

Strategy for Integrated Biosurveillance

July 30, 2019 Fiscal Year 2018 Report to Congress



Foreword from the Office of the Under Secretary for Management

July 30, 2019

I am pleased to submit the "Strategy for Integrated Biosurveillance" (Strategy), which was prepared by the Department of Homeland Security (DHS) Countering Weapons of Mass Destruction Office (CWMD).

The report has been compiled pursuant to a requirement in the Joint Explanatory Statement that accompanies the Fiscal Year (FY) 2018 DHS Appropriations Act (P.L. 115-141). The Strategy presents a forward-looking approach to biosurveillance with an outline of capabilities and objectives, and a roadmap to achieving those objectives. The Strategy also includes performance metrics to justify appropriations.



DHS CWMD supports DHS Components, first responders, and other operators to develop and enhance programs and capabilities that defend the homeland against weapons of mass destruction, biological threats, and pandemics. The Strategy reflects this approach with a vision of equipping operators and responders with actionable information to save lives and minimize economic impacts from biological threats of natural, man-made, and accidental origin. Additionally, the Strategy aligns with the President's national security strategies, including the National Biodefense Strategy and the 2017 National Security Strategy.

The following Members of Congress receive this report pursuant to congressional requirements:

The Honorable Lucille Roybal-Allard Chairwoman, House Appropriations Subcommittee on Homeland Security

The Honorable Chuck Fleischmann Ranking Member, House Appropriations Subcommittee on Homeland Security

The Honorable Shelley Moore Capito Chairman, Senate Appropriations Subcommittee on Homeland Security

The Honorable Jon Tester Ranking Member, Senate Appropriations Subcommittee on Homeland Security Please direct any questions about this report to James McDonnell, the Assistant Secretary for the Countering Weapons of Mass Destruction Office at (202) 254-2391.

Sincerely,

R. D. Alles

Deputy Under Secretary for Management

Executive Summary

The Strategy outlines goals and objectives for integrated biosurveillance with the purpose of achieving the desired end-state–efficient biosurveillance early warning analysis to DHS Components and operators and responders at all levels of government in order to reduce the risk of health security incidents effectively.

Goal 1: Provide Biosurveillance Early Warning Analysis

- Objective 1.1: Access new data sets and integrate with information sources that signal that a biological threat is emerging or that an active event has evolved to trigger a new impact.
- Objective 1.2: Enhance current technological portfolio leveraging government-off-theshelf software from the U.S. Department of Defense's Defense Threat Reduction Agency and prior DHS Science and Technology Directorate biosurveillance investments.

Goal 2: Reduce the Risk of Nationally Significant Biological Catastrophes

- **Objective 2.1:** Provide decision support to operators and responders and DHS Components through analyses that are relevant, reliable, and timely.
- **Objective 2.2:** Evaluate current biosurveillance products and services against DHS operators' and first responders' information needs and gaps, and tailor information products.

Goal 3: Improve Biosurveillance Enterprise Efficiencies and Effectiveness

- **Objective 3.1:** Integrate partner information and data to increase capabilities and to reduce redundant data collection and analysis.
- **Objective 3.2:** Establish a secure, trusted, and accessible platform to store partner information and to conduct analysis.

CWMD will implement the Strategy through an implementation plan (IPLAN), which breaks down each goal and objective into specific initiatives with accompanying metrics and timelines. Appendix B details the overall framework and year-one milestones of the IPLAN.

Ultimately, the goals and objectives outlined in the Strategy will allow integrated biosurveillance leadership to develop premier capabilities to drive the success of its mission, provide support to partners, improve analysis, and reduce the risk of biological threats to the Nation.



Strategy for Integrated Biosurveillance

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I. Legislative Language

The DHS Countering Weapons of Mass Destruction Office (CWMD) prepared this report pursuant to a requirement in the Joint Explanatory Statement that accompanies the Fiscal Year (FY) 2018 Department of Homeland Security (DHS) Appropriations Act (P.L. 115-141). The Joint Explanatory Statement states:

INTEGRATED OPERATIONS

The total includes \$9,400,000 for Integrated Operations. This amount includes an increase above the request of \$8,000,000 to continue support for the National Biosurveillance Integration Center, as authorized by Public Law 110–53. Not later than 90 days after the date of enactment of this Act, the Department shall submit a five-year strategic plan that outlines NBIC's proposed capabilities, objectives, a roadmap to achieving those objectives, and performance metrics by which to measure success. NBIC is encouraged to continue its engagement in support of a visualization tool that incorporates data from state and local entities that can serve as a bio-preparedness tool for emergency response, emergency management, and law enforcement at all levels of government.

II. Background

In a world of rapid transit, global trade, and instability, the United States faces increased threats of intentional acts of bioterrorism, naturally occurring outbreaks of infectious disease, and accidental exposure to biological hazards. As evidenced by outbreaks of Ebola, Middle East Respiratory Syndrome, Zika, avian influenza, and Rift Valley Fever, infectious diseases emerge and spread quickly. A catastrophic biological incident, such as a terrorist attack with a weapon of mass destruction (WMD) or a naturally occurring pandemic, could cause thousands of casualties, weaken the economy, damage public morale and confidence, and threaten national security.

CWMD's integrated biosurveillance subject matter experts (SME) fuse human, animal, and environmental health threat information to detect such incidents rapidly and to enable operators and responders to respond earlier and more effectively to impactful biological events.

DHS has made significant progress to address biosurveillance gaps identified in recent reports by the U.S. Government Accountability Office (GAO)¹ and the Blue Ribbon Study Panel on Biodefense². These reports have pointed to the need for specific improvements, such as new data sets, expanded partnerships, and a more effective use of technological mechanisms for data

integration. This strategic plan builds on DHS efforts to address these gaps and highlights opportunities to address the gaps that remain.

The CWMD integrated biosurveillance effort includes capabilities developed through the National Biosurveillance Integration Center (NBIC) and new information-integration initiatives. These efforts are based in the DHS CWMD Information Analysis Division (IAD), which serves as the coordination hub for collection, integration, and analysis of threat information across the WMD threat space. Within IAD, NBIC generates biosurveillance products, such as reports and alerts for federal interagency partners and state, local, tribal, and territorial authorities, as well as for operators and first responders in the field.

