Free Summary

Evaluation of a Site-Specific Risk Assessment for the Department of Homeland Security's Planned National Bio- and Agro-Defense Facility in Manhattan, Kansas

Committee on the Evaluation of a Site-Specific Risk Assessment for the Department of Homeland Security's Planned National Bio-and Agro-Defense Facility in Manhattan, Kansas; National Research Council

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Summary

The Department of Homeland Security (DHS) is preparing to build the National Bio- and Agro-Defense Facility (NBAF), a new state-of-the-art high-containment facility that will replace the aging Plum Island Animal Disease Center and will serve as a linchpin in protecting U.S. agriculture from foreign animal disease threats. DHS selected Manhattan, Kansas, as the site for the new NBAF after a site-selection process that involved an environmental impact statement to model the potential spread of foot-and-mouth disease (FMD), one of the most serious foreign animal disease threats, and a threat risk assessment (TRA) to estimate security risks associated with sites under consideration. The Government Accountability Office (GAO) had raised concerns about DHS's analysis and methods. Hearing those concerns, Congress instructed DHS to complete a site-specific biosafety and biosecurity risk assessment (SSRA) of the proposed NBAF facility in Manhattan, Kansas, before construction funds would be obligated. The legislation (P.L. 111-83, see Box 1-1) also directed the National Research Council to conduct an independent evaluation of the SSRA to determine its adequacy and validity (see Box 1-2 for the Statement of Task).

The National Research Council convened a multidisciplinary committee of experts (see Appendix A for committee biosketches) to provide DHS with feedback on its initial work plan and to evaluate the adequacy and validity of the final SSRA. In March 2010, the committee issued a privileged preliminary letter report to provide DHS with guidance on its proposed approach for conducting the SSRA; DHS accepted most of the committee's recommendations and revised its work plan accordingly. In June 2010, the completed SSRA was delivered to the committee for review. During July and August 2010, DHS supplemented the SSRA with responses to questions and concerns from the committee.

Assembling the data and performing the SSRA of NBAF was a large undertaking; therefore DHS and its contractors should be commended for performing the SSRA within a remarkably short time frame. This final report constitutes the committee's evaluation of DHS's SSRA.

OVERALL ASSESSMENT

The committee evaluated the SSRA's methods, facility design plans, and mitigation strategies. The committee found that the models used in performing the SSRA appear to be appropriate and that many of the SSRA's general conclusions are valid. The SSRA has considered the major release pathways (aerosols, fomites, liquid waste, and solid waste), as recommended in the committee's preliminary letter report (see Appendix B), and has addressed mitigation strategies for each. DHS has also appropriately responded to GAO's prior criticism that it had inappropriately dealt with a potential plume from an airborne release of foot-and-mouth disease virus (FMDv); the SSRA uses a state-of-the-art puff dispersion model to simulate the aerosol transport of pathogens, which turned out to be a less critical pathway of FMDv spread than the near-site exposure of cattle. However, as described in the findings below, the

committee found that the SSRA had several major shortcomings with respect to potential risks and impact scenarios, and there are some critical limitations in the SSRA's execution and analysis.

The committee found that the SSRA has many legitimate conclusions, but the SSRA is not entirely adequate or valid. The SSRA does not account for the overall risks associated with operating the NBAF and conducting FMDv work in Manhattan, Kansas. The inputs and assumptions for the models are inadequate because they do not fully account for how a biosafety level 3 agriculture (BSL-3Ag) and BSL-4 facility would operate, how pathogens might be released, and which animal populations might be exposed. The SSRA sometimes used arbitrary assumptions and did not account for uncertainties, some of which require experimental data that are currently not available but that could greatly alter the outputs. Consequently, the committee is concerned about the validity of the actual risk and impact levels determined by the SSRA's outcomes from the models.

Given more time, the SSRA may have progressed further and may have better addressed some of the concerns expressed in this report. The committee thus views this as a notable first step in an iterative process aimed at identifying and minimizing risk and determining actions that will need to be taken.

FINDINGS

The SSRA shows that constructing the NBAF in Manhattan, Kansas, carries a number of risks and that the impact of an FMDv release could potentially have significant economic, health, and national security impacts. Some risks and impacts are generic to any high-containment large-animal facility, whereas others are specific to the Manhattan, Kansas, site. The risk of release is primarily a generic concern, whereas the risk of infection, spread, and impact is largely related to the site. The SSRA's estimates indicate that the probability of an infection resulting from a laboratory release of FMDv from the NBAF in Manhattan, Kansas approaches 70% over 50 years (see Figure 3-1) with an economic impact of $9-50 billion. The committee finds that the risks and costs could well be significantly higher than that, and elaborates on those findings below.

