

(c) The HHS Secretary may exempt from the requirements of this part on a case-by-case basis an investigational product that is, bears, or contains a select agent or toxin, when such product is being used in an investigation authorized under a Federal Act referred to in paragraph (b) of this section and additional regulation under this part is not necessary to protect public health and safety. To apply for an exemption an applicant must submit to the HHS Secretary in accordance with § 73.21 a completed CDC Form 0.1317 certifying that the product is being used in an investigation authorized under a Federal Act referred to in paragraph (b) of this section, and that additional regulation under this part is not necessary to protect public health and safety. The HHS Secretary shall make a determination regarding the application within 14 calendar days after receipt, provided the application meets all of the requirements of this section and the application establishes that the investigation has been authorized under the cited Act. The HHS Secretary will provide a written decision granting the request, in whole or in part, or denying the request. The applicant must notify the HHS Secretary when an authorization for an investigation no longer exists. This exemption automatically ceases when such authorization is no longer in effect.

(d) The HHS Secretary may temporarily exempt an entity from the requirements of this part, in whole or in part, based on a determination that the exemption is necessary to provide for the timely participation of the entity in response to a domestic or foreign public health emergency. With respect to the emergency involved, the exemption may not exceed 30 days, except that the HHS Secretary may grant one extension of an additional 30 days. To apply for an exemption or an extension of an exemption, an applicant must submit to the HHS Secretary in accordance with § 73.21 a completed CDC Form 0.1317 establishing the need to provide for the timely participation of the entity in a response to a domestic or foreign public health emergency. The HHS Secretary will provide a written decision granting the request, in

whole or in part, or denying the request.

(e) Upon request of the USDA Secretary, after the USDA Secretary has granted an exemption under section 212(g)(1)(D) of the Agricultural Bioterrorism Protection Act of 2002 based on a finding that there is an agricultural emergency, the HHS Secretary may temporarily exempt an entity from the applicability of the requirements of this part, in whole or in part, to provide for the timely participation of the entity in response to the agricultural emergency. With respect to the emergency, the exemption under this part may not exceed 30 days, except that upon the request of the USDA Secretary, the HHS Secretary may grant one extension of an additional 30 days.

§ 73.7 Registration.

(a) An entity may not possess or use in the United States, receive from outside the United States, or transfer within the United States, any select agent or toxin unless the entity has been granted a certificate of registration by the HHS Secretary or the USDA Secretary.

(b) To apply for a certificate of registration an entity must:

(1) Obtain a registration application number from the HHS Secretary and then apply for approval under § 73.8 for the entity, the Responsible Official, and any individual who owns or controls the entity; and

(2) In accordance with § 73.21, submit the information requested to the HHS Secretary or the USDA Secretary as specified in the registration application package [CDC Form 0.1319]. Information submitted will be used to determine whether the applicant would be eligible to conduct activities under this part. Minimum information required includes:

(i) Identification information (e.g., name, address, contact numbers, identification number assigned by the Attorney General for compliance with § 73.8);

(ii) The name, source, and characterization information on select agents and toxins included in the registration, and quantities held at the time of the application;

(iii) The location, including building and room and floor plans for each building and room, where each select agent or toxin will be stored or used;

(iv) Information addressing safety, security, emergency response plans, and training, including descriptions of any equivalent measures adopted pursuant to § 73.11(d);

(v) The name, position, and identification information regarding the Responsible Official, including the identification number assigned by the Attorney General for compliance with § 73.8;

(vi) A list of individuals who will need access to select agents and toxins;

(vii) A certification statement signed by the Responsible Official attesting to the accuracy of the information submitted; and

(viii) Any other information necessary for the determination.

(c) An application that covers any HHS select agents or toxins (regardless of whether it also covers overlap select agents or toxins) must be submitted to the HHS Secretary in accordance with § 73.21. An application that covers only overlap select agents or toxins may be submitted to either the HHS Secretary or the USDA Secretary.

(d) A certificate of registration will be valid only for the specific select agents and toxins, and the specified activities and locations that are consistent with the information provided by the entity upon which the certificate of registration or amendment was granted. The Responsible Official must promptly notify the HHS Secretary in writing in accordance with § 73.21, if a change occurs in any information submitted to the HHS Secretary in the application for the certificate of registration or amendments. This includes modifications to the list of individuals approved under § 73.8, changes in area of work, or changes in protocols or objectives of studies. To apply for an amendment to a certificate of registration to add select agents or toxins or to change specified activities or locations, an entity must obtain the relevant portion of the registration application package and submit the information requested in the package to the agency that issued the certificate of registration. The package must be submitted

to the appropriate address specified in the package.

