

environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. GSA has determined that this final rule is not a significant regulatory action is not subject to review under section 6(b) of Executive Order 12866. GSA has further determined that this final rule is not a major rule under 5 U.S.C. 804.

D. Regulatory Flexibility Act

This final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* This final rule is also exempt from the Administrative Procedure Act pursuant to 5 U.S.C. 553(a)(2) because it applies to agency management or personnel.

E. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the changes to the FTR do not impose recordkeeping or information collection requirements, or the collection of information from offerors, contractors, or members of the public that require the approval of the Office of Management and Budget (OMB) under 44 U.S.C. 3501, *et seq.*

F. Small Business Regulatory Enforcement Fairness Act

This final rule is also exempt from Congressional review prescribed under 5 U.S.C. 801. This final rule is not a major rule under 5 U.S.C. 804.

List of Subjects in 41 CFR Parts 301–51 and 301–70

Government employees, Travel and transportation expenses, Paying travel expenses, Internal policy and procedure requirements.

Dated: August 3, 2016.

Denise Turner Roth,

Administrator of General Services.

For the reasons set forth in the preamble, pursuant to 5 U.S.C. 5701–5711, GSA amends 41 CFR parts 301–51 and 301–70 as set forth below:

PART 301–51—PAYING TRAVEL EXPENSES

■ 1. The authority citation for 41 CFR part 301–51 continues to read as follows:

Authority: 5 U.S.C. 5707. *Subpart A* is issued under the authority of Sec. 2, Pub. L. 105–264, 112 Stat. 2350 (5 U.S.C. 5701 note); 40 U.S.C. 121(c).

■ 2. Revise § 301–51.1 to read as follows:

§ 301–51.1 How must I use the Government contractor-issued travel charge card?

You are required to activate the Government contractor-issued travel charge card once you receive it, and then use it as the method of payment for all official travel expenses unless exempted under § 301–51.2.

■ 3. Revise § 301–51.2 to read as follows:

§ 301–51.2 Are there any official travel expenses that are exempt from the mandatory use of the Government contractor-issued travel charge card?

Expenses for which payment through the Government contractor-issued travel charge card is impractical (*e.g.*, vendor does not accept credit cards) or imposes unreasonable burdens or costs (*e.g.*, fees are charged for using the card) are exempt from use of the travel charge card. Your agency may also exempt an official travel expense when it is necessary in the interest of the agency (see § 301–51.4).

§§ 301–51.3 through 301–51.8 [Redesignated as §§ 301–51.4 through 301–51.9]

■ 4. Redesignate §§ 301–51.3 through 301–51.8 as §§ 301–51.4 through 301–51.9, respectively.

■ 5. Add a new § 301–51.3 to read as follows:

§ 301–51.3 What classes of employees are exempt from mandatory use of the Government contractor-issued travel charge card?

The Administrator of General Services exempts the following classes of employees from mandatory use of the Government contractor-issued travel charge card:

(a) Any employee who has an application pending for the Government contractor-issued travel charge card;

(b) Any employee, when issuance of the Government contractor-issued travel charge card would adversely affect the mission or put the employee at risk; and

(c) Any employee who is not eligible to receive a Government contractor-issued travel charge card.

§ 301–51.6 [Amended]

■ 6. In the newly designated § 301–51.6, after paragraph (c), revise the heading of the note to read “Note to § 301–51.6”.

PART 301–70—INTERNAL POLICY AND PROCEDURE REQUIREMENTS

■ 7. The authority citation for 41 CFR part 301–70 continues to read as follows:

Authority: 5 U.S.C. 5707; 40 U.S.C. 121(c); Sec. 2, Pub. L. 105–264, 112 Stat. 2350 (5

U.S.C. 5701, note), OMB Circular No. A–126, revised May 22, 1992, and OMB Circular No. A–123, Appendix B, revised January 15, 2009.

§ 301–70.702 [Amended]

■ 8. Amend § 301–70.702 by removing “MTT” and adding “MAE” in its place.

■ 9. Revise § 301–70.704 to read as follows:

§ 301–70.704 What classes of employees are exempt from mandatory use of the Government contractor-issued travel charge card?

The Administrator of General Services exempts the following classes of employees from mandatory use of the Government contractor-issued travel charge card:

(a) Any employee who has an application pending for the Government contractor-issued travel charge card;

(b) Any employee, when issuance of the Government contractor-issued travel charge card would adversely affect the mission or put the employee at risk; and

(c) Any employee who is not eligible to receive a Government contractor-issued travel charge card.

