Analysis&Perspective

The Bioterrorism Act of 2002: Improving Laboratory Safety and Security

By Michael J. Vernick

In the wake of the terrorist attacks on Washington, D.C., and New York and the subsequent anthrax mail attacks, the security of hazardous biological materials in U.S. research laboratories has become a critical element of the nation's homeland defense initiatives. One significant step in improving research laboratory security was taken on June 12, when President Bush signed into law the Public Health Security and Bioterrorism Preparedness Act of 2002 (the "Bioterrorism Act").[1] This new law will bring about significant changes in the measures that academic and commercial research laboratories are required to take in dealing with biosafety and security risks.

The first major impact of the Bioterrorism Act is already being felt, as research facilities prepare to respond to the Act's impending Sept. 10 deadline for reporting on possession of dangerous biological agents. This reporting requirement is the initial step in implementing the broad-based regulatory changes required by the Bioterrorism Act. After discussing what research facilities will have to do to comply with the Sept. 10 reporting deadline, this article reviews the likely elements of the Bioterrorism Act's implementing regulations, expected late in 2002, and compares those measures with the current state of biosafety regulation. This article concludes by suggesting actions that can be taken now to facilitate timely compliance with the forthcoming regulations.

A. The September 10 Data Collection Deadline

One of the primary weaknesses of the existing biosafety regulatory regime is that the government has little knowledge about which facilities possess dangerous biologic agents. The Bioterrorism Act seeks to solve that problem by requiring all "facilities" possessing so-called "select agents" (a list of over 30 dangerous viruses, bacteria, rickettsiae, fungi, and toxins)[2] to notify the Department of Health and Human Services ("HHS") within 90 days after the enactment of the new law—that is, by Sept. 10.[3]

HHS has delegated its data collection responsibility to the Centers for Disease Control and Prevention. On Aug. 6, CDC published in the *Federal Register* a Data Collection Form, and an accompanying guidance document, which "facilities" in possession of select agents or "overlap agents"[4] are required to use in reporting to HHS or the U.S. Department of Agriculture ("USDA")[5] (or both agencies) by the Sept. 10 deadline.[6] The Data Collection Form lists the select agents, overlap agents, and high consequence pathogens[7] and toxins that must be reported. Although the Data Collection Form is only two pages long, completing it may not be a simple task for many research facilities, as substantial work may be required to gather the information requested by the form.

According to the *Federal Register* notice,[8] the government planned to mail the Data Collection Form to approximately 190,000 "facilities," all of which must complete the form—including research, clinical, and diagnostic laboratories. The only "facilities" exempt from filing are those that possess products that "are, bear, or contain select agents or toxins that have been cleared, approved, licensed, or registered under the Federal Food, Drug, and Cosmetic Act, Section 351 of the Public Health Service Act, the Virus-Serum-Toxin Act, and the Federal Insecticide, Fungicide, and Rodenticide Act ('FIFRA')."[9]

As is evident from the Data Collection Form, the concept of a "facility" is critical to the regulation of select agents. During the notice and comment process, several institutions took issue with the lack of a definition of the term "facility," on the ground that without such a definition, it would be difficult to determine whether it would even be necessary to complete the form. CDC responded to those comments by defining a "facility" as

[1] Pub. L. No. 107-188.

[2] This list was promulgated by the Centers for Disease Control and Prevention ("CDC") under the authority of the Antiterrorism and Effective Death Penalty Act of 1996 and is published at 42 C.F.R. Part 72, Appendix A. On Aug. 23, as part of the process of implementing the Bioterrorism Act, CDC published a proposed revised select agent list. *See* 67 Fed. Reg. 54605 (Aug. 23, 2002). However, for purposes of the Sept. 10 deadline, facilities should rely on the existing list. *Id.*

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[3] Pub. L. No. 107-188 at § 202(a).

[4] An "overlap agent" is an agent that appears on both the select agent list and the "High Consequence Livestock Pathogens and Toxins" list prepared by the Department of Agriculture. *See* 67 Fed. Reg. 51058, 51060 (Aug. 6, 2002). The "High Consequence Livestock Pathogens and Toxins" list was published on Aug. 12 by the Department of Agriculture in the form of an interim final rule that addresses biological agents considered a threat to animal or plant health or to animal or plant products. *See* 67 Fed. Reg. 52383 (Aug. 12, 2002).

[5] A separate subtitle of the Bioterrorism Act, the "Agricultural Bioterrorism Protection Act of 2002," addresses threats to animal and plant health or products. That subtitle, which will be administered by the Department of Agriculture, also contains a notification requirement. Because the Bioterrorism Act directs the USDA and HHS to coordinate their activities, CDC's Data Collection Form address both subtitles.

