Laboratory Biosafety Regulation: A Comparison and Analysis of "Public Health Security and Bioterrorism Preparedness and Response Act of 2002", Pub. L. No. 107-188 ("The New Law"), to Prior Law 1/

The intent of this chart is to provide a side-by-side comparison of the manner in which the "Public Health Security and Bioterrorism Preparedness Act of 2002", changes the law governing the handling, use and transportation of etiologic agents. 2/ Current law is primarily derived from two sources. The first is the Antiterrorism and Effective Death Penalty Act of 1996 (the "AEDPA"). 3/ In accordance with the AEDPA, the Centers for Disease Control and Prevention (the "CDC") enacted regulations found at 42 C.F.R. § 72.6 4/ that have provided much of the regulatory guidance regarding etiologic agents. The CDC also promulgated a "select agent" list, see Appendix A to 42 C.F.R. Part 72, which sets forth the etiologic agents currently subject to regulation. The second source is the USA PATRIOT Act, enacted in late 2001. 5/ That statute created new biosafety-related criminal offenses, but did not address the regulatory regime in effect since the 1996 enactment of the AEDPA.

The New Law	Commentary on Language in The New Law	Prior Law
Requires HHS by regulation to maintain and establish a list of each biological agent and toxin (hereinafter "select agents") that has the potential to pose a severe threat to the public's health and safety.	This provision is essentially the same as the directive found in Section 511 of the AEDPA and carried out in 42 C.F.R. Part 72, Appendix A.	42 C.F.R. Part 72, Appendix A sets forth a list of more than 30 "select agents", including viruses, bacteria, rickettsiae, fungi and toxins.

1/ Section 203 of the new law provides that existing regulations will remain in effect until modified.

2/ This chart addresses only Title II, Subtitle A of Pub. L. No. 107-188. It does not, for example, address Subtitle B, which is designated the Agricultural Bioterrorism Protection Act of 2002. This chart is also directed toward university, as opposed to commercial laboratories.

3/ Available at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=104_cong_public_laws&docid=f:publ132.104.

4/ Available at: http://www.cdc.gov/od/ohs/lrsat/42cfr72.htm.

5/ Available at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_bills&docid=f.h3162enr.txt.pdf.

The New Law	Commentary on Language in The New Law	Prior Law
Criteria for including an agent or toxin on the select agent list include: (i) the effect on human health of exposure to the agent or toxin; (ii) the degree of contagiousness of the agent or toxin and the method by which the agent or toxin is transferred to humans; (iii) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin; and (iv) any other criteria, including the needs of children and other vulnerable populations.	Makes a minor change in existing law; the AEDPA allowed HHS to consider "any other criteria" that it deemed appropriate and did not specifically mention children and other vulnerable populations.	Section 511 of the AEDPA required HHS to consider: (i) the effect on human health of exposure to the agent; (ii) the degree of contagiousness of the agent and the methods by which the agent is transferred to humans; (iii) the availability and effectiveness of immunizations to prevent and treatments for any illness resulting from infection by the agent; and (iv) any other criteria that the Secretary considers appropriate.
Compilation of the select agent list should include consultations with appropriate Federal departments and agencies, as well as with scientific experts representing appropriate professional groups (including those with pediatric expertise).	Makes a minor change in existing law. The AEDPA made no mention of consulting with individuals possessing pediatric expertise.	Section 511 of the AEDPA required HHS to consider scientific experts representing appropriate professional groups.
Requires HHS to review and republish the listed agents at least biennially.	***This provision indicates a more aggressive approach to keeping the select agent list up-to-date and reflective of current threats to public health and safety***.	There is currently no specific guidance with respect to updating the select agent list.

