (FTAC-SAR, which conducted an external review that focused on the effects of the select agent regulations on researchers and laboratories). Recommendations made by both the FESAP and FTAC-SAR address culture of responsibility, oversight, outreach and education; applied biosafety research; incident reporting; material accountability; inspection processes; and regulatory changes and guidance to improve biosafety and biosecurity. In addition, an approach was identified to determine the appropriate number of high-containment U.S. laboratories required to possess, use, or transfer biological select agents and toxins. More information is available on the FESAP website at: http://www.phe.gov/Preparedness/legal/boards/fesap/Pages/default.aspx.

The U.S. Government has developed a plan to implement the FESAP and FTAC-SAR recommended actions, available at: http://www.phe.gov/s3/Documents/fesap-ftac-ip.pdf. The U.S. Government expects that implementing the FESAP and FTAC-SAR recommended actions will strengthen biosafety and biosecurity practices and oversight activities. The Administration is committed to fostering progress in the life sciences while
ensuring that work is conducted in a safe and secure manner. A summary is available at:  

Workshop on Stakeholder Engagement on the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC)  
On September 24, 2014, the USG released the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC). The Policy addresses institutional oversight of DURC, which includes policies, practices, and procedures to ensure DURC is identified and risk mitigation measures are implemented, where applicable. The White House Office of Science and Technology Policy and the National Institutes of Health co-hosted a public workshop on July 22, 2015, for institutional stakeholders to discuss implementation of the 2014 policy; to inform and engage stakeholders; to collect feedback about resources needed for implementation; and to discuss stakeholder experiences, challenges, and innovative practices. Information about the workshop and DURC educational materials are available at:  
http://www.phe.gov/about/OPP/DURCworkshop/Pages/overview.aspx
Form F

BWC - Confidence Building Measure

Declaration of Past Activities in Offensive and/or Defensive Biological Research and Development Programmes

United States of America

April 15, 2016
Declaration of Past Activities in Offensive and/or Defensive Biological Research and Development Programmes

1. Date of entry into force of the Convention for the State party
   26 March 1975

2. Past offensive biological research and development programmes:
   Nothing new to declare
Form G
BWC - Confidence Building Measure

Declaration of Vaccine Production Facilities

United States of America
April 15, 2016
The U.S. Food and Drug Administration publishes a current list of human vaccines licensed in the United States, including associated production facilities. This list is available at: [http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm](http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm).

Data provided on CBM Form G are excerpted from the publicly available website listed above (as accessed on February 3, 2016). Trade names are included when provided by the manufacturer. Specific and current information about a vaccine, and contact information for the manufacturer, are available by following the hyperlinks provided on the above website.

<table>
<thead>
<tr>
<th>1. Name of facility</th>
<th>Barr Laboratories, Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Location (Mailing Address)</td>
<td>1235 Mays Mill Road, Forrest, Virginia 24551</td>
</tr>
<tr>
<td>3. General description of the types of diseases covered:</td>
<td>Acute respiratory disease caused by Adenovirus Type 4 and Type 7</td>
</tr>
<tr>
<td>Vaccines:</td>
<td>Adenovirus Type 4 and Type 7 Vaccine, Live, Oral</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Location (Mailing Address)</td>
<td>3500 N. Martin Luther King Jr. Boulevard, Lansing, Michigan 48906</td>
</tr>
<tr>
<td>3. General description of the types of diseases covered:</td>
<td>Anthrax disease caused by <em>Bacillus anthracis</em></td>
</tr>
<tr>
<td>Vaccines:</td>
<td>Anthrax Vaccine Adsorbed - [BioThrax]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1. Name of facility</th>
<th>MassBiologics</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Location (Mailing Address)</td>
<td>University of Massachusetts Medical School, Boston, Massachusetts 02130</td>
</tr>
<tr>
<td>3. General description of the types of diseases covered:</td>
<td>Diphtheria and tetanus caused by <em>Corynebacterium diphtheriae</em> and <em>Clostridium tetani</em>.</td>
</tr>
<tr>
<td>Vaccines:</td>
<td>Tetanus and Diphtheria Toxoids Adsorbed</td>
</tr>
</tbody>
</table>
Declaration of vaccine production facilities

