



Materials Distributed at the National Bio and Agro-Defense Facility Draft Environmental Impact Statement Public Meetings

July 24, 2008, 12:30 pm
Grand Hyatt Washington
1000 H Street, NW
Washington, DC 20001

July 29, 2008, 12:30 pm and 6:00 pm
Butner-Stem Middle School
501 East D. Street
Butner, NC 27509

July 31, 2008, 12:30 pm and 6:00 pm
Kansas State University
K-State Student Union
Manhattan, KS 66506

August 5, 2008, 12:30 pm and 6:00 pm
First Baptist Church
Christian Life Center
121 Center Street
Flora, MS 39071

August 7, 2008, 12:30 pm and 6:00 pm
Radisson Hill Country Resort
9800 Westover Hills Blvd.
San Antonio, TX 78251

August 11, 2008, 6:00 pm
Saybrook Point Inn
Two Bridge Street
Old Saybrook, CT 06475

August 12, 2008, 6:00 pm
Greenport School
720 Front Street
Greenport, NY 11944

August 14, 2008, 12:30 pm and 6:00 pm
The University of Georgia
Center for Continuing Education
1197 South Lumpkin Street
Athens, GA 30602



National Environmental Policy Act Process

NATIONAL BIO AND AGRO-DEFENSE FACILITY
Science and Technology Directorate/Office of National Laboratories

The National Environmental Policy Act (NEPA) of 1969 requires the preparation of an environmental impact statement (EIS) for major federal actions that may significantly affect the quality of the environment. Under NEPA, the term “environment” encompasses the natural and physical environment (i.e., air, water, geography, and geology), as well as the relationship of people with that environment (i.e., health and safety, socioeconomic conditions, cultural resources, noise, and aesthetics). NEPA requires federal agencies to use all practicable means within their authority and consistent with other essential considerations of national policy, to create and maintain conditions under which people and nature can exist in productive harmony. Congress enacted NEPA to ensure that, before any action is taken, federal agencies consider the potential environmental impacts of their proposed actions and alternatives that would avoid or minimize adverse effects upon the quality of the environment.

The Council on Environmental Quality established regulations for implementing NEPA applicable to all federal agencies, including procedures for preparing an EIS. Individual agencies, including the U.S. Department of Homeland Security (DHS), have established their own implementing regulations to meet or exceed these requirements. Issuing a Notice of Intent begins the EIS process, followed by gathering input on the issues and alternatives to be considered in the EIS (scoping process) from federal agencies, state and local governments, Native American tribes, and other interested individuals and organizations. This information is analyzed to determine the potential for significant impacts to the environment. The environmental impact analysis is presented in the draft EIS, which is released to the public for comment. Public comments on the draft EIS are analyzed, responded to, and any resulting changes to the analyses are documented in the final EIS. Decisions are not made in the EIS, but are issued in a Record of Decision published after the final EIS.

Scoping Process

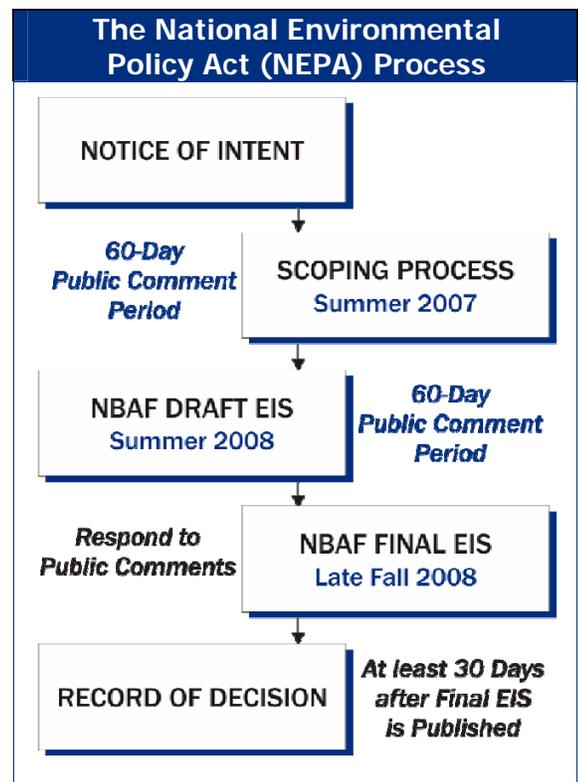
DHS announced its intention to prepare an EIS to evaluate siting alternatives for the proposed National Bio and Agro-Defense Facility (NBAF) on July 31, 2007. A 60-day public comment period followed during which comments were collected and issues identified. During that time, DHS conducted eight public meetings at which nearly 300 people provided oral comments. DHS also received more than 880 comment documents during the comment period.

