

BIODEFENSE STRATEGY ACT OF 2016

R E P O R T

OF THE

COMMITTEE ON HOMELAND SECURITY AND
GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

TO ACCOMPANY

S. 2967

TO AMEND THE HOMELAND SECURITY ACT OF 2002 TO REQUIRE
THE OFFICE OF MANAGEMENT AND BUDGET TO EXECUTE A
NATIONAL BIODEFENSE STRATEGY, AND FOR OTHER PURPOSES



AUGUST 30, 2016.—Ordered to be printed
Filed, under authority of the order of the Senate of July 14, 2016

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BIODEFENSE STRATEGY ACT OF 2016

AUGUST 30, 2016.—Ordered to be printed

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Mr. JOHNSON, from the Committee on Homeland Security and
Governmental Affairs, submitted the following

R E P O R T

[To accompany S. 2967]

The Committee on Homeland Security and Governmental Affairs, to which was referred the bill (S. 2967) to amend the Homeland Security Act of 2002 to require the Office of Management and Budget to execute a national biodefense strategy, and for other purposes, having considered the same, reports favorably thereon with amendments and an amendment to the title and recommends that the bill, as amended, do pass.

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I. PURPOSE AND SUMMARY

The purpose of S. 2967, the National Biodefense Strategy Act of 2016, is to require the President to develop and execute a comprehensive national biodefense strategy. In 2014, several high-ranking Government officials, including former Senator Joseph Lieberman and former Department of Homeland Security (DHS) Secretary Thomas Ridge, convened the Blue Ribbon Study Panel on Biodefense to assess the state of our nation's biodefense capabilities

and to recommend improvement measures.¹ S. 2967 codifies key recommendations of this panel by requiring a holistic national strategy that aims to direct and harmonize all existing agency-specific strategies with respect to biodefense. This strategy would be required to be updated every five years. The bill also requires the President to establish and utilize a Biodefense Coordination Council, which consists of representatives from key Federal agencies in developing the strategy. The Council is directed to review, prioritize and align biodefense activities and spending across the Federal Government in coordination with the Office of Management and Budget. Finally, the bill requires the creation of an annual biodefense expenditures report that details amounts spent on biodefense activities by all Federal departments and agencies.

II. BACKGROUND AND THE NEED FOR LEGISLATION

In 2001, immediately following the September 11, 2001 terrorist attacks, deadly anthrax spores were mailed in letters to several offices in the United States.² The 2001 anthrax attacks serve as an example of a biological agent used domestically for nefarious purposes.³ During the course of these attacks, at least 22 people were infected, with five of them succumbing to the disease.⁴ Identification of a suspect by the FBI took six years.⁵ In the years leading up to and following these attacks, the topic of biodefense came under intense scrutiny. Several bipartisan and independent commissions along with the Government Accountability Office (GAO) and Congressional Research Service (CRS) have issued reports identifying significant gaps in the nation's biodefense capabilities and within the biodefense enterprise as a whole, which includes preparedness for natural disease outbreaks.⁶

Most of the commissions convened on biodefense have urged the United States to place a higher priority on addressing biological threats through various broad, but interrelated recommendations. For example, the U.S. Commission on National Security/21st Century (Hart-Rudman Commission) reported that the United States needs an enforceable international ban on the transfer, trade, and weaponization of biological pathogens.⁷ The National Commission on Terrorist Attacks upon the United States (9/11 Commission) expressed concern in 2004 about the number of terrorist groups pursuing chemical, biological, radiological and nuclear materials.⁸ In 2008, the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism (Graham-Talent WMD Commission) said that the United States must place a higher priority on biological weapons and bioterrorism in order to bring about sub-

¹A *National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts*, Blue Ribbon Study Panel on Biodefense (Oct. 28, 2015), <http://www.hudson.org/research/11824-a-national-blueprint-for-biodefense-leadership-and-major-reform-needed-to-optimize-efforts>.

²Dept. of Justice, *Amerithrax Investigative Summary* (2010), <http://www.justice.gov/archive/amerithrax/docs/amx-investigative-summary.pdf> [hereinafter Dept. of Justice, *Amerithrax Investigative Summary*].

