

SELECT AGENT AND TOXIN SECURITY

I. Purpose

The Management Directive (MD) establishes security procedures and assigns responsibilities for safeguarding select agents and toxins. It implements the requirements for possession, use, and transfer of select agents and toxins set forth in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and established by the Department of Health and Human Services (HHS) in 42 Code of Federal Regulations (CFR) 73 and U.S. Department of Agriculture (USDA) in 9 CFR 121 and 7 CFR 331.

II. Scope

This MD applies to any activities conducted by the Department of Homeland Security (DHS) or sponsored or funded by DHS through a contract, grant, cooperative agreement, other transaction, or other arrangement that involves the use of select agents and toxins justified for prophylactic, protective or other peaceful purpose.

III. Authorities

- A. Public Law 107-188, "Public Health Security and Bioterrorism Preparedness and Response Act of 2002"
- B. Public Law 107-56, Section 817 (2) of the "Uniting and Strengthening America By Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA Patriot Act) Act of 2001"
- C. Title 6, U.S.C., Section 182, Responsibilities and authorities of the Under Secretary for Science and Technology
- D. Title 7, CFR, Part 331, "Possession, Use, and Transfer of Select Agents and Toxins"
- E. Title 9, CFR, Part 121, "Possession, Use, and Transfer of Select Agents and Toxins"
- F. Title 42, CFR, Part 73, "Select Agents and Toxins"

IV. Definitions

- A. **Biological Agents**: Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa) or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.
- B. **Department**: DHS.
- C. **DHS Biosafety Officer**: The official with appropriate training who is responsible for biosafety programs in the Department and acts as the focal point for biosafety training, oversight and regulatory compliance.
- D. **DHS Components**: Shall have the same meaning as “Components” in DHS Management Directive 0010.2, Management Directives System.
- E. **Entity**: Any government agency (Federal, State, or local), academic institution, corporation, partnership, society, association, firm, sole proprietorship, or other legal entity.
- F. **Overlap Select Agents and Toxins**: Select agents and toxins regulated by both HHS and USDA that have the potential to pose a severe threat to public health and safety, to animal health, or to animal products. The lists of overlap select agents and/or toxins are found in Authorities E and F at Part III of this MD.
- G. **Responsible Official**: The individual designated by an entity with the authority and control to ensure compliance with the select agent and toxin regulations.
- H. **Vulnerability Assessment**: An evaluation to determine the susceptibility to attack from the full range of threats to the security of personnel, the general public, facilities, and the environment that provides a basis for determining antiterrorism measures that can provide protection from attack.
- I. **Select Agents and Toxins**: Biological agents and toxins selected by the Centers for Disease Control and Prevention (CDC) and Animal and Plant Health Inspection Service (APHIS) that present a high bioterrorism risk to national security and have the potential to pose a severe threat to public health and safety, to animal health or animal products, or to plant health or plant products. The lists of select agents and toxins are found in Authorities D, E, and F at Part III of this MD.

J. **Toxins**: The toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance or a recombinant or synthesized molecule, whatever their origin and method of production, including any poisonous substance or biological product that may be engineered as a result of biotechnology, produced by a living organism, or any poisonous isomer or biological product, homolog, or derivative of such a substance.

V. Responsibilities

A. **The Under Secretary for Science and Technology** is the DHS Senior Responsible Official (SRO) and has the responsibility of ensuring the proper implementation of and compliance with this MD, statutes and related regulations for the safeguard of select agents and toxins in activities conducted or sponsored by DHS. To this end, the SRO may delegate specific authority to train for, monitor, and oversee select agent and toxin security within DHS to activities and offices within the Science and Technology Directorate.

1. To establish executive oversight, the SRO will:
 - a. Ensure that the heads of DHS Components incorporate the provisions of this MD into their policies, procedures, and programs that utilize and involve select agents and toxins as defined herein.
 - b. Approve any further DHS-wide practice, procedure, or guidance to ensure the safeguard of select agents and toxins in Department activities.
 - c. Immediately report any substantive incidents of non-compliance with this MD to the Secretary.
 - d. Coordinate with the Chief Security Officer on the development of minimum security standards for safeguarding select agents and toxins and standards for individuals with access to select agents and toxins, as necessary and appropriate.
 - e. Support budget requests to meet the requirements of this MD.
2. In addition, to ensure operational compliance the SRO will:
 - a. Establish and maintain a secure database of all select agent registration documents submitted to the CDC or APHIS by entities performing work on DHS-funded projects. The database will include the current and previous Responsible Officials and alternates.

- b. Develop training and information, as needed, to ensure the safeguard of select agents and toxins DHS-wide.
- c. Monitor compliance with the provisions of this MD, to include the development of written security, biosafety/ biocontainment, and incident response plans by DHS Components and sponsored non-DHS entities, as required.
- d. Approve any DHS practice, procedure, or guidance concerning select agent and toxin security prior to implementation.
- e. Conduct or sponsor site visits and vulnerability assessments of DHS Components and, as authorized, other entities that perform activities utilizing or involving select agents and toxins for DHS when deemed necessary to assess the adequacy of security.
- f. Ensure proper reporting of incidents of select agent and toxin theft, loss, or release, and work with the Chief Security Officer to ensure appropriate action is taken with respect to such theft, loss, or release.
- g. Monitor remedial activity, as appropriate, with regard to incidents of substantive non-compliance with this MD.
- h. Act as the DHS point of contact for the coordination and response to inquiries from public and private entities not involved in the DHS program concerning the safeguard of select agents and toxins utilized or involved in DHS activities.
- i. Ensure the maintenance of positive control over select agents and toxins utilized in DHS-supported projects or in the possession of DHS, and monitor and account for these select agents and toxins as mandated in this MD.