The New Law	Commentary on Language in The New Law	Prior Law
Requires HHS to promulgate regulations: (i) establishing and enforcing safety procedures for the ***transfer*** of select agents, including measures to ensure: (a) proper training and appropriate skills to handle such agents; and (b) proper laboratory facilities to contain and dispose of such agents; (ii) establishing and enforcing safety and security measures to prevent access to such agents and toxins for use in domestic or international terrorism or any other criminal purpose; (iii) establishing procedures to protect the public safety in the event of a transfer or potential transfer in violation of the safety procedures and safeguards referred to in ¶¶ (i-ii); and (iv) ensuring the appropriate availability of biological agents and toxins for research, education and other legitimate purposes.	As evidenced by the discussion of the AEDPA in the next column, the new law contains no meaningful textual changes from the AEDPA. However, it can be contended that the current transfer regulations (42 C.F.R. § 72.6) do not fully implement the language of the AEDPA. For example, the current regulations do not expressly mention the need to prevent access to etiologic agents for terrorism-related purposes. Likewise, those regulations do not expressly address training of laboratory personnel. It is likely that any new regulations will comply more carefully with Congress's directive as expressed in the new law.	The AEDPA set forth the following factors to be considered when promulgating transfer regulations: (i) establishment and enforcement of safety procedures for the transfer of select agents, including measures to ensure: (a) proper training and appropriate skills to handle such agents; and (b) proper laboratory facilities to contain and dispose of such agents; (ii) safeguards to prevent access to such agents for use in domestic or international terrorism or for any other criminal purpose; (iii) establishment of procedures to protect the public safety in the event of a transfer or potential transfer of a biological agent in violation of the safety procedures established under paragraph (i) or the safeguards established under paragraph (ii); and (iv) appropriate availability of biological agents for research, education, and other legitimate purposes.

The New Law	Commentary on Language in The New Law	Prior Law
Requires HHS to promulgate regulations: (i) establishing and enforcing standards and procedures governing the ***possession and use*** of biological agents and toxins on the select agent list and ensuring (a) proper training and appropriate skills to handle such agents, and (b) proper laboratory facilities to contain and dispose of such agents; (ii) establishing and enforcing safety and security measures to prevent access to such agents and toxins for use in domestic or international terrorism or any other criminal purpose; (iii) establishing procedures to protect the public safety in the event of a transfer or potential transfer in violation of the safety procedures and safeguards referred to in ¶¶ (i-ii); and (iv) ensuring the appropriate availability of biological agents and toxins for research, education and other legitimate purposes.	This is a ***significant new provision*** that will require HHS to expand its regulations beyond transfers of select agents.	Section 817 of the USA PATRIOT Act enacted new criminal offenses concerning possession and use of select agents, but contained no parallel regulatory requirements. The USA PATRIOT Act amended 18 U.S.C. § 175 by creating (i) a broader definition of the phrase "for use as a weapon", and (ii) criminalizing, with limited exceptions, the ***possession*** of any biological agent, toxin or delivery system of a type or in a quantity that is not reasonably justified for prophylactic, protective, bona fide research or other peaceful purposes. Section 817 of the PATRIOT Act also created a new section 18 U.S.C. § 175b that prohibits “restricted persons” from ***transporting, shipping or possessing*** select agents.
Both the possession/use and transfer regulations require prompt notification of the release of a select agent outside the biocontainment area.	This is a ***new requirement*** intended to facilitate timely involvement of appropriate public health authorities.	Neither the AEDPA nor the CDC regulations contains a similar provision. However, a CDC publication entitled *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) contains guidance stating that laboratories should have emergency plans and incident reporting systems in place. The BMBL is incorporated by reference into 42 C.F.R. § 72.6(a)(5). Likewise, the Preamble to 42 C.F.R. Part 72.6 notes that transportation incidents, including a damaged package, must be reported to the CDC.

