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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 final rule and request for comments.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) is adding *Bacillus cereus* Biovar *anthracis* to the list of HHS select agents and toxins as a Tier 1 select agent. We are taking this action to regulate this agent that is similar to *B. anthracis* to prevent its misuse, which could cause a biological threat to public health and/or national security.

DATES: Effective date: The interim final rule is effective on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Public comment period: Written or electronic comments must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Applicability dates: By [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], any individual or entity that possesses *B. cereus* Biovar *anthracis* must provide notice to the CDC's DSAT regarding their possession of this agent and must secure the agent against theft, loss, release, or unauthorized access; and by [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], an individual or entity that intends to continue to possess, use, or transfer this agent will be 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).

ADDRESSES: You may submit comments, identified by Docket No. CDC-2016-0045 or RIN 0920-AA64 by any of the following methods:

- Federal eRulemaking Portal:
<http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: 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, Attn: Docket CDC-2016-0045

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All relevant comments received will be posted without change to <http://regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

Comments will also be available for public inspection from Monday through Friday, except for legal holidays, from 9 a.m. to 5 p.m., Eastern Time, at 1600 Clifton Road, N.E., Atlanta, Georgia, 30329. Please call ahead to (404) 718-2000 and ask for a representative from the Division of Select Agents and Toxins to schedule your visit.

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: The interim final rule is
organized as follows:

- I. Public Participation
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I. Public Participation

Interested persons or organizations are invited to
participate in this rulemaking by submitting written views,

recommendations, and data. HHS/CDC invites 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?

Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. HHS/CDC will consider comments that are received within 60 days of publication of this rule in the Federal Register. After the comment period closes, we will publish another document in the Federal Register. The document will include a discussion of any comments we receive and any amendments that will be made to the rule as a result of the comments.

II. Background

A. Legal Authority

HHS/CDC is promulgating this rule under the authority of sections 201-204 and 221 of Title II of Public Law 107-188, 116 Stat 637 (42 U.S.C. 262a).

Subtitle A of Title II of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, (42 U.S.C. 262a), requires HHS to regulate the possession, use, and transfer of biological agents or toxins that the HHS Secretary determines have the potential to pose a severe threat to public health and safety (select agents and toxins). Subtitle B of Title II of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (which may be cited as the Agricultural Bioterrorism Protection Act of 2002), (7 U.S.C. 8401), requires the United States Department of Agriculture (USDA) to regulate the possession, use, and transfer of biological agents or toxins that the USDA Secretary determines have the potential to pose a severe threat to animal or plant health, or animal or plant products (select agents and toxins). Accordingly, HHS and USDA have promulgated regulations requiring individuals or entities that possess, use, or transfer select agents and toxins to register with HHS/CDC or USDA/Animal and Plant Health Inspection Service (APHIS). See 42 CFR part 73, 7 CFR part 331, and 9 CFR part 121 (the select agent regulations). The Federal Select Agent Program, a collaboration of HHS/CDC/Division of Select Agents and Toxins and USDA/APHIS/Agriculture Select Agent Services, administers the select agent regulations in

a manner that minimizes the administrative burden on persons subject to the select agent regulations. USDA/APHIS is currently considering whether *B. cereus* Biovar *anthracis* should also be listed as a USDA select agent.

B. Historical background to this rulemaking

Emerging *B. cereus* strains that cause anthrax-like disease have been isolated in Cameroon (CA strain) and Côte d'Ivoire (CI strain). We are currently aware that geographic distribution of *B. cereus* Biovar *anthracis* is limited to some African countries, one registered entity in the United States, and one facility in Germany. The *B. cereus* strain being added to the HHS list of select agents is identified as *B. cereus* Biovar *anthracis* and described in the publication "Characterization of Bacillus anthracis-like bacteria isolated from wild great apes from Cote d'Ivoire and Cameroon" (Ref. 3, see table below). Recent research demonstrates that *B. cereus* Biovar *anthracis* has all of the virulence determinants and threat potential of *Bacillus anthracis*, a Tier 1 select agent (Ref. 1). A biovar is a group of microorganisms that are genetically similar but differ from other members of the species by biochemical or genetic characteristics. *B. cereus* Biovar *anthracis* was originally isolated about a decade ago from

