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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 73

RIN 0920-AA34

**Possession, Use, and Transfer of Select Agents and Toxins;
Biennial Review, Technical Amendment**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Final rule; technical amendment

SUMMARY: In a final rule that was published in the Federal Register on October 5, 2012, we amended and republished the list of select agents and toxins that have the potential to pose a severe threat to public health and safety; reorganized the list of select agents and toxins based on the relative potential of each select agent or toxin to be misused to adversely affect human health (designation of Tier 1); and amended the regulations in order to add definitions and clarify language concerning security, training, biosafety, biocontainment, and incident response. In that final rule, all of our regulatory language was not precisely aligned with that used by the Animal and Plant

Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA) in their parallel select agent regulations published on the same day in the Federal Register. This document corrects inconsistencies in language between the HHS/CDC and USDA/APHIS regulations. We are also correcting an improper term used in those sections of the regulations associated with identification of a viral strain or subspecies that is excluded from the requirements of the regulations, modifying the terms used when a select toxin is excluded from the regulations, clarifying those parts of the regulations that deal with temporary exemptions granted during periods of public health or agricultural emergencies, and adding language to specify that individuals not approved for unescorted access to registered space for activities not related to select agents or toxins (e.g., routine cleaning, maintenance, and repairs) would not have to be continuously escorted by an approved individual so long as those non-approved persons would not be able to gain access to select agents or toxins.

EFFECTIVE DATE: [Insert date of publication in the Federal Register].

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SUPPLEMENTARY INFORMATION: On October 5, 2012, HHS/CDC and USDA/APHIS published parallel Final Rules in the Federal Register (77 FR 61084 and 77 FR 61056, respectively) amending and republishing the list of select agents and toxins as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Because of the overlapping nature of the regulatory requirements, HHS/CDC and USDA/APHIS strive to establish identical language in their respective regulations wherever possible. A post publication review of the regulatory language of both rules identified sections in which the regulatory language used by HHS/CDC was not precisely aligned with that used by USDA/APHIS.

In addition, we are also clarifying a term used in §73.3(d)(5) and §73.4(d)(3), which addresses the circumstances in which a virus strain or agent subspecies is excluded from the requirements set out in the regulations. Specifically, these paragraphs need to clearly identify those strains of viruses and subspecies of

agents that we do not consider to have the potential to pose a severe threat to public health and safety. As published, these sections allowed the listed specific virus strains and agent subspecies to be excluded from the requirements of the select agent regulations provided that an entity could "verify" that the virus strain or agent subspecies in their possession was within the listed strain or subspecies. We are replacing the word "verify" with the word "identify," as identification is a more precise description of the categorization of a viral strain or subspecies of agent. We note that before one can verify, one must identify. The following changes are made to correct the discrepancies in language in order to fully harmonize the regulations, to replace "verify" with the proper term "identify", and to clarify that a person without approval to have access to select agents and toxins needs to be continuously escorted only if that person will have the ability to gain access to select agents or toxins.

We are also are also clarifying terms used in §73.3(e), §73.3(e)(2), and §73.4(e), §73.4(e)(2), which addressed the circumstances under which select toxins may be excluded from the requirements of the regulations. In these sections, we are replacing the words "inactive" and "inactivated" with the phrase "modified to be less toxic or

potent." This is necessary because a select toxin may be modified to be less toxic or potent in such a way that it loses some but not necessarily all functional activity (e.g., modifying a toxin by chemical, genetic, or other means such that the toxin still retains some of its toxic activity). By comparison, an inactive select toxin is completely non-functional. For the purposes of regulatory applicability, before a select toxin will be considered "modified to be less toxic or potent," a written request and supporting scientific information must be submitted to either HHS/CDC or USDA/APHIS so that a determination on whether to exclude the less toxic or potent select toxin can be made by the HHS Secretary.

Paragraphs 73.6(e) and (f) address temporary exemptions to all or part of the regulations concerning select agents and toxins which may be granted by the HHS Secretary to respond to a public health emergency. We are amending the language in order to clarify that entities will not request these exemptions, as is the case with the other potential exemptions listed in §73.6, since the decision regarding whether to issue "public health emergency" exemptions is predicated on an initial determination by the HHS Secretary of the existence of a public health emergency.

Finally, §73.11(d)(2) makes clear that individuals not approved for access to select agents and toxins may have access to registered space for activities not related to select agents or toxins (e.g., routine cleaning, maintenance, and repairs) without being continuously escorted by an approved individual so long as those non-approved individuals will not be able to gain access to select agents or toxins.

List of Subjects in 42 CFR Part 73

Biologics, Packaging and containers, Penalties, Reporting and recordkeeping requirements, Transportation.

Accordingly, 42 CFR part 73 is corrected by making the following correcting amendments:

PART 73— SELECT AGENTS AND TOXINS

1. The authority citation for part 73 continues to read as follows:

Authority: 42 U.S.C. 262a; sections 201-204, 221 and 231 of Title II of Public Law 107-188, 116 Stat. 637 (42 U.S.C. 262a).

2. In §73.3:

a. Paragraph (d) (5) is amended by removing the word "verify" and adding the word "identify" in its place.

b. Paragraph (e) introductory text is revised.

c. Paragraph (e) (2) is amended by removing the word "inactivated" and adding the word "modified" in its place.

The revision reads as follows:

§73.3 HHS select agents and toxins.

* * * * *

(e) An attenuated strain of a select agent or a select toxin modified to be less potent or toxic may be excluded from the requirements of this part based upon a determination by the HHS Secretary that the attenuated strain or modified toxin does not pose a severe threat to public health and safety.

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3. In §73.4:

a. Paragraph (d) (3) is amended by removing the word "verify" and adding the word "identify" in its place.

b. Paragraph (e) introductory text is revised.

c. Paragraph (e) (2) is amended by removing the word "inactivated" and adding the word "modified" in its place.

d. Paragraph (f) (3) (i) is amended by adding the word "overlap" before "select agent or toxin."

The revision reads as follows:

§73.4 Overlap select agents and toxins.

* * * * *

(e) An attenuated strain of a select agent, or a select toxin modified to be less potent or toxic, may be excluded from the requirements of this part based upon a determination by the HHS Secretary that the attenuated strain or modified toxin does not pose a severe threat to public health and safety.

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4. In §73.6, revise paragraphs (e) and (f) to read as follows:

§73.6 Exemptions for overlap select agents and toxins.
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(e) The HHS Secretary may exempt an individual or entity from the requirements of this part based on a determination that the exemption is necessary to provide for the timely participation of the individual or entity in response to a domestic or foreign public health emergency.

The HHS Secretary may extend the exemption once for additional 30 days.

(f) Upon request of the Administrator, the HHS Secretary may exempt an individual or entity from the requirements, in whole or in part, of this part for 30 calendar days if the Administrator has granted the exemption for agricultural emergency. The HHS Secretary may extend the exemption once for an additional 30 calendar days.

5. Section 73.11 is amended as follows:

a. In paragraph (c)(2), remove the commas before "including" and after "arthropods" and put parentheses around the words "including arthropods" after the word "animals."

b. Revise paragraph (c)(9)(iii).

c. In paragraph (d)(2) by adding "if the potential for access to select agents or toxins exists" after "approved individual."

d. Revise paragraph (f)(4)(viii)(A).

e. Revise paragraph (g).

The revisions read as follows:

§73.11 Security.

* * * * *

(c) * * *

(9) * * *

(iii) Ensure that controls are in place that are designed to prevent malicious code (such as, but not limited to, computer virus, worms, spyware) from compromising the confidentiality, integrity, or availability of information systems which manage access to spaces registered under this part or records in §73.17;

* * * * *

(f) * * *

(4) * * *

(iv) * * *

(A) Determine that the response time for security forces or local police will not exceed 15 minutes where the response time is measured from the time of an intrusion alarm, or report of a security incident, to the arrival of the responders at the first security barrier or;

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(g) In developing a security plan, an individual or entity should consider the document entitled, "Security Guidance for Select Agent or Toxin Facilities." This document is available on the National Select Agent Registry at <http://www.selectagents.gov/>.

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6. Section 73.13 is amended as follows:

a. By revising paragraph (a).

b. By removing paragraph (b).

c. By redesignating paragraphs (c) and (d) as paragraphs (b) and (c), respectively.

d. In newly redesignated paragraph (b), by removing the words "paragraph (b)" and adding the words "paragraph (a)" in their place.

The additions read as follows:

§73.13 Restricted experiments.

(a) An individual or entity may not conduct, or possess products resulting from, the following experiments unless approved by and conducted in accordance with the conditions prescribed by the HHS Secretary:

(1) Experiments that involve the deliberate transfer of, or selection for, a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture.

(2) Experiments involving the deliberate formation of synthetic or recombinant DNA containing genes for the

biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight."

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§73.16 [Amended]

7. In §73.16, paragraph (g) is amended by removing the words "concerning shipping" and adding "governing packaging and shipping" after the words "applicable laws".

Dated: May 6, 2014.

Kathleen Sebelius,
Secretary.

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