1. Name of facility
Merck Sharp & Dohme Corp.

2. Location (Mailing Address)
PO Box 1000, UG2D-68, North Wales, Pennsylvania 19454

3. General description of the types of diseases covered:
Invasive disease caused by *Haemophilus influenzae* type b; infection caused by all known subtypes of hepatitis B virus; Hepatitis A disease; cervical, vulvar and vaginal cancer and certain other diseases caused by Human Papillomavirus (HPV); Measles; Mumps; diseases caused by *Streptococcus pneumoniae*; Rotavirus disease; Rubella (German measles) disease; Varicella disease caused by the varicella-zoster virus (VZV); Herpes zoster (shingles) disease.

Vaccines:
- Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) - [PedvaxHIB]
- Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) & Hepatitis B (Recombinant) Vaccine - [COMVAX]
- Hepatitis A Vaccine, Inactivated - [VAQTA]
- Hepatitis B Vaccine (Recombinant) - [Recombivax HB]
- Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant [Gardasil]
- Human Papillomavirus 9-valent Vaccine, Recombinant - [GARDASIL 9]
- Measles, Mumps, and Rubella Virus Vaccine, Live - [M-M-R II]
- Measles, Mumps, Rubella and Varicella Virus Vaccine Live - [ProQuad]
- Pneumococcal Vaccine, Polyvalent - [Pneumovax 23]
- Rotavirus Vaccine, Live, Oral, Pentavalent - [RotaTeq]
- Varicella Virus Vaccine Live - [Varivax]
- Zoster Vaccine, Live, (Oka/Merck) - [Zostavax]

---

1. Name of facility
Organon Teknika Corporation, LLC

2. Location (Mailing Address)
100 Rodolphe Street, Building 1300, Durham, North Carolina 27712

3. General description of the types of diseases covered:
For the prevention of tuberculosis

Vaccines: BCG Live [BCG Vaccine]
## Declaration of vaccine production facilities

### 1. Name of facility
Protein Sciences Corporation

### 2. Location (Mailing Address)
1000 Research Parkway, Meriden, Connecticut 06450-7159

### 3. General description of the types of diseases covered:
Disease caused by influenza virus subtypes A and B

**Vaccines:** Influenza vaccine for subtypes A and B, (Flublok)

---

### 1. Name of facility
Sanofi Pasteur Biologics Co.

### 2. Location (Mailing Address)
38 Sidney Street, Cambridge, Massachusetts 02139

### 3. General description of the types of diseases covered:
Smallpox disease

**Vaccines:** Smallpox (Vaccinia) Vaccine, Live - [ACAM2000]

---

### 1. Name of facility
Wyeth Pharmaceuticals, Inc.

### 2. Location (Mailing Address)
Pfizer, Inc., 401 N. Middletown Road, Pearl River, New York 10965

### 3. General description of the types of diseases covered:
Invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F and otitis media caused by *Streptococcus pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F and 23F; and invasive disease caused by *Neisseria meningitides* serogroup B.

**Vaccines:**
- Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein) - [Prevnar 13]
- Pneumococcal 7-valent Conjugate Vaccine (Diphtheria CRM197 Protein)
Declaration of vaccine production facilities

1. Name of facility
Sanofi Pasteur, Inc.

2. Location (Mailing Address)
Discovery Drive, Swiftwater, Pennsylvania 18370

3. General description of the types of diseases covered:
Diphtheria caused by *Corynebacterium diphtheria*; tetanus caused by *Clostridium tetani*; pertussis (whooping cough) caused by *Bordetella pertussis*; influenza disease caused by pandemic (H1N1) 2009 virus; influenza disease caused by H5N1 subtype; influenza disease caused by influenza virus subtypes A and B; invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135; meningitis and meningococcemia caused by *N. meningitidis*; and Yellow fever acute viral illness caused by a mosquito-borne flavivirus.