(e) In response to an application to the HHS Secretary for a certificate of registration or amendment for select agents and toxins, the HHS Secretary will issue a certificate of registration or amendment if it is determined that the stated activities would be lawful (based on information submitted by the applicant or otherwise obtained by the HHS Secretary) and meet the requirements of this part. Otherwise, the application for a certificate of registration or amendment will be denied. The HHS Secretary will issue a certificate of registration or amendment for an overlap select agent or toxin only if the USDA Secretary concurs that the requirements for obtaining a certificate of registration or amendment under 9 CFR part 121 have been met. The determination of whether a certificate of registration or amendment will be granted may be contingent upon inspection or submission of additional information.

(f) A certificate of registration will cover activities at only one general physical location (a building or a complex of buildings at a single mailing address).

(g) Unless terminated sooner in accordance with this paragraph, a certificate of registration will be valid for up to three years. To obtain a new certificate of registration an entity must submit a new application. (Note: To help ensure timely processing of an application for a certificate of registration or amendment, the applicant should submit the application at least eight weeks prior to the expiration date.)

(1) The HHS Secretary will terminate a certificate of registration based on a determination that the recipient no longer conducts activities covered by the certificate.

(2) Also, the HHS Secretary may terminate a certificate of registration based on a security risk assessment under § 73.8 or failure to comply with the provisions of this part, and may take such action immediately if necessary to protect the public health or safety. Upon such termination, any select agent or toxin in the possession of

the entity must be destroyed or transferred as directed by the HHS Secretary.

(h) An entity must provide notice in writing to the HHS Secretary in accordance with § 73.21 at least five business days before destroying a select agent or toxin, if the destruction would be for the purpose of discontinuing activities with a select agent or toxin covered by a certificate of registration. This will allow the HHS Secretary to observe the destruction or take other action as appropriate.

§ 73.8 Security risk assessment.

(a) An entity may not possess or use in the United States, receive from outside the United States, or transfer within the United States, any select agent or toxin unless approved by the HHS Secretary or the USDA Secretary based on a security risk assessment by the Attorney General. This paragraph does not apply to Federal, State, or local governmental agencies, but does apply to the Responsible Official and others working for or otherwise acting on behalf of such agencies.

(b) An entity may not provide an individual access to a select agent or toxin and an individual may not access a select agent or toxin, unless the individual is approved by the HHS Secretary or the USDA Secretary, based on a security risk assessment by the Attorney General.

(c) To obtain a security risk assessment under this section, an entity must submit to the Attorney General the information requested for the entity, the Responsible Official, any individual who owns or controls the entity, and any other individuals required to obtain approval under this section. The determinations regarding approval will be made by the agency that is responsible for making determinations regarding the corresponding certificate of registration. An entity will receive prompt notice of action taken in response to a request for approval for the entity, the Responsible Official, and individuals. An individual will receive prompt notice of a denial of approval.

(d) The Attorney General will conduct a security risk assessment on entities and individuals whose identifying information is properly sub-

mitted. Based on the security risk assessment, the Attorney General will notify the HHS Secretary if the Attorney General identifies any entity, individual who owns or controls the entity, or any other individual who is:

(1) A restricted person under 18 U.S.C. 175b; or

(2) Reasonably suspected by any Federal law enforcement or intelligence agency of:

(i) Committing a crime specified in 18 U.S.C. 2332b(g)(5);

(ii) Having a 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

(iii) Being an agent of a foreign power (as defined in 50 U.S.C. 1801).

(e) The HHS Secretary will deny or revoke access to any select agent or toxin to an entity or individual identified by the Attorney General as a restricted person under paragraph (d)(1). The HHS Secretary will deny or revoke access to any select agent or toxin to an entity or individual identified by the Attorney General as meeting the criteria of paragraph (d)(2) unless determined by the HHS Secretary to be warranted in the interest of the public health and safety or national security. For individuals meeting the criteria of paragraph (d)(2) the HHS Secretary may provide a limited approval for a specified time based upon the finding that circumstances warrant such action in the interest of the public health and safety or national security.

(f) Unless a shorter period is granted under paragraph (e) of this section, an approval for an entity or individual under this section will be valid for five years unless terminated sooner. The HHS Secretary may terminate an approval for an entity or an individual based on a request from the entity or individual, a security risk assessment under this section, or a failure to comply with the provisions of this part, and may take such action immediately if necessary to protect the public health and safety, or national security.

(g) The HHS Secretary will request the Attorney General to expedite the review process for an individual and will take action to expedite the HHS