gorillas and chimpanzees exhibiting anthrax-like disease in Cameroon and Cote d'Ivoire (Ref. 3 - 6). Genomic characterization showed that these organisms belong to the *B. cereus* species and harbor two plasmids that are referred to as pBCX01 and pBCX02. The plasmid (pBCX01) is very similar to pX01, which is found in *B. anthracis*, and encodes active edema and lethal toxins. The plasmid (pBCX02) is very similar to pX02, which is found in *B. anthracis*, and encodes the enzymes that synthesize the poly-D-glutamic acid capsule. Thus, these organisms are genetically similar and produce all of the primary virulence factors (toxins and capsule) of *B. anthracis*. In addition, pBCX02 has a functional *hasACB* operon that encodes a second capsule composed of hyaluronic acid (HA), which enhances the neuro-invasiveness of these organisms in laboratory models of infection (Ref. 1). Accordingly, because 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, we are adding *Bacillus cereus* Biovar *anthracis* to HHS select agent list by an interim final rule because we believe that any delay in bringing the possession, use, or transfer into the United States of this pathogen is contrary to the public interest. A biological agent is

designated as Tier 1 when it is determined that it presents the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effect to the economy, critical infrastructure, or public confidence, and poses a severe threat to public health and safety. We believe that *Bacillus cereus* Biovar anthracis presents the same threat to public health and national security as does *Bacillus anthracis*.

In December 2015, the question of whether *B. cereus* Biovar *anthracis* should be regulated as a select agent was considered by HHS/CDC's Intragovernmental Select Agents and Toxins Technical Advisory Committee (ISATTAC). The ISATTAC is comprised of Federal government employees from CDC, the Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response (ASPR), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Department of Homeland Security (DHS), the Department of Defense (DOD), the USDA/Animal and Plant Health Inspection Service (APHIS), USDA/Agricultural Research Service (ARS), and USDA Center for Veterinary Biologics (CVB). Based on the criteria outlined in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 262a), the ISATTAC considered the following

in their review: the degree of pathogenicity (ability of an organism to cause disease), communicability (ability to spread from infected to susceptible hosts), ease of dissemination, route of exposure, environmental stability, ease of production in the laboratory, ability to genetically manipulate or alter, long-term health effects, untreated acute mortality, available therapeutics and vaccines, status of immunity, vulnerability of special populations, and the burden or impact on the health care system. The ISATTAC also considered whether *B. cereus* Biovar *anthracis* should be designated as a Tier 1 select agent. Executive Order 13546, "Optimizing the Security of Biological Select Agents and Toxins in the United States," defines as "Tier 1" those select agents and toxins that present the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy, critical infrastructure; or public confidence (Ref. 7). At this time, 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. 8).

The table below comes from "Bacteriological discrimination characteristics of atypical *B. anthracis* strains isolated from great apes, classic *B. anthracis* strains, and other strains of the *B. cereus* group" (Ref. 3).

Microbiological Characteristic	Result ^a					
	<i>B. anthracis</i> CI		<i>B. anthracis</i> CA		<i>B. anthracis</i> s	<i>B. cereus</i>
	Primary culture	Sub culture	Primary Culture	Sub culture		
Hemolysis	-	+/-	-	+/-	-	+
Motility	+	+	+	+	-	+
Susceptibility to gamma phage	-	+/-	-	+/-	+	-
Penicillin G	S	S/R	R	R	S	R
Capsule	+ ^b	+/-	+	+/-	+	Absent in vitro ^c

^aS, sensitive; R, resistant; -, negative; +, positive; +/-, some subclones positive, others negative.

^bCapsule production on bicarbonate agar under a CO₂ atmosphere and on blood agar under an ambient atmosphere.

^cCertain other *Bacillus* spp. can produce a polypeptide capsule but not under normal culture conditions.

After reviewing scientific publications and consulting with subject matter experts, ISATTAC recommended that *B. cereus* Biovar *anthracis* should be listed as a HHS select agent and regulated as Tier 1 agent because:

- Genomic characterization showed that *B. cereus* Biovar *anthracis* belongs to the *B. cereus* species, but it

harbors virulence-associated plasmids that are similar to *B. anthracis*, a Tier 1 select agent (Ref. 1-2).

- Fully virulent (pXO1+ pXO2+) strains of *B. anthracis* are currently regulated as Tier 1 select agent.
- To date, there have been no reports of this biovar having been isolated from humans. However, *B. cereus* Biovar *anthracis* exhibited virulence, comparable to *B. anthracis* in animal models of subcutaneous and intranasal/inhalational anthrax (Ref. 3). Thus, it is reasonable to assume that *B. cereus* Biovar *anthracis* can infect humans by the same routes as *B. anthracis*. In areas (Cameroon and Cote d'Ivoire) where *B. cereus* Biovar *anthracis* has been isolated from gorillas and chimpanzees (Ref. 4-6), it is possible that isolates from human cases could be missed due to the lack of laboratory capacity and to the thorough characterization needed to differentiate *B. anthracis* from *B. cereus* Biovar *anthracis*.
- As with *B. anthracis*, the virulence of this strain as a spore-forming bacterium may make it attractive to those that wish to circumvent the select agent regulations for nefarious purposes.

