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September 11, 2009

Dear Sirs,

The American Biological Safety Association (ABSA) is an international group of biological safety professionals that is recognized as one of the world's foremost resources on biological safety practices.

We have reviewed the proposal announced in the July 13, 2009 issue of the Federal Register to classify the SARS-associated coronavirus (SARS-CoV) as a Select Agent under the Centers for Disease Control and Prevention's Select and Toxin Program. Please consider the following comments.

The anthrax attacks which began in 2001 prompted the adoption of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. This Act expanded the scope of the Centers of Disease Control and Prevention Select Agent and Toxin Program. The Act requires the Department of Health and Human Services (DHHS) to establish a list of biological agents and toxins which pose severe threats to public health and safety. Criteria noted in the Act as having a role in the Select Agent risk determination are the potential for the agent or toxin to be used as a biological weapon and the potential for acute toxicity posing a significant mass casualty threat. All agents listed thus far by the DHHS have been so listed considerate of these criteria.

SARS-CoV has been proposed for inclusion as a Select Agent independent of its weaponization potential. This pathogen is recognized by a number of national and world health agencies as a significant public health concern, but not as a possible weapon. We recognize that as a threat to public health the inclusion of SARS-CoV is within the original scope of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. However, there are a number of other agents

which also have high mortality on certain population segments, which possess the ability to be transmitted from person to person, and which are environmentally persistent, but which have not been listed as Select Agents (i.e. seasonal influenza virus). We believe this actions establishes a precedent that threatens important research on infectious disease agents, particularly emerging and re-emerging agents. Congress has recognized the possible public health impact of these types of infectious agents by its enactment of the Pandemic and All-Hazards Preparedness Act of 2006 which deals with public health emergencies such as pandemic influenza. Management of infectious agents of public health consequence such as SARS-CoV would be more appropriate under the provisions of this 2006 legislation.

During the initial 2003 SARS outbreak, none of the public health SARS cases were known to have been attributed to improper handling of the SARS-CoV within the laboratory. There have been no laboratory acquired cases of SARS-CoV illness reported in the world since 2004, a period of five years. Through appropriate BIOSAFETY risk assessment and practices, we have learned to manage SARS-CoV in the laboratory. Before the last SARS case in China in 2004, there had been two other laboratory acquired cases of SARS Co-V illness reported (Singapore, Taiwan) independent of the global public health outbreak which led to the discovery of SARS Co-V. However, all of these cases were in foreign countries and not in the United States. None of these countries had standards of care for the safe handling and security of this type of pathogen comparable to the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). These facts are supportive of continued safe management of SARS-CoV in laboratories which conduct investigations of this virus consistent with the appropriate BMBL provisions.

The possible public health impact of another outbreak of SARS-CoV illness has prompted much research with this virus, such that the effects of another such outbreak can be more readily mitigated. This research has been extremely fruitful and has contributed much to our understanding of how to best manage this virus, both in the laboratory and in the clinic. The proposed regulation of this virus would prompt some entities currently in possession of this virus to destroy its stocks in order to avoid the significant costs associated with implementing a program compliant with the select agent regulations. Loss of these strains could have a detrimental impact on current and future SARS-CoV research. The costs associated with obtaining and maintaining a Select Agent registration are significant. The application process is burdensome and time consuming, resulting in significant administrative burdens and costs. Also, the additional expenses associated with meeting the facility design criteria required for security generate no quantifiable benefits in terms of increased safety for the public or the scientific staff actually conducting the research.

These outcomes would diminish overall SARS-CoV research activity and would compromise efforts to identify treatment and prevention therapies in the event of another SARS-CoV public health outbreak. Should SARS-CoV once again emerge as a public health emergency, the SARS-CoV isolates from the previous outbreak could be valuable reference points in assessing possible changes in the new SARS-CoV outbreak strain.

In summary, we do not believe that SARS-CoV should be added to the Select Agent list. Doing so will not enhance public safety. Rather, it has the potential to decrease public safety and security by preventing expert researchers from pursuing this important work due to the additional costs and onerous burdens inherent with the Select Agent registration and compliance process.

In short, we believe that SARS-CoV represents a public health threat best managed in the context of biosafety (BSL3 management), but NOT in a context consistent with its designation as a biosecurity threat (Select Agent).

We appreciate the opportunity to have provided these comments to you.

Sincerely,

A handwritten signature in black ink that reads "Robert P. Ellis". The signature is fluid and cursive, with "Robert" and "P." sharing a common initial stroke, and "Ellis" having a distinct, flowing style.

Robert Ellis, PhD, CBSP
President, American Biological Safety Association