

Q's and A's About the Agricultural Bioterrorism Protection Act of 2002

Q. What is the Agricultural Bioterrorism Protection Act of 2002?

A. The Agricultural Bioterrorism Protection Act of 2002 is a subpart of the Public Health Security and Bioterrorism Preparedness Response Act of 2002, which was signed into law by the President on June 12, 2002. Both require that entities, such as private, State, and Federal research laboratories, universities, and vaccine companies, that possess, use, or transfer agents or toxins deemed a threat to public health or animal or plant health or products register these agents with the appropriate Federal Department.

Q. Under these Acts, what Departments are responsible for regulating the possession of these agents and toxins?

A. Under the Agricultural Bioterrorism Protection Act, entities that possess, use, or transfer agents or toxins deemed a severe threat to animal or plant health or products must notify and register with the Secretary of the U.S. Department of Agriculture (USDA). USDA's Animal and Plant Health Inspection Service (APHIS) has been designated by the Secretary as the Agency for implementing the provisions of the law for USDA.

Under the Public Health Security and Bioterrorism Preparedness Response Act, entities that possess, use, or transfer toxins or agents deemed a threat to public health must register with the Secretary of the U.S. Department of Health and Human Services (HHS). The Centers for Disease Control and Prevention (CDC) has been designated by the HHS Secretary as the Agency for implementing the provisions of the law for HHS.

Q. Why was the law enacted?

A. The law is designed to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies that could threaten public safety or American agriculture.

Q. What agents or toxins pose a severe threat to animal or plant health and or products?

A. The list of agents and toxins deemed to pose a severe threat to animal or plant health or products is published in the December 13, 2002, *Federal Register*. To see the text, go to <http://www.aphis.usda.gov/vs/ncie/bta.html>. The agents and toxins that pose a severe threat to animal health have been designated "high consequence livestock pathogens and toxins."

Q. What were the criteria used to determine whether an agent or toxin should be on the USDA list?

A. In determining whether an agent or toxin should be included on the USDA list, the following were considered:

- The effect of an agent or toxin on animal or plant health or products.
- The virulence of an agent or degree of toxicity of the toxin and the methods by which the agents or toxins are transferred to animals or plants.
- The availability and effectiveness of medicines and vaccines to treat and prevent any illness caused by an agent or toxin.

Q. What agents or toxins are deemed a severe threat to public health?

A. The agents and toxins deemed a severe threat to public health (select agents) are published in the December 13, 2002, *Federal Register*. To see the text, go to <http://www.cdc.gov>. These agents and toxins fall under the responsibility of HHS.

Q. What are "overlap agents?"

A. Some of the agents and toxins that pose a severe threat to animal health and animal products also pose a severe threat to public health. As such, these agents and toxins also appear on both the HHS and the USDA's lists of agents and toxins and have been designated "overlap agents" since both USDA and HHS have regulatory authority over them.

Q. Who is affected by the new regulations?

A. Anyone possessing, using, or transferring any "select agents," "high consequence livestock pathogens and toxins," and/or agents or toxins deemed a severe threat to plant health and plant products are affected by the new regulations. Some examples include private, State, and Federal research laboratories; universities; and vaccine companies.

Q. What are these entities required to do and when?

A. Entities in possession of any of the USDA “high consequence livestock pathogens,” toxins, or listed plant agents were required to provide a “notification of possession” to the Secretary of Agriculture by October 11, 2002. Entities in possession of any of the HHS select agents were required to provide notification of possession to the HHS Secretary by September 10, 2002.

Entities have until March 12, 2003, to apply to register their facilities with either APHIS or CDC. Controls to restrict access to the agents and toxins must be in place by February 2003. Capital improvements and other physical security requirements necessary to bring facilities into full compliance must be completed by September 12, 2003.

Registration of an entity requires that the U.S. Department of Justice (DOJ) complete a security risk assessment for the facility, its owners, and the designated responsible official. Before registration is granted, the facility must also meet biosafety requirements that are commensurate with the risk that the agent or toxin poses and must establish security measures that provide graded protection in accordance with the threat that the agent or toxin poses.