[6] 67 Fed. Reg. 51058 (Aug. 6, 2002)

[7] *See supra*, note 4.

[8] 67 Fed. Reg. 51058 (Aug. 6, 2002).

[9] *Id.* at 51060.

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"any individual or government agency, university, corporation, company, partnership, society, association, firm, or other legal entity located at a single geographic site. A single geographic site is a building or complex of buildings at a single mailing address."[10] That definition does not, however, tie a "facility" to the possession of select agents.

The lack of any language tying a "facility" to the possession, or possible possession, of select agents is significant. Probably the most controversial aspect of the Data Collection Form is that if a "facility" does not possess reportable biological agents, it must complete a "Declaration of Non-Possession." This requirement is broader than the language of the Bioterrorism Act, which calls for notification only from facilities that *do* possess select agents. Absent language tying the definition of a "facility" to the possession of select agents, one could interpret the Data Collection Form as applying to virtually any building or site. It hardly could have been the intent of Congress that every facility of any description in the United States that does not possess select agents must file a "Declaration of Non-Possession" by Sept. 10. As a practical matter, however, any research facility, and certainly any facility engaged in biomedical research, should assume that it is subject to the reporting deadline.

Obviously, in order to be in a position to complete the form, and, if necessary, complete the Declaration of Non-Possession, facilities must conduct an inventory of all of their laboratories. This is not a simple task, nor is it one that necessarily can be completed in a short period of time. That is especially true for large facilities with multiple laboratories, such as a research university. However, only after completing that task would a facility be in a position to report on the select agents in its possession. For each agent or toxin used or possessed by the reporting facility, one of the following descriptive categories is to be indicated:

1. Viable.
2. Recombinant organism, nucleic acid, genetic elements from agent:
   - Nonviable agents.
   - Full-length nucleic acid from any of the viruses on the list. For Variola major virus (smallpox), any segment that exceeds 100 nucleotides in length.
   - Natural or synthetic nucleic acids from bacteria, fungi, or viruses on the list that encode for either a functional toxin or virulence factor sufficient to cause disease, or natural or synthetic nucleic acid that encodes for a functional toxin of any of the toxins listed, if: (1) expressed in vivo, (2) in an expression vector or host chromosome, or (3) in a carrier plasmid.
3. Altered vaccine strain approved by USDA or the Food and Drug Administration ("FDA").[11]

In order to complete the Data Collection Form, "facilities" are required to designate a Responsible Facility Officer ("RFO") who will be charged with completing the form by the Sept. 10 deadline for reporting possession of select agents or overlap agents.[12] The RFO must be a "safety officer" and/or "senior management official," but "whenever possible" should not be an individual who actually uses, transfers, or possesses select agents.[13]

[10] *Id.* at 51061.
[11] *Id.* at 51062.
[12] *Id.*

B. The Existing Regulatory Regime

If the Data Collection Form is any indication of the kinds of burdens that may be imposed by the forthcoming regulations implementing the Bioterrorism Act, biosafety and security is going to become a significantly more resource-intensive obligation than it is currently. Biosafety and security obligations currently are derived from the existing regulations implementing the Antiterrorism and Effective Death Penalty Act ("AEDPA") of 1996.[14] The AEDPA was a broad-ranging statute that included numerous provisions to assist the government in combating terrorism. With respect to biosafety, AEDPA required HHS to promulgate regulations that would, *inter alia*, list the biological agents that pose a significant risk to the public's health and safety, establish and enforce safety procedures governing the transportation of certain agents, implement safeguards to prevent unauthorized access to such agents, and ensure the appropriate availability of regulated agents for research, educational, and other legitimate purposes.[15]

As a result of the AEDPA, CDC issued the regulations now codified at 42 C.F.R. § 72.6. These regulations impose stringent requirements on facilities that *transfer* and *receive* select agents, including the following:

- registration with the CDC;[16]
- completion, prior to the transfer of a select agent, by both the transferring and receiving facilities, of a CDC form detailing the transaction;[17]
- pre-transfer verification by the transferring facility of the receiving facility's registration;[18]
- use of special packaging procedures intended to prevent leakage and to protect against shocks, pressure changes, and other stresses (these requirements are supplemented by, among other sources, the Department of Transportation's Hazardous Materials Regulations);[19]
- post-transfer verification that the select agent has arrived at its intended destination;[20] and
- utilization of appropriate disposal techniques.[21]

The CDC regulations also contain limited exemptions for certain clinical and research purposes.[22]

Although providing relatively thorough coverage of select agent transfers, the existing CDC regulations do not expressly address the possession and use of select agents. In part to rectify that regulatory gap, in the immediate aftermath of last fall's terrorist attacks, Congress passed the Uniting and Strengthening America by Providing Appropriate Tools Required To Intercept and Obstruct Terrorism ("USA PATRIOT") Act of 2001.[23] A key aspect of the PATRIOT Act is its provision prohibiting "restricted persons" from transporting, shipping, or