³*Id.*

⁴Gov't Accountability Office, *GAO-15-80, Anthrax: Agency Approaches to Validation and Statistical Analyses Could Be Improved* 5 (2014), <http://gao.gov/products/GAO-15-80>.

⁵Dept. of Justice, *Amerithrax Investigative Summary*.

⁶See *infra* notes 7-14, 18, 20-25.

⁷Report, U.S. Comm'n on National Security, *New World Coming: American Security in the 21st Century* (2001), <http://fas.org/man/docs/nwc/>.

⁸Report, National Comm'n on Terrorist Attacks Upon the U.S., *9-11 Comm'n Report* (2004), <http://www.9-11commission.gov/report/>.

stantial improvements in global biosecurity.⁹ Additionally, the Graham-Talent Commission recommended that the United States develop a national strategy for advancing bioforensic capabilities.¹⁰

GAO has issued several reports in recent years on the state of biodefense strategy development, biosurveillance, and biodefense leadership in the United States.¹¹ In 2010 and again in 2011, GAO reported that there was neither a comprehensive national strategy, nor a designated focal point to lead to the development of a national biosurveillance capability.¹² GAO then recommended that the Homeland Security Council develop an overarching national biodefense strategy as well as a national biosurveillance strategy that considers non-Federal capabilities.¹³

In recognition of the threat posed to the United States by biological threats, recent Presidential Administrations have taken steps to strengthen Federal strategies for biodefense. In 2004, President George W. Bush issued Homeland Security Presidential Directive 10, which detailed the pillars of the Federal biodefense system—threat awareness, prevention and protection, surveillance and detection, and response and recovery—and assigned responsibilities for these efforts to Federal agencies.¹⁴ President Bush later issued Homeland Security Presidential Directive 21 in 2007, which established a National Strategy for Public Health and Medical Preparedness, including a focus on biosurveillance and medical countermeasures.¹⁵

In 2009, President Obama built on the work of his predecessor by releasing the National Strategy for Countering Biological Threats, which outlined the President’s vision for addressing terrorist use of biological weapons.¹⁶ In 2011, President Obama then issued Presidential Policy Directive-8, an Executive Order intended to guide the nation in an all-hazards approach to preventing, responding to, and recovering from threats including terrorist acts, natural disasters, and other man-made incidents.¹⁷ Finally, in 2012, the Obama Administration released the National Strategy for Biosurveillance, to strengthen the nation’s ability to gather, inte-

⁹ Report, Prevention of Weapons of Mass Destruction Proliferation and Terrorism Report Card (January 2010), <http://www.cfr.org/terrorism/world-risk-report-commission-prevention-umd-proliferation-terrorism/p17910>.

¹⁰ *Id.*

¹¹ Gov’t Accountability Office, GAO–16–413T, Ongoing Challenges and Future Considerations for DHS Biosurveillance Efforts (2016), <http://www.gao.gov/products/GAO-16-413>.

¹² Gov’t Accountability Office, GAO–10–645, Efforts to Develop a National Biosurveillance Capability Need a National Strategy and a Designated Leader (2010), <http://www.gao.gov/assets/310/306362.pdf>; see also Gov’t Accountability Office, GAO–11–318SP, Opportunities to Reduce Potential Duplication in Government Programs, Save Tax Dollars, and Enhance Revenue (2011), <http://www.gao.gov/assets/320/315920.pdf> (noting that the “overarching biodefense enterprise would benefit from strategic oversight mechanisms, including a focal point such as a national biodefense coordinator and a national strategy, to ensure efficient, effective, and accountable results.”).

¹³ *Id.*; see also Gov’t Accountability Office, GAO–15–664T, Biosurveillance: Additional Planning, Oversight, and Coordination Needed to Enhance National Capability (2015), <http://www.gao.gov/assets/680/671245.pdf>.

¹⁴ Homeland Security Presidential Directive 10, “Biodefense in the 21st Century” (2004), <http://fas.org/irp/offdocs/nspd/hspd-10.html>.

