
42 U.S. Code § 262a

Enhanced control of dangerous 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 shall by regulation establish and maintain a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety.

(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 on human health of exposure to the agent or toxin;

(II) the degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans;

(III) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin; and

(IV) any other criteria, including the needs of children and other vulnerable populations, that the Secretary considers appropriate; and

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

(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, including with respect to notification requirements under this section, of—

(i) individuals who are involved in the handling and use of such agents and toxins, including appropriate skills to handle such agents and toxins;

(ii) individuals whose responsibilities routinely place them in close proximity to laboratory facilities in which such agents and toxins are being transferred, possessed, or used; and

(iii) individuals who perform administrative or oversight functions of the facility related to the transfer, possession, or use of such agents and toxins on behalf of registered persons;

- (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 the public safety 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.

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