Vaccines:
- Diphtheria & Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed - [Tripedia; Daptacel]
- Diphtheria and Tetanus Toxoids Adsorbed USP (For Pediatric Use) (DT)
- Influenza Virus Vaccine (Fluzone, Fluzone High-Dose, Fluzone Intradermal and Fluzone Quadrivalent)
- Influenza Virus Vaccine, H5N1
- Meningococcal Polysaccharide (Serogroups A, C, Y and W-135) Diphtheria Toxoid Conjugate Vaccine - [Menactra]
- Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined - [Menomune®- A/C/Y/W-135]
- Tetanus and Diphtheria Toxoids Adsorbed for Adult Use - [DECAVAC]
- Tetanus Toxoid for Booster Use Only
- Yellow Fever Vaccine - [YF-VAX®]
Appendix A

Biological Select Agents and Toxins

Biological Select Agents and Toxins are biological pathogens and toxins that the United States has determined have the potential to pose a severe threat to public health and safety, animal and plant health, or animal and plant products. The possession, use, and transfer of these agents is regulated by the U.S. Department of Health and Human Services (HHS) Centers for Disease Control and Prevention and the U.S. Department of Agriculture Animal and Plant Health Inspection Service under the Select Agent Regulations found in Part 73 of Title 42 of the Code of Federal Regulations, Part 331 of Title 7 of the Code of Federal Regulations, and Part 121 of Title 9 of the Code of Federal Regulations. Information on Biological Select Agents and Toxins can be found on the National Select Agent Registry website: http://www.selectagents.gov.

HHS Select Agents and Toxins

Abrin
Botulinum neurotoxins
Botulinum neurotoxin-producing species of Clostridium
cercopithecine herpesvirus 1 (Herpes B virus)
Clostridium perfringens epsilon toxin
Coccidioides posadasii/Coccidioides immitis
Conotoxins
Coxiella burnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus
Ebola virus
Francisella tularensis
Lassa fever virus
Marburg virus
Monkeypox virus
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed1918 Influenza virus)
Ricin
Rickettsia prowazekii
Rickettsia rickettsii
Saxitoxin
Shiga-like ribosome inactivating proteins
Shigatoxin
South American Haemorrhagic Fever viruses: Flexal, Machupo, Guanarito, Sabia, Junin
Staphylococcal enterotoxins
T-2 toxin
Tetrodotoxin
Tick-borne encephalitis complex (flavi) viruses: Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever, Russian Spring and Summer encephalitis
Variola major virus (Smallpox virus)
Variola minor virus (Alastrim)
Yersinia pestis
OVERLAP Select Agents and Toxins
Bacillus anthracis
Brucella abortus
Brucella melitensis
Brucella suis
Burkholderia mallei (formerly Pseudomonas mallei)
Burkholderia pseudomallei (formerly Pseudomonas pseudomallei)
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan Equine Encephalitis virus

USDA Select Agents and Toxins
African horse sickness virus
African swine fever virus
Akabane virus
Avian influenza virus (highly pathogenic)
Bluetongue virus (exotic)
Bovine spongiform encephalopathy agent
Camel pox virus
Classical swine fever virus
Ehrlichia ruminantium (Heartwater)
Foot-and-mouth disease virus
Goat pox virus
Japanese encephalitis virus
Lumpy skin disease virus
Malignant catarrhal fever virus (Alcelaphine herpesvirus type 1)
Menangle virus
Mycoplasma capricolum subspecies capripneumoniae (contagious caprine pleuropneumonia)
Mycoplasma mycoides subspecies mycoides small colony (Mmm SC) (contagious bovine pleuropneumonia)
Peste des petits ruminants virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus
Vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3
Virulent Newcastle disease virus 1

USDA PLANT PROTECTION AND QUARANTINE (PPQ) Select Agents and Toxins
Peronosclerospora philippinensis (Peronosclerospora sacchari)
Phoma glycinicola (formerly Pyrenochaeta glycines)
Ralstonia solanacearum race 3, biovar 2
Rathayibacter toxicus
Sclerophthora rayssiae var zeae
Synchytrium endobioticum
Xanthomonas oryzae
Xylella fastidiosa (citrus variegated chlorosis strain)
NIAID Category A, B, and C Priority Pathogens

The National Institute of Allergy and Infectious Disease (NIAID) categorization of pathogens identifies specific pathogens as priorities for additional research efforts as part of the NIAID biodefense research agenda.