NBAF Draft EIS

DHS announced the availability of the *National Bio and Agro-Defense Facility Draft Environmental Impact Statement* (NBAF Draft EIS) for public review in the *Federal Register* on June 27, 2008. The NBAF Draft EIS evaluates the potential environmental impacts from siting, constructing and operating the NBAF. A 60-day comment period, ending August 25, 2008, gives the public the opportunity to review and submit comments on the NBAF Draft EIS.

NBAF Final EIS and Record of Decision

All comments on the NBAF Draft EIS, regardless how they are submitted, will be given equal consideration in finalizing the EIS. The NBAF Final EIS is expected in late fall 2008. As the designated DHS decision-maker, Under Secretary for Science and Technology Jay M. Cohen will consider the analyses in the final EIS along with other factors such as technical feasibility, cost and national objectives. A Record of Decision that explains the final decisions regarding the NBAF will be made available 30 days after the NBAF Final EIS is published.





Opportunities for Public Comment

NATIONAL BIO AND AGRO-DEFENSE FACILITY
Science and Technology Directorate/Office of National Laboratories

The U.S. Department of Homeland Security (DHS) is committed to providing the public with access to pertinent information and opportunities for involvement in the environmental impact statement decision-making process. Accordingly, the DHS Science and Technology Directorate is soliciting written and oral comments on the *National Bio and Agro-Defense Facility Draft Environmental Impact Statement* (NBAF Draft EIS). The NBAF Draft EIS may be reviewed at designated reading rooms or downloaded and/or requested at <http://www.dhs.gov/nbaf> (click on Public Involvement).

The following communication mechanisms are available for providing comments. All comments received by close of business **August 25, 2008**, both written and oral, will be given equal consideration when finalizing the NBAF EIS.



U.S. Department of Homeland Security
Science and Technology Directorate
James V. Johnson
Mail Stop #2100
245 Murray Lane, SW
Building 410
Washington, DC 20528



<http://www.dhs.gov/nbaf> (click on Public Involvement)



Oral comments may be submitted by calling our 24-hour toll-free number, which is equipped with a voice mail system:
1-866-501-NBAF (6223)



Written comments may be submitted by faxing to our 24-hour toll-free number:
1-866-508-NBAF (6223)



Participants in public meetings will have access to the following tools to assist them in submitting comments:

<i>Comment Forms:</i>	To prepare and submit written comments
<i>Court Reporter:</i>	To record oral comments
<i>Exhibit Area:</i>	To view exhibits and speak with subject matter experts



National Bio and Agro-Defense Facility Public Reading Rooms

NATIONAL BIO AND AGRO-DEFENSE FACILITY
Science and Technology Directorate/Office of National Laboratories

The U.S. Department of Homeland Security has designated the following locations to provide information repositories for documents and publications regarding the National Bio and Agro-Defense Facility (NBAF). The public is encouraged to visit the reading rooms to gain a better understanding of the NBAF and learn more about public involvement opportunities. These materials are also available online at <http://www.dhs.gov/nbaf>.

GEORGIA

University of Georgia Main Library
320 South Jackson Street
Athens, GA 30602
(706) 542-3251

Oconee County Library
1080 Experiment Station Road
P.O. Box 837
Watkinsville, GA 30677
(706) 769-3950

KANSAS

Manhattan Public Library
629 Poyntz Avenue
Manhattan, KS 66502
(785) 776-4741

Hale Library
Kansas State University
Manhattan, KS 66506
(785) 532-7421

MISSISSIPPI

City of Flora Library
144 Clark Street
Flora, MS 39071
(601) 879-8835

NEW YORK SITE

Acton Public Library
60 Old Boston Post Road
Old Saybrook, CT 06475
(860) 395-3184

Southold Free Library
53705 Main Road
Southold, NY 11971
(631) 765-2077

NORTH CAROLINA

Richard H. Thornton Library
210 Main Street
Oxford, NC 27565-0339
(919) 693-1121

South Branch Library
1547 South Campus Drive
Creedmoor, NC 27522
(919) 528-1752

TEXAS

Central Library
600 Soledad
San Antonio, TX 78205
(210) 207-2500



National Bio and Agro-Defense Facility

NATIONAL BIO AND AGRO-DEFENSE FACILITY
Science and Technology Directorate/Office of National Laboratories

NEED FOR A BIOSAFETY LEVEL 4 FACILITY

The proposed National Bio and Agro-Defense Facility (NBAF) would provide an integrated facility for studying foreign animal and zoonotic diseases (transmitted from animals to human beings).

The Plum Island Animal Disease Center (PIADC) currently performs much of this research but is nearing the end of its lifecycle, is too small to accommodate necessary research, and does not have biosafety level 4 (BSL-4) capabilities. The Homeland Security Act of 2002 recognized that protection of U.S. agriculture is a critical element of homeland security and transferred ownership of PIADC from the U.S. Department of Agriculture (USDA) to the U.S. Department of Homeland Security (DHS). While DHS now has responsibility for operating PIADC, both DHS and USDA conduct scientific research, diagnostic, and training programs there as part of an integrated strategy to protect U.S. agriculture.

