

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

The Department of Homeland Security has selected Manhattan, Kansas, as the location for a new, state-of-the-art research facility that will study foreign animal and zoonotic diseases. This report evaluates the site-specific risk assessment conducted by the Department of Homeland Security, and finds that the risk assessment did not adequately identify the unique risks associated with this location or properly account for risks and impacts associated with work on the most dangerous pathogens.

Protecting our nation's farms, animals, economy, and food supply from a foreign animal or zoonotic disease outbreak is an important challenge—one that can be overcome with improved disease detection, diagnostics, and the development of new vaccines. To fulfill the obligations under Homeland Security Presidential Directive 9 to support this critical mission of basic and applied research, the Department of Homeland Security will build a state-of-the-art laboratory to replace the aging Plum Island Animal Disease Center, which is located off the coast of Long Island in New York. The new facility will be called the National Bio- and Agro-Defense Facility, and it



Credit: USDA Agricultural Research Service/Scott Bauer

will differ from other high-containment laboratories in that it will be capable of conducting research using large animals, such as cattle and swine, and will be equipped for work on some of the most dangerous pathogens, including the virus that causes foot-and-mouth disease.

On the basis of its environmental impact statement and its threat risk assessment, the Department of Homeland Security selected the Manhattan, Kansas site as the proposed location to construct and operate the National Bio- and Agro-Defense Facility; however, the Government Accountability Office raised concerns about the adequacy of the analysis and methods used to determine this site. In response, Congress instructed the Department of Homeland Security to complete a site-specific biosecurity and biosafety risk assessment of the proposed facility before construction funds could be obligated. The legislation also asked the National Research Council to conduct an independent evaluation of the site-specific risk assessment to determine its adequacy and validity.

A **foreign animal disease** is an animal disease caused by an agent that does not occur naturally in the United States. The disease is limited to agricultural animals (NRC, 2005).

A **zoonotic disease or infection** is transmissible between animals and humans. Zoonoses are a public health concern for people, and may also affect animal health and thus prevent the efficient production of food animals and create obstacles to international trade in animals and animal products (WHO, 2008; IOM and NRC, 2009).

Evaluation of the Assessment

The report's authoring committee commended the Department of Homeland Security for performing the site-specific risk assessment within a remarkably short time frame, and found that the risk assessment used appropriate methods and made many legitimate conclusions. However, the committee determined that the site-specific risk assessment is not entirely adequate or valid because of several shortcomings with respect to the potential risks and impact scenarios and some limitations in executing and analyzing the data. The risk assessment did not account for the overall risks associated with operating the facility in Manhattan, Kansas, nor did it account for the risks associated with work on the most dangerous pathogens in a large animal facility.

Overall, the Department of Homeland Security's site-specific risk assessment concluded that the threat of a pathogen release from the facility resulting in a disease outbreak is "extremely low," compared to the risk of an outbreak from an outside source. The committee observed that no estimates on external sources of pathogen introduction were presented, making this comparison invalid. The risk assessment estimates provided by the Department of Homeland Security show that there is at least a 70 percent chance over the facility's 50-year lifespan of foot-and-mouth disease virus being released outside the laboratory and causing an infection—a level of risk that cannot be considered low. The risk assessment also estimated the economic impacts of such an outbreak at \$9-\$50 billion. The committee found that because the risk assessment contained assumptions that were arbitrary and subject to user bias for modeling aerosol dispersal of disease agents, tornadoes, and the scope and extent of disease spread, many scenarios were potentially overoptimistic and could well have led to major underestimations of the risks and subsequent costs related to an outbreak.

The risk assessment proposed some mitigation strategies, but did not calculate the risk reduction levels for such proposed actions. With the information provided, the committee could only comment on the probabilities and costs as presented in the risk assessment, and the committee was not able to speculate on how risk reduction practices may impact the overall risk of operating the National Bio- and Agro-Defense Facility in Manhattan, Kansas.

Outlined below are the four main elements of the risk assessment, along with the key points the committee identified in each section.

Estimating the Chance of a Pathogen Release

The risk assessment considered the major pathways by which a pathogen could be released: via aerosols, fomites (contaminated objects), liquid waste, and solid waste. The committee agreed with the site-specific risk assessment's conclusion that human error is the most likely cause of an accidental pathogen release – but found certain facility characteristics were not considered that would significantly elevate the risk of accidental pathogen release. For example, the daily maintenance and cleaning of animal pens in the facility would create an aerosol of pathogens more frequently than was accounted for in the risk assessment, and could increase the risk of pathogens being carried outside through overburdening the facility's air filtration system or by laboratory workers spreading contamination. Even if only one room in the facility were used for foot-and-mouth disease experiments, cleaning the room daily would produce the equivalent of 365 spills each year that could potentially lead to a foot-and-mouth disease virus infection and outbreak.

In other parts of the risk assessment, lessons learned from past animal disease outbreaks were not applied to estimate the risk of pathogen escape and disease spread. The site-specific risk assessment estimated that the facility's liquid waste decontamination system would fail just once every 2.1 million years. However, such a failure was the cause of the 2007 release of foot- and-mouth disease virus in the United Kingdom. Another incident occurred in June 1999 at the National Centre for Foreign Animal Disease in Winnipeg, Canada before the facility was handling live pathogens: a batch of untreated wastewater was accidentally released into the local sewage system. Perhaps of greater significance is that in the past 50 years, there have been 15 documented releases of foot-and-mouth disease virus from laboratories around the world, including one from Plum Island.