Integrated Biosurveillance Primary Support Activities

- Integrate and analyze data and information from a broad spectrum of sources to operators and responders with early warning of potential acts of bioterrorism and disease outbreaks.
- Monitor and report the status of high-priority biological threats of natural, intentional, and accidental origin to operators and responders. Information would be used to make informed decisions regarding risk and employment of valuable resources.
- 3. **Engage and support** DHS operators and first responders with relevant, timely, and accurate biosurveillance data and information that enable an effective response.
- Improve and advance biosurveillance early warning capabilities by obtaining new data sources and innovative technologies and methodologies.

¹ U.S. GAO, *Biosurveillance Challenges and Options for the National Biosurveillance Integration Center*, GAO-15-793. Washington, DC, 2015, https://www.gao.gov/assets/680/672732.pdf.

² A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts – Bipartisan Report of the Blue Ribbon Study Panel on Biodefense. Hudson Institute: Washington, DC, October 2015, http://www.biodefensestudy.org/LiteratureRetrieve.aspx?ID=144258.

CWMD's integrated biosurveillance efforts align with the President's 2017 National Security Strategy and the National Biodefense Strategy. Appendix A outlines how CWMD's integrated biosurveillance effort aligns with key strategic documents.

This integrated biosurveillance strategy also fulfills the mandate of the Implementing Recommendations of the 9/11 Commission Act of 2007 (P.L. 110-53), which established the capability of the U.S. Government (USG) to enable early warning and shared situational awareness of acute biological events that, in turn, inform decisions through integration of human health, animal, plant, food, and environmental monitoring systems.

Purpose and Scope

The "CWMD Strategy for Integrated Biosurveillance" (Strategy) establishes a roadmap for integrated biosurveillance led by DHS CWMD. The Strategy presents an overarching set of goals and objectives, building from the Department's integrated biosurveillance efforts, to date, and greatly expanding their reach. The Strategy's end-state is integrated biosurveillance that maximizes access to and use of DHS Component data for biological threat recognition and response to give early warning information and shared situational awareness to operators.

To execute the Strategy, CWMD will develop an implementation plan (IPLAN) as a tactical guide for achieving the integrated biosurveillance mission. The IPLAN will prioritize annual goals and objectives and break each objective down into specific initiatives. The IPLAN also will include specific metrics to track the initiatives' progress and effectiveness. Appendix B lays out the overall framework and year-one milestones incorporated into the IPLAN.

The Strategy serves as a reference for all planned activities to help leadership shape operations and allocate resources accordingly. The Strategy also outlines the unique services and expertise of the integrated biosurveillance effort with respect to the priorities and demonstrated needs of operators, responders, and DHS Components.



Figure 1. CWMD Integrated Biosurveillance Implementation Plan – Thematic Years

III. Mission, Vision, and Concept of Operations

Mission and Vision

Mission

Enable early warning to operators and responders at all levels of government and shared situational awareness of acute biological events, and support better decisions through rapid identification, characterization, localization, and tracking.

Strategic Vision

Operators and responders are equipped with the information that they need to save lives and minimize economic impact from biological threats of natural, man-made, and accidental origin.

Included in CWMD's integrated biosurveillance effort is a congressional mandate³ to detect, as early as possible, an event of national concern in order to enhance the response capacity of agencies at all levels of government.⁴ By design, this effort supports and directly engages with responders and operators charged with mitigating and, when possible, preventing impact to the United States. Moreover, the effort serves as needed analytical support to existing sensor-based systems when contextual information is needed to elucidate the significance of a perceived threat at the national and local levels.

Desired End-State

To provide efficient biosurveillance early warning analysis to operators and responders at all levels of government and DHS Components in order to reduce effectively the risk of health security incidents.

Concept of Operations

To achieve its responder-focused mission, CWMD collects and integrates biosurveillance data for analyses that result in early detection notifications and improved situational awareness. CWMD leverages open and commercial data sources, as well as government-owned data, such as travel and cargo data sets made available from U.S. Customs and Border Protection (CBP). CWMD also works with interagency partners to select and acquire sophisticated software and

³ NBIC was formed by the Implementing Recommendations of the 9/11 Commission Act of 2007 (P.L. 110-53) to detect biological events of national concern across human, animal, and plant species in service to the federal interagency and to state, local, territorial, and tribal governments.

⁴ Biosurveillance efforts are exercised through CWMD authorities, including NBIC legislation.

systems to meet the information needs of responders and DHS partners. CWMD promotes its technological assets and data access with an integrated team of data scientists, biosurveillance analysts, microbiologists, and SMEs in such fields as bioterrorism and risk analysis.

CWMD enhances it partners' awareness of biothreats by developing and disseminating biosurveillance reports, summaries, and other information-sharing tools that identify and contextualize risks for partners. These products provide timely and relevant information that enable decision-makers and operators to prepare for and respond to biological threats in a way that saves lives and minimizes economic impact.

The integrated biosurveillance mission consists of five functional areas. Decision Support, Analytics, Data Integration, and Outreach represent its four core functions. Workforce Development serves as a foundation for the other four. All five functional areas are tied to each goal and objective (see Appendix B).

Extensive Network

Integrated biosurveillance efforts, including those developed through NBIC, tap into 14 federal departments and agencies to meet requirements toward better early warning and enhanced situational awareness for biological events of national concern. CWMD's IAD augments its capabilities through acquisition, integration, analysis, and dissemination of relevant, timely, and accurate information often obtained through its interagency partnerships. In addition to direct contacts, the effort pushes information to multiple portals that reach thousands more customers. Appendix E depicts the federal customer base.

To expand its network of information access, CWMD is a core member of the Biosurveillance Indications and Warning Analytic Community. This community provides a secure interagency forum for timely collaborative exchange of critical information pertaining to biological events that may threaten the U.S. national interests.

