

## Summary of Title II--Enhancing Controls on Dangerous Biological Agents and Toxins

### Subtitle A--Health and Human Services

Requires the Secretary of HHS, by regulation, to establish and maintain a list of biological agents and toxins that could pose a severe threat to public health and safety.

Secretary, by regulation, must establish and enforce safety procedures for transfer of listed agents and toxins, including safeguard and security measures to prevent access to agents and toxins for terrorism or criminal purpose.

- the regulations must ensure appropriate availability of agents and toxins for research, education and other legitimate purposes.

Secretary, by regulation, must establish and enforce standards and procedures governing possession and use of agents and toxins, including

- required registration with HHS for possession, use and transfer of agents and toxins to assure a lawful purpose
- creation of national database to include names and locations of registered persons, agents and toxins possessed, used or transferred, and characterization of the agents and toxins
- appropriate safeguards and security to be commensurate with risk posed
- access must be limited to those registered persons with a legitimate need; access must be denied to restricted persons or other individuals identified by US Attorney General

Attorney General, upon receiving registration information from HHS, does background check using available and appropriate databases to assure person is not

- a restricted person
- or reasonably suspected of committing a crime, knowing involvement with terrorist organization or an agent of a foreign power

AG then notifies HHS, who notifies registered person whether individual's access has been granted or denied; if denied, individual must be notified. An expedited review process must be established. Federal, State or local governmental agencies may be exempt from some of these review requirements.

Regulations must provide for an appeal process for individuals denied access or when revoking or denying registration of a person, other than an individual.

Regulations must provide for the prompt notification of HHS and law enforcement of theft or loss of agents or toxins.

HHS is given inspection authority to assure compliance, including prohibitions on restricted persons.

Regulations must exempt certain clinical or diagnostic laboratories, certain products, and may exempt certain investigational products; exemption procedures will be established by regulation. Temporary exemptions may be granted in the case of public health or agricultural emergencies.

Almost all the information developed under Title II is made confidential and may not be disclosed, including site-specific registration and transfer information, identity or location of specific registered persons, or the listed agent or toxin possessed, used or transferred.

Violations of regulations subject to civil penalty not to exceed \$250,000 for individual or \$500,000 for other person.

Regulations must provide for registered persons to promptly notify HHS of any release meeting certain criteria outside of a biocontainment area. HHS will then notify appropriate health authorities.

Implementation:

--Within 90 days of enactment, all non-exempt persons in possession of listed agents and toxins must notify HHS of such possession. HHS must provide guidance on notification procedures within 30 days of enactment.

--Within 180 days of enactment, interim final rules must be issued, containing all the above requirements, to take effect 60 days after issuance

--Interim final rule must include time frames that minimize disruption of research and educational projects

**Subtitle B--Department of Agriculture**

Provides almost identical responsibilities for the Secretary of Agriculture to issues rules safeguarding against severe threat to animal or plant health, or to animal or plant products. Recognizes that there will be "overlap agents and toxins".

**Subtitle C--Interagency Coordination Regarding Overlap Agents and Toxins**

Requires HHS and Agriculture to minimize impacts of dual regulatory system, single submission of forms, etc.

## **Subtitle D--Criminal Penalties Regarding Certain Biological Agents and Toxins**

Restructures and clarifies §175b and 178, which were rewritten by USA Patriot Act. Definition of "restricted person" not changed. Additional criminal provisions added regarding transfers to unregistered persons and possession by unregistered persons--standard is "knows or has reasonable cause to believe" person is not registered; in case of possession, person must "knowingly possess".

Because Subtitle D is the most cryptic because of the summary amending provisions, the full text of the new §§175b and 178 will be provided.