Additional information on NIAID Category A, B, and C Priority Pathogens is available at:
http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/research/Pages/CatA.aspx

Category A pathogens are those organisms/biological agents that pose the highest risk to national security and public health because they
- Can be easily disseminated or transmitted from person to person
- Result in high mortality rates and have the potential for major public health impact
- Might cause public panic and social disruption
- Require special action for public health preparedness

**Category A Priority Pathogens**

*Bacillus anthracis* (anthrax)
*Clostridium botulinum* toxin (botulism)
*Yersinia pestis* (plague)
*Variola major* (smallpox) and other related pox viruses
*Francisella tularensis* (tularemia)
Viral hemorrhagic fevers
Arenaviruses (LCMV, Junin virus, Machupo virus, Guanarito virus, Lassa virus)
Bunyaviruses (Hantaviruses, Rift Valley Fever virus)
Flaviruses (Dengue virus)
Filoviruses (Ebola, Marburg viruses)

Category B pathogens are the second highest priority organisms/biological agents. They
- Are moderately easy to disseminate
- Result in moderate morbidity rates and low mortality rates
- Require specific enhancements for diagnostic capacity and enhanced disease surveillance

**Category B Priority Pathogens**

*Burkholderia pseudomallei*
*Coxiella burnetii* (Q fever)
*Brucella* species (brucellosis)
*Burkholderia mallei* (glanders)
*Chlamydia psittaci* (Psittacosis)
Ricin toxin (from *Ricinus communis*)
Epsilon toxin of *Clostridium perfringens*
Staphylococcus enterotoxin B
Typhus fever (*Rickettsia prowazekii*)

Food- and Waterborne Pathogens
- Bacteria: Diarrheagenic *E.coli*, Pathogenic *Vibrio*, *Shigella* species, *Salmonella*, *Listeria monocytogenes*, *Campylobacter jejuni*, *Yersinia enterocolitica*
- Viruses: Caliciviruses, Hepatitis A virus
- Protozoa: *Cryptosporidium parvum*, *Cyclospora cayatanensis*, *Giardia lamblia*, *Entamoeba histolytica*, *Toxoplasma*
- Fungi: *Microsporidia*

Additional viral encephalitides: West Nile Virus, LaCrosse virus, California encephalitis virus, Venezuelan equine encephalitis virus, Eastern equine encephalitis virus, Western equine encephalitis virus, Japanese Encephalitis Virus, Kyasanur Forest Virus

Category C pathogens are the third highest priority and include emerging pathogens that could be engineered for mass dissemination in the future because of:
- Availability
- Ease of production and dissemination
- Potential for high morbidity and mortality rates and major health impact

**Category C Priority Pathogens**
Emerging infectious disease threats such as Nipah virus and additional hantaviruses
Tickborne hemorrhagic fever viruses (Crimean-Congo Hemorrhagic fever virus)
Tickborne encephalitis viruses
Yellow fever
Tuberculosis, including drug-resistant TB
Influenza
Other Rickettsias
Rabies
Prions
Chikungunya virus
Severe acute respiratory syndrome associated coronavirus (SARS-CoV)
*Coccidioides immitis*
*Coccidioides posadasii*

Antimicrobial resistance, excluding research on sexually transmitted organisms:
- Research on mechanisms of antimicrobial resistance
- Studies of the emergence and/or spread of antimicrobial resistance genes within pathogen populations
- Studies of the emergence and/or spread of antimicrobial-resistant pathogens in human populations
- Research on therapeutic approaches that target resistance mechanisms
- Modification of existing antimicrobials to overcome emergent resistance

