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SUBCHAPTER II—INTERAGENCY COORDINATION
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SUBCHAPTER I—DEPARTMENT OF
AGRICULTURE

**§ 8401. Regulation of certain biological agents
and toxins**

**(a) Regulatory control of certain biological
agents and toxins**

(1) List of biological agents and toxins

(A) In general

The Secretary of Agriculture shall by regulation establish and maintain a list of each biological agent and each toxin that the Secretary determines has the potential to pose a severe threat to animal or plant health, or to animal or plant products.

(B) Criteria

In determining whether to include an agent or toxin on the list under subparagraph (A), the Secretary shall—

- (i) consider—
 - (I) the effect of exposure to the agent or toxin on animal or plant health, and on the production and marketability of animal or plant products;
 - (II) the pathogenicity of the agent or the toxicity of the toxin and the methods by which the agent or toxin is transferred to animals or plants;
 - (III) the availability and effectiveness of pharmacotherapies and prophylaxis to treat and prevent any illness caused by the agent or toxin; and
 - (IV) any other criteria that the Secretary considers appropriate to protect animal or plant health, or animal or plant products; and

(ii) consult with appropriate Federal departments and agencies and with scientific experts representing appropriate professional groups.

(2) Biennial review

The Secretary shall review and republish the list under paragraph (1) biennially, or more often as needed, and shall by regulation revise the list as necessary in accordance with such paragraph.

(b) Regulation of transfers of listed agents and toxins

The Secretary shall by regulation provide for—

- (1) the establishment and enforcement of safety procedures for the transfer of listed agents and toxins, including measures to ensure—

(A) proper training and appropriate skills to handle such agents and toxins; and

(B) proper laboratory facilities to contain and dispose of such agents and toxins;

(2) the establishment and enforcement of safeguard and security measures to prevent access to such agents and toxins for use in domestic or international terrorism or for any other criminal purpose;

(3) the establishment of procedures to protect animal and plant health, and animal and plant products, in the event of a transfer or potential transfer of such an agent or toxin in violation of the safety procedures established under paragraph (1) or the safeguard and security measures established under paragraph (2); and

(4) appropriate availability of biological agents and toxins for research, education, and other legitimate purposes.

(c) Possession and use of listed agents and toxins

The Secretary shall by regulation provide for the establishment and enforcement of standards and procedures governing the possession and use of listed agents and toxins, including the provisions described in paragraphs (1) through (4) of subsection (b) of this section, in order to protect animal and plant health, and animal and plant products.

(d) Registration; identification; database

(1) Registration

Regulations under subsections (b) and (c) of this section shall require registration with the Secretary of the possession, use, and transfer of listed agents and toxins, and shall include provisions to ensure that persons seeking to register under such regulations have a lawful purpose to possess, use, or transfer such agents and toxins, including provisions in accordance with subsection (e)(6) of this section.

(2) Identification; database

Regulations under subsections (b) and (c) of this section shall require that registration include (if available to the person registering) information regarding the characterization of listed agents and toxins to facilitate their identification, including their source. The Secretary shall maintain a national database that includes the names and locations of registered persons, the listed agents and toxins such persons are possessing, using, or transferring, and information regarding the characterization of such agents and toxins.

(e) Safeguard and security requirements for registered persons

(1) In general

Regulations under subsections (b) and (c) of this section shall include appropriate safeguard and security requirements for persons possessing, using, or transferring a listed agent or toxin commensurate with the risk such agent or toxin poses to animal and plant health, and animal and plant products (including the risk of use in domestic or international terrorism). The Secretary shall establish such requirements in collaboration with the Secretary of Homeland Security and the Attorney General, and shall ensure compliance with such requirements as part of the registration system under such regulations.