[13] *Id.*
[14] Pub. L. No. 104-132.
[15] *Id.* at § 511.
[16] 42 C.F.R. § 72.6(a).
[17] 42 C.F.R. § 72.6(d).
[18] 42 C.F.R. § 72.6(e).
[19] *See generally,* 42 C.F.R. Part 72.
[20] 42 C.F.R. § 72.6(f).
[21] 42 C.F.R. § 72.6(i).
[22] 42 C.F.R. § 72.6(h).
[23] Pub. L. No. 107-56.

possessing select agents.[24] The PATRIOT Act defines "restricted persons" to include individuals under indictment for, or convicted of, a crime punishable by imprisonment for more than one year, fugitives from justice, unlawful users of controlled substances, illegal or unlawful aliens in the United States, individuals adjudicated mentally defective, individuals who have been dishonorably discharged from the U.S. Armed Services, and aliens who are nationals of countries that are designated as supporting acts of international terrorism.[25] Violators are subject to substantial fines and imprisonment.

Compliance with the "restricted persons" element of the PATRIOT Act has proven problematic for many laboratories, especially academic laboratories, because in many cases they are unequipped to obtain the information necessary to ensure compliance with the PATRIOT Act's provisions. For example, most universities do not test their employees for the use of controlled substances. More generally, the PATRIOT Act does not address the question of how far an employer must go to determine whether its employees fall within the definition of a "restricted person." In practical terms, the PATRIOT Act seems to make employers responsible for performing a background check or taking some other steps to ensure that "restricted persons" are not gaining access to select agents—a responsibility that many research institutions feel ill-equipped to take on.

C. Expected Elements of the Bioterrorism Act's Implementing Regulations

The Bioterrorism Act requires that an interim rule implementing its provisions be promulgated within 180 days[26] of its enactment, which would be in mid-December.[27] That interim final rule would become effective 60 days after its promulgation. The Bioterrorism Act and its implementing regulations will effect a significantly more robust regulatory regime than that created under AEDPA, even as supplemented by the PATRIOT Act. Among the act's new requirements are the following:

- A more aggressive approach to CDC's establishment and maintenance of the "select agent" list. For example, CDC will be required to review and revise the list at least biennially.[28]
- When preparing the select agent list, CDC will be required to consult with various federal departments and agencies, as well as with scientific experts representing various professional groups.[29]
- The regulatory regime will be expanded to reach not only transfers, but also possession and use of select agents.[30]
- Significant new safety and security requirements will be established for persons possessing, using, or transferring select agents. For example, access to select agents will be limited to those with a "legitimate need." Justice Department background checks will be required before access is granted.[31]
- Registration applications will require submission of information to facilitate identification and source of select agents. Once obtained, this information will be stored in a national database.[32]
- Registered persons will be required to notify CDC of the theft or loss of any select agent.[33]
- CDC will have broad inspection authority to ensure compliance not only with the possession, use, transfer, and security requirements, but also with respect to the "restricted person" provisions of the USA PATRIOT Act.[34]
- There will be new criminal offenses. For example, knowing possession of listed agents without proper registration, and transferring a select agent to a person who the transferrer knows or has reason to believe has not obtained the required registration, will be criminalized.[35]

From a compliance standpoint, the new law implements certain significant, and potentially problematic, changes. Chief among the changes is the concept of "need-based" access to select agents. Under the Bioterrorism Act, the burden is placed on the registered person to identify those whom he or she deems to have a legitimate need, and to provide "promptly" to the government the "names and other identifying information" of the individuals for whom the person is seeking access.[36]

Upon receipt of the information, the Justice Department will conduct a background check.[37] The registered person will be notified of the results of the background check and then will be responsible for (a) denying access to restricted persons, and/or, (b) denying or limiting the access of individuals reasonably suspected of being terrorists, being affiliated with a terrorist organization, or of being an agent of a foreign power attempting covertly to obtain information.[38] Although there are provisions in the new law to expedite the background checks, it is uncertain how long they will take, and the delays that they may cause to ongoing research therefore are unknown.[39]

The new law also alters the available exemptions. First, like the existing law, the new law includes an exemption for clinical or diagnostic laboratories.[40] Second, the new law contains an exemption for products that bear or contain select agents and that are cleared, approved, licensed, or registered under the Food, Drug, and Cosmetic Act; Section 351 of the Public Health Service Act; the Virus-Serum-Toxin Act; or FIFRA.[41] Third, CDC will have the discretion to exempt products being

