Specific Measures Taken by the United States Relevant to Security of Dangerous Pathogens and Toxins

Prepared by the United States of America

Background

1. Since the late 1990s the United States Government has worked to put in place effective measures to protect dangerous pathogens and toxins from illicit or malicious diversion (“biosecurity”). To implement enhanced biosecurity of dangerous human, plant, and animal pathogens and toxins, the United States has sought to identify those pathogens and toxins requiring special oversight, and to provide for the safe and secure possession, storage, transfer, and disposal of these agents without unduly inhibiting peaceful and positive scientific research and application. To meet these demands it was determined that measures should include proper risk assessment, identification of appropriate physical and personnel security practices, and regular review of safety and security procedures.

Establishment of a Select List of Agents and Toxins

- The Department of Health and Human Services, through its Centers for Disease Control and Prevention (CDC), in consultation with other agencies and with additional guidance, has identified a list of select agents and toxins relevant to human disease.

- The United States Department of Agriculture, in consultation with other agencies and with additional guidance, has identified a list of livestock select agents and toxins and a list of plant select agents and toxins relevant to commercially significant plant and livestock diseases.

- Both lists are codified in accordance with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). The combined list can be found at the following Internet web address: www.cdc.gov/od/sap/docs/salist.pdf.
Measures for Enforcement of Biosecurity of Dangerous Pathogens and Toxins
(DPTs - Referred to as “Select Agents and Toxins” in U.S. Legislation)

2. The United States has adopted the following national measures:

Relevant Statutes

- The Biological Weapons Anti-Terrorism Act of 1989 (Public Law 101-298)
- The Chemical and Biological Weapons Control and Warfare Elimination Act of 1991 (Public Law 102-182, Title III).
- The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT ACT) of 2001 (Public Law 107-56).
- The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188) and The Agricultural Bioterrorism Protection Act of 2002 (Public Law 107-188, Title II, Subtitle B).
  - Determination of which facilities currently possess DPTs within the boundaries of the United States.
  - Requirements for registration and approval of facilities that acquire, use, store, transfer, and dispose of DPTs.
  - Requirements for those entities that possess, use, or transfer DPTs to implement measures to ensure security of those DPTs.
  - Requirements for personnel having access to select agents to undergo a security check and to be approved.

Technical and Legal Advice

- Creation of a list of technical and legal experts to advise the United States Government on biosecurity issues and necessary national measures.
- Preparation of a list of contacts within and outside the United States Government with expertise in these areas.

Emergency Response

- Establishment of a nationwide laboratory response network by the CDC.
- Establishment of Emergency Management Agencies in each State by the Federal Emergency Management Agency (FEMA).

Establishment of Specific Guidelines for Achieving Adequate Protection of the DPTs

- An interagency committee of the United States Government, led by the White House Office of Science and Technology Policy and established by the CDC, has developed guidelines for biosecurity of pathogens (DPTs) that augment the provisions (42 CFR
Part 1003) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. These guidelines provide information about risk assessments, access control, and emergency response plans.

Establishment of Specific Requirements for Safe and Secure Transport of DPTs

- Requirements for safe and secure transport of DPTs have been established and were recently revised (49 CFR 171). In response to the Public Health Security and Bioterrorism and Response Act of 2002 (Public Law 107-188) and its implementing regulations, requirements for security assessments of personnel handling shipments have been developed (49 CFR 172)

Identification of National Bodies to Oversee Biosecurity

- Designation of the CDC, an agency of the Department of Health and Human Services, as the national body to oversee biosecurity of dangerous human pathogens and toxins, and the Animal and Plant Health Inspection Service, a division of the United States Department of Agriculture, as the national body to oversee biosecurity of dangerous plant and animal pathogens and toxins.

Maintaining and Monitoring National Biosecurity of Dangerous Pathogens and Toxins

- A United States Government Interagency Working Group will monitor the national activities of DPTs and will periodically review the list of DPTs.