The New Law	Commentary on Language in The New Law	Prior Law
Both the possession/use and the transfer regulations require registration with HHS to ensure that persons seeking to posses, use or transfer select agents have a lawful purpose. The registration must include (if available) information to facilitate the identification and source of the select agents. The information obtained by HHS will be maintained in a national database that will include (i) names and locations of registered persons, (ii) the select agents being transferred, used or possessed, (iii) and information pertaining to the characterization of the select agents.	This changes existing law. Although current CDC regulations include registration requirements (including compilation of a database), the express concept of facilitating the identification and source of select agents is new. Indeed, the Joint Explanatory Statement (available at http://energycommerce.house.gov/) of the Conference Committee notes that information in the database should be sufficiently detailed to differentiate among strains of select agents, and should be in a form that allows public health and law enforcement officials to identify the origin and source of a select agent used to harm the public.	42 C.F.R. § 72.6 describes previous registration requirements. To transfer or receive a select agent lawfully, a Facility must register with an approved entity or be approved by the CDC as being equipped to handle select agents at Biosafety Levels 2 – 4, depending on the agent being handled. When seeking to become a registered facility, an applicant must provide the reviewer with sufficient information to determine whether it is equipped to handle select agents at Biosafety Levels 2 – 4, depending on the agent and the work contemplated, and also must agree to submit to potential inspections. Once registered, the facility receives a unique registration number. Moreover, a registered facility is subject to additional inspections to ensure that it remains capable of handling select agents.
Both the possession/use and transfer regulations must include safeguard and security provisions that are commensurate with the risk posed to the public's health and safety (including the risk of use in domestic or international terrorism) by the select agent being used, transferred or possessed. HHS will consult with the Justice Department when establishing these provisions. Compliance with the safeguard and security measures will be a condition of registration.	This is an ***expanded statement*** of the safety and security requirements mentioned in the AEDPA. As evidenced by the next row of this chart, the new law provides significantly more guidance vis-à-vis the actual requirements that must be implemented than did the AEDPA. Also, the concept of creating risk-based security requirements is new.	The BMBL contains high-level laboratory security guidelines.

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A critical element of the safety and security provisions will be limiting access to select agents. Thus, the safety and security provisions will require registered persons to: (i) limit access to those with a "legitimate need"; (ii) provide names and other identifying information of individuals seeking access to select agents to the Justice Department "promptly" (and at least every five years provide the same information, assuming the individual continues to have access); (iii) deny access to individuals identified by the Justice Department as a restricted person; and (iv) limit or deny access to individuals identified by the Justice Department as being reasonably suspected of having committed a terrorism-related crime, having a knowing involvement with a domestic or international terrorism organization (or any organization engaging in intentional violent crime), or being an agent of a foreign power.	***This is a significant change in law. The concept of restricting access to those individuals with a "need" to handle or use select agents potentially represents a major compliance challenge***. For example, determinations of "need" may be difficult to secure on a timely basis. Moreover, the new law does not provide any criteria to be applied when making such a determination.	Prior law does not address "need" based access.
Once the Justice Department has received the name of individual designated by the registered entity as having a legitimate need, it will "promptly" use criminal, immigration, national security and other databases to assess whether the individual should be approved. The Justice Department will provide its decision to HHS, which will also "promptly" notify the registered entity of the decision. The statute allows a registered entity to request an expedited review for "good cause".	***Conducting background checks on individuals requesting access to select agents is a major change in existing law***. With respect to the background checks, it is important to note that the new law merely requires registered entities to provide information to the Justice Department and does not mandate that the registered entity actually conduct the background check. Despite use of the word "prompt", there is a possibility that it will take some time to complete the background checks. Whether an expedited review will alleviate this problem is unclear.	Prior law does not contemplate background checks.