IV. Goals and Objectives

Goal 1: Provide Biosurveillance Early Warning Analysis

Provide timely, relevant, and accurate early warning for biological events of concern to interagency partners, the DHS workforce, and first responders.

Decision-makers and responders need information to guide their decision-making processes and to take effective action when faced with an emerging or potential biological threat. CWMD's integrated biosurveillance relays reliable information, provides dynamic situational awareness, and serves as a reachback resource for responders across the USG.

As such, the biosurveillance efforts help operators, responders, and DHS Components by collecting, integrating, analyzing, and synthesizing biological threat information from a range of data sets and sources and disseminating the results as quickly as possible.

The goal of early warning in a biological event is to increase awareness of the risks associated with the pending threat and its likelihood of occurrence, thereby increasing the response options for officials and, at times, the public. On the basis of the needs of operators and responders, analysts will develop holistic solutions, categorize biological threat environments, and determine implications for defense of the homeland. Analysts will assist in the development and maintenance of an environmental baseline picture to enable the development and deployment of more advanced change (anomaly) detection capabilities.

Goal Outcome: Improved source of information for DHS operators, responders, and interagency partners on the risk of a new biological threat emerging or an active event evolving and causing a new impact.

Objective 1.1: Access new data sets and integrate with information sources that signal that a biological threat is emerging or that an active event has evolved to trigger a new impact.

To identify new relevant and valuable data sets, CWMD will continue to engage government and industry partners to evaluate available data and to determine the effectiveness, feasibility, and cost of integrating into the portfolio. An example of novel data sets is the cargo and travel data collected at the National Targeting Center (NTC), with which CWMD is closely partnered. Similarly, CWMD will tap into the growing network of CWMD personnel stationed at key DHS Components and interagency partners, and will build its biosurveillance data and support.

CWMD analysts will develop and refresh consistent baseline data to enable a more effective use of automated capabilities. The enhanced baseline data will increase the effectiveness for the detection of anomalies by analysts and operational partners. Further aggregation of these

baseline data will enable future investments in accurate WMD threat detection through artificial intelligence and machine-learning techniques.

The end-state is improved signal recognition of biological threats through increased access to data sets and information sources among interagency partners and intradepartmental Components.

Objective 1.2: Enhance current technological portfolio, leveraging government-off-the-shelf software from the U.S. Department of Defense's (DOD) Defense Threat Reduction Agency (DTRA) and prior DHS Science and Technology Directorate biosurveillance investments.

CWMD is engaged in an active partnership with DTRA to finalize the development and near-term operationalization of the Biosurveillance Ecosystem (BSVE)—a system designed to provide all-in-one support to data collection, analysis, and dissemination to detect and evaluate biological threats. Applications and models currently under refinement in the system will support government programs responsible for recognizing early indicators that a biological threat of concern is emerging or changing.

CWMD will assess new, innovative technologies emerging from other government entities and industry and will identify assets that can improve early warning capabilities in support of operators and interagency partners. To conduct these assessments, analysts will use existing information and analytic systems of interagency partners, ideally through joint initiatives and liaison officers at key information programs.

Initial efforts will focus on key players such as CBP's NTC, U.S. Immigration and Customs Enforcement's Homeland Security Investigations, DOD's Joint Improvised-Threat Defeat Organization, DTRA, and U.S. Health and Human Services' (HHS) Office of the Assistant Secretary for Preparedness and Response and the Centers for Disease Control and Prevention.

Additionally, CWMD will incorporate a broader scope of targets into Biofeeds. Biofeeds is a DHS-developed, open-source biosurveillance information technology (IT) tool that uses machine learning, natural language processing, and other advanced analytics components. CWMD will add more biological as well as chemical and radiological/nuclear threat domains to Biofeeds, expanding the system's early detection/early warning capabilities to meet the priorities of CWMD better.

The end-state is improving effectiveness of the CWMD technological portfolio by incorporating new technologies and data.

Performance Outcomes and Indicators

| | Means of Measurement |
|---|--|
| | (How information will be |
| Goal 1 – Performance – Outcomes and Indicators | collected) |
| Outcome #1.1: Increased access to data sets and information sources between interagency partners | Data obtained from a network of CWMD sensors |
| <i>Indicator #1.1:</i> Increase in signal recognition of potential or emerging biological threats obtained from data sets and information sources provided by interagency partners within the network | and other related systems and assessed, at a minimum, semiannually |
| Outcome #1.2: Improved analytical insights on biological and chemical threats | Data streams and applications that are |
| <i>Indicator #1.2:</i> Increase in data streams and applications that are integrated into the technological portfolio | integrated into portfolio, at a minimum, semiannually |

Goal 2: Reduce the Risk of Nationally Significant Biological Catastrophes

Provide information and support to DHS operators, first responders, and interagency partners to reduce the risk of health security incidents cascading into health catastrophes of national concern.

Risk is a function of the hazards to which a community is exposed and the vulnerabilities of that community. The integrated biosurveillance effort integrates and analyzes data obtained from various sources to identify active and potential biological threats that may affect the DHS workforce, assets, or national security. Through collaborative relationships with partners, CWMD provides products and services that inform preparedness and response activities for intentional, accidental, and naturally occurring biological events.

To anticipate new or altered biological risks emerging throughout the world, CWMD will increase the scope of risks analyzed, leaning forward on factors that prime an environment (natural or man-made) for biological agent propagation or release. CWMD will prioritize expanded access to and use of interagency and DHS Component data to enhance anticipatory analyses.

This capability will fill a gap currently encountered by operators and responders charged with preparing for and responding to a biological threat of concern. Moreover, obtaining expanded data access and improved analytics to recognize, if not predict, evolution of a biological incident into a catastrophe will fill critical information requirements of operators and responders.

Goal Outcome: Provide biological threat analyses of direct utility to operators and first responders.

Objective 2.1: Provide decision support to operators and responders, and DHS Components, through analyses that are relevant, reliable, and timely.

Working with operational partners, integrated biosurveillance analysts will identify methods for partners to access information of specific interest to them easily and to incorporate it into their internal processes and products efficiently (see Appendix F). This improved access will allow CWMD to expand and tailor its biological threat targets further to the needs of the operators and responders. Improved access also will integrate these targets into current data collection and analysis methodologies and technologies, such as Biofeeds (operational) and BSVE (in development) by integrating more information and data from our partners. Moreover, the effort will identify, evaluate, and implement new data sets for biological threats, targeting sources useful in identifying the potential impact of threats to DHS operators and first responders, many of which stem from nonhuman domains.

NBIC, as a part of CWMD integrated biosurveillance efforts, jointly designed BSVE with DTRA to serve as an all-in-one biosurveillance data collection, analysis, and dissemination platform. The platform is able to process varying data types (i.e., structured, semi-structured, unstructured) and to provide users with dozens of analytic applications to evaluate the data and to conduct modeling and forecasting on biological incidents that have the potential to escalate into crisis situations in the United States or abroad. CWMD IAD is the technology transfer partner for DTRA, and intends to expand use of the system beyond current users from DTRA Reach Back, U.S. Special Operations Command, and the U.S. Northern Command to DHS Components and other interagency partners.

The end-state is for targeting to encompass all biological threats with the potential to affect operators and evolve into a health security crisis.

Objective 2.2: Evaluate current biosurveillance products and services against information needs and gaps of DHS operators and first responders and tailor information products.

CWMD recognizes that men and women serving on the front lines of homeland security need to know as early as possible if they are at risk of exposure to a biological agent of concern. They also need to understand quickly the significance of the risk so that they can take action to protect themselves and others.

For example, emerging disease threats in wildlife or the environment may exhibit features that indicate a risk for evolution to a significant outbreak of disease that ultimately could spread rapidly from person to person, resulting in a global pandemic. To identify these potential threats, the integrated biosurveillance effort is part of a CWMD structure that maintains a staff of SMEs in the areas of bioterrorism; biological, chemical, and radiological threats; intelligence; emergency response; and other areas. This staff informs biosurveillance analyses daily and serves as reachback to DHS operators in the field.

Working with the intelligence community and other USG entities, analysts will identify technically and operationally feasible threat scenarios and the indications and warnings that are associated with these scenarios to drive intelligence collection and analysis requirements. Analysts and SMEs will work with operational partners to identify priority pathways for analysis and exploitation. Analysts and SMEs will evaluate the specific elements of the pathway such as environmental conditions, threat actors, equipment, and expertise to identify the critical nodes within the pathway. By focusing on those sections of the pathway that have a higher probability of indicating nefarious activity or detrimental conditions, analysts can exploit large sets of data more efficiently.

CWMD will tailor its technologies further for direct use by DHS operators or to generate products that meet known information gaps of DHS personnel. Analysts will identify current best practices in tradecraft related to the assessment of WMD and threat actors. They will develop and follow formalized standard operating procedures for the integration of analytical processes to ensure the integrity of finished products. Additionally, analysts will develop a structured process to develop new methodologies that ensure that the relevant subject matter expertise is included and that the methodology is intellectually sound and repeatable. Analysts periodically will review partner feedback and lessons learned. Analysts will support the periodic testing and improvement of the methodologies in a structured manner to ensure that they meet the requirements of a rapidly changing CWMD environment.

The desired end-state is production of tailored products that enable more efficient and effective response to emerging biological threats.

Performance Outcomes and Indicators

| | Means of Measurement |
|--|-------------------------|
| | How information will be |
| Goal 2 - Performance – Outcomes and Indicators | collected |
| <i>Outcome</i> #2.1: DHS operators provided with expanded access to | Federal stakeholder |
| tailored biological threat targets | annual survey |
| <i>Indicator #2.1:</i> Increase in the number of DHS operators that report receiving, and are satisfied with access to, biological threat targets that are tailored to their needs | |
| Outcome #2.2: Current products and services are evaluated and | Federal stakeholder |
| modified to address the information needs and gaps of DHS | annual survey |
| Components | |
| <i>Indicator</i> #2.2: Percent improvement of products and services as reported by DHS Components | |

Goal 3: Improve Biosurveillance Enterprise Efficiencies and Effectiveness

Demonstrate increased value of integrated data, analytics, expertise, and contributions to DHS operators and first responders.

For the CWMD problem set, effective data collection and integration is a significant challenge and one of the most important aspects of understanding WMDs. Understanding the current threat environment requires that locational data (facilities, ports, routes, borders and location of personnel, manufacturing capability, and expertise) be integrated with:

- Scientific data (chemical, biological, and nuclear production pathways, precursor requirements, equipment needs, and infrastructure requirements),
- Health reporting (syndromic surveillance, agency and media reports, and laboratory results),
- Financial and logistical data (front companies, transport routes, supply company records, and health and commercial insurance reimbursement data),
- Sociocultural data (tribal, criminal, and familial relationships along potential avenues of approach to continental United States),
- Network data (threat actors, support personnel, facilitators, and financiers), and
- Sensor data.

Each of these types of data has its own collection, integration, and retrieval challenges. Regulations protect individual privacy and healthcare information and dictate information collection processes. ^{5 6} In appropriate cases, de-identified and aggregated information will provide overall biosurveillance awareness.

Additionally, the volume of data collected creates its own set of challenges. Employing advanced approaches, such as machine learning, will help CWMD to exploit these data effectively.

CWMD biosurveillance and other analytic efforts will enable improved situational awareness of the CWMD environment by leveraging data from widely disparate sources. These sources include the following:

- Geospatial data such as facilities, routes, threat actor operating areas, etc.,
- Network data such as threat actor networks, financial networks, and commercial networks,
- Organizational constructs,
- Intelligence,

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⁵ Standards for Privacy of Individually Identifiable Health Information and Security Standards for the Protection of Electronic Protected Health Information (HIPAA Privacy and HIPAA Security Final Rules), 45 C.F.R. §§ 160, 164.512(b); 164.512(k)(2).

⁶ Privacy Act, 5 U.S.C. 552a (b)(7).

- Agency reporting,
- Open-source information such as news reporting or social media, and
- Scientific data such as information about chemical weapon precursors, biological seed stock, equipment and facility requirements, etc.

CWMD efforts will contribute to a layered CWMD and pandemic information architecture. The architecture allows capabilities and limits of each individual system to complement each other. It also will generate a comprehensive threat picture that includes food, agriculture, and veterinary threats as part of a *One Health* approach.

Information relating to human, animal, plant, food, and environmental health data is distributed widely among federal, state, local, tribal, and territorial entities, but the entities often are reluctant to share data because of privacy, security, and other concerns. Previously, NBIC established a number of data-sharing agreements to facilitate data exchange with the program.

The CWMD Integrated Biosurveillance effort will advance development and implementation of technologies, policies, and procedures that allow for a broad exchange of data and information. Enabling shared access to data will enhance the biosurveillance capabilities of CWMD and its partners, while also maintaining the security and privacy of the exchanged data. The program understands the expected value of expanding data access to the NTC, as well as to DOD and other agencies, to improve biological threat detection and analysis.

Integral to the WMD and pandemic defense mission, the integrated biosurveillance effort will continue to evaluate data sets available from NTC and other DHS Components. When combined with the current data and analytics portfolio, these data sets will enhance the program's ability to provide early warning and early detection support to operators and responders and with DHS Components. CWMD will continue to cultivate relationships with interagency partners charged with biosurveillance responsibilities to leverage new data and information sources from those partners.

Goal Outcome: Establish routine access and analysis of new data and information integrated into technologies for shared, rapid analysis, and distribution of findings.

Objective 3.1: *Integrate partner information and data to increase capabilities and reduce redundant data collection and analysis.*

The sheer size and complexity of worldwide WMD data require that analysts employ advanced tools to support their efforts. A variety of tools already exist or are in development, such as Biofeeds, DTRA's BSVE, the Defense Advanced Research Project Agency's Sigma, Analyst Notebook, and others, to support the analysts. However, integration of specific and varied types of data such as sensor data and sociocultural data may require highly modified or unique tools to exploit the information. The exact nature of the tool suite will depend on the requirements of our operational partners, methodological requirements, data visualization, and other relevant issues.

To make effective use of available information, identifying the correct sources and data, and effectively integrating the data into an analytic process with the proper tools to exploit that data, are critical. Analysts will assist in the development of a consolidated data integration plan to ensure that the integrated data can be leveraged by the developers, analysts, and operational partners throughout the CWMD enterprise (see Appendix F).

Through increased coordination, CWMD and its partners will create an accessible network of data, technology, and tools. The network will allow users to conduct analysis and share results, while allowing data owners to retain ultimate control over what information that they share, who can access it, and how it is used. Data filtering will save users from sifting through large amounts of raw or irrelevant data and ensures appropriate data sharing. CWMD will accomplish this activity by leveraging new or existing systems and by implementing the recommendations of leadership, SMEs, and industry best practices.

The end-state is to leverage CWMD's enterprisewide collaboration, including the sharing of resources, data, analyses, and biosurveillance tools, through integrated resources and capabilities.

OBJECTIVE 3.2: *Establish a secure, trusted, and accessible platform to store partner information and conduct analysis.*

Interagency partners will have access to IT platforms to support the unique aspects of their own mission while sharing findings with other agencies. Products available through the platform will include unique, dynamic tools and analysis that incorporate advanced analytics to address the critical information needs of partners better. This platform will expand greatly the ability to collect, analyze, and disseminate information, thus strengthening the overall biosurveillance capability of CWMD.

The end-state is the establishment and continued maintenance of a collaborative biosurveillance platform used to enhance biosurveillance products for DHS operators and first responders.

Performance Outcomes and Indicators

| | Means of Measurement |
|--|--------------------------|
| | (How information will be |
| Goal 3 – Performance – Outcomes and Indicators | collected) |
| Outcome #3.1: Increase biosurveillance integration capabilities | Internal user survey |
| and reduce redundant data collection and analysis | annually |
| <i>Indicator #3.1:</i> Reduce the time that it takes for system users to | |
| identify relevant data and perform meaningful analyses | |
| Outcome #3.2: Improve effectiveness of a platform that | Biosurveillance platform |
| provides biosurveillance data, analytics, and expertise to DHS | metrics from dashboard |
| operators and first responders | obtained, at a minimum, |
| Indicator #3.2: Percent increase of DHS operators and first | semiannually |
| responders that request and utilize biosurveillance data, analytics, | |
| and expertise | |

V. Appendices

Appendix A: Alignment with Key Strategic Documents

A number of policies and directives have highlighted biosurveillance as a critical capability to the U.S. biodefense efforts and the importance of integrating the biosurveillance information at the federal level and, in some instances, with state and local entities. In 2004, the President issued two directives, Homeland Security Presidential Directives (HSPD) 9 and 10. Specifically, HSPD-9 directs various departments and agencies to develop surveillance systems as appropriate to the mission and domain focus of that agency and provides a reminder that biosurveillance includes more than the traditional human health information but also information from the food and agricultural sector.

The National Biodefense Strategy identifies ways to strengthen the biodefense enterprise. One primary objective is to ensure that domestic and international biosurveillance and information-sharing systems are coordinated and are capable of timely bio-incident prevention, detection, assessment, response, and recovery.

Also, the Pandemic All-Hazards Preparedness Act of 2006 (P.L. 109-417) required the U.S. Department of Health and Human Services (HHS) to develop and sustain essential public health security capabilities, including disease detection and investigation. HSPD-21, Public Health and Medical Preparedness, builds upon principles set forth in HSPD-10 (now superseded and replaced by National Security Presidential Memorandum (NSPM)-14, Support for National Biodefense), explicitly defines biosurveillance, and provides a detailed explanation of what a nationwide, robust, and integrated biosurveillance capability must include (e.g., epidemiological surveillance) and accomplish.

