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Department of Health and Human Services

42 CFR Part 73

CDC Docket No. CDC-2016-0045

RIN 0920-AA64

**Possession, Use, and Transfer of Select Agents and Toxins -
Addition of *Bacillus cereus* Biovar *anthracis* to the HHS
List of Select Agents and Toxins**

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

ACTION: Interim rule; adoption as final and response to
public comments.

SUMMARY: On September 14, 2016, the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) published in the Federal Register (81 FR 63138) an interim final rule and request for comments which added *Bacillus cereus* Biovar *anthracis* to the list of HHS select agents and toxins as a Tier 1 select agent. CDC received two comments, both of which supported the rule change.

DATES: Effective [insert date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Dr. Samuel Edwin,
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SUPPLEMENTARY INFORMATION: Effective on October 14, 2016,
Bacillus cereus Biovar *anthracis* was added to the list of
HHS select agents and toxins as a Tier 1 select agent (81
FR 63138, September 14, 2016). In the interim final rule,
HHS/CDC invited comments on the following questions:

- 1) Are there other virulent (pBCX01+ and pBCX02+) strains
of *Bacillus* species that should also be regulated?
- 2) What is the impact of designating *B. cereus* Biovar
anthracis as a Tier 1 select agent?

The comment period ended November 14, 2016.

We received two comments, both of which supported
adding *B. cereus* Biovar *anthracis* to the list of HHS select
agents and toxins. While both commenters supported the
addition, one commented that the regulation of *B. cereus*
Biovar *anthracis* will "restrict the ability of future
laboratories and organizations to test for and analyze

possible pBX01 and pBX02 isolates.” The commenter further argued that “new laboratories seeking the ability to analyze this select agent will incur substantial costs and urged HHS/CDC reassess the impacts that a \$37,000 buy-in for new laboratories might have on the ability to understand this deadly microbe.” HHS/CDC made no changes based on this comment. HHS/CDC is not proposing to regulate other strains of *B. cereus* that have *B. anthracis* toxin genes as the data available do not suggest those strains pose a severe threat to public health (Ref. 1 and Ref. 2). HHS/CDC agrees that the regulations will impact new laboratories wishing to perform research with *B. cereus* Biovar *anthracis*. However, we believe that *B. cereus* Biovar *anthracis* has the same potential to pose a severe threat to public health as does *Bacillus anthracis*, currently regulated as a Tier 1 pathogen.

HHS/CDC adopts the interim rule, which was effective October 14, 2016 (81 FR 63138, September 14, 2016), as final without change. In accordance with the interim final rule, any individual or entity that possessed *B. cereus* Biovar *anthracis* on or after October 14, 2016, must provide notice to the CDC regarding their possession and must secure the agent against theft, loss, release, or unauthorized access; and by March 13, 2017, an individual

or entity that intends to continue to possess, use, or transfer this agent is required to either register in accordance with 42 CFR part 73 or amend their current registration in accordance with 42 CFR 73.7(h) and meet all of the requirements of select agent regulations (42 CFR Part 73).

References:

1. Brezillon, C, Hauslant, M, Dupke, S, Corre, JP, Lander, A, Franz, T, Monot, M, Couture-Tosi, E, Jouvion, G, Leendertz, FH, Grunow, R, Mock, ME, Klee, SR, and Goossens, L. (2015) Capsules, toxins and AtxA as virulence factors of emerging *Bacillus cereus* Biovar *anthracis*. PLOS Negl. Trop. Dis. 9(4):e0003455.
2. Avashia SB, et al. (2007) Fatal pneumonia among metalworkers due to inhalation exposure to *Bacillus cereus* containing *Bacillus anthracis* toxin genes. Clin. Infect. Dis. 44:414-416.

Dated: April 4, 2017

Thomas E. Price,
Secretary

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