Antimicrobial research, as related to engineered threats and naturally occurring drug-resistant pathogens, focused on development of broad-spectrum antimicrobials

Innate immunity, defined as the study of nonadaptive immune mechanisms that recognize, and respond to, microorganisms, microbial products, and antigens

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13 NIAID Category C Antimicrobial Resistance—Sexually Transmitted Excluded Organisms: Bacterial vaginosis, Chlamydia trachomatis, Cytomegalovirus, Granuloma inguinale, Hemophilus ducreyi, Hepatitis B virus, Hepatitis C virus, Herpes Simplex virus, Human immunodeficiency virus, Human papillomavirus, Neisseria gonorrhea, Treponema pallidum, Trichomonas vaginalis
## Compiled list of microorganisms and toxins used for biodefense research

<table>
<thead>
<tr>
<th>MICROORGANISM</th>
<th>CATEGORY</th>
</tr>
</thead>
<tbody>
<tr>
<td>African horse sickness virus</td>
<td>USDA Select Agent</td>
</tr>
<tr>
<td>African swine fever virus</td>
<td>USDA Select Agent</td>
</tr>
<tr>
<td>Avian influenza virus (highly pathogenic)</td>
<td>USDA Select Agent</td>
</tr>
<tr>
<td><em>Bacillus anthracis</em></td>
<td>Overlap Select Agent + NIAID Category A</td>
</tr>
<tr>
<td><em>Bacillus anthracis</em> (inactivated)</td>
<td>Simulant</td>
</tr>
<tr>
<td><em>Bacillus anthracis</em> Pasteur strain</td>
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</tr>
<tr>
<td><em>Bacillus anthracis</em> Sterne</td>
<td>Simulant</td>
</tr>
<tr>
<td><em>Bacillus anthracis</em> (killed)</td>
<td>Simulant</td>
</tr>
<tr>
<td><em>Brucella abortus</em></td>
<td>Overlap Select Agent</td>
</tr>
<tr>
<td><em>Brucella melitensis</em></td>
<td>Overlap Select Agent</td>
</tr>
<tr>
<td><em>Brucella suis</em></td>
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<tr>
<td><em>Burkholderia mallei</em></td>
<td>Overlap Select Agent</td>
</tr>
<tr>
<td><em>Burkholderia mallei</em> (killed)</td>
<td>Simulant</td>
</tr>
<tr>
<td><em>Burkholderia pseudomallei</em></td>
<td>Overlap Select Agent</td>
</tr>
<tr>
<td>Chapare virus</td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td>Classical swine fever virus</td>
<td>USDA Select Agent</td>
</tr>
<tr>
<td>Clostridium species producing botulinum neurotoxin</td>
<td>HHS Select Agent + NIAID Category A</td>
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<tr>
<td><em>Coxiella burnetti</em></td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td><em>Coxiella burnetti</em> (inactivated)</td>
<td>Simulant</td>
</tr>
<tr>
<td><em>Coxiella burnetti</em> (killed)</td>
<td>Simulant</td>
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<tr>
<td>Crimean-Congo hemorrhagic fever virus</td>
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<tr>
<td>Dengue virus</td>
<td>NIAID Category A</td>
</tr>
<tr>
<td>Dengue virus (inactivated)</td>
<td>Simulant</td>
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<tr>
<td>Eastern equine encephalitis virus</td>
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</tr>
<tr>
<td>Ebola virus</td>
<td>USDA Select Agent + NIAID Category A</td>
</tr>
<tr>
<td>Ebola virus (inactivated)</td>
<td>HHS Select Agent + NIAID Category A</td>
</tr>
<tr>
<td>Ebola virus (killed)</td>
<td>Simulant</td>
</tr>
<tr>
<td>Foot-and-mouth disease virus</td>
<td>USDA Select Agent</td>
</tr>
<tr>
<td><em>Francisella philomiragia</em></td>
<td>Simulant</td>
</tr>
<tr>
<td><em>Francisella tularensis</em></td>
<td>HHS Select Agent + NIAID Category A</td>
