

Section 7 Registration and Security Risk Assessments

An individual shall not possess, use, or transfer any HHS or overlap select agent or toxin without a certificate of registration issued by the HHS Secretary or Administrator, unless exempted under §73.5, §73.6, or 9 CFR part 121.6.

As a condition of registration, each individual with access to a HHS or overlap select agent or toxin must:

1. Have the appropriate education, training, and/or experience to handle or use such agents or toxins,
2. Submit the information necessary to conduct a security risk assessment to the Attorney General
3. Be approved by the HHS Secretary or Administrator based on a security risk assessment by the Attorney General.

An application may be denied or certificate of registration revoked or suspended if:

1. The individual is within any of the categories described in 18 U.S.C. 175b
2. The individual is reasonably suspected by any Federal law enforcement or intelligence agency of:
 - a) Committing a crime specified in 18 U.S.C. 2332b(g)(5), or
 - b) Knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence, or
 - c) Being an agent of a foreign power (as defined in 50 U.S.C. 1801).
3. The individual does not meet the requirements of this part, or
4. It is determined that such action is necessary to protect public health and safety

Upon revocation or suspension of a certificate of registration, the individual must:

1. Immediately stop all use of each select agent or toxin covered by the revocation or suspension order,
2. Immediately safeguard and secure each select agent or toxin covered by the revocation or suspension order from theft, loss, or release, and
3. Comply with all disposition instructions issued by the HHS Secretary for the select agent or toxin covered by the revocation or suspension.

Denial of an application for registration and revocation of registration may be appealed under §73.20.

Access approval is valid for a maximum of five years