**Title:** To improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies.

**Sponsor:** Rep W. J. (Billy) Tauzin (introduced 12/11/2001)

**Latest Major Action:** 5/23/2002 Cleared for White House. Was signed by President to become law 6/12/02.

**Note:** On 12/20/2001, the provisions of S. 1765 were incorporated in H.R. 3448 as substitute amendment S.Amdt. 2692.

### Summary:

- **Registration of All Persons Possessing Deadly Biological Agents and Toxins.** Expands current transfer regulations governing "select agents" (biological agents or toxins determined by CDC to pose "a severe threat to public health and safety") to require that all persons who possess or use such agents register with the Secretary of Health and Human Services and be subject to reasonable safety and security requirements and inspections. Directs that the Secretary maintain a national database of all such agents, with sufficient information to facilitate their identification and traceability. Requires notification to the Secretary by all possessors within 60 days of enactment.

- **Imposition of Security Requirements and Personnel Screening Protocols.** Directs that the Secretary, in consultation with the Attorney General, establish specific security requirements for registered facilities and a personnel screening protocol to ensure that access to such agents is not permitted by individuals who have criminal felony records, are named in a warrant for violent criminal or terrorist activity, are fugitives from justice, are under investigation for involvement in domestic or international terrorist or criminal organizations, or are foreign nationals illegally in the United States, from terrorist-sponsoring countries, or suspected of spying for the military or intelligence operations of a foreign nation. Provides the Secretary with grant authority to assist public and nonprofit private entities in meeting such security requirements.

- **Enhancement of Criminal and Civil Penalties for Enforcement.** Imposes tough new criminal and civil penalties for those who violate the regulations, including up to five years in jail and civil penalties up to $500,000 for those who are caught either possessing or transferring such agents without registration and approval.

- **Establishment of Exemptions Consistent with Protecting Public Health and Safety.** Permits the Secretary to make exemptions to the registration requirements only where those exemptions are consistent with protecting the public health and safety -- for example, with respect to inactivated or attenuated strains of select agents used in vaccines or other products for legitimate medical research or use -- or when the agent is presented for diagnosis, verification or proficiency testing purposes at a clinical laboratory and is promptly destroyed or transferred to a registered facility after such identification.
Key:
- Denotes location of current bill
- Denotes chamber where bill has passed

- Coordination with USDA Regulations on Dangerous Animal Agents and Toxins. Ensures that the Secretary coordinate these regulations with the regulations of the Department of Agriculture governing certain of the select agents that are used in the development of vaccines or other products for the treatment of domestic animals, in order to minimize conflict and duplication of administrative burdens on registered persons. Clarifies that the HHS Secretary’s new authorities do not limit the existing authorities of the Secretary of Agriculture in such circumstances.

- Protection of Sensitive Information from Mandatory Public Disclosure. Exempts from mandatory disclosure under the Freedom of Information Act site-specific or identifying information submitted under these regulations concerning registered persons, registered agents, and security mechanisms.

In a brief note at a conference on 17 June 02, Deputy Chief Counsel (Majority) for Oversight and Investigations of the House Energy and Commerce Committee outlined the key differences this law provides as compared to the original Select Agent rule as being:

- All possessors of “select agents” must be registered with the Secretary (HHS).
- A national database of possessors, locations, and agents (with their characteristics) will be developed/information not available through FOIA.
- Requirements for enhanced security and restricted access to agents.

Time frames after enactment of the Law (effective 6/12/02):

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Time until due date</th>
<th>*Approx. Date Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>HHS publishes guidance on notice of possession</td>
<td>30 days</td>
<td>7/12/02</td>
</tr>
<tr>
<td>HHS receives notice of possessions</td>
<td>90 days</td>
<td>9/12/02</td>
</tr>
<tr>
<td>USDA publishes Interim Final Rule of initial list/Notice guide</td>
<td>60 days</td>
<td>8/12/02</td>
</tr>
<tr>
<td>USDA receives notice of possessions</td>
<td>120 days</td>
<td>10/12/02</td>
</tr>
<tr>
<td>HHS/USDA publish interim final rule</td>
<td>6 months</td>
<td>12/12/02</td>
</tr>
<tr>
<td>Rule effective (HHS/USDA)</td>
<td>8 months</td>
<td>2/12/03</td>
</tr>
<tr>
<td>HHS/USDA MOU on overlapping agents</td>
<td>6 months</td>
<td>12/12/02</td>
</tr>
<tr>
<td>HHS/USDA joint regulation issued</td>
<td>2 years</td>
<td>6/12/04</td>
</tr>
</tbody>
</table>

‘Requirement’ and ‘time until due’ information graciously provided by CDC, External Activities Program.

*Dates will change based on weekends and holidays, these dates are purely for illustration of deadlines and do not constitute actual due dates.
Example:

HHS will publish its guidance on notice of possession (in Code of Federal Register) on 7/12/02. Institutes possessing/using/transporting select agents (existing list) will have 60 days from the publication of the CFR (90 days from when the law was signed) to register with CDC/HHS.

USDA will publish its guidance on notice of possession (in Code of Federal Register) on 8/12/02. Institutes possessing/using/transporting select agents (existing list) will have 60 days from the publication of the CFR (120 days from when the law was signed) to register with CDC/HHS.

Recommendation:

Institutes possessing select agents will have a relatively short deadline to register, and may wish to begin compiling an inventory identifying select agents and the form in which they exist (live, inactivated/killed, DNA preparations). Additional information requirements will be developed and provided by HHS and the USDA in the CFR. The ABSA Biosecurity Task Force will provide new information as it becomes available on the website at www.absa.org. These agents may be found in a number of locations to include but not be limited to: freezers, working stocks in laboratories, archival repositories, clinical archives/samples (confirmed as containing the select agent), tissue samples from infected test material (animals, cell cultures, etc), etc.

Submitted by:

Barbara Johnson, PhD, RBP
Chair, Biosecurity Task Force
703-676-8344
Barbara.Johnson@saic.com