The New Law	Commentary on Language in The New Law	Prior Law
Individuals and entities seeking a registration must undergo the same process as that used to determine whether someone will be granted access to select agents, e.g., a background check. When determining whether to deny or revoke a person's registration, the regulations will require HHS to submit the registrant's name to the Justice Department, which will conduct a background check on the person (or, if relevant, the individual who controls the person) to determine whether the person is a restricted person, or is reasonably suspected of having committed a terrorism-related crime, having a knowing association with a terrorist or other violent criminal organization, or being an agent of a foreign country.		As stated above, prior law does not address the use of background checks.
The safety and security provisions will set forth a review process to be used when a registration or request for access is denied. Ex parte communications are permitted when required for national security or law enforcement purposes. HHS's final determination may be appealed to a court of competent jurisdiction where ex parte communications are also permitted for national security or law enforcement purposes.	This is a minor modification to prior law, which contemplates appeals of a denial or revocation of a registration. There is currently no express recognition of the right to judicial review, nor is there language concerning ex parte contacts.	42 C.F.R. § 72.(b) provides that appeals may be made to HHS within 14 days of a registration denial or revocation.
The safety and security provisions will require prompt notification to HHS and appropriate law enforcement authorities of the theft or loss of a select agent.	***This effects a change in law,*** in that to comply with this provision a registrant must have a comprehensive inventory of its select agents.	The CDC regulations currently require notice to the CDC if a select agent is not received at its intended destination within five days of its anticipated delivery date. Likewise, the Preamble to CDC regulations states that transportation incidents (such as a lost or stolen package) must be reported to the CDC.

The New Law	Commentary on Language in The New Law	Prior Law
HHS in consultation with the Justice Department may provide technical assistance to registered entities to improve their facility security.	This is a new provision, although the extent of the assistance is not clear.	Neither the AEDPA nor the CDC regulations contains such a provision.
HHS will have authority to conduct inspections to ensure compliance with the possession/use and the transfer regulations, as well as with the prohibitions on access to select agents by restricted persons and the other safety and security provisions.	This represents ***a significant difference from existing inspection authority, e.g., the authority to conduct inspections regarding the access of restricted persons to select agents***. This expanded authority should facilitate compliance with Section 817 of the USA PATRIOT Act (discussed above).	42 C.F.R. § 72.6(g) addresses inspection authority, which includes: (i) random and for-cause inspections, (ii) examination of relevant transfer records, and (iii) intrafacility transfer and disposal mechanisms.
Clinical and diagnostic laboratories and other persons that possess, use or transfer select agents would be exempt from the possession/use and transfer regulations when utilizing select agents: (i) if diagnosis, verification or proficiency testing; (ii) if the identification of such agents is, when required by law, properly reported; *and* (iii) if the agents are transferred and destroyed in accordance with the regulations.	Prior law contains a "CLIA" exemption.	Current exemptions are set forth at 42 C.F.R. § 72.6(h) and Appendix A to 42 C.F.R. Part 72.

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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 are exempt from the regulations. HHS may, however, issue an order making a specific product subject to the possession/use and transfer regulations.	This ***exemption*** will permit development of commercial products and may therefore have more relevance to commercial, as opposed to university, laboratories. Moreover, this exemption is not significantly broader than HHS's existing authority. In the Joint Explanatory Statement accompanying the new law, the Managers note that "HHS currently exempts the FDA-approved medical product Botox, which is the select agent botulinum toxin, when it is used by licensed physicians in the treatment of patients. However, when it is used in purely research settings or as part of early-stage clinical trials, HHS has chosen not to exempt Botox from current regulations. The Managers do not intend to alter this flexibility."	
HHS may exempt a product that is, bears or contains a select agent from the possession/use and transfer regulations in instances when the product is being used in an investigation authorized by any Federal agency and HHS determines that the possession/use and transfer regulations need not apply. To obtain an exemption under this section of the regulations, an entity will be required to submit an application and notify HHS that an investigation has been authorized under the Food, Drug, and Cosmetic Act; Section 351 of the Public Health Service Act; the Virus-Serum-Toxin Act; or FIFRA. HHS will be required to respond to the request within 14 days.	This ***exemption*** will be of significant assistance to organizations conducting studies or trials under INDs.	The CDC website contains guidance suggesting that attenuated strains of select agents that have received an IND would be exempt.