Finding 1: The SSRA lacks evidence to support the conclusion that the risk of release that results in infection is very low relative to the risk of infection introduced from an external source.

The SSRA states that "given the combination of proven biocontainment design and robust operation procedures and response planning, the NBAF operations in Manhattan, Kansas overall brings extremely low risk relative to the greater risk of the intentional or accidental introduction of FMDv by an external source" (page 1, SSRA follow-up letter, July 28, 2010). Although the committee affirms that engineering and operational safeguards can substantially lower the risk of release, the committee does not concur with the implied conclusion of the SSRA that there is a very low risk of release that would result in an infection. That comparison "to the risk of intentional or accidental introduction" is misleading because the SSRA does not consider or quantify the risk of infection from an external source; thus, with no data for comparison, the SSRA's conclusion of "extremely low risk" is invalid.

Furthermore, the SSRA's characterization of risk as very low is inconsistent with the risk of infection presented in the SSRA's estimates over the expected lifetime of the NBAF. The SSRA did not account for the cumulative risk of a release and infection that could spread across the expected life span of the NBAF. Assuming that the SSRA risk estimates are credible and reliable, if the risk probabilities across all escape pathways and scenarios had been taken into account, the SSRA would have indicated that an escape of a pathogen, such as FMDv, and an ensuing disease outbreak is more likely than not to occur within the 50-year life span of the NBAF. As previously mentioned, the SSRA's estimates indicate that a release of FMDv resulting in infection outside the laboratory has a nearly 70% chance of occurring with an economic impact of $9-50 billion. Also, because the SSRA did not account for important uncertainties and risk factors as discussed below, the SSRA could well have underestimated the risk of pathogen release and transmission and its consequences. In many scenarios considered, the numbers probably represent conservative estimates of risk.

Finding 2: The SSRA overlooks some critical issues, both site-specific and non-site-specific, that could significantly elevate the risk of accidental release and spread of pathogens.

While the SSRA considered site-specific characteristics that affect risk— including the area's high risk of tornadoes and it being in the vicinity of a transportation hub for cattle and other livestock—it neglected to consider the risks associated with the NBAF's proximity to a metropolitan area and other animal facilities. This includes exposure and fomite risks for Kansas State University (KSU) and its football stadium (which would potentially expose a large human population), its College of Veterinary Medicine (where sick and susceptible animals are treated and where there are large numbers of transient animal patients), and other research facilities (and movement of personnel between KSU, the Biosecurity Research Institute, and the NBAF). In addition, the SSRA neglected to consider the maintenance and cleaning of BSL-3Ag and BSL-4 large animal pens, which would result in aerosol formation of pathogens and emissions much greater than were assumed in the aerosol scenario in the SSRA. The cleaning scenario is likely to lead to significantly increased risks of infection through fomites and airborne pathways.

Finding 3: The SSRA has several methodological flaws related to dispersion modeling, tornado assessment, and epidemiological modeling. Thus the committee believes that questions remain about the validity of the overall risk estimates.

A common flaw in the execution of the dispersion, tornado, and epidemiological models was that many of the assumptions used for the model parameters were arbitrary and subject to user bias. Although sensitivity analyses were conducted, these did not systematically address many important uncertainties and risks related to release, transmission, and mitigation. Many scenarios were potentially overoptimistic, and could well have led to major underestimations of the risks. Specifically, the committee could not determine the input parameters used for the NAADSM and could not independently validate the results.

Finding 4: The committee agrees with the SSRA's conclusion that for FMDv, long-distance plume transport will likely be less important than the near-site exposure of cattle.

Near-site exposure of cattle and other livestock are especially a concern in Kansas State University's College of Veterinary Medicine, sales barns, and the many cow-calf operations and feedlots within a few miles of the NBAF; beef cattle sales barns are a particular focal point for secondary transmission of FMDv in this setting. These livestock and their transport across neighboring states will serve as major factors in the spread and amplification of an FMD outbreak throughout the United States. As shown in the SSRA, the high level of animal movement and the presence of sales barns near Manhattan, Kansas, significantly increase the degree of FMD spread and its economic impact.