¹⁵ Homeland Security Presidential Directive 21, “National Strategy for Public Health and Medical Preparedness” (2007), <http://fas.org/irp/offdocs/nspd/hspd-21.htm>.

¹⁶ *National Strategy for Countering Biological Threats*, National Security Council, Nov. 2009, available at https://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf.

¹⁷ Congressional Research Service, R42073, Presidential Policy Directive 8 and the National Preparedness System: Background Issues for Congress (Oct. 21, 2011), <https://www.fas.org/sgp/crs/homesecc/R42073.pdf>.

grate, interpret, and communicate information on biological threats affecting human, animal, and plant health.¹⁸

Though GAO has acknowledged the progress made over the years in promoting coordination in the biodefense space as a result of Federal efforts, it determined these strategies have not succeeded in fully addressing its recommendations.¹⁹ In March 2016, GAO noted that despite national security staff statements that the National Strategy for Countering Biological Threats works in concert with the National Biosurveillance Strategy and Presidential Policy Directive-8 to provide comprehensive strategic guidance to stakeholders with biodefense responsibilities, and though these documents demonstrate a clear commitment to coordinating inter-agency biodefense efforts, the documents do not provide the strategic approach that GAO recommended in 2011.²⁰ In testimony given before this Committee, Chris Currie, Director of Homeland Security and Justice for GAO, reiterated the urgent need for an overarching biodefense strategy, stating that “while some high-level biodefense strategies have been developed, there is no broad, integrated national strategy that encompasses all stakeholders with biodefense responsibilities.”²¹ Given the aforementioned criticisms, a 2011 CRS report noted that “Congress, as a body, could enact legislation to require a more robust and transparent government-wide strategic plan that articulates clear goals, metrics, and priorities.”²²

In 2011 and again in 2016, GAO also highlighted the fragmentation of biodefense leadership, reporting that “there are more than two dozen presidentially appointed individuals with biodefense responsibilities and numerous Federal agencies with mission responsibilities for supporting biodefense activities, but no individual or entity with responsibility for overseeing the biodefense enterprise.”²³ GAO reported that despite National Security Council statements that two of its directorates work together as the focal point for Federal biodefense efforts, strategic leadership issues still persist.²⁴

In 2015, the Blue Ribbon Study Panel on Biodefense (BRSPB) underscored critical vulnerabilities in the United States’ biodefense enterprise.²⁵ In their final report released on October 28, 2015, the BRSPB determined that the United States “does not afford the biological threat the same level of attention as it does other

¹⁸ *National Strategy for Biosurveillance*, National Security Council, Jul. 2012, available at https://www.whitehouse.gov/sites/default/files/National_Strategy_for_Biosurveillance_July_2012.pdf.

¹⁹ Gov’t Accountability Office, GAO–16–547T, *The Nation Faces Multiple Challenges in Building and Maintaining Biodefense and Biosurveillance* (2016), <http://www.gao.gov/assets/680/676548.pdf>.

²⁰ *Duplication and Cost Savings Action Tracker*, Gov’t Accountability Office (Mar. 2, 2016) http://www.gao.gov/duplication/action_tracker/Biological_Threats/action1#t=1.

²¹ Gov’t Accountability Office, GAO–16–547T, *The Nation Faces Multiple Challenges in Building and Maintaining Biodefense and Biosurveillance* (2016), <http://www.gao.gov/assets/680/676548.pdf>.

²² Congressional Research Service, R41123, *Federal Efforts to Address the Threat of Bioterrorism: Selected Issues and Options for Congress* (Feb. 8, 2011), <https://www.fas.org/sgp/crs/terror/R41123.pdf>.

²³ Gov’t Accountability Office, GAO–16–547T, *The Nation Faces Multiple Challenges in Building and Maintaining Biodefense and Biosurveillance* (2016), <http://www.gao.gov/assets/680/676548.pdf>.