- PBCX02- strains of *B. cereus* Biovar *anthracis* (analogous to *B. anthracis* veterinary vaccine Sterne strain) produce a HA capsule from genes present on pBCX01. Studies have shown such variants (pBCX02-) are still as virulent as *B. anthracis* in animal models (Ref. 1).
- There is no apparent difference between this organism and *B. anthracis* with respect to the criteria used to designate *B. anthracis* as a Tier 1 agent.

In addition, the Federal Experts Security Advisory Panel (FESAP) provided policy and technical input for the recommendation to list *B. cereus* Biovar *anthracis* as an HHS select agent and regulated as Tier 1 agent. The mission of the FESAP is to make technical and substantive recommendations concerning the appropriate safeguards and security standards for persons possessing, using, or transferring BSAT. The goal of the FESAP is that their recommendations be commensurate with the risk that such agents or toxins pose to public health and safety, including the risk of their use in domestic or international terrorism. The FESAP drew from the expertise of its membership, information from presentations by several federal department and agency subject matter experts, and technical input from the Directors of the

Federal Select Agent Program (FSAP) to develop its recommendation. The FESAP has issued a draft report that recommended listing *B. cereus* biovar *anthracis* as a select agent (not Tier 1).

After consideration of all of the above, HHS/CDC has determined that *B. cereus* Biovar *anthracis* should be listed as a Tier 1 HHS select agent given its similarities to *B. anthracis*, which is consistent with current regulatory requirements for *B. anthracis*.

III. Rationale for Issuance of an Interim Final Rule

Agency rulemaking is governed by section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553) which, unless the rule falls within one of the exemptions, requires that HHS/CDC publish a notice of proposed rulemaking in the *Federal Register* that provides interested persons an opportunity to submit written data, views, or arguments. Section 553(b) (B) of the APA authorizes a department or agency to dispense with the prior notice and opportunity for public comment requirement for "good cause" if the department or agency finds that it is contrary to the public interest.

B. cereus Biovar *anthracis* has all of the virulence characteristics and threat potential of *Bacillus anthracis*,

which is already regulated as a Tier 1 select agent. Accordingly, for the reasons stated above, we have determined that *B. cereus* Biovar *anthracis* not only also has the potential to pose a severe threat to public health and safety; but that it may present a great risk for deliberate misuse with a significant potential for mass casualties or devastating effects to the economy, critical infrastructure; or public confidence. We are taking this action to place this agent under the biosafety and security requirements of the select agent regulations; and to regulate its possession and transfer to prevent an accidental release or its misuse. We believe this interim final rule is in the best interest of public health and national security.

Pursuant to 5 U.S.C. 553(b) (3) (B), and for the reasons stated above, we therefore find that there is good cause to dispense with prior public notice and the opportunity to comment on this rule before it becomes effective because any delay in promulgating the rule would be contrary to the public interest.

IV. Alternatives considered

In researching this addition to the HHS select agents and toxins list, we also considered whether *B. cereus*

Biovar *anthracis* should be designated as a non-Tier 1 agent. We concluded that *B. cereus* Biovar *anthracis* should be regulated as a Tier 1 select agent for the same reason that we currently regulation *B. anthracis* as a Tier 1 select agent.

V. Required Regulatory Analyses

A. Executive Orders 12866 and 13563

HHS/CDC has examined the impacts of this interim final rule (IFR) under Executive Order 12866, Regulatory Planning and Review (58 FR 51735, October 4, 1993) and Executive Order 13563, Improving Regulation and Regulatory Review, (76 FR 3821, January 21, 2011). Both Executive Orders direct agencies to evaluate any rule prior to promulgation to determine the regulatory impact in terms of costs and benefits to United States populations and businesses. Further, together, the two Executive Orders set the following requirements: quantify costs and benefits where the new regulation creates a change in current practice; define qualitative costs and benefits; choose approaches that maximize benefits; support regulations that protect public health and safety; and minimize the impact of regulation. HHS/CDC has analyzed this IFR as required by

these Executive Orders and has determined that it is consistent with the principles set forth in the Executive Orders and the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA). We anticipate that the rule will create minimal impact.

This regulatory impact section presents the anticipated costs and benefits that are quantified where possible. Where quantification is not possible, a qualitative discussion is provided of the costs and/or benefits that HHS/CDC anticipates from issuing this regulation.