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HHS will have authority to exempt a person temporarily from any or all of H.R. 3448's requirements for up to 30 days if HHS determines that doing so is necessary to allow that person's timely participation in a domestic or foreign public heath emergency involving a select agent.	This is a ***new exemption***.	Neither the AEDPA nor the CDC regulations provide a similar exemption.
Upon request of the Secretary of Agriculture, HHS will have authority to exempt a person temporarily from any or all of H.R. 3448's requirements for up to 30 days if HHS determines that doing so is necessary to allow that person's timely participation in an agricultural emergency involving a select agent. One 30 day extension of the exemption may be granted.	This is a ***new exemption***.	Neither the AEDPA nor the CDC regulations provide a similar exemption.
In general, exempt from disclosure under FOIA are: (i) registration or transfer documentation or information derived therefrom that identifies the select agents possessed, used or transferred by a specific person or that discloses the identity or location of a registered person, (ii) information concerning the national database or any similar compilations, (iii) any portion of a record regarding site-specific or transfer-specific safeguard and security measures, (iv) notices of a release, theft or loss or a select agent, and (v) any portion of an evaluation or report of an inspection of a registered person.	This new provision is intended to limit unauthorized access to critical information pertaining to select agents.	Current law does not expressly address the FOIA. However, the CDC's laboratory registration application states that the contents of the application will be made available in accordance with the FOIA.

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Civil penalties for violating the possession/use or transfer regulations may amount to $250,000 for an individual or $500,000 for other persons.	Consistent with existing penalties.	42 C.F.R. § 72.7 contains identical penalties: up to $250,000 for individuals and up to $500,000 for organizations. However, the current regulations also provide for a possible criminal penalty of up to one year in jail for individuals.
No more than 90 days after the new law was enacted, persons possessing select agents must notify HHS of that fact. HHS will provide guidance on how this notice is to be provided.	***This may be a significant new provision,*** depending on how it is construed. If an entity needs only to provide notice of possessing select agents, the provision may prove not onerous. However, if the entity has to provide a list of each select agent currently in its possession, that will require compilation of a detailed inventory. Because the HHS guidance will be issued 30 days after the law's effective date, entities required to provide notice will have only 60 days in which to do so.	
Amends 18 U.S.C. § 175b by creating new criminal offenses: (i) transfer of a select agent to a person when the transferor knows or should reasonably believe that the transferee is not registered will result in a fine or imprisonment for up to 5 years, (ii) knowing possession of a select agent without being registered is punishable by a fine or imprisonment for up to 5 years. The same crimes reach actions concerning agents and toxins listed pursuant to the Agricultural Bioterrorism Protection Act of 2002.	Essentially, this provision continues the work begun by the USA PATRIOT Act, *i.e.*, establishing new biosafety-related crimes.	The amendments to 18 U.S.C. § 175b are new provisions that further amend a portion of the U.S. Code recently revised in accordance with the USA PATRIOT Act.
HHS must promulgate an interim final rule within 180 days of the date the new law was enacted. The interim final rule will become effective 60 days after it is promulgated.	***When the interim final goes into effect, so too will the criminal penalties under the revised 18 U.S.C. § 175 and the civil penalties addressed above***.	

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The interim final rule will set forth timeframes for its applicability intended to minimize the disruption to ongoing research and educational projects.	This will potentially prevent ongoing projects from being halted or disturbed by, for example, the newly required background checks. The Joint Explanatory Statement notes that the new regulations will become effective at approximately the same time that NIH is making FY 2003 grant awards. The Joint Explanatory Statement further notes that the Conference Managers expect that HHS will encourage applicants to begin the registration and screening process required by H.R. 3448 at same time they submit a grant application involving select agents. The intent is that HHS will "ensure" completion of the select agent registration process to avoid delaying research projects.	