

COGR COUNCIL ON GOVERNMENTAL RELATIONS
AAU ASSOCIATION OF AMERICAN UNIVERSITIES

August 27, 2010

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road
MS A-46
Atlanta GA 30333
RIN 0920-AA34

Docket No. APHIS-2009-0070
Regulatory Analysis and Development
Animal and Plant Health Inspection Service
Station 3A-03.8
4700 River Road Unit 118
Riverdale MD 20737-1238
RIN 0579-AD09

SUBJECT: Biennial Review and Republication of the Select Agent and Toxin List
Reorganization of the Select Agent and Toxin List

The Council on Governmental Relations (COGR) is an association of 183 research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions. The Association of American Universities (AAU) represents 61 leading US public and private universities and is devoted to maintaining a strong national system of academic research and graduate education.

The performance of research with select agents and toxins at our member institutions and the entire research community will be directly affected by the resolution of the questions posed during the biennial review of the list of the agents and toxins. We, therefore, welcome the consideration of these questions by the Departments of Health and Human Services and Agriculture.

We believe the Departments should construct a tiered list of select agents and toxins that reflects the relative bioterrorism risk of each agent and toxin. In its report on *Responsible Research with Biological Select Agents and Toxins* (NAS, 2009), the National Research Council (NRC) outlined key criteria that can be used for developing a tiered list. The NRC report recommends that if the purpose of the select agent/toxin program is to secure and protect the public against agents and toxins that might be used as biothreat agents where the consequences cannot be easily managed, the list of select agents and toxins should not include microorganisms with little or no potential use as a biothreat agent or those whose impact can be effectively managed in other ways.

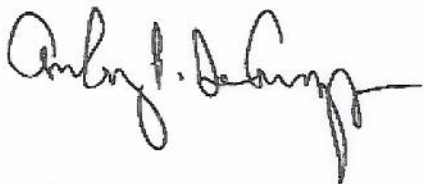
The inter-agency Working Group on Strengthening the Biosecurity of the United States made similar recommendations arguing that "there are 82 biological select agents and toxins on the select agent list, but not all pose the same level of risk to public and agricultural health. The list should be either reduced or stratified so that biosecurity measures can more easily be applied by the registered entities according to the level of risk." The Working Group's report serves as the basis for the July 2, 2010 Executive Order 13546, *Optimizing the Security of Biological Select Agents and Toxins in the United States*. The Executive Order calls for the agents and toxins "to be secured in a manner appropriate to their risk of misuse, theft, loss, and accidental release" and directs the Departments to "explore options for graded protection of Tier 1 agents and toxins . . . to permit tailored risk management. "

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The implementation of a tiered approach to the select agents and toxins should be complemented with graded security requirements including a reduction in the security requirements for lower tier agents. Such a stratified approach to security requirements will allow organizations and institutions to focus time and resources in those areas that pose the greatest threat. In assessing the security requirements, we urge the Departments to consider the examination of personnel reliability conducted by the National Science Advisory Board for Biosecurity (NSABB) in 2009, *Enhancing Personnel Reliability Among Individuals with Access to Select Agents*. THE NSABB acknowledged that it may be appropriate “to enhance extant personnel reliability measures,” but it warns against “promulgation of a formal, national Personnel Reliability Program” and calls on the institutions conducting such research and the professional societies of scientists to ensure a “culture of responsibility and accountability” through education and outreach. This is a responsibility that the research community takes seriously and will continue to pursue in close cooperation with the Departments.

As a part of the Departments’ review of the select agent and toxin program, we echo the President’s call for harmonization and coordination of the oversight of the program across the Federal government. Finally, we urge the Departments to give serious consideration to removing agents and toxins entirely from the list as a part of the deliberation of a tiered approach. We remind the Departments that the addition of agents or toxins to the list may have a significant impact on the conduct of research, with the prospect that some research currently requiring no special security requirements being reclassified as research requiring compliance with the complete select agents/toxin regulations. As the NRC notes in its report, such a change in status would put long-standing research programs at risk.

We welcome a review and reconsideration of the list of select agents and toxins and encourage the appointment of an Advisory Committee drawn from the stakeholder communities as proposed by the NRC to join with Federal representatives in designing a new, tiered approach to the management of biological select agents and toxins.



Anthony P. DeCrappeo
President



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