BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

August 30, 2010

Robbin Weyant, Director
Division of Select Agents and Toxins
Centers for Disease Control and Prevention
1600 Clifton Rd
MS A-46
Atlanta, GA 30333

RE: Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List: Comments on the Changes to the List of Select Agents and Toxins

Dear Mr. Weyant,

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Disease Control and Prevention's (CDC) republication of the Select Agent and Toxin (SAT) List[1]. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

BIO represents an industry that is devoted to discovering new drugs, vaccines and diagnostic tools that can aid in the event of a chemical, biological, radiological and nuclear (CBRN) incident. BIO membership includes many developers and manufacturers who have worked closely with the public health and security communities to support policies that help ensure access to innovative and life-saving medical countermeasures for our national security. Therefore, we continue to monitor those policies and rules that could both positively and negatively impact the development of these important products.

Tiers within the Select Agent List:

BIO agrees that prioritizing the select agents into stratified tiers based on an assessment of relative risk would be appropriate. We feel that such an exercise would help set federal government research, development and procurement priorities. This in turn would help the private industry and investor communities to allocate scarce resources towards the best opportunities. The policy and intelligence communities, working with DHS, HHS and USDA, can best ascertain the right criteria to use to determine these new tiers.

It is important that any efforts to tier the Select Agent List not negatively impact current investments and innovation related to agents currently on the list. Should the SAT be organized into tiers some pathogens and toxins will be shifted into lower tiers which may limit the discovery and development of new technologies that might prove

[1] 75 Fed. Reg. 50730-50731 (August 17, 2010)

useful for future countermeasures. To maintain its relevancy, the SAT list should be assessed routinely to help ensure that the priorities continue to match allocated funds. Given the long lead-times for the development of new medical countermeasures, assessments of the known threats and any subsequent changes to the prioritized tiers should be implemented with enough advanced notice that companies conducting research and development in specific threat areas can make strategic adjustments if required.

Enhanced Security for Top Tier Agents:

The broader policy community has highlighted the possible need for enhanced, targeted security measures for the top tier agents. In general, BIO supports such an initiative as long as these new measures are not so complex that they have a negative impact on medical countermeasure development timelines, costs and therefore scientific innovation. The development of new security measures should be done cautiously, in a way that is mindful of their impact on both physical and human capital.

BIO has seven primary concerns related to the creation of any new security measures. In general, any new regulations should:

1) Afford ample time for public and private laboratories to implement the measures in order to demonstrate their compliance;
2) Make every attempt to streamline duplicative regulations and inspections between various government agencies (CDC, NIH, FDA, DHS, DOD);
3) Include clear legal protections for contractual partners of high security labs in situations where a laboratory is found to be non-compliant;
4) Not further slow down or hinder the hiring process with lengthy personnel clearance procedures for newly hired researchers;
5) Not be so cumbersome that they deter talented researchers and scientists from working on key projects involving these agents;
6) Not impact the use of scientific, research or production equipment that may also be used for the development and manufacturing of commercial products; and
7) Not diminish the ability of industry and academia to respond to emergency situations when called upon by the federal government.

Private companies, public and private laboratories and academic institutions will need clear and thoughtful guidance from the federal agencies on these new security requirements.

It is essential that any new approaches to the determination of select agents and measures to better secure their use take into account the long lead times for development of medical countermeasures and the specialized personnel, skill sets and equipment required for their successful development.

Conclusion

BIO appreciates the opportunity to comment on Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List: Comments on the Changes to the List of Select Agents and Toxins. We look forward to continuing to work with the CDC to address these critical issues in the future. Please feel free to contact me at 202-962-6664 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,

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Biotechnology Industry Organization