

Development of New Biotech Products and Technologies: Rules of the Road to Use, Possess or Transfer Select Agents and Toxins

CONTACTS

The Current Situation

The *Houston Chronicle* reported on July 2, 2007 that due to violations of the Select Agent and Toxins Regulations, the Centers for Disease Control and Prevention (CDC) had suspended a license granted to Texas A&M University, which allowed the University to perform research on infectious diseases. Given the widespread nature of individuals and institutions who are involved with work utilizing the select agents and toxins, and the growing concern that the security and regulatory framework surrounding these pathogens is too lenient, it is expected that the number of citations for violations of the Select Agent and Toxins Regulations is likely to increase.

Background

The market for novel and transformative bio-pharmaceutical products is increasing exponentially. Unfortunately, while both the biotech and pharmaceutical industries have, in creating life-saving advances, paid considerable attention to the properties of infectious pathogens, toxins, and their derivatives, too often companies have paid no attention at all to the complex set of regulations which govern this research. These regulations include the Department of Health and Human Services (HHS) Select Agent and Toxins Regulations, the Department of Commerce Export Administration Regulations, and the Department of State International Traffic in Arms Regulations. This advisory is the first in a series of advisories that McKenna Long & Aldridge LLP will publish regarding the regulations governing the Select Agent and Toxins.

What are the Select Agents?

The Select Agents are a relatively small list of public health pathogens considered by the CDC and USDA to be particularly dangerous and includes pathogens such as Ebola virus, Marburg virus, and *Yersinia pestis* which is the causative agent of plague. Even agents for which there is a vaccine can still be on the Select Agent list, such as anthrax and smallpox. HHS maintains a current, complete list of Select Agents located at <http://www.cdc.gov/od/sap/>¹.

How are the Select Agents and Toxins Regulated?

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the USA PATRIOT Act legislated the development of the current Select Agent regulations governing transfer, possession and use of Select Agents. The regulations were finalized on March 18, 2005 and impose restrictions on the possession, use, and transfer of both naturally occurring agents and genetic elements which contain amino acid sequences related to these agents. Particular attention must be paid to synthetic constructs. Increasingly, scientists are generating these materials to further ongoing research and development and even production activities, often with varying degrees of informality. It is this component of the regulations many researchers and institutions do not adequately understand and with which they fail to comply when developing new biotech products.

Requirements

The overarching goal of the Select Agent and Toxins Regulations is to prevent the intentional or unintentional access, use, or transfer of an agent to someone who does not have necessary credentials to work with the agent, which includes proper authority, expertise, and scientific motivation. Compliance with the requirements of the Select Agent Regulations requires:

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- Application for a certificate of registration issued by the HHS Secretary (APHIS/CDC Form 1 <http://www.selectagents.gov/registrationForm.htm>);
- Designation of a Responsible Official;
- Performance of a security risk assessment by the Attorney General for individuals and entities desiring to possess or use or receive Select Agents;
- Development and implementation of a written security plan according to the requirements identified in section 73.11 of the regulations;
- Development and implementation of a written biosafety plan that is commensurate with the risk of the toxin, taking into account relevant CDC, NIH and OSHA regulations and guidelines²;
- Development and implementation of an incident response plan;
- Provision of information and training on biosafety and security to each individual with access approval from the HHS Secretary or Administrator; and
- Maintenance of complete records relating to the activities covered by these regulations.

Failure to comply with these regulations can result in the suspension of work involving select agents (as in the case with Texas A&M), but may also include civil and criminal penalties.

Conclusions

The Select Agent and Toxins Regulations are meant to prevent the misuse of the most deadly pathogens known. These regulations only have authority over the possession, use, and transfer of these pathogens inside the United States. A much broader list of regulated materials and related technologies is governed by the Department of Commerce and the Department of State export control regulations. It is critical to remember that more than one of these separate regulatory schemes may be applicable to any given material or technology. Companies must also be aware that the regulations focus on who is receiving knowledge as much as they do who is receiving research material. Clearly, the select agents and toxins have the potential to pose a significant threat to public health and should be closely safeguarded in the interests of national security. However, compliance with the requirements of the Select Agent and Toxins Regulations pose challenges even for biotechnology and pharmaceutical companies with a high degree of regulatory sophistication.

¹The EAR and the ITAR both address a list of pathogenic materials and related technologies, equipment and countermeasures significantly larger than the set comprising the Select Agents.

²Specific regulations required to be considered include the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories" (<http://www.cdc.gov/OD/ohs/biosfty/bmb14/bmb14toc.htm>), the Occupational Safety and Health Administration regulations in 29 CFR parts 1910.1200 and 1910.1450 (http://www.osha.gov/pls/oshaweb/owastand.display_standard_group?p_toc_level=1&p_part_number=1910), and the "NIH Guidelines for Research Involving Recombinant DNA Molecules." (http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Gdlnes_Ink_2002z.pdf).

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