Need for the regulation

Bacillus cereus Biovar *anthracis* is a recently recognized, emerging pathogen that has all the virulence characteristics and threat potential of *Bacillus anthracis*, a Tier 1 select agent. This organism is not currently on the HHS List of Select Agents and Toxins; we are proposing regulating this organism as a Tier 1 select agent because of its potential for misuse and its threat to public health and safety.

Regulatory Impact Analysis

Costs

Currently, the only entity in possession of this agent is already registered to possess Tier 1 select agents. As a result, the burden associated with this entity is minimal. However, this rule will also affect entities which plan to possess the agent in the future. We believe that these entities fall into three categories: entities not currently registered for a select agent or toxin, and entities already registered with the Federal Select Agent Program (FSAP) but not for a Tier 1 agent or toxin, and entities already registered to possess a Tier 1 agent, such as the one already in possession of the agent. Based on the 2012 Select Agent Final Rule, entities already registered with the FSAP but not for a Tier 1 agent or toxin will incur costs of approximately \$10,000-\$15,000 in order to possess the agent, and median annualized costs to entities not currently registered to possess select agent or toxin are estimated to be approximately \$37,000 in order to possess the agent. As noted, for entities already registered to possess a Tier 1 agent, costs are estimated to be minimal. However, we lack data to forecast the number of entities beyond the one entity we are currently aware of that will possess this agent in the future, and as

a result we do not estimate the total associated costs.

Benefits:

The agents and toxins placed on the HHS selects and toxins list have the potential to pose severe threats to public health and safety. The benefits of the HHS/CDC interim final rule derive from the strengthened prevention against the accidental or intentional release of *B. cereus* Biovar *anthracis*. We based the following assumption on the release of *B. anthracis* that occurred in 2001. The cost of such an event in human life could be high. An outbreak of *B. cereus* Biovar *anthracis* also would require a complex and expensive emergency response effort. This effort would include extensive public health measures, such as quarantine, isolation, preventive treatment and health testing for large numbers of potentially exposed persons, and extensive decontamination. Substantial costs would likely be incurred by hospitals and other medical facilities and institutions of government at all levels.

An outbreak of *B. cereus* Biovar *anthracis*, or widespread fear of one, also would likely create significant secondary effects to society including a potentially rapid increase in health anxiety among healthy individuals. This may result in overcrowded healthcare

facilities and emergency rooms, and the disruption of everyday business operations, transportation, and other normal behavior.

Impacts from the October 2001 anthrax attacks exemplify the costs that the regulatory revisions will help to prevent. The anthrax attacks caused five fatalities and seventeen illnesses, disrupted business and government activities, closed substantial parts of the U.S. Postal Service, and caused widespread apprehension and changes in behavior. Costs included more than \$23 million to decontaminate one Senate office building, approximately \$2 billion in revenues lost to the postal service, and as much as \$3 billion in additional costs to the U.S. Postal Service for cleanup of contamination and procurement of mail-sanitizing equipment (referenced from the Regulatory Impact Analysis from the 2012 Select Agent Regulations Final Rule). There were substantial costs due to lost productivity throughout the economy and investigations into the incident (referenced from the Regulatory Impact Analysis from the 2012 Select Agent Regulations Final Rule).

A deliberate release of *B. cereus* Biovar *anthracis* may cause wide-ranging impacts to the economy, potential loss of market access for consumer goods and services, other

disruptions to society, and diminished confidence in public and private institutions.

Comparison of Costs and Benefits:

In our analysis, we determined that only one entity that already possesses Tier 1 select agents in the United States is in possession of *B. cereus* Biovar *anthracis*. As noted above, the cost to the entity would be minimal. Also noted above, this rule will affect entities that plan to possess the agent in the future. Based on the 2012 Select Agent Final Rule, entities already registered with the FSAP but not for a Tier 1 agent or toxin will incur costs of approximately \$10,000-\$15,000 in order to possess the agent, and median annualized costs to entities not currently registered to possess select agent or toxin are estimated to be approximately \$37,000 in order to possess the agent. For entities already registered to possess a Tier 1 agent, costs are estimated to be minimal.

The benefit of regulating this organism is the prevention of an outbreak of disease due to this organism. An analysis of the 2001 anthrax incident shows the impact of the outbreak in terms of loss of life, illness, decontamination costs, and loss of productivity.

Based on this analysis, we believe the benefit of this rulemaking outweighs the costs.