Congress passed the Implementing Recommendations of the 9/11 Commission Act of 2007 (P.L. 110-53) with a key provision to codify the Federal Government's expectations for biosurveillance integration and coordination. The law directed the Department of Homeland Security (DHS) Secretary to "establish, operate, and maintain a National Biosurveillance Integration Center (NBIC)" having a mission to:

- (1) "enhance the capability of the federal government to rapidly identify, characterize, localize, and track a biological event of national concern and disseminate alerts and other information to Member Agencies and, in coordination with them, to agencies of state, local, and tribal governments"; and
- (2) "oversee the development and operation of the National Biosurveillance Integration System."

| Date | Law & Presidential Directive | Impact on Biosurveillance |
|---------------|--|---|
| July 2002 | Public Health Security and Bioterrorism Preparedness and Response Act of 2002 P.L. 107-188 § 103, 116 Stat. 594, 604 (2002) (codified at 42 U.S.C. § 247d-4(b)) | Requires HHS to establish an integrated system of public health alert communications and surveillance networks between and among federal, state, and local public health officials, and public and private health-related laboratories, hospitals, and other healthcare facilities. |
| January 2004 | HSPD-9: Defense of United States Agriculture and Food | Directs the U.S. Department of the Interior, U.S. Department of Agriculture, HHS, and U.S. Environmental Protection Agency to develop – for animals, plants, wildlife, food, human health, and water – robust, comprehensive, and fully coordinated surveillance and monitoring systems and new tracking systems and integrated laboratory networks that use standardized protocols and procedures. Directs DHS to coordinate with other named departments and agencies to create a biological threat awareness capacity that enhances detection and characterization of biological attacks and that integrates and analyzes data on human, animal, and plant health; food; and water quality. |
| April 2004 | HSPD-10: Biodefense for the 21st Century (superseded and replaced by NSPM-14) | • States that the Federal Government is working to develop an integrated and comprehensive system to recognize and characterize rapidly the dispersal of biological agents in human and animal populations, food, water, agriculture, and the environment. This will permit the recognition of a biological attack at the earliest possible moment and permit initiation of a robust response to prevent unnecessary loss of life, economic losses, and social disruption. |
| December 2006 | Pandemic and All-Hazards Preparedness Act of 2006 P.L. 109-417 § 202(2), 120 Stat. 2831, 2845 (2006) (codified at 42 U.S.C. § 247d-4) | Requires HHS to establish a near real-time, electronic, nationwide, public health situational awareness capability through an interoperable network of systems to share data and information to enhance early detection of, rapid response to, and management of potentially catastrophic infectious disease outbreaks and other public health emergencies. |

| Date | Law & Presidential Directive | Impact on Biosurveillance |
|----------------|--|--|
| August 2007 | Implementing Recommendations of the 9/11 Commission Act of 2007 P.L. 110-53, § 1101, 121 Stat. 266, 375 (2007) (codified at 6 U.S.C. § 195b) | Requires DHS to establish a program to enhance the ability of the Nation to identify, characterize, localize, and track rapidly a biological event of national concern by integrating and analyzing data relating to human health, animal, plant, food, and environmental monitoring systems. |
| October 2007 | HSPD-21: Public Health and Medical Preparedness | States that the United States must develop a nationwide, robust, and integrated biosurveillance capability with connections to international disease surveillance systems, to provide timely warning and situational awareness. |
| January 2011 | Food Safety Modernization Act P.L. 111-353, 124 Stat. 3885. § 205 | Directs the HHS Secretary, through the Director of the Centers for Disease Control and Prevention, to enhance foodborne illness surveillance systems by integrating foodborne illness surveillance systems and data with other biosurveillance and public health situational awareness capabilities at all levels of government, including by sharing foodborne illness surveillance data with NBIC. |
| July 2012 | National Strategy for Biosurveillance | Promotes an all-of-Nation approach that brings together government agencies at all levels of government, the private sector, nongovernmental organizations, and international partners to identify and understand threats as early as possible and to provide accurate and timely information to support life-saving responses. |
| June 2014 | Quadrennial Homeland Security Review | Identifies major biological threats and hazards and outlines a strategy to prevent and/or mitigate the effects of priority biological incidents. |
| February 2015 | National Health Security Strategy | Addresses the importance of biosurveillance as a key information-gathering activity that encompasses human disease surveillance, animal disease surveillance, environmental monitoring, and gathering of intelligence and other information for early warning. |
| September 2018 | National Biodefense Strategy and NSPM-14 | Prioritizes improving biosurveillance capabilities including early notification, modeling, information-sharing, training, and risk analysis. |

| Date | Law & Presidential Directive | Impact on Biosurveillance |
|---------------|--|---|
| December 2018 | Countering Weapons of Mass Destruction Act P.L. 115-387; 6 U.S.C. § 195b | • Amends Section 316 of the Homeland Security Act (6 U.S.C. 195b) establishing the Countering Weapons of Mass Destruction Office (CWMD) and directing the Secretary, acting through the Assistant Secretary for CWMD, to establish, operate, and maintain NBIC. |

Appendix B: Strategic Framework

| Goals | Objectives | 5-Year Outcomes | Year 1 Milestones |
|---|---|---|--|
| Provide Biosurveillance Early Warning Analysis. Countering Weapons of Mass Destruction Office's (CWMD) integrated biosurveillance efforts will provide timely, relevant, and accurate early warning for biological events of concern to interagency partners, the DHS workforce, and first responders. | Objective 1.1: CWMD integrated biosurveillance efforts will access new data sets and information sources (e.g., modeling output from partner agencies) that, on their own or when integrated with other data sets and analyzed, allow for signal recognition that a biological threat has the potential to emerge, or that an active event has the potential to evolve and trigger a | Outcome #1.1: Increased access to data and information sources between interagency partners through CWMD integrated biosurveillance efforts. | Gain access to National Targeting Center (NTC) systems and send information back to NTC systems. Obtain access to CWMD deployed sensor data. Secure access to additional |
| | new impact. Objective 1.2: Continue to enhance its current technological portfolio, which is based on government-off-the-shelf software leveraged from U.S. Department of Defense's Defense Threat Reduction Agency (DTRA) and DHS biosurveillance investments. | Outcome #1.2: Improved analytical insights on biological and chemical threats. | Operationalize Biosurveillance Ecosystem (BSVE) and complete technology transfer agreements with DTRA. Integrate and implement Biofeeds and BSVE in a DHS environment. Mature analytics capabilities in Biofeeds to improve early detection of biological threats globally. Increase new federal partners using Biofeeds for surveillance operations. Incorporate at least one interagency partner into the VA data-sharing initiative. Integrate animal wildlife die-off data from state and locals into BSVE. |