Q. How do these new registration requirements differ from existing regulations?

A. APHIS’ Veterinary Services program has regulated overlap and animal-specific agents and toxins as “organisms and vectors,” just as APHIS’ Plant Protection and Quarantine program has regulated plant-specific agents and toxins as “plant pests.” In both cases, the existing regulations focus on addressing the risks associated with the importation and interstate movement of specific organisms. Generally speaking, these regulations prohibit the importation into the United States or interstate movement within the United States of organisms, vectors, and plant pests unless a permit has been issued by APHIS authorizing their importation or interstate movement. In addition, these existing regulations require that the importation or interstate movement be carried out in accordance with the safeguards and other requirements assigned as conditions of the permit, such as requirements for packaging during transport and safeguards to ensure the adequate containment of the organisms, vectors, or pests at their destination.

The requirements of the new Act build on these existing regulations. For example, where the existing regulations cover importation and interstate movement, the new rule also covers movement within a State as well as possession (cases where no movement is involved). Similarly, where permit requirements under the existing regulations focus on the animal or plant health risks associated with organisms,

vectors, and plant pests, the new rule also contains registration and security requirements that will advance the goal of preventing access to listed agents and toxins for use in domestic or international terrorism or for any other criminal purpose.

Q. Are there any exemptions to the new registration requirements?

A. Entities such as pharmacies, clinics, and hospitals that exclusively possess products that contain any of these agents or toxins and that are cleared, approved, licensed, or registered under any of the Acts listed below are exempt from the registration requirement:

- Federal Food, Drug, and Cosmetic Act
- Section 351 of the Public Health Service Act
- Virus-Serum-Toxin Act
- Federal Insecticide, Fungicide, and Rodenticide Act

Clinical and diagnostic facilities that do not maintain viable agents or active toxins are exempt from the registration requirements provided that they notify APHIS of the identification of the agent and toxin and then either destroy it or transfer the agent or toxin within 7 days of identification. For overlap agents, a clinical or diagnostic facility must notify either APHIS or CDC.

APHIS will determine on a case-by-case basis whether certain investigational products that contain “high consequence livestock pathogens and toxins” pose no threat to animal health or animal products and may be exempted.

Q. How can a facility register?

A. An “Application for Laboratory Registration for Possession, Use, and Transfer of Select Agents or High Consequence Livestock Pathogens and Toxins” should be completed and submitted to CDC for agents and toxins on the HHS list or to APHIS for agents and toxins on USDA’s list. Applications must be submitted to either CDC or APHIS for overlap agents. The DOJ security risk assessment of the entity, its owners, and the responsible official should also be completed and submitted to DOJ.

Q. Do entities that possess overlap agents need to be registered with both USDA and HHS?

A. An entity/facility that needs to register in order to possess, use, or transfer an overlap agent must submit its registration information to either APHIS or CDC, but is not required to submit the application to both APHIS and CDC.

Q. What is the penalty for noncompliance under the new regulations?

A. Entities found to possess select agents or “high consequence livestock pathogens and toxins” that are not registered with either CDC or APHIS are

subject to a fine of \$500,000 for the entity and \$250,000 and/or imprisonment for up to 5 years for an individual. These penalties also apply to an entity or individual transferring any of these agents or toxins to a nonregistered entity.

Q. Where can applicants get the forms associated with the Agricultural Bioterrorism Protection Act of 2002?

A. Copies of the forms may be printed from the APHIS Web site at <http://www.aphis.usda.gov/vs/ncie/bta.html> or the CDC Web site at <http://www.cdc.gov>. APHIS and CDC have developed joint reporting systems so that the same forms may be used for either Agency.

Q. Where should registration applications be sent?

A. For USDA animal agents, submit documents to: National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231. For HHS/USDA overlap agents submit the forms to either CDC or APHIS. For USDA plant agents and toxins, return completed forms to: Biological and Technical Services, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236. For HHS agents, submit applications to: Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Rd. NE, Mailstop E-79, Atlanta, GA 30333.

Q. Where can applicants get additional information?

A. For animal agents and toxins on the USDA list, the applicant should contact APHIS at 301-734-3277 (facsimile: 301-734-3652). For HHS agents and toxins, the applicant should contact CDC at 404-498-2255 (facsimile: 404-498-2265). For HHS/USDA overlap agents, the applicant should contact either APHIS or CDC at the numbers above.

For plant agents and toxins, the applicant should contact APHIS at 301-734-5519 (facsimile: 301-734-8700).

A listing of USDA animal agents and toxins is available at <http://www.aphis.usda.gov/vs/ncie/bta.html>. The list of plant agents and toxins is available at <http://www.aphis.usda.gov/ppq/permits>. A listing of HHS select biological agents and toxins is available at <http://www.cdc.gov>. You may also contact USDA/APHIS by e-mailing your question to vs_content_management@aphis.usda.gov.

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