Finding 5: Substantial gaps in knowledge make predicting the course of an FMD outbreak very difficult, which led to weaknesses in the SSRA.

Predictions of epidemic size are only as robust as the weakest links in the model, and the SSRA identified a lack of good records and data on interstate livestock transport. Without data, there is no way to fill in the gaps and improve precision beyond the scope of expert opinion. In addition, without improvements in data quality, it remains difficult to obtain any robust forecasts of overall outbreak effects. Even though specific data are lacking for predicting the nature and scope of SSRA escape scenarios, data are available on recent FMDv introductions or laboratory escapes and they provide valuable lessons in understanding realistic expectations for mitigation measures and disaster preparation plans for various outbreak scenarios.

Finding 6: Although the economic modeling was conducted with appropriate methods, the epidemiological estimates used as inputs to the SSRA were flawed.

The epidemiological modeling assumptions that were used in the economic assessment, such as depopulation rates and outbreak duration, were overoptimistic in their estimates. The committee questions the SSRA's assumption that its proposed mitigation strategy would contain the spread of FMD by culling 120-720 herds per day (page 230 of the SSRA). The committee does not think that infected herds could be detected and culled at that rate, and therefore questions the validity of the mitigation strategy to limit the effects of an outbreak. If fewer herds could be culled each day, the spread and impact would be much higher than indicated by the SSRA. Consequently, the use of flawed epidemiological inputs resulted in economic estimates that were also flawed and invalid, albeit derived in a methodologically sound manner.

Finding 7: The committee agrees with the SSRA's conclusion that early detection and rapid response can limit the impact of an FMDv release from the NBAF, but is concerned that the SSRA does not describe how the NBAF could rapidly detect such a release.

Early detection is critical for limiting the spread of infection, therefore it will be important to develop extensive real-time surveillance for FMDv and other pathogens being worked on at the NBAF before the laboratory becomes operational. Surveillance will also be critical in detecting whether a leak or spill has occurred within the NBAF so that steps can be taken to minimize and mitigate its release. To implement FMD surveillance and response in the United States, numerous capabilities will need to be developed related to real-time diagnostics,

real-time full-genome surveillance, a real-time active surveillance system, and response plans with appropriate parties involved in FMD diagnosis, control, and eradication.

Finding 8: The SSRA lacks a comprehensive mitigation strategy developed with stakeholder input for addressing major issues related to a pathogen release. The mitigation strategies that are provided do not realistically demonstrate current or foreseen capacity for how federal, state, and local authorities would effectively respond to and control a pathogen release.

With regard to human health and the NBAF's site in Manhattan, Kansas, the committee is concerned about the lack of clinical isolation facilities and world-class infectious disease clinicians experienced in diagnosing and treating laboratory staff or communities exposed to BSL-4 pathogens. With regard to animal health, the SSRA acknowledges that the Manhattan, Kansas, region is a hub of animal movement for the entire United States and that infected animals would be expected to move across the country and cause pockets of infection at great distances from the initial source of infection, but the mitigation strategies do not address outbreaks of such magnitude. Given that a pathogen release from the NBAF may occur despite all efforts to prevent that from occurring, it will be necessary to create realistic and credible mitigation strategies for the release of a pathogen.

Finding 9: The committee agrees with the SSRA's conclusion that human error will be the most likely cause of an accidental pathogen release, and fomite carriage is the most likely way that a pathogen would escape the facility's outer biocontainment and biosecurity envelope.

Safe practices are of paramount importance given that the SSRA presents human error as the most likely source of accidental releases. To enhance safe operation and reduce the risk of human error identified in the SSRA, the committee agrees that key NBAF personnel will need adequate ongoing training, education, and evaluation of skills. Furthermore, there will need to be zero tolerance of deviations from biosafety standards and practices recommended by the CDC and USDA.

Finding 10: The committee agrees with the SSRA's conclusion that investment in biosafety and biosecurity engineering and the training of personnel and responders can reduce the risks, but is concerned about current design plans that potentially compromise safety measures.