²⁴ *Id.*

²⁵ *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts*, Blue Ribbon study panel on Biodefense, Oct. 2015, available at <http://www.hudson.org/research/11824-a-national-blueprint-for-biodefense-leadership-and-major-reform-needed-to-optimize-efforts>.

threats.”²⁶ Among the report’s chief findings was the conclusion that the United States lacks a single Federal leader, a comprehensive national strategy, and a dedicated biodefense budget.²⁷ Additionally, the BRSPB found that while the nation spends \$6 billion each year on biodefense activities, no comprehensive, specific accounting of those activities occurs within the Federal Government.²⁸ Therefore, it is difficult to know how that money is spent, and what activities are being pursued by the Federal Government in this area. At a hearing before this Committee in October 2015, former Senator Lieberman and former Secretary of Homeland Security Ridge reiterated the key findings of this report.²⁹

S. 2967 addresses the recommendations of the BRSPB, GAO, and others by requiring a comprehensive National Biodefense Strategy and facilitating inter-governmental and multi-disciplinary leadership and coordination through the establishment of a Biodefense Coordination Council. This bill will provide the mechanisms for overarching leadership and direction for Federal biodefense activities and much needed prioritization and accounting of investments across the biodefense enterprise (the combination of systems, including government and private sector entities that contribute to protecting the nation from potentially catastrophic biological events).³⁰

Status updates on the National Biodefense Strategy must be submitted to appropriate Congressional committees every 180 days until complete and updates of the completed strategy are required every five years thereafter. The President is also required to submit to Congress, alongside each budget submission, an annual report detailing total biodefense expenditures by all Federal departments and agencies.

III. LEGISLATIVE HISTORY

Chairman Ron Johnson and Senator Joni Ernst introduced S. 2967 on May 23, 2016, which was referred to the Committee on Homeland Security and Governmental Affairs.

The Committee considered S. 2967 at a business meeting on May 25, 2016. An amendment was offered by Chairman Johnson to correct the long title of the bill and to require the President to execute the National Biodefense Strategy, rather than the Office of Management and Budget. Another amendment was offered by Chairman Johnson to move the analysis section of the strategy to an appendix within the strategy. An amendment was offered by Senator Claire McCaskill to make it clear that the President may use the Public Health Emergency Medical Countermeasures Enterprise in developing the strategy. Senator McCaskill subsequently modified her amendment to include any interagency body in the strategy’s development.

The Committee adopted both Johnson amendments and the McCaskill amendment, as modified, and ordered the bill, as amend-

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ See *Assessing the State of Our Nation’s Biodefense: Hearing Before the S. Comm. on Homeland Sec. & Governmental Affairs*, 114th Cong. (2015).

³⁰ Gov’t Accountability Office, GAO-16-547T, *The Nation Faces Multiple Challenges in Building and Maintaining Biodefense and Biosurveillance* (2016), <http://www.gao.gov/assets/680/676548.pdf>.

ed, reported favorably, all by voice vote. Senators present for each of the votes were: Johnson, Portman, Paul, Lankford, Ayotte, Ernst, Sasse, Carper, McCaskill, Tester, Baldwin, Heitkamp, Booker, and Peters.

Consistent with the Committee's order on technical and conforming changes at the business meeting, the Committee reports the bill with a technical amendment by mutual agreement of the full Committee majority and minority staff.

IV. SECTION-BY-SECTION ANALYSIS OF THE BILL, AS REPORTED

Section 1. Short title

This section provides the bill's short title, the "National Biodefense Strategy Act of 2016."

Section 2. Biodefense strategy

This section amends Title V of the Homeland Security Act of 2002 to add the National Biodefense Strategy.

Subsection (a) defines the terms "biodefense," "Council," "Federal biodefense enterprise," and "Strategy."

Subsection (b) directs the President to establish a Biodefense Coordination Council (Council), which, at a minimum, will be comprised of the Secretary of Health and Human Services, the Secretary of Agriculture, the Secretary of Defense, the Secretary of Homeland Security, the Secretary of State, the Director of National Intelligence, and the Administrator of the Environmental Protection Agency. Subsection (b) also requires the President to develop a National Biodefense Strategy which shall direct and align intergovernmental efforts of the Federal government towards an effective biodefense enterprise, including threat awareness, prevention and protection surveillance and detection and response and recovery to major biological incidents.