Predicting the Extent of Disease Spread

While pathogen release is an inherent risk for any high-containment laboratory, the degree of resulting infection, spread, and impact will be strongly related to a laboratory's location. The Department of Homeland Security's risk assessment noted that tornado conditions could carry air-borne pathogens long distances from the facility in the event of a release; however, this was a less critical pathway for foot- and-mouth disease virus spread

than the near-site exposure of cattle. About 9.5 percent of the U.S. cattle population is located within 200 miles of the proposed facility. The region also serves as a hub for livestock transportation for the whole United States, meaning that infected animals could easily enter the transportation chain, allowing the infection to spread quickly across great distances from the initial focus of the outbreak.

The risk assessment also overlooked some important site-specific factors that could elevate the risks of spread of a disease pathogen originating from the laboratory. For example, the proximity of the proposed laboratory to other animal facilities is a cause for concern. The laboratory will be adjacent to the Kansas State University's College of Veterinary Medicine, which treats sick and disease-susceptible animals. Once the animals return home with their owners, they could serve as a conduit for disease spread. This is in stark contrast to the Plum Island research facility, which is located on an otherwise uninhabited island with limited visitor access.

Developing Mitigation Strategies

Because the most probable cause of pathogen release identified by the risk assessment is human error, safe practices are of paramount importance in mitigating a disease outbreak. To reduce the risk of human error, the committee agrees that key National Bio- and Agro-Defense Facility personnel would need ongoing training, education, and evaluation of skills, together with zero tolerance for deviations from biosafety standards and practices recommended by the Centers for Disease Control and Prevention and the U.S. Department of Agriculture.

To minimize the impact of a pathogen outbreak, it is essential to have mitigation strategies in place with plans to treat infected people and animals and measures to limit the spread of disease. The committee found that the mitigation strategies described in the risk assessment did not realistically estimate current or future capabilities for how federal, state, tribal, and local authorities would respond to and control a pathogen release.

For example, because the proposed research facility will handle dangerous zoonotic pathogens that can cause severe illness and death in humans, and for which there is no available treatment, the proximity to adequate clinical facilities is important.

The risk assessment identified the Mercy Regional Health Center as the major medical center in the area. However, the committee found that the health center does not have the appropriate clinical



isolation facilities, diagnostic laboratory capability, or infectious disease clinicians experienced in diagnosing and treating patients exposed to the most dangerous pathogens, to meet the community's needs in developing response measures.

Epidemiological studies were used to model the outcomes of disease outbreaks using various mitigation strategies, but in some cases the inputs to the models were unrealistic. For example, one mitigation strategy assumed that if a disease outbreak occurred, workers would be able to cull and bury or burn 120 herds of farm animals per day, destroy their feed, and thoroughly clean and disinfect the premises to prevent the spread of disease. Culling on this scale would place considerable logistical demands on personnel and equipment, and most likely would not even be possible with military intervention. The committee also questioned overly optimistic estimates of the amount of time it would take for disease symptoms to be recognized and reported as a disease outbreak.

Furthermore, the modeling did not consider the impacts of a foot-and-mouth disease virus epidemic on the entire nation. Instead, epidemiological and economic impacts were modeled in only seven states, selected based on their swine and cattle populations. The committee found that limiting the study in this way means that it is unlikely to accurately reflect the impact of an epidemic. Current livestock transportation and management practices mean that infected animals could easily be transported beyond the seven states, and even across country borders to and from Canada or Mexico. The committee also observed that states with lower animal populations may actually have the highest numbers of livestock sales barns and less stringent animal inspection standards than other states, so that the rate of infection and disease spread could have been underestimated.

Evaluating the Facility Design Plans

Design guidelines for high-containment facilities have been developed to reduce the likelihood of a pathogen escape due to mechanical failure, ensure that conditions in rooms that house animals are relatively constant, and enable the continuity of operations. If appropriately informed with more accurate probabilities on wind speed and tornado occurrences, the committee is confident that a facility can be built to withstand high-wind events, and engineering and operational safeguards can lower the risk of release. One operational safeguard that is strongly recommended for high-containment laboratories is the use of two redundant sets of HEPA filters that allows one set to be taken out of operation at any time for repair or maintenance without the need to shut down the facility.

To function safely, the facility will need to have state-of-the-art equipment and use state-of-the-art biosafety practices. The committee noted that in some features of the facility's design, cost-saving measures appeared to trump critical biosafety features. For example, the current design omits a parallel redundant bank of HEPA filters for the animal rooms, but does not suggest what to do if, for example, the filters for a room housing animals infected with a dangerous pathogen were to become blocked. The risk assessment stated that cost and practicality were considered in that decision.

Deciding What to Do Next

The nation clearly needs an institution to support comprehensive research programs for the study of foreign animal and zoonotic disease, including detection, diagnosis, drugs, and vaccines. This need is currently served by the Plum Island Animal Disease Center, an aging facility in much need of repair.

Though the Department of Homeland Security risk assessment and this 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 of constructing the National Bio- and Agro-Defense Facility in Manhattan, Kansas, are acceptable. If construction and operation should proceed as planned, the Department of Homeland Security will need to consider steps that minimize risk and impact.

References

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- WHO (United Nations World Health Organization). 2008. *Zoonoses*. <http://www.who.int/topics/zoonoses/en/> [accessed September 1, 2010].

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The National Academies appointed the above committee of experts to address the specific task requested by the U.S. Department of Homeland Security. The members volunteered their time for this activity; their report is peer-reviewed and the final product signed off by both the committee members and the National Academies. This report brief was prepared by the National Research Council based on the committee's report.

For more information, contact the Board on Life Sciences at (202) 334-2187 or visit <http://dels.nas.edu/bls>.

Copies of *Evaluation of a Site-Specific Risk Assessment for the Department of Homeland Security's Planned National Bio- and Agro-Defense Facility in Manhattan, Kansas* are available from the National Academies Press, 500 Fifth Street, NW, Washington, D.C. 20001; (800) 624-6242; www.nap.edu.

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