■ 10. Revise § 301–70.708 to read as follows:

§ 301–70.708 What actions may we take if an employee fails to activate the Government contractor-issued travel charge card and/or misuses the travel charge card?

Internal agency policies and procedures should be established defining what are considered to be misuses of the Government contractor-issued travel charge card. Appropriate action may be taken pursuant to those policies if an employee fails to activate the Government contractor-issued travel charge card within 60 days of receipt or misuses the travel charge card.

[FR Doc. 2016–21987 Filed 9–13–16; 8:45 am]

BILLING CODE 6820–14–P

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 October 14, 2016.

Public comment period: Written or electronic comments must be submitted by November 14, 2016.

Applicability dates: By October 14, 2016, 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 March 13, 2017, 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 NE., 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 NE., 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 NE., MS-A46, Atlanta, Georgia 30329. Telephone: (404) 718-2000.

SUPPLEMENTARY INFORMATION: The interim final rule is organized as follows:

- I. Public Participation
- II. Background
 - A. Legal Authority
 - B. Historical Background to This Rulemaking
- III. Rationale for Issuance of an Interim Final Rule
- IV. Alternatives Considered
- V. Required Regulatory Analyses
 - A. Executive Orders 12866 and 13563
 - B. The Regulatory Flexibility Act
 - C. Paperwork Reduction Act of 1995
 - D. EO 12988: Civil Justice Reform
 - E. EO 13132: Federalism
 - F. Plain Language Act of 2010
- VI. References

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 (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?

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 pBCXO1 and pBCXO2. The plasmid (pBCXO1) is very similar to pXO1, which is found in *B. anthracis*, and encodes active edema and lethal toxins. The plasmid (pBCXO2) is very similar to pXO2, 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, pBCXO2 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> | <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 |

^a S, sensitive; R, resistant; –, negative; +, positive; +/-, some subclones positive, others negative.
^b Capsule production on bicarbonate agar under a CO₂ atmosphere and on blood agar under an ambient atmosphere.
^c Certain 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.

- PBCXO2—strains of *B. cereus* Biovar *anthracis* (analogous to *B. anthracis* veterinary vaccine Sterne strain) produce a HA capsule from genes present on pBCXO1. Studies have shown such variants (pBCXO2 –) 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 regulate *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 pathogens 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 select 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. E.O. 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. E.O. 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 (Pub. 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

- 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.
- 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.
- 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.
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- 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.
- 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.
- 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>).
- 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 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 9–13–16; 8:45 am]

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NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1816, 1832, 1842, and 1852

RIN 2700–AE34

NASA Federal Acquisition Regulation Supplement: Revised Voucher Submission & Payment Process (NFS Case 2016–N025)

AGENCY: National Aeronautics and Space Administration.

ACTION: Interim rule.

SUMMARY: NASA is issuing an interim rule amending the NASA Federal Acquisition Regulation Supplement (NFS) to implement revisions to the voucher submittal and payment process. These revisions are necessary due to section 893 of the National Defense Authorization Act for Fiscal Year 2016 prohibiting the Defense Contract Audit Agency (DCAA) from performing audit work for non-Defense Agencies. NASA had delegated to DCAA the task of reviewing contractor requests for payment under NASA cost-type contracts.

DATES:

Effective: September 14, 2016.

Comment date: Comments on the interim rule should be submitted in writing to the address shown below on or before November 14, 2016, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by NFS Case 2016–N025, using any of the following methods:

- Regulations.gov: <http://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by entering “NFS Case 2016–N025” under the heading “Enter keyword or ID” and selecting “Search.” Select the link “Submit a Comment” that corresponds with “NFS Case 2016–N025.” Follow the instructions provided at the “Submit a Comment” screen. Please include your name, company name (if any), and “NFS Case 2016–N025” on your attached document.

- Email: John.J.Lopez@nasa.gov. Include NFS Case 2016–N025 in the subject line of the message.

- Fax: (202) 358–3082.

- Mail: National Aeronautics and Space Administration, Headquarters, Office of Procurement, Contract and Grant Policy Division, Attn: John J. Lopez, LP–011, 300 E Street SW., Washington, DC 20546–0001.

FOR FURTHER