The NBAF will venture into a new and unprecedented area of BSL laboratory operations with respect to its mainland location, scale of operations, and scope of agents. Given that the SSRA states that the cost of a release (such as a release of FMDv) would be very high, the facility will need to be engineered beyond the accepted standards to an exceptionally high level of biosafety and biosecurity. To function safely, it will need to be a state-of-the-art facility with state-of-the-art equipment and state-of-the-art biosafety practices. It would be prudent not only to abide by the strongly recommended guidelines set forth in the most recent *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, but to also glean best practices and guidance from existing BSL-4 laboratories. The committee is seriously concerned about the

SSRA's current designs which omit redundant HEPA filters—but are strongly recommended by the *BMBL*—for reasons of practicality and cost-savings. Any facility design compromises due to budgetary limitations will need to be viewed as inconsistent with the mission of providing a state-of-the-art facility with minimal risk of pathogen escape from containment. The critical engineering and construction plans will affect the containment potential for the life span of the facility. Once construction of the NBAF is complete regardless of the location, funding will need to be maintained to assure continued safe operation and maintenance.

Finding 11: The SSRA's qualitative risk assessment of work with BSL-4 pathogens in large animals was inadequate.

The qualitative risk assessment was inadequate because it failed to fully consider the characteristics of the pathogens and the risks of working with BSL-4 pathogens in large animal facilities. The committee does not concur with the SSRA's finding that its quantitative risk assessment regarding FMDv and Rift Valley fever virus (RVFV) sufficiently represents the range of risk regarding the other pathogens that will be studied at the NBAF, that is, the pathogens that are included in the qualitative risk assessment. The committee does not agree that the BSL-3 quantitative risk assessment adequately frames the risks associated with operating a BSL-4 large animal facility, because it is insufficient to use BSL-3 pathogens to predict risks associated with BSL-4 pathogens that are zoonotic and for which no treatment is available. Given that the qualitative risk assessment was inadequate and that the SSRA did not perform a quantitative risk assessment for BSL-4 agents, further evaluation of risks and mitigation strategies will need to be established for BSL-4 agents (for example, Nipah and Hendra viruses or other emerging BSL-4 zoonotic pathogens) to identify ways of minimizing the risks associated with working with those agents in a large animal facility setting.

ADDITIONAL REMARKS

The SSRA team should be applauded for its effort in conducting an extensive risk assessment in such a short period of time. Although the committee's findings express major concerns about the validity of some of the SSRA's conclusions, the work that was completed constitutes a huge step forward compared with previous risk assessments of its kind and should be viewed as a solid starting point.

The nation clearly needs an institution to support comprehensive research programs for the study of foreign animal and zoonotic diseases, including detection, diagnosis, and means of mitigation (drugs, vaccines, and genomic forensics). Such activities require a capability to work with all known threat agents (not just the eight infectious agents listed in the SSRA), multiple pathogen introductions, and emerging and unknown disease threats. For these reasons, the committee agrees that there is a need for a facility like the NBAF to be constructed and operated in the United States.

Constructing a BSL-3Ag and BSL-4 facility of the magnitude planned for the NBAF, one that is capable of large animal work on a scale greater than other high-containment laboratories, undoubtedly presents new and unknown risks that could not be accounted for in the SSRA because of a lack of data and experience. Given the constraints of the design framework and the short timeframe available for data collection and analysis, the committee finds that the

limitations of the data, facility design details, and operating practices may have limited the scope that the SSRA could adequately address at this time. As more data, facility designs, and operational plans emerge, updated analyses may be appropriate to better evaluate the risks posed by a BSL-3Ag and BSL-4 large animal facility in Manhattan, Kansas.

The SSRA and the committee identify some sources of risk that can be addressed as part of the design, preparation, and long-term operation of the NBAF to reduce risk wherever it is located. Though the SSRA and the committee offer several points for consideration to reduce the risk of a pathogen release and its consequences, further risk analysis is needed to determine the extent to which these measures would reduce risk. Ultimately, policymakers will need to decide whether the risks are acceptable related to constructing and operating the NBAF in Manhattan, Kansas, and DHS will need to determine steps to minimize risk and impact if construction and operation should proceed as planned.

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COMMITTEE ON THE EVALUATION OF A SITE-SPECIFIC RISK ASSESSMENT FOR THE DEPARTMENT OF HOMELAND SECURITY'S PLANNED NATIONAL BIO- AND AGRO-DEFENSE FACILITY IN MANHATTAN, KANSAS

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This report has been reviewed in draft form by persons chosen for their diverse perspectives and technical expertise in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of the independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards of objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the process. We thank the following for their review of this report:

E. Paul Gibbs, *University of Florida*
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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The review of this report was overseen by **Corrie Brown**, *University of Georgia*, and **Lynn Goldman**, *George Washington University*. Appointed by the National Research Council, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered.[1] Responsibility for the final content of this report rests with the author committee and the institution.