The missions of the DHS, USDA Animal and Plant Health Inspection Service-Veterinary Services (APHIS-VS), and the Agricultural Research Service (ARS) are expanding to ensure protection of the nation's livestock and, thereby, public health. The NBAF would:

- serve as a unique BSL-3 and BSL-4 livestock laboratory capable of developing countermeasures for foreign animal and zoonotic diseases;
- provide advanced test and evaluation capability for threat detection, vulnerability, diagnostics, and countermeasure assessment for agricultural and zoonotic diseases; and
- support licensing of vaccines and other countermeasures developed jointly by ARS and DHS.

The NBAF would provide a safe and secure facility in which basic research, diagnostic development and validation, diagnostic testing, advanced countermeasure development, and training for high-consequence livestock diseases can occur. Approximately 10 percent of the 520,000 square foot NBAF would be designed for BSL-4 research. This would allow directed research on diseases not previously well characterized.

RESEARCH TO BE CONDUCTED IN THE NBAF

Research performed at the NBAF would include basic discovery and countermeasure development, advanced countermeasure development (in collaboration with industry), and diagnostic assay development and validation. In some cases, researchers would study a disease to determine:

- the mechanism it uses to enter animals;
- the type cell the disease affects, and the effects the disease causes on the cells;
- how to develop countermeasures to help animals develop protection against the disease; and
- how quickly animals can become protected from the disease after they are vaccinated.

DHS and USDA have identified the following diseases that would potentially be studied at the NBAF. This list may change based upon continued evaluation of risks to the U.S. agricultural system.

- **Foot and Mouth Disease (FMD).** Viral disease of domestic and wild cloven-hoofed animals; acute disease characterized by fever, lameness, and vesicular lesions on the feet, tongue, mouth and teats; FMD is considered to be one of the most contagious, infectious diseases known; cost estimates of an introduction of FMD in the U.S. are more than \$37 billion.
- **Classical Swine Fever (CSF).** Wild and domestic swine are the only known natural reservoir; widespread throughout the world and has the potential to cause devastating epidemics, particularly in countries free of the disease; any outbreak of CSF would have serious consequences for domestic and international trade of swine and swine products; improved countermeasures are needed.
- **African Swine Fever (ASF).** Infected animals have high mortality rates; effective countermeasures are not available for infected animals; no vaccines are available to prevent infection; no treatment exists for ASF and countermeasures need improvements.

- **Rift Valley Fever (RVF).** Virus affects human beings and cloven-hoofed animals (sheep, goats, cattle, camels, buffalo and deer); suitable countermeasures to respond in the U.S. do not exist; risk for establishment of endemic disease; ranked as a major disease of concern with USDA, DHS, and other stakeholders.
- **Contagious Bovine Pleuropneumonia (CBPP).** Caused by an infective microorganism (*Mycoplasma mycoides*); primarily affects cattle including European-bred cattle and Zebu; a related form can affect goats; may survive for days in the environment; no treatment available.
- **Japanese Encephalitis (JE) Virus.** Similar to St. Louis encephalitis virus; JE virus is amplified in the blood of domestic pigs and wild birds; the virus can infect humans, most domestic animals, birds, bats, snakes and frogs.

Diseases Studied in BSL-4 Facilities

- **Nipah Virus.** Virus was discovered in 1999; causes disease in swine and in humans through contact with infectious animals; mode of transmission between animals and from animals to humans is uncertain (appears to require close contact with infected tissues or body fluids); caused respiratory disease and encephalitis in people in Malaysia and Singapore; no drug therapies have yet been proven to be effective in treating Nipah infection; no countermeasures exist.
- **Hendra Virus.** Formerly called equine morbillivirus; first isolated in 1994; the natural reservoir for Hendra virus is still under investigation; human beings and equines seem to be predominately affected; caused respiratory and neurological disease in horses and humans in Australia.

BIOCONTAINMENT AND SAFETY FEATURES OF THE NBAF

The NBAF would include the latest advances in security and technology. Safety features would include Class III gloveboxes, Class I or II biological safety cabinets (BSCs) in BSL-3 labs, and Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive-pressure personnel suits in BSL-4 labs. There would be personnel controls to include federal background checks, biometric testing required for entry to the labs and no solitary access to BSL-4 microorganisms would be allowed.

The NBAF BSL-4 lab design would employ a box-in-box principle with a pressure-controlled buffer surrounding it. There would be air pressure differentials between zones of containment and directional airflow would be exhausted toward high-efficiency particulate air (HEPA) filters. The exhaust air would not be recirculated and all water and air that leaves the lab would be purified (i.e., no research microorganism would enter the sewage system or outside air). All critical functions would have redundant systems.