[24] *Id.* at § 817.
[25] *Id.*
[26] Pub. L. No. 107-188 at § 202(b).
[27] A recent *Federal Register* notice states that CDC "anticipates" publishing the interim final rule on or before Dec. 9. *See* 67 Fed. Reg. 54605, 54606 (Aug. 23, 2002).
[28] Pub. L. No. 107-188 § 201(a).
[29] *Id.*
[30] *Id.*
[31] *Id.*
[32] *Id.*
[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] *Id.*
[37] *Id.*
[38] *Id.*
[39] The Bioterrorism Act does contain language requiring the interim final rule to "include timeframes for applicability of the rule that minimize disruption of research or educational activities." Pub. L. No. 107-188 at § 202(c).
[40] *Id.* at § 201(a).
[41] *Id.* This exemption is substantially similar to the existing authority under which products such as Botox are exempted from the select agent regulations.

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used in an authorized investigation.[42] Fourth, there are a series of temporary exemptions that can be granted in the event of an emergency.[43]

D. Suggested Compliance Actions

Assuming CDC is able to meet the mid-December statutory deadline for promulgating implementing regulations, research institutions have little time to prepare for the requirements the new regulations will impose. One potentially useful step that institutions may take is a preemptive audit of their biosafety and security policies, to determine the types of changes that they will need to implement in order to remain in compliance. Such an audit should not necessarily be limited to an analysis of the institution's compliance with the provisions of the Bioterrorism Act, as there are numerous other relevant regulations, such as:

- Occupational Safety and Health Administration standards (particularly Bloodborne Pathogens[44] and Exposure to Hazardous Chemicals in Laboratories[45]);
- Department of Transportation Hazardous Materials Regulations ("HMR");[46]
- NIH's Recombinant DNA Guidelines;[47]
- Numerous environmental standards, including the Resource Conservation and Recovery Act,[48] Toxic Substances Control Act,[49] Clean Air Act,[50] Clean Water Act,[51] Emergency Planning and Community Right-to-Know Act,[52] and the Comprehensive Environmental Response, Compensation, and Liability Act;[53]
- Permitting programs administered by the Department of Agriculture;[54] and
- Export control regulations, including the Export Administration Regulations ("EAR")[55] and the International Traffic in Arms Regulations ("ITAR").[56]

Because the Department of Transportation's Hazardous Materials Regulations recently have been revised,[57] facilities should thoroughly assess their compliance with those important standards. Among the changes effected by the recent rule are revised (a) defining criteria and packaging requirements that are intended to make the HMR consistent with international transportation standards, (b) exceptions for diagnostic specimens and biological products, and (c) bulk packaging options for certain medical waste.[58] The commentary accompanying the final rule also notes that DOT currently is assessing whether it is necessary to initiate rulemaking proceedings for the purpose of ensuring the security of hazardous materials during transportation.[59]

Facilities also should review their physical security measures to prevent unauthorized access to laboratories handling dangerous biological agents, as well as to research information stored in such laboratories. Another important question to address is the extent to which institutions have safeguarded electronic research data pertaining to experiments involving etiologic agents. Although there is little formal guidance on these topics, incorporated by reference into the existing CDC regulations is a CDC publication entitled *"Biosafety in Microbiological and Biomedical Laboratories,"*[60] which sets forth certain helpful guidelines.

By taking action now, facilities will be better able to meet the new regulatory requirements that are expected later this year, and to minimize the disruptions to their ongoing research operations.

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[42] *Id.*
[43] *Id.*
[44] 29 C.F.R. § 1910.1030.
[45] 29 C.F.R. § 1910.1450.
[46] 49 C.F.R. Parts 171-180.
[47] *Available at* http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html.
[48] 42 U.S.C. §§ 6901-6992(k).
[49] 15 U.S.C. §§ 2601-92.
[50] 42 U.S.C. §§ 7401-7671q.
[51] 33 U.S.C. §§ 1281-1387.
[52] 42 U.S.C. §§ 1101-11050.
[53] 42 U.S.C. §§ 9601-9675.
[54] *See, e.g.*, vectors and organisms, 9 C.F.R. Part 122; plant pests, 7 C.F.R. Part 330; and genetically engineered organisms, 7 C.F.R. Part 340.
[55] 15 C.F.R. Parts 730-774.
[56] 22 C.F.R. Parts 120-130.
[57] *See* 67 Fed. Reg. 53118 (Aug. 14, 2002). *See also, "Final Rule Issued to Revise Regulations For Transportation of Infectious Substances,"* 1 MRLR 324, 8/21/02.
[58] *See generally*, 67 Fed. Reg. 53118, 53133-44 (Aug. 14, 2002).
[59] *Id.* at 53131.
[60] *Available at* http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm.