FAQ for New Select Agent Regulation (42 CFR 73)

General Questions Concerning Select Biological and Toxins

1. What is the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and how do I find a copy?

On June 12, 2002, President Bush signed the "Public Health Security and Bioterrorism Preparedness Response Act of 2002" (Public Law 107-188). The law is designed to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. Section 202(a) of the Law requires that all persons possessing biological agents or toxins deemed a threat to public health to notify the Secretary, Department of Health and Human Services (HHS). Section 213(b) of Law requires all persons possessing biological agents or toxins deemed a threat to animal or plant health and to animal or plant products notify the Secretary, United States Department of Agriculture (USDA).

The Law also requires that both Secretaries be notified when a person possesses agents that appear on both the HHS and the USDA list of agents and toxins. These agents and toxins have

- After diagnosis, verification or proficiency testing, the entity either transfers the specimens or isolates to a registered facility or destroys them on-site by an appropriate method.
- Select agents used for diagnosis, verification or proficiency testing are transferred or destroyed within 7 days after identification, unless directed

of *Clostridium* [illegible] *cs* [illegible] *borne enceph* [illegible] *ca* [illegible] *clitis com* [illegible] *cp* [illegible] *lex* [illegible]

- Reporting the identification of a select agent or toxin as a result of diagnosis, verification or proficiency testing.

CDC recommends that the RO and alternate RO are biosafety officers or senior management officials of the entity/facility, or both. Although we understand that some entities have limited staff, we recommend that the RO not be an individual actually using, working with, or transferring or receiving the select agents and toxins to minimize potential conflicts of interest.

14. What is the responsibility of the alternate RO?

The alternate RO must meet all the qualifications for the RO and must be able to conduct all the activities of the RO (listed above) in the absence of the RO.

15. What agency should the application be submitted to?

The agency that the Responsible Official (RO) should contact is determined by the type of select biological agent or toxin that is possessed.

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73.21. This includes modifications to the list of individuals that have been approved under 42 CFR 73.8 to work/access select agents, changes in work locations, and changes in protocols or objectives of the studies. The entity must submit the information requested in the relevant portion of the application package to the agency that issued the certificate of registration.

19. Under what conditions could a registration be terminated?

The HHS Secretary will terminate a certificate of registration based on a determination that the entity no longer conducts activities covered by the certificate. It may also be terminated based on the security risk assessment from Department of Justice, or if the entity fails to meet or maintain safety or security requirements as specified in 42 CFR 73. The HHS Secretary may take such action immediately if necessary to protect the public health or safety. Upon such termination the select agent or toxin possessed by the entity must be destroyed or transferred as directed by the HHS Secretary.

20. Who has to have a security risk assessment?

All entities (except for Federal, State, or local governmental agencies), the RO, alternate RO, and all individuals working with or having access to select agents or toxins must have an approved security risk assessment. An entity may not provide an individual access to a select agent or toxin unless the individual has been approved by the HHS Secretary or USDA Secretary based on this security risk assessment.

21.How does an entity obtain a security risk assessment?

Information will be posted on our website when it becomes available.

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Questions Regarding the New Select Agent Regulation (42 CFR 73) for Facilities Currently Registered under 42 CFR 72.6

1. I was just registered for a period of three years, is anything further required of our institution as a result of the new regulation?

5. Our institution now has occasion to register additional agents and laboratories, is this still a simple amendment?

If you request an amendment to your registration under 42 CFR 72.6, the amendment will only be effective until the applicable phase-in date of 42 CFR 73. Please note that you will be required to submit an application for all work performed at your institution, including the amendment to meet the requirements of 42 CFR 73 on or around March 12, 2003.

6. How do I determine whether to submit my registration to CDC or USDA for the overlap select agents?

You may submit your new registration package to either agency. A joint reporting system has been developed between CDC and APHIS to approve your application for use of HHS/USDA overlap agents.

7. If I have a CDC select agent and a USDA select agent in the same lab with the same Principal Investigator (PI), do I have to register the same lab with both agencies for each select agent?

Yes. Even if you are registering the same laboratory and PI with the two agencies, you must submit a separate package to each agency for the agent under their control.

8. Our registration is about to expire. Are there changes in the process since our previous registration?

There are new requirements and a new application. 42 CFR 72.6 is being superceded by 42 CFR 73 on November 12, 2003, with phase-in requirements from February 2003 through November 2003. Please use the new application when it becomes available (information to be posted on our website) to renew your registration under 42 CFR 73.

9. Will you utilize documentation on file which I have sent in for my current registration?

Some documentation on file from your current registration will be used for activities such as transfers under 42 CFR 72.6 ***until March 12, 2003***. After the date the 73.14 Transfer Section becomes effective, a new version of the transfer form will be used. To accomplish transfers, the 42 CFR 73 application must be on file and approved between February 7, 2003 and March 12, 2003. New documentation must be submitted because HHS and USDA are required to evaluate and concur on registrations for HHS/USDA overlap agents.

10. It may take some time to have the personnel in our laboratories approved for the security risk assessment by DOJ. How will this affect my registration and the processing of our application?

Your entity will receive an application number when your application has been approved under 42 CFR 73. The DOJ component of the rule becomes effective on June 12, 2003, and compliance

with each phase of the registration process will enable you to conduct business legally until a registration number is issued under 42 CFR 73, as it supercedes 42 CFR 72.6 in November 2003.

11. We have select agents on the exclusive HHS list as well as on the exclusive USDA list. How do we coordinate the registration?

You must register with both agencies if you have agents on both lists. If you are also working with an overlap agent, then continue with your initial registering agency. The two agencies will be jointly reviewing that portion of the evaluation.

12. Currently we only store select agents and toxins, do we have to register personnel with access to the freezers with DOJ?

Yes. You must submit application for a security risk assessment to DOJ for any individuals that require access, including the appointed RO and alternate RO.

13. I just received a letter with a response due date from the inspector assigned to my facility. Is there a process by which I can request to extend this response date?

The regulation specifically provides for an 8 week period of processing of the application. This time is to allow you to provide information that is required, but was not furnished with your application. As noted on the application, information not provided can seriously delay processing of your application, and may result in delaying your registration.

14. We are a facility that is currently registered with CDC to transfer select agents, but due to funding constraints for the select agent project, we are considering eliminating the project and destroying the agent. What should we do?

Until on or around March 12, 2003 when the new transfer section becomes effective under 42 CFR 73.14, an EA-101 must be submitted to CDC to report the destruction of the agents or toxins (as specified in 42 CFR 72.6; see http://www.cdc.gov/od/sap/docs/attach6.pdf). After March 12, 2002, CDC must be notified in writing at least 5 business days prior to destruction.

Questions Regarding the New Select Agent Regulation (42 CFR 73) for Facilities Not Currently Registered under 42 CFR 72.6 and Not Currently Possessing Select Agents

1. I did not possess select agents or toxins prior to February 7, 2003. What timeline must I meet to register my entity?

As of February 7, 2003, to register your entity, you must submit an application that certifies your compliance with the designation of a Responsible Official; development of a safety plan and laboratory compliance with the requirements of the BMBL, 29 CFR 1910.1450, and/or NIH Guidelines for recombinant DNA; an emergency response plan; security risk assessment; training requirements; select agent tral6.Ne wi96L, 29 CFR 1910.1450, a871 47i 0 0 12 155.5615 88.0(ents; s)Tj

o112 acknowledgment of inspection requirement; theft, loss, or release notification procedure; and acknowledgement of administrative review of adverse actions, civi Tc, 02