B. **The Associate General Counsel for Science and Technology** will coordinate on all policies and procedures concerning select agent and toxin security.

C. **The DHS Chief Medical Officer (CMO)** will review all biosafety/ biocontainment and incident response plans; and coordinate the DHS medical response to all incidents involving a select agent or toxin.

D. **All DHS Components** will ensure all activities that they conduct or sponsor comply with this MD and the other related Federal laws and regulations. In exercising this authority, each DHS Component will:

1. Establish procedures or guidance to ensure sufficient select agent and toxin security for all activities conducted or sponsored by that DHS Component.
2. Register and obtain the appropriate certificates for all activities utilizing or involving select agents and toxins, as required in Authorities D–F at Part III of this MD. Provide information, as appropriate, to the SRO for inclusion in the secure database.
3. Ensure that select agents and toxins utilized or involved in activities by entities that are sponsored by DHS are registered and have the appropriate certificates as required in Authorities D–F at Part III of this MD. Provide information, as appropriate, to the SRO for inclusion in the secure database.
4. Develop, implement, review annually, and revise appropriately written security, biosafety/biocontainment, and incident response plans that are in compliance with Authorities D–F at Part III of this MD and other Department guidance for all DHS activities that utilize or involve select agents and toxins.
5. Ensure that sponsored entities develop written security, biosafety/biocontainment, and incident response plans that comply with Authorities D–F at Part III of this MD and other Department guidance, for all activities utilizing or involving select agents and toxins.
6. Conduct drills or exercises in DHS facilities at least annually to test and evaluate the effectiveness of the security, biosafety/biocontainment, and incident response plans. The plans must be reviewed and revised, as necessary, after every drill or exercise and after any incident.
7. Cooperate with and assist, as appropriate, HHS and APHIS personnel conducting inspections as authorized in Authorities D–F at Part III of this MD.
8. Ensure that all personnel who require access to select agents and toxins in DHS facilities receive the required approvals and authorizations (as specified in Authorities D–F at Part III of this MD) as well as appropriate training and information, and are cleared by the DHS Biosafety Officer (BSO).
9. Promptly report the loss, theft, damage, or release of any select agents and toxins through the Chief Security Officer and CMO to the SRO, CDC, and APHIS, and any incidents of noncompliance with this MD through the Chief Security Officer to the SRO.

10. Forward inquiries from public and private entities not involved in the DHS program concerning select agent and toxin security at DHS or at entities performing activities for DHS through the Chief Security Officer to the SRO for coordination and response.

VI. Policy & Procedures

A. Policy:

1. The establishment and execution of appropriate select agent and toxin security measures are essential to protect important DHS missions and avoid civil and criminal liability.

2. Select agent and toxin security measures compliant with Department standards and the HHS and USDA regulations implementing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 shall be applied to all activities conducted or sponsored by the Department. In the event of any conflict between this MD and the HHS and USDA regulations, those regulations will control.

3. All DHS Components, and all entities performing activities for the Department shall have a certificate of registration from HHS or APHIS, as required by Authorities D–F at Part III of this MD, before using, possessing, transferring, or receiving select agents and toxins; and a certificate of registration from HHS and APHIS, as required by Authorities E and F at Part III of this MD, before using, possessing, transferring, or receiving overlap select agents and toxins.

4. Proper storage, management, and safeguards which may be issued by the Department, will be used to prevent loss, theft, diversion, damage, and unauthorized use of all select agents and toxins. Additionally, security controls, as required by Authorities D-F at Part III of this MD, shall be provided against unauthorized access.

5. Select agents and toxins shall be actively monitored and accounted for from identification through transfer and final disposition, to include destruction, via the employment of stringent property control processes including the execution of chain-of-control documentation and destruction logs.

6. Incidents of loss, theft, damage, or release of any select agents and toxins will be reported promptly through the Chief Security Officer and CMO to the SRO, CDC, and APHIS.

7. Incidents of noncompliance with this MD by any DHS Component or activity thereof will be reported immediately to the next higher management level and through the Chief Security Officer to the SRO. No action, administrative or disciplinary, will be taken against a person for the act of reporting any such noncompliance.

8. Individuals who have a legitimate need to handle or use select agents and toxins, or whose duties afford access to storage and work areas, storage containers, and equipment containing select agents or toxins shall be screened initially for suitability and reliability in accordance with DHS Management Directive 11050.2, Personnel Security and Suitability Program and any other specific standards issued by the Department.

9. Security, biosafety/biocontainment, and incident response plans shall be written and implemented in accordance with Authorities D–F at Part III of this MD prior to the conduct of activities utilizing or involving select agents and toxins by the Department or its sponsored entities.

10. A restricted person, as defined in 18 U.S.C 175b may not have access to select agents and toxins.

11. Department personnel who have access to select agents and toxins shall be approved in accordance with Authorities D–F at Part III of this MD, receive training and information commensurate with the work they do and the risks posed by the select agents and toxins and be cleared by the BSO (see MD 066-02, Biosafety).

12. Export Control requirements in the Export Administration Regulations (15 CFR Parts 730-774) shall be strictly followed to restrict the export or transfer to foreign nationals of national security sensitive dual-use goods, technology, and information.

B. **Procedures:**

All officials and employees shall conduct themselves in accordance with the responsibilities set forth in Section V as well as with any subsequently developed and properly approved policy, procedure, or guidance to ensure the proper security in all DHS activities utilizing or involving select agents and toxins.

VII. Questions

Any questions or concerns regarding this MD should be addressed to the Under Secretary for Science and Technology.