| Goals | Objectives | 5-Year Outcomes | Year 1 Milestones |
|---|--|---|---|
| Reduce the Risk of Nationally Significant Biological Catastrophes. Provide information and support to DHS operators, first responders, and interagency partners to reduce the risk of health security incidences cascading into health catastrophes of national concern. | Objective 2.1: For CWMD integrated biosurveillance efforts analyses to be relevant, reliable, and timely for DHS operators and other recipients, they must provide decision support to operators and responders. | Outcome #2.1: DHS operators and responders, provided with expanded access to tailored targets. | Incorporate the following targets into its reporting and products: a. Chemical/radiological/nuclear b. DHS facilities and personnel c. Illicit network analysis d. Inbound cargo CWMD threats Institute process for quality assurance/quality control. |
| | Objective 2.2: Evaluate current biosurveillance products and services against the information needs and gaps of the biosurveillance enterprise and DHS Components – specifically, DHS operators and first responders – and then design new, or modify existing, offerings to address biosurveillance decision support in the field. | Outcome #2.2: Current products and services are evaluated and modified to address the information needs and gaps of the biosurveillance enterprise and DHS Components. | Collaborate with the CWMD Policy, Plans, Analysis, and Requirements Directorate to obtain needs-based assessment for DHS operator and first responder groups. Determine product/service needs of targeted DHS operators and first responder groups. Leverage expertise of targeted operator managers to validate product and service recommendations. Make custom technological enhancements to existing capabilities (e.g., Biofeeds) specific to targeted interagency partner needs. |

| Goals | Objectives | 5-Year Outcomes | | Year 1 Milestones |
|--|--|--|------------------------------------|--|
| Strategic Goal 3: Improve Biosurveillance Enterprise Efficiencies and Effectiveness. Demonstrate increased value of integrated data, analytics, expertise, and contribution to DHS operators and first responders. | Objective 3.1: Bring together partner information, integrating data to increase capabilities and reduce redundant data collection and analysis. | Outcome #3.1: Increase biosurveillance data capabilities of integrated data and reduce redundant data collection and analysis. | 2. | Integrate Biofeeds with BSVE for broader, interagency and DHS Component utilization in a secure, cloud-based, DHS environment. Ensure that systems (i.e., BSVE, Biofeeds, Wildlife Health Information Sharing Partnership – event reporting system, VA) are interoperable systems with user-level access controls. |
| | Establish a secure, trusted, and accessible platform to store partner information and conduct analysis. This platform will expand greatly the ability to collect, analyze, and disseminate information, thus strengthening the overall biosurveillance capability of CWMD. | Outcome #3.2: Improve effectiveness of a biosurveillance platform that provides biosurveillance data, analytics, and expertise to DHS operators and first responders. | 2. 3. | Complete authority to operate for BSVE. Expand operational users for BSVE. Establish the BSVE Operations and Maintenance Contract. |

Each strategic goal and objective is supported by five functional proficiency areas: Decision Support, Analytics, Data Integration, Outreach, and Workforce Development.

| Functional Area 1: | Provide decision support | Integrated biosurveillance |
|-------------------------|------------------------------------|---|
| Decision Support | products tailored to operator | products will contribute |
| | and responder needs. | meaningful, timely, and accurate |
| | | information that will facilitate |
| | | technical assistance and decision |
| | | support to mitigate, harden, or |
| | | respond to biological threats |
| | | stemming from man-made or |
| | | naturally occurring origins. |
| | | Whenever possible, information |
| | | will be tailored to meet the |
| | | needs of recipients including, |
| | | but not limited to, DHS CBP |
| | | operators at the NTC; state, |
| | | local, tribal, and territorial |
| | | authorities charged with |
| | | biological event prevention and |
| | | response; and Federal |
| | | Government partners requiring |
| | | biosurveillance data and |
| | | information to meet their |
| | | specific mission objectives. |
| Functional Area 2: | Increase advanced analytic | The integrated biosurveillance |
| Analytics | capabilities to identify risks and | effort will determine whether a |
| | forecast impacts. | biological event has |
| | | materialized or the likelihood |
| | | that it will occur, and anticipate |
| | | the potential impact of a new or |
| | | evolving event through |
| | | collection, integration, and |
| | | analysis of disparate data. It |
| | | will obtain analyses in a timely |
| | | manner and allow for operators |
| | | and responders to shape courses |
| | 4 | of action. |
| Functional Area 3: Data | Acquire and integrate human, | The integrated biosurveillance |
| Integration | animal, plant, food, and | effort will identify near real- |
| | environmental data and | time data sets and information |
| | information. | sources available on human, |
| | | animal, plant, food, and |
| | | environmental health to process, integrate, and store, as |
| | | |
| | | appropriate, in order to obtain |
| | | relevant insights on potential |
| | | and active biological threats. These data sets will include |
| | | |
| | | government-owned, |

| Functional Area 4: Outreach and Communications | Build mutually beneficial partnerships to enhance biosurveillance offerings. | commercially owned, and open- source data and information relevant to the integrated biosurveillance mission. The integrated biosurveillance effort will expand its current network of partners to: (1) tailor its biosurveillance analytic support to meet the needs of operators, first responders, and interagency partners better; (2) understand the value provided to these entities and the information gaps that emerge as new threats are detected; and (3) communicate products to them in a timely |
|--|--|--|
| Functional Area 5: Workforce Development | Cultivate an innovative and outcome-driven workforce that supports the integrated biosurveillance mission. | manner. The integrated biosurveillance effort will maintain an adaptive, resilient, and passionate workforce that is highly skilled and knowledgeable in its functional areas. It will use its resources efficiently to establish the necessary scope needed to conduct biosurveillance activities, including data analysis and product generation in support of decision makers and those who are responding to biological threats |

