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, Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-A46, Atlanta, Georgia 30329. Telephone: (404) 718-2000.

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 (pBCXO1+ and pBCXO2+) 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 pBXO1 and pBXO2 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:


Dated: April 4, 2017

Thomas E. Price,
Secretary

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