New Rules for Biosecurity

BIOSECURITY REGULATIONS ARE BACK ON THE TABLE AGAIN, AND REVISED POLICIES COULD have broad implications for the entire scientific enterprise. In response to an Executive Order by President Bush on 9 January 2009, an interagency working group is reviewing all U.S. laws and regulations governing the conduct of research with biological materials that are potential security threats—so-called select agents. The issue at hand concerns how to balance the risks associated with select agents against ensuring that the public can reap the full potential benefits of research on them. The report of the working group is expected in July, and it will propose an array of policies for improving laboratory biosafety and security, from defining what select agents are and who has access to them, to specifying the oversight of laboratories that handle them. Done well, the review could greatly improve biosecurity and the climate for biological research in the United States and abroad. Done poorly, there could be a variety of unintended negative consequences, including over-restricted access to vital resources and a constrained ability to collaborate internationally on a broad range of topics.

The existing U.S. biosecurity policies have hindered international collaboration and they need revision. For example, in 2003, expert scientists had to plead with the U.S. government to keep the virus responsible for severe acute respiratory syndrome (SARS) off the select agent list, so as to facilitate international collaboration. This resulted in rapid identification of the causative agent and the development of the first vaccine against SARS. Most recently, Mexican officials sent the first 200 samples of H1N1 influenza to Canada for identification rather than to the U.S. Centers for Disease Control and Prevention, because of the U.S. rules on importing biological materials.

The interagency working group is not operating in a vacuum. For example, in 2008, the National Science Advisory Board for Biosecurity (NSABB) issued recommendations for adjusting the existing select agent classification system to accommodate scientific advances. Last month, the NSABB released recommendations for determining who can get access to select agents; that is, the rules for “personnel reliability.” The U.S. National Academies have also charged a committee to review personnel reliability, and its report is expected in September.

The Executive Branch is not alone in worrying about biosecurity; Congress is considering several bills. Among them is one in preparation by the Senate Homeland Security and Governmental Affairs Committee that addresses security concerns of high-containment laboratories. Other bills governing criteria for including agents on the select agent list, biosafety training, and developing a voluntary reporting system for laboratory exposures to these agents have also been introduced in Congress.

The definitions, rules, and regulations that emerge from these activities will not only affect the accessibility, handling, and transport of almost 80 select agents. New policies may also affect both the climate for U.S. science and how inviting America will be to international scientific guests. The ability to perform beneficial research on many materials beyond known select agents that could have both positive and ill-intended uses—such as nanomaterials, immunomodulatory molecules, or the products of synthetic biology—could also be severely constrained.

The White House Office of Science and Technology Policy (OSTP) and the interagency working group are seeking input from the scientific community and the broader public as they carry out their review, and it is critical that scientists respond as quickly as possible, well before the report is finalized in early July.* This is the most comprehensive review of biosecurity research policies since 2001, when biodefense funding and programs substantially increased. The scientific community should seize this opportunity to help guide policy decisions that will have broad ramifications for both national security and the climate for science in the United States and globally.

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*Recommendations to OSTP and the interagency working group can be made before 12 June 2009 at http://cstsp.aaas.org/BiosecurityComment.html, a Web site created by the American Association for the Advancement of Science (AAAS), the publisher of Science.

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