B. The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA)

We have examined the impacts of the interim final rule under the Regulatory Flexibility Act (5 U.S.C. 601-612). Unless we certify that the interim final rule is not expected to have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), requires agencies to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. Based on our current knowledge of who possesses *B. cereus* Biovar *anthracis*, we certify that this interim final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA.

This regulatory action is not a major rule as defined by Sec. 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This interim final rule will not result in an annual effect on the economy of \$100,000,000

or more; a major increase in cost or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

C. Paperwork Reduction Act of 1995

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rulemaking are currently approved by the Office of Management and Budget (OMB) under OMB control number 0920-0576, expiration date 12/31/2018. This includes the burden on entities to submitted amendments to their registrations.

We expect that the entities who will register for possession, use, or transfer of *B. cereus* Biovar *anthracis* will already be registered with the Federal Select Agent Program. This rulemaking will require such an entity to amend its registration with the Federal Select Agent Program using relevant portions of APHIS/CDC Form 1 (Application for Registration for Possessing, Use, and Transfer of Select Agents and Toxins). Estimated time to amend this form is one hour for one select agent.

Additionally, any registered entity that wishes to transfer *B. cereus* Biovar *anthracis* will be required to submit information using APHIS/CDC Form 2 (Request to Transfer of Select Agent and Toxins). Estimated average time to complete this form is one hour. Based upon the limited publications on this agent at this time, we estimate that only one registered entity may add *B. cereus* Biovar *anthracis* to their registration or transfer *B. cereus* Biovar *anthracis* to another registered entity. Therefore, we calculate that there is no increase in the number of respondents that need to submit an application for registration, we estimate the total number of responses for entities to submit an amendment to their registration may increase by one, and the total burden hours may increase to one hour.

D. EO 12988: Civil Justice Reform

This rule has been reviewed under E.O. 12988, Civil Justice Reform. Once the interim final rule is in effect, HHS/CDC notes that: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) No retroactive effect will be given to this rule; and (3) Administrative proceedings will not be

required before parties may file suit in court challenging this rule.

E. EO 13132: Federalism

HHS/CDC has reviewed this interim final rule in accordance with Executive Order 13132 regarding Federalism, and has determined that it does not have “federalism implications.” The rule does not “have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.”

In accordance with section 361(e) of the PHSA [42 U.S.C. 264(e)], nothing in this rule would supersede any provisions of State or local law except to the extent that such a provision conflicts with this rule.

F. Plain Language Act of 2010

Under the Plain Language Act of 2010 (P.L. 111-274, October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal Government administers or enforces. HHS/CDC has attempted

to use plain language in promulgating this rule consistent with the Federal Plain Writing Act guidelines.

VI. 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. Helgason E, Tourasse NJ, Meisal R, Caugant DA, Kolstø AB (2004) Multilocus sequence typing scheme for bacteria of the *Bacillus cereus* group. Appl Environ Microbiol 70: 191-201.
3. Klee SR, Ozel M, Appel B, Boesch C, Ellerbrok H, et al. (2006) Characterization of *Bacillus anthracis*-like bacteria isolated from wild great apes from Cote d'Ivoire and Cameroon. J Bacteriol 188: 5333-5344.
4. Leendertz FH, Ellerbrok H, Boesch C, Couacy-Hymann E, Matz-Rensing K, et al. (2004) Anthrax kills wild chimpanzees in a tropical rainforest. Nature 430: 451-452.
5. Leendertz FH, Yumlu S, Pauli G, Boesch C, Couacy-Hymann E, et al. (2006) A new *Bacillus anthracis* found

- in wild chimpanzees and a gorilla from west and central Africa. Plos Pathog 2: e8.
6. Leendertz FH, Lankester F, Guislain P, Néel C, Drori O, et al. (2006) Anthrax in Western and Central African great apes. Am J Primatol 68: 928-933.
 7. Report of the Working Group on Strengthening the Biosecurity of the United States, Executive Order 13486 Working Group (<http://edocket.access.gpo.gov/2009/pdf/E9-818.pdf>).
 8. 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.

List of Subjects in 42 CFR Part 73

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

For the reasons stated in the preamble, we are amending 42 CFR part 73 as follows:

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 No. 107-188, 116 Stat. 637 (42 U.S.C. 262a).

§ 73.3 [Amended]

2. Amend § 73.3(b) by adding the term "*Bacillus cereus* Biovar *anthracis**" in alphabetical order.

Dated: September 8, 2016.

Sylvia M. Burwell,
Secretary.

[FR Doc. 2016-22049 Filed: 9/13/2016 8:45 am; Publication Date: 9/14/2016]