AGENCY RESPONSIBILITIES

The NBAF would be owned by DHS with ARS and APHIS-VS as primary partners. These same agencies are currently working at PIADC. The Department of Health and Human Services and other agencies may also occupy space in the NBAF as dictated by the need for assistance.

DHS and USDA work cooperatively to set priorities regarding diseases to be researched. Interagency working groups utilize a variety of agricultural risk assessments and gap analyses to prioritize research and diagnostic capabilities. ARS performs basic research in discovery in mechanisms of disease and countermeasure development and works to transition prospective candidates for advanced countermeasure development to DHS. DHS further develops these candidates and transitions them to commercial partners for complete development and hand off to APHIS-VS for deposition in the National Veterinary Stockpile. DHS, ARS, and APHIS-VS work to develop diagnostic tools to be utilized in the reference and state laboratories.

Once developed, APHIS-VS is responsible for validating the new assays/tools and deploying them to the National Animal Health Laboratory Network. APHIS-VS is also responsible for operating the Foreign Animal Disease Diagnostic Laboratory for diagnosis of FMD and other high-consequence foreign animal diseases (FADs), as well as training veterinarians (as part of the Foreign Animal Disease Diagnostician's school) in the recognition and diagnosis of FADs.

CONSORTIUM ROLE

The site consortium would assist in the NBAF's mission but would not have a direct role in overall operations. The consortium would provide access to:

- a vibrant research area for collaboration between NBAF researchers and others such as veterinary diagnostic laboratories, the state veterinary office, students and faculty;
- a trained workforce with graduate and post doctoral degrees; and
- continuing education and sabbatical opportunities for NBAF researchers.



Biosafety Levels

BIOSAFETY LEVELS (BSL)

- There are four levels of biosafety used to designate and regulate lab work with microorganisms.
- Each level is designed to prevent lab-acquired infections and to protect the environment from potentially hazardous agents.
- The higher the level of the biosafety lab, the more stringent the level of protection required to work in these areas.

BSL-1: Microorganisms not known to cause disease in healthy adult human beings.

- Potential hazards to laboratory personnel and the environment are minimal.
- Work is conducted on open bench tops using standard microbiological practices (lab coats, safety glasses and gloves).
- Lab personnel have specific training in the procedures conducted in the lab and are supervised by a scientist with general training in microbiology or a related science.
- BSL-1 labs are located in high school and college-level biology and chemistry classrooms and research institutions.

BSL-2: Microorganisms of moderate potential hazard to personnel and the environment.

- Lab personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures.
- Access to the lab is limited when work is being conducted.
- All procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.
- BSL-2 labs are located in research institutions, essentially all hospitals, and medical and veterinary schools.
- **An example of a microorganism that would be studied in a NBAF BSL-2 lab is the inactivated virus that causes foot and mouth disease.**

BSL-3: Microorganisms present in the United States, and foreign and emerging agents that may cause serious consequences in livestock but are not harmful to human beings because of available protective measures.

- Lab personnel have specific training in handling pathogenic microbes potentially lethal to animals and are supervised by trained scientists who are experienced in working with these agents and associated procedures.
- Access to the lab is controlled (i.e., card reader for entry; self-sealing, double door access, etc.)
- All procedures involving the manipulation of infectious materials are conducted within biological safety cabinets or other physical containment devices, or by personnel wearing appropriate personal protective clothing and equipment.
- BSL-3 labs have special engineering and design features to enhance safety.
- BSL-3 labs are located in research institutions, hospitals, and medical and veterinary schools.
- **An example of a microorganism that would be studied in a NBAF BSL-3 lab is the live virus that causes foot and mouth disease in cloven-hoofed animals.**



BSL-4: Microorganisms that pose a high risk of life-threatening disease and for which there is no known vaccine or therapy.

- Lab personnel have specific and thorough training in handling extremely hazardous infectious agents and fully understand all containment functions, practices, equipment and lab design characteristics.
- Lab personnel are supervised by trained scientists who are experienced in working with the microorganisms and with associated procedures.
- Access to the lab is strictly controlled. The facility is in a controlled area within a building, which is completely isolated from all other areas.
- There are four BSL-4 facilities currently operating in the United States in populated urban areas: Atlanta, Georgia; Fort Detrick, Maryland; Galveston, Texas; and San Antonio, Texas. There has never been a public exposure at a BSL-4 lab in the United States.
- **Examples of microorganisms that could possibly be studied in a NBAF BSL-4 lab include Nipah and Hendra viruses, both of which are emerging zoonotic diseases that can spread from their natural reservoir to human beings, and are often fatal.**