[1]After the prepublication version of the report was provided to the sponsor for a required security review, the committee provided a few modifications in the text to clarify statements that may be misconstrued.

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ACRONYMS AND ABBREVIATIONS

BMBL – Biosafety in Microbiological and Biomedical Laboratories
BRI – Biosecurity Research Institute
BSE – bovine spongiform encephalopathy
BSL – biosafety level

CDC – Centers for Disease Control and Prevention
CEEZAD – Center of Excellence for Emerging and Zoonotic Animal Diseases (DHS)

DADS – Davis Animal Disease Simulation
DHS – Department of Homeland Security

EIS – environmental impact statement

FAD – foreign animal disease
FADD – foreign animal disease diagnostician
FMD – foot-and-mouth disease
FMDv – foot-and-mouth disease virus

GAO – Government Accountability Office

HAN – Health Alert Network
HEPA – high-efficiency particulate air
HSPD-9 – Homeland Security Presidential Directive 9, "Defense of United States Agriculture and Food"
HVAC – heating, ventilating, and air conditioning

IAQ – indoor air quality
ID – infectious dose

KSU – Kansas State University

MRHC – Mercy Regional Health Center

NAADSM – North American Animal Disease Spread Model
NAHLN – National Animal Health Laboratory Network
NBAF – Nation Bio- and Agro-Defense Facility
NCMI – National Center for Medical Intelligence
NIH – National Institutes of Health
NOAA – National Oceanic and Atmospheric Administration
NorthCom – U.S. Northern Command
NVS – National Veterinary Stockpile

NWS – National Weather Service

OIE – Organisation Mondiale de la Santé Animale (World Organisation for Animal Health)

PCR – polymerase chain reaction
PFU – plaque-forming units
PIADC – Plum Island Animal Disease Center

RVF – Rift Valley fever
RVFV – Rift Valley fever virus

SCIPUFF – second-order closure integrated puff model
SME – subject matter experts
SPC – Storm Prediction Center
SSRA – site-specific risk assessment

TRA – threat risk assessment

USAMRIID – U.S. Army Medical Research Institute for Infectious Diseases
USDA – U.S. Department of Agriculture
UTMB – University of Texas Medical Branch

WTP – willingness to pay

THE NATIONAL ACADEMIES
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November 1, 2010

The Honorable Tara O'Toole, M.D., M.P.H.
Under Secretary for Science and Technology
U.S. Department of Homeland Security
Washington, DC 20528

Dear Dr. O'Toole:

At the request of the U.S. Congress and the Department of Homeland Security (DHS), the National Research Council's Division on Earth and Life Studies established the ad hoc Committee on the Evaluation of a Site-Specific Risk Assessment (SSRA) for the Department of Homeland Security's Planned National Bio- and Agro-Defense Facility (NBAF) in Manhattan, Kansas. The SSRA is extremely important for understanding the risks posed by and the potential effects of placing the NBAF in Manhattan, Kansas. It provides critical guidance for design and operation of the facility to ensure that risk can be reduced through appropriate design, training, and operational procedures; effects can also be reduced through surveillance and mitigation planning. The involvement of this committee is an important component of this critical activity. The committee examined the SSRA work plans and specific questions posed by DHS so that it could advise DHS about the approach to the SSRA. DHS completed the SSRA in late June 2010. In July and August 2010, DHS supplied additional written responses to the committee's questions about the SSRA. All page references in this report are to the June 2010 version of the SSRA and the follow-up materials provided in July and August, which were submitted to the committee for its evaluation. Because of the time constraints imposed by Congress, the SSRA and its evaluation turned out to be a heroic effort, on the part of both DHS and the committee. A great deal of work was accomplished in a very short time.

As chair of the committee, I wish to thank the NRC staff, the committee members, and DHS for their responsiveness to the demands of generating the SSRA and its review within the required time. This has been an interactive and iterative process aimed at producing the best estimates of risk and of potential effects associated with construction of the NBAF in Manhattan, Kansas. This final report constitutes the committee's evaluation of the SSRA.

Sincerely,

Ronald M. Atlas, *Chair*
COMMITTEE ON THE EVALUATION OF A SITE-SPECIFIC RISK ASSESSMENT FOR THE DEPARTMENT OF HOMELAND SECURITY'S PLANNED NATIONAL BIO- AND AGRO-DEFENSE FACILITY IN MANHATTAN, KANSAS