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ABSA Comments to the **Working Group on Strengthening the Biosecurity of the United States** Following the Public Meeting May 13-14, 2009

The American Biological Safety Association (ABSA) is pleased to have the opportunity to offer comments to the Working Group on Strengthening the Biosecurity of the United States following the Public Meeting held May 13-14, 2009. First, we will comment on the topic of each of the panels held at the meeting, and then will offer general comments.

Panel I – Select Agent Regulations

ABSA believes that the current Select Agent Regulations are sufficiently rigorous and effective. They should not be made more prescriptive. Measures used by the research community to safely work with and contain biological materials also inherently enhance the security of those materials. The list of select agents should be reviewed and revised with advice from the scientific community. This list should focus on the organisms most likely to be used as agents of bioterrorism or as biological weapons.

The topic of inventories should be revisited by the Select Agent Programs. Counting vials or volumes of a culture that can be grown overnight to exponentially increase the number of vials or the volume makes an inventory meaningless.

Panel II – Physical/Facility Security at Select Agent Program Entities

The Federal government absolutely should not develop prescriptive physical security requirements. This could inhibit or prevent much important microbiological research. Each entity must develop and implement security measures based upon their individual risk assessments, physical facilities and operations. Stratification of select agents is of no value; each entity must develop site-specific written security, biosafety and incident response plans.

Panel III – Oversight and Inspection of Select Agent Facilities

Inspections under the Select Agent Program could benefit by careful selection and training of inspectors to assure consistency across the country. Some inspections have enhanced biosafety

and biosecurity at entities with select agent programs while some entities report unproductive requests by inspectors for additional enhancements with limited contribution to safety and security and not predicated on evidence-based risks. Many institutions have multiple inspections from several different agencies. An effort should be made by agencies to coordinate such inspections with each other to reduce disruptions and the administrative burden on institutions. In addition, there is a need for harmonization of inspections and interpretations across all agencies.

Panel IV – Transportation of Select Agents

ABSA and the transportation community are unaware of security problems with the transport of select agents under the current IATA (International Air Transport Association) and DOT (Department of Transportation) regulations. The transport requirements for select agents in most cases cause them to be shipped as Category A Infectious Substances, with the appropriate packaging and labeling prescribed by the regulations. Packages containing select agents should most certainly **not** be labeled differently than other infectious agents, due to security concerns. A registration program for carriers is likely to deter carriers from accepting Category A substances for transport, as it is already difficult to find carriers who transport Category A, especially internationally. Carriers have a system for security approval under the SRA (security risk assessment), so they do not need an additional security review and approval. Additional restrictions on shipping will inhibit important research and has already caused barriers to the transport of samples for diagnosis (e.g., samples for H1N1 analysis from Mexico had to be shipped to Canada, because the U.S. import and shipping regulations were excessively restrictive).

There are no current regulations for plant pathogens; they are not regulated by IATA/ICAO (International Civil Aviation Organization) or DOT for transit. Improper packaging and handling of plant pathogens could present a risk to the U.S. agricultural community, and therefore our economy.

The approval to transport select agents is well controlled by both the CDC (Centers for Disease Control and Prevention) and APHIS (U.S. Department of Agriculture Animal and Plant Health Inspection Service). Form 2 must be approved prior to shipping an agent. The Form 2 allows CDC and APHIS to confirm that both the Recipient and Sender entities and individuals are approved for the select agent(s) to be shipped. This approval process has worked very well since it was instituted in 2003.

Panel V – Personnel Security/Reliability Programs

Existing personnel reliability programs used in other industries should not be applied to all select agent research. This would only serve to deter qualified scientists from pur-suing important research on select agents. The “two person rule” must not be applied universally to select agent research; it would significantly inhibit or prohibit research at Biosafety Level 3 (BSL-3) in academic institutions. It must be determined by entities on an individual basis after appropriate risk assessments whether it is necessary to require a “two-person

rule". ABSA strongly recommends that this working group adopt the recommendations of the National Science Advisory Board for Biosecurity (NSABB) personnel reliability working group.

Panel VI – Culture of Security and Responsibility and Training Programs

A culture of responsibility has existed in containment laboratories in the U.S. for decades. Federal funds could best be used to develop or enhance existing biosafety and biosecurity training programs offered by a number of organizations. Federal funds should also used to help develop biosafety/biosecurity curricula at the baccalaureate and postbaccalaureate levels in universities. The sharing of best practices and lessons learned must be encouraged and enabled in a non-threatening, non-punitive atmosphere. ABSA endorses the AAAS (American Association for the Advancement of Science) report "*Biological Safety Training Programs as a Component of Personnel Reliability*."

ABSA would like to address additional issues introduced at the public meeting:

ABSA believes that licensure of individual researchers in the life sciences is unnecessary and undesirable. Research in the life sciences, and especially with the most hazardous microbial pathogens, has been performed by the most qualified and dedicated scientists for decades. A licensure requirement would deter many qualified scientists from pursuing work in high and maximum containment laboratories.

The oversight of select agent research must remain with HHS/CDC and USDA/APHIS, as the scientific knowledge resides in these agencies. Further, oversight of select agent research must be consolidated. The ability to complete the public health and scientific mission of analysis and research on pathogens of significance to humans, animals, and plants in the United States must not be neglected or compromised.