Appendix C: Definition of Terms

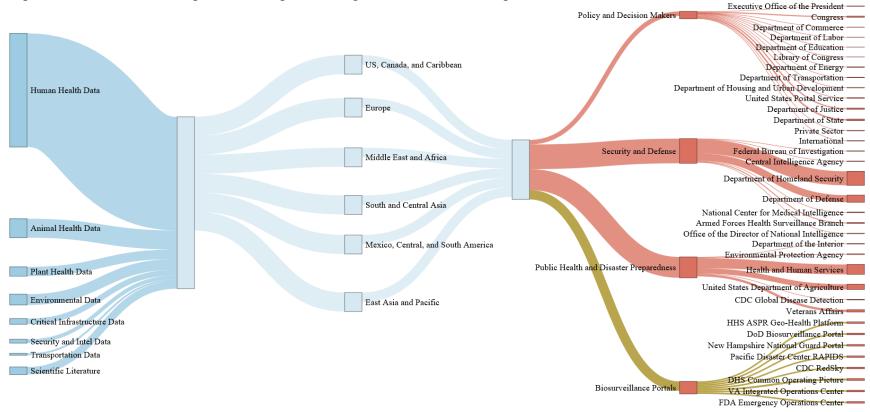
| Term | Definition |
|--------------------------|--|
| Biohazard | A biological agent or biologically active substance, regardless of origin (e.g., naturally occurring or bioengineered), that represents an actual or potential danger to humans, animals, plants, or the environment. |
| Biological threat | An entity involved with, or a situation involving, a biohazard that potentially can cause: 1. An act of biological warfare or terrorism; 2. A crime involving a biohazard consistent with the scope of the National Biodefense Strategy; or 3. Any natural or accidental occurrence in which a biohazard harms humans, animals, plants, or the environment consistent with the scope of the National Biodefense Strategy. |
| Biosurveillance | The process of gathering, integrating, interpreting, and communicating essential information and indications related to all-hazard threats or disease activity affecting human, animal, plant, and environmental health to achieve early detection and provide early warning, to contribute to overall situational awareness of the health aspects of the incident, and to enable better decision-making at all levels. |
| Desired End-State | The set of required conditions that defines achievement. The situation to be obtained at the end of an operation. The specified situation at the successful completion of the final phase of an operation. |
| Goal | Broad statement or statements about the general intent in terms of desired. |
| Health Security | Activities required, both proactive and reactive, to minimize vulnerability to acute public health events that endanger the collective health of populations living across geographical regions and national boundaries. |
| Initiatives | An action to be taken. A plan of action to accomplish a specified end. Collaborative effort. Collaborative technology. |
| Objective | Statement that describes milestones or actions to achieve the goal. |
| Performance Indicator | Determination and evaluation of the results of an activity, plan, process, or program and their comparison with the intended or projected results. |
| Performance Outcome | Intended result of a planned activity attained through stated objectives. |

Appendix D: Abbreviations

| Abbreviation | Definition |
|--------------|--|
| BSVE | Biosurveillance Ecosystem |
| CBP | U.S. Customs and Border Protection |
| CWMD | Countering Weapons of Mass Destruction Office |
| DHS | U.S. Department of Homeland Security |
| DOD | U.S. Department of Defense |
| DTRA | Defense Reduction Threat Agency |
| FY | Fiscal Year |
| GAO | U.S. Government Accountability Office |
| HHS | U.S. Health and Human Services |
| HSPD | Homeland Security Presidential Directive |
| IAD | Information Analysis Division |
| IPLAN | Implementation Plan for the CWMD Strategy for Integrated Biosurveillance |
| IT | Information Technology |
| NBIC | National Biosurveillance Integration Center |
| NSPM | National Security Presidential Memorandum |
| NTC | National Targeting Center |
| SME | Subject Matter Expert |
| Strategy | CWMD Strategy for Integrated Biosurveillance |
| USG | U.S. Government |
| VA | U.S. Department of Veterans Affairs |
| WMD | Weapons of Mass Destruction |

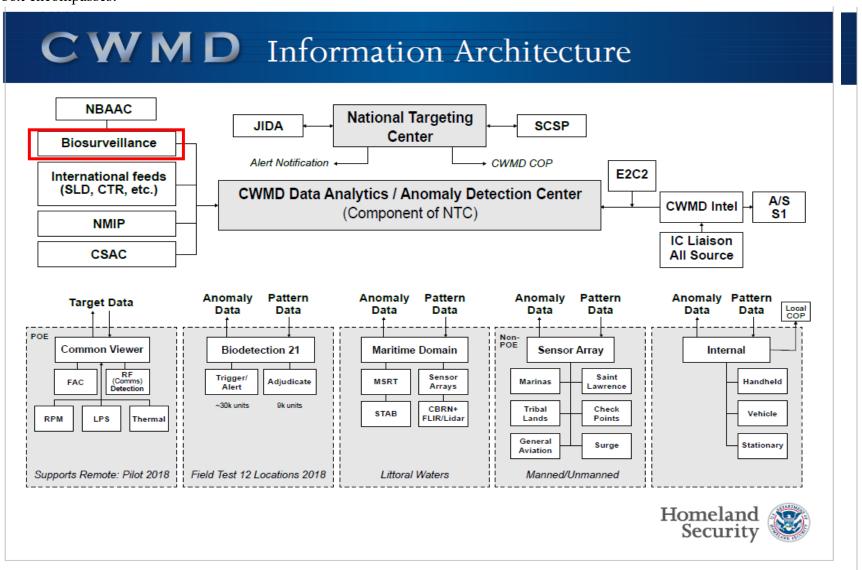
Appendix E: Integrated Biosurveillance Reach and Partner Relationships

Biosurveillance products and services are provided to an extensive network of operators and responders at all levels of government. Depicted here are the federal partners, components, organizations, and online portals:



Appendix F: Architecture

The first flowchart depicts CWMD's high-level information architecture, and the second one shows what the red "Biosurveillance" box encompasses:



The following depicts near-term biosurveillance integration (the architecture will be revised continuously as new capabilities and partnerships develop):