The Council is to provide the expertise necessary to develop the National Biodefense Strategy and, in coordination with the Office of Management and Budget, review, prioritize and align necessary Federal Government activities and expenditures on biodefense. The Council will be chaired by the Secretary of Health and Human Services, the Secretary of Agriculture, the Secretary of Defense, or the Secretary of Homeland Security for one-year intervals. The Secretary of Health and Human Services shall serve as the first chairperson of the Council. At the end of the one-year term, the chairperson position shall rotate to another Department Secretary. The subsection also requires the recommendations of the Council to inform the President's annual budget submission with respect to biodefense activities.

Subsection (c) requires the President to utilize the Council in the development of the National Biodefense Strategy. In addition to Council members, the President may choose to utilize the Secretary of Commerce, the Attorney General, and any agency or interagency body deemed appropriate, including the Public Health Emergency Medical Countermeasures Enterprise. The President may also receive input from private companies, academia, and state, local, tribal, and territorial governments in developing the strategy.

Subsection (d) stipulates that the National Biodefense Strategy shall serve as a comprehensive guide for United States biodefense

that directs and harmonizes all existing Federal Government biodefense plans and strategies.

Subsection (e) specifies the contents of the National Biodefense Strategy, requiring the strategy to include a description of the entities and positions of leadership with responsibility, authority, and accountability for implementing, overseeing and coordinating Federal biodefense activities, as well as a description of how these entities coordinate; five-year priorities, goals, and metrics to prevent, detect, respond to, and recover from a major biological incident; and short and long-term research and development projects and recommended legislative action needed to move towards the Strategy's goals. Further, the strategy shall include an appendix with a detailed analysis of current and previous collaborative efforts between military and civilian federal entities on biodefense activities and coordination; prior recommendations from panels and commissions, lessons learned from prior public health emergency responses; risks associated with major biological incidents; resources and capabilities needed to address identified risks; and resource and capability gaps in the Federal biodefense enterprise. The appendix shall also contain a prioritization and allocation of investments across the Federal biodefense enterprise.

Subsection (f) directs the President to submit the National Biodefense Strategy to Congress not later than two years following the bill's enactment.

Subsection (g) requires status updates on the strategy to be submitted to appropriate Congressional committees every 180 days from enactment until the strategy is complete.

Subsection (h) requires the President to make all parts of the strategy that are releasable to the public available on a public internet website.

Subsection (i) requires updates of the completed strategy every five years.

Subsection (j) requires the President to submit to Congress a biodefense expenditure report with each fiscal year budget, and to detail how those expenditures relate to the goals and priorities in the Strategy.

Subsection (k) allows for the strategy to include classified annexes.

V. EVALUATION OF REGULATORY IMPACT

Pursuant to the requirements of paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the Committee has considered the regulatory impact of this bill and determined that the bill will have no regulatory impact within the meaning of the rules. The Committee agrees with the Congressional Budget Office's statement that the bill contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments.

VI. CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

JULY 11, 2016.

Hon. RON JOHNSON, *Chairman,*
Committee on Homeland Security and Governmental Affairs,
U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 2967, the National Biodefense Strategy Act of 2016.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Ellen Werble.

Sincerely,

KEITH HALL.

Enclosure.

S. 2967—National Biodefense Strategy Act of 2016

S. 2967 would require the President to establish a Biodefense Coordination Council to develop a national strategy to help the federal government prevent and respond to major biological incidents. Under the bill, the President would be required to report to the Congress on the status of the strategy every 180 days until it is completed and to update the strategy at least every five years thereafter. The bill also would require the President to submit an annual report detailing total federal expenditures on biodefense activities and how those expenses relate to the priorities established in the strategy.

CBO estimates that implementing S. 2967 would require a couple of employees annually to coordinate the Council's work and to produce the reports. CBO estimates that enacting S. 2967 would cost less than \$500,000 annually and about \$2 million over the 2017–2021 period; any such spending would be subject to the availability of appropriated funds. Pay-as-you-go procedures do not apply to this legislation because it would not affect direct spending or revenues.

