

## Post September 11th Bioterrorism Legislation

<b>Public Health Security and Bioterrorism Response Act of 2001</b> Signed into law June 12, 2001	<b>USA PATRIOT Act</b> Signed into Law October 26, 2001
Through regulations, establishes a national database of dangerous pathogens, and toxins. This list will be published biennially, following the review of the HHS Secretary.	The terms “biological agent,” “select agent,” and “toxin” do not encompass any biological agent or toxin that is in its naturally occurring environment, or if it has not been cultivated, collected, or extracted from its natural source.
Through regulation, the Secretary shall establish safety procedures for the transfer of biological agents and toxins including: <ul style="list-style-type: none"> <li>• Proper training and ensuring appropriate skills to handle agents and toxins</li> <li>• Proper laboratory facilities to contain and dispose of the agents and toxins.</li> <li>• Safeguards to prevent access to such agents and toxins for use in domestic or international terrorism or for any other criminal purpose.</li> </ul>	
The Secretary must also through regulation ensure the appropriate availability of biological agents and toxins for research, education, and other legitimate purposes.	“Bona fide research” has now been included in the uses for biological agents or toxins that are excluded from the classification of “for use as a weapon.”
The possession, use and transfer of all biological agents and toxins on the list must be registered including appropriate characterization of such agents and toxins in order to allow traceability.	
Inspection may occur in order to ensure that persons who handle or transfer listed select agents are in compliance with regulation, including prohibitions on restricted persons.	

<p>Clinical labs will be exempt from registration provided only if the agent or toxin has been presented for diagnosis, verification or proficiency testing.</p> <ul style="list-style-type: none"> <li>Once identified, when required by federal and state law, the select agent or toxin must be reported to public health authorities, and transferred or destroyed according to regulations.</li> </ul>	
<p>Registered facilities/institutions must submit the names and other identifying information for those individuals who have a legitimate need to handle and or use the listed select agent, to the Secretary and the Attorney General, once the need for access is determined. Individual names must also be submitted periodically (at least once every five years) thereafter while the individual has access to the listed agent.</p>	<p>No restricted person (see details below) can ship, possess, or receive any biological agent or toxin that is listed as a “select agent” (as identified in previous HHS regulations).</p>
<p>Registered facilities/institutions must deny access to select agents and toxins to individuals that the Attorney General has identified as “restricted persons” (see USA PATRIOT Act). Access must also be denied to an individual that is reasonably suspected by any Federal law enforcement or intelligence agency of committing a federal crime of terrorism; knowing involvement with an organization that engages in domestic or international terrorism; or being an agent of a foreign power, as determined by the Secretary in consultation with the Attorney General</p>	<p>Restricted Persons include those who:</p> <ul style="list-style-type: none"> <li>Are under indictment for a crime punishable by imprisonment for a term exceeding 1 year;</li> <li>Have been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;</li> <li>Are an unlawful user of any controlled substance</li> <li>Are an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country that is, according to the State Department, considered to be a sponsor of terrorism.</li> <li>Have been discharged from the Armed Services of the United States under dishonorable conditions.</li> <li>Are an illegal aliens</li> <li>Are fugitives from justice</li> <li>Have been declared mentally defective or committed to a mental institution.</li> </ul>
<p>Expedited review will be possible. However, it is only available for a registered facility/institution to request when submitting an individual’s name and identifying information, and when good cause can be demonstrated.</p>	

<p>Should a registration be rejected or revoked, the individual involved can request an additional review by the Secretary. Forthcoming regulations will determine the review procedures. The final review is considered final agency action on the matter.</p>	
<p>Imposes criminal and civil penalties for those who violate the regulations, including up to five years in jail and civil penalties up to \$250,000.</p>	<p>Those who knowingly possess an agent or toxin that is not reasonably justified by prophylactic, protective, bona fide research or any other peaceful purpose, shall be fined and or jailed for up to 10 years.</p>
<p>The final regulations (to be promulgated no later then 180 days after enactment) will include time frames for the applicability of the rule that minimize disruption of research or education projects that involve listed agents that were underway as of the effective date of the rule (60 days after promulgation).</p>	