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<tr>
<td><em>Francisella tularensis</em> (killed)</td>
<td>Simulant</td>
</tr>
<tr>
<td>Goatpox virus</td>
<td>USDA Select Agent</td>
</tr>
<tr>
<td>Guanarito virus</td>
<td>HHS Select Agent + NIAID Category A</td>
</tr>
<tr>
<td>Hantaviruses</td>
<td>NIAID Category A</td>
</tr>
<tr>
<td>Hendra virus</td>
<td>Overlap Select Agent</td>
</tr>
<tr>
<td>Influenza A virus, reconstructed replication-competent pandemic 1918 strains</td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td>Junin virus</td>
<td>HHS Select Agent + NIAID Category A</td>
</tr>
<tr>
<td>Kyasanur Forest disease virus</td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td>Lassa virus</td>
<td>HHS Select Agent + NIAID Category A</td>
</tr>
<tr>
<td>Lujo virus</td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td>Lumpy skin disease virus</td>
<td>USDA Select Agent</td>
</tr>
<tr>
<td>Lymphocytic choriomeningitis virus</td>
<td>NIAID Category A</td>
</tr>
<tr>
<td>Machupo virus</td>
<td>HHS Select Agent + NIAID Category A</td>
</tr>
<tr>
<td>Marburg virus</td>
<td>HHS Select Agent + NIAID Category A</td>
</tr>
<tr>
<td>Monkeypox virus</td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td><em>Mycoplasma capricolum</em></td>
<td>USDA Select Agent</td>
</tr>
<tr>
<td><em>Mycoplasma mycoides</em></td>
<td>USDA Select Agent</td>
</tr>
<tr>
<td>Newcastle disease virus</td>
<td>USDA Select Agent</td>
</tr>
<tr>
<td>Nipah virus</td>
<td>Overlap Select Agent</td>
</tr>
<tr>
<td>Peste-des-petits-ruminants virus</td>
<td>USDA Select Agent</td>
</tr>
<tr>
<td>Omsk hemorrhagic fever virus</td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td><em>Phoma glycinicola</em></td>
<td>PPQ Select Agent</td>
</tr>
<tr>
<td><em>Rathayibacter toxicus</em></td>
<td>PPQ Select Agent</td>
</tr>
<tr>
<td><em>Rickettsia prowazekii</em></td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td>Rift Valley fever virus</td>
<td>Overlap Select Agent + NIAID Category A</td>
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<tr>
<td>Sabia virus</td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td>Severe acute respiratory syndrome-related coronavirus</td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td>Sheep pox virus</td>
<td>USDA Select Agent</td>
</tr>
<tr>
<td>Tick-borne encephalitis complex flavivirus, Far Eastern subtype</td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td>Tick-borne encephalitis complex flavivirus, Siberian subtype</td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td>Variola major virus</td>
<td>HHS Select Agent + NIAID Category A</td>
</tr>
<tr>
<td>Variola minor virus</td>
<td>HHS Select Agent</td>
</tr>
<tr>
<td>Venezuelan equine encephalitis virus</td>
<td>Overlap Select Agent</td>
</tr>
<tr>
<td><em>Yersinia pestis</em></td>
<td>HHS Select Agent + NIAID Category A</td>
</tr>
<tr>
<td><em>Yersinia pestis</em> (killed)</td>
<td>Simulant</td>
</tr>
</tbody>
</table>

### TOXINS

| Abrin                                | HHS Select Toxin |
| Alpha conotoxins                     | HHS Select Toxin |
| Botulinum neurotoxins                | HHS Select Toxin |
| Diacetoxyscirpenol                   | HHS Select Toxin |
| Ricin                                | HHS Select Toxin |
| Saxitoxin                            | HHS Select Toxin |
| Staphylococcal enterotoxins A, B, C, D, E subtypes | HHS Select Toxin |
| T-2 toxin                            | HHS Select Toxin |
| Tetrodotoxin                         | HHS Select Toxin |