CBO estimates that enacting S. 2967 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2027.

S. 2967 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would not affect the budgets of state, local, or tribal governments.

The CBO staff contact for this estimate is Ellen Werble. The estimate was approved by Theresa Gullo, Assistant Director for Budget Analysis.

VII. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, changes in existing law made by S. 2967 as reported are shown as follows (existing law proposed to be omitted is enclosed in brackets, new matter is printed in *italic*, and existing law in which no change is proposed is shown in roman):

HOMELAND SECURITY ACT OF 2002

* * * * *

TITLE V—EMERGENCY PREPAREDNESS AND RESPONSE

* * * * *

Sec. 501. Definitions.

* * * * *

Sec. 526. Integrated Public Alert and Warning System Modernization.
Sec. 527. National Biodefense Strategy.

SEC. 527. NATIONAL BIODEFENSE STRATEGY.

(a) *DEFINITIONS.—In this section—*

(1) *the term ‘biodefense’ means any involvement in mitigating the risks of major biological incidents and public health emergencies to the United States, including with respect to—*

- (A) *threat awareness;*
- (B) *prevention and protection;*
- (C) *surveillance and detection;*
- (D) *response and recovery; and*
- (E) *attribution of an intentional biological incident;*

(2) *the term ‘Council’ means the Biodefense Coordination Council established under subsection (b);*

(3) *the term ‘Federal biodefense enterprise’ means the programs, projects, activities, and resources across the Federal government that are involved in biodefense; and*

(4) *the term ‘Strategy’ means the National Biodefense Strategy required to be established under subsection (b)(5).*

(b) *BIODEFENSE COORDINATION COUNCIL.—*

(1) *ESTABLISHMENT.—The President shall establish a Biodefense Coordination Council, which shall be comprised of, at a minimum—*

- (A) *the Secretary of Health and Human Services;*
- (B) *the Secretary of Agriculture;*
- (C) *the Secretary of Defense;*
- (D) *the Secretary*
- (E) *the Secretary of State;*
- (F) *the Director of National Intelligence; and*
- (G) *the Administrator of the Environmental Protection Agency.*

(2) *DUTIES.—The Council shall—*

(A) *provide the expertise necessary to develop the Strategy; and*

(B) *in coordination with the Office of Management and Budget, review, prioritize, and align necessary biodefense activities and spending across the Federal Government, in a manner consistent with the Strategy.*

(3) *ROTATING CHAIR.—During the 4-year period beginning on the date on which the Council is established, and each 4-year period thereafter, each of the 4 Secretaries described in subparagraphs (A) through (D) of paragraph (1) shall serve as the chairperson for the Council for 1 year. The first chairperson of the Council shall be the Secretary of Health and Human Services.*

(4) *PRESIDENT’S ANNUAL BUDGET.—The recommendations of the Council shall inform the budget submitted by the President under section 1105 of title 31, United States Code, with respect to biodefense activities.*

(5) *STRATEGY.*—*The President shall develop a National Bio-defense Strategy to direct and align the inter-governmental and multi-disciplinary efforts of the Federal Government towards an effective and continuously improving biodefense enterprise, including threat awareness, prevention and protection, surveillance and detection, and response and recovery to major biological incidents.*

(c) *COORDINATION.*—

(1) *COUNCIL.*—*In developing the Strategy, the President shall utilize the Council.*

(2) *OTHER AGENCIES.*—*In developing the Strategy, the President may utilize—*

(A) *the Secretary of Commerce;*

(B) *the Attorney General; and*

(C) *any other Federal department agency, or interagency body the President determines appropriate, including the Public Health Emergency Medical Countermeasures Enterprise.*

(3) *OTHER ENTITIES.*—*The President may receive input on elements of the Strategy from private sector biodefense entities and State, local, tribal, and territorial governments.*

(4) *ACADEMIC INSTITUTIONS.*—*The President may receive input on elements of the Strategy from academic institutions.*

(d) *COORDINATION WITH EXISTING STRATEGIES.*—*The Strategy shall serve as a comprehensive guide for United States biodefense that directs and harmonizes all other strategies or plans established or maintained by a Federal department or agency with respect to biodefense.*

