

Select Agent Provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Title II, Sections 201-231)-Enacted June 12, 2002

1. Requires the Secretary of Health and Human Services (HHS) to adopt regulations creating a list of biological agents and toxins with “potential to pose a severe threat to public health and safety,” considering their effect on human health, contagiousness, the availability of effective immunizations, and their effects on vulnerable populations. The Secretary is to consult with scientific experts in developing the list. The list must be reviewed and republished at least biennially and revised by regulation. (This list will replace the list at 42 CFR 72.6, Appendix A, under Section 511 of the 1996 Anti-terrorism and Effective Death Penalty Act relating to registering facilities prior to transfer or receipt of CDC-listed and non-exempt biological agents or toxins, which has been in effect since 1996.)
2. Requires the Secretary to adopt regulations establishing standards and procedures governing transfer, possession and use of listed agents/toxins, including:
 - (a) safety procedures for transfer of listed agents/toxins, including training on handling and requirements for laboratory facilities to contain and dispose of listed agents/toxins;
 - (b) security measures to prevent access to listed agents/toxins for terrorist or criminal purposes;
 - (c) “appropriate availability of biological agents and toxins for research, education, and other legitimate purposes.”
3. Requires the Secretary to include in such regulations:
 - (a) requirements for registration of the possession, use and transfer of listed agents/toxins, including assurances that persons (i.e., entities, government agencies, and individuals) seeking to register have a “lawful purpose to possess, use, or transfer such agents and toxins,” and the characterization and source of the agents/toxins if such information is “available to the person registering;”
 - (b) that such registration require security commensurate with the risk posed by the agent/toxin;
 - (c) that such registration ensure that registered persons (individuals and entities) (i) provide access to listed agents/toxins only to individuals determined by the registered person to have a “legitimate need” to handle or use listed agents/toxins; and (ii) promptly after determining an individual’s need for such access, submit “names and other identifying information” about the individual to the Secretary and Attorney General, and at least once every five years resubmit such information; and (iii) deny access to such agents/toxins to individuals identified by the Attorney General as “restricted persons” (as defined in §817 of the USA Patriot Act, 18 USC 175b); and (iv) if the Secretary in consultation with the Attorney General deems it “appropriate,” limit or deny access to listed agents/toxins to individuals identified by the Attorney General as “reasonably suspected” by any Federal law enforcement or intelligence agency of committing certain federal crimes relating to terrorism or knowing involvement with certain terrorist or violent organizations, or being an agent of a foreign power under federal law.

4. Requires the Attorney General, upon receiving the name of an individual or entity needing access to listed agents/toxins, to promptly use databases available to the Federal Government to identify whether the individual or entity is (a) a “restricted person”, or (b) “reasonably suspected by any Federal law enforcement or intelligence agency of committing certain federal crimes relating to terrorism, knowing involvement with certain terrorist organizations, engaging in violent crimes, or being an agent of a foreign power under federal law. The Attorney General must promptly after receiving the individual’s or entity’s name, notify the Secretary whether the individual or entity (or its owners) falls under any of these categories. The Secretary must then promptly notify the registered person whether the individual or entity is denied access to listed agents/toxins (which is required if the person is a “restricted person”), and if denied access, notify the individual or entity as well.
5. Requires the Secretary’s regulations to provide for the Secretary to request the Attorney General for expedited review of the names of individuals needing access with “demonstrated good cause” and to provide expedited notice of whether access is denied.
6. Requires the Secretary’s regulations to provide for the Secretary’s review of the denial of an individual’s access to listed agents/toxins and of the denial or revocation of registration. The decision may then be appealed to federal court. The review may be ex parte if disclosure of information “could compromise national security or an investigation by any law enforcement agency.”
7. Secretary’s regulations to require notice of the theft or loss of listed agents/toxins to the Secretary, and as appropriate federal, state and local law enforcement. Allows the Secretary to inspect persons who are subject to the regulations to ensure compliance. Requires the Secretary to notify Congress of number and nature of thefts/losses annually.
8. Secretary must exempt from the regulations:
 - (a) clinical/diagnostic laboratories and others who possess, use or transfer specimens for diagnosis, verification or proficiency testing, provided that the agents/toxins are reported to the Secretary and, if required by federal, state or local law, to other authorities, and that the agents/toxins are transferred or destroyed in accordance with the Secretary’s regulations;
 - (b) products that are, bear or contain listed agents/toxins and are cleared, approved, licensed or registered under The Federal Food, Drug and Cosmetic Act, Section 351 of the Public Health Service Act/Antiterrorism and Effective Death Penalty Act, the Virus-Serum-Toxin Act, or the Federal Insecticide, Fungicide and Rodenticide Act, unless the Secretary determines by order that additional regulation of a specific product is required to protect public health and safety.
9. Secretary may exempt from the regulations:

Investigational products that are, bear, or contain listed agents/toxins being used in an investigation authorized under any Federal Act if the Secretary determines that additional regulation is not necessary to protect public health and safety. Exemption is subject to an application process to be specified in regulations.
10. Secretary may temporarily exempt a person from the regulations for 30 days, plus one 30-day extension, if the Secretary determines the exemption is necessary for the person’s participation in a response to a domestic or foreign public health emergency and certain agricultural emergencies.

12. Imposes civil penalties of up to \$250,000 for an individual and \$500,000 for an entity, in addition to any other penalties under law, for violations of the regulations. Also imposes criminal penalties.
13. Secretary's regulations must require notice to the Secretary of any release of listed agents/toxins outside the biocontainment area meeting regulatory criteria. Requires Secretary to notify Congress of the number and nature of releases annually.
14. Requires the Secretary to report to Congress within one year after the enactment of the new Act, on the extent to which government and private entities are complying with the regulations and evaluating the impact of the regulations on research, among other topics.
15. The new Act provides for the Secretary of Agriculture to promulgate a similar list and regulations to protect animal and plant health and products. The two Secretaries' regulations must provide for coordination of registration, etc.
16. Within 90 days of enactment, persons possessing listed agents or toxins under 42 CFR 72.6, Appendix A must notify the Secretary of HHS of such possession in accordance with a guidance to be issued by the Secretary within 30 days of enactment. (Presumably, this information will go to the Attorney General for background checks, although the Act doesn't say.) Within 180 days of enactment, the Secretaries of HHS and Agriculture are to promulgate the regulations, which generally will take effect 60 days thereafter. The regulations are to apply an effective date to educational and research projects existing on the regulations' effective date, which minimizes disruption of such projects.
17. Within 60 days of enactment, the Secretary of Agriculture must by regulation create a list of agents and toxins, and issue a guidance on notice of possession. Within 60 days of the creation of the list, non-exempt persons possessing listed agents and toxins must notify the Secretary of such possession in accordance with the guidance.