(e) *CONTENTS.*—

(1) *REQUIREMENTS.*—*The Strategy shall include, at a minimum—*

(A) *a comprehensive description of the entities and positions of leadership with responsibility, authority, and accountability for implementing, overseeing, and coordinating Federal biodefense activities described in subsection (b)(5), including a description of how such entities coordinate on each aspect of biodefense;*

(B) *5-year goals, priorities, and metrics to improve and strengthen the ability of the Federal Government to prevent, detect, respond to, and recover from a major biological incident;*

(C) *short- and long-term research and development projects or initiatives planned to improve biodefense capability; and*

(D) *recommendations for legislative action needed to expedite progression toward the goals identified in the Strategy.*

(2) *CONSIDERATIONS.*—*In developing the Strategy, the President may consider—*

(A) *the trade-offs made between differing goals and requirements, due to constraints in expected assets and resources over the time period of such goals and requirements; and*

(B) *any other analysis the President determines appropriate.*

(3) *ANALYSIS.*—*The Strategy shall include an appendix, which shall contain—*

(A) *a review of current and previous collaborative efforts between the Armed Forces and the civilian sector of the Federal Government on biodefense activities and coordination;*

(B) *a detailed analysis of the—*

(i) *relevant recommendations issued by external biodefense review panels or commissions, and the extent to which the recommendations have been considered and implemented by Federal departments and agencies;*

(ii) *lessons learned from the response of the Federal Government to public health emergencies occurring within the 5 years preceding the submission of the strategy;*

(iii) *risks associated with major biological incidents;*

(iv) *resources and capabilities needed to address identified risks; and*

(v) *resource and capability gaps in the Federal biodefense enterprise, including gaps in—*

(I) *each category of biodefense activity described in subsection (a)(1);*

(II) *identification and research of emerging biological threats;*

(III) *programs, projects, and activities in effect before the date of enactment of this section;*

(IV) *strategies and implementation plans related to biodefense activities in effect before the date of enactment of this section;*

(V) *the ability to reallocate Federal resources to address risks posed by emerging biological threats; and*

(VI) *meeting the needs of vulnerable populations during the response to and recovery from a public health emergency; and*

(C) *prioritization and allocation of investment across the Federal biodefense enterprise.*

(f) *DEADLINE.*—*Not later than 24 months after the date of enactment of this section and in accordance with subsection (k), the President shall submit the Strategy to the Committee on Homeland Security and Governmental Affairs of the Senate and the Committee on Homeland Security of the House of Representatives.*

(g) *STATUS UPDATES.*—*Not later than 180 days after the date of enactment of this section, and every 180 days thereafter until the date on which the Strategy is submitted to the congressional committees described in subsection (f), the President shall submit to such congressional committees an update on the status of the Strategy.*

(h) *REQUIREMENT.*—*In accordance with subsection (k), the Strategy shall be made available on a public Internet website.*

(i) *FIVE-YEAR UPDATE.*—*Beginning 5 years after the date on which the Strategy is submitted to the congressional committees described in subsection (f), and not less frequently than every 5 years thereafter, the President shall update the Strategy.*

(j) *ANNUAL BIODEFENSE EXPENDITURES REPORT.*—

(1) *IN GENERAL.*—Not later than 30 days after the date on which the President submits a budget to Congress under section 1105 of title 31, United States Code, the President shall submit to the appropriate congressional committees a report detailing the total amount of expenditures on biodefense activities by all Federal departments and agencies and how the expenditures relate to the goals and priorities required under subsection (e)(1)(B).

(2) *REQUIREMENT.*—The first report submitted under paragraph (1) shall provide historical context by detailing the total amount of expenditures on biodefense for the 3 preceding fiscal years, in addition to the fiscal year requirements for the fiscal year covered by the report.

(k) *CLASSIFIED ANNEX.*—To the fullest extent possible, any reports required to be made publicly available under this section shall be unclassified, but may include classified annexes that shall be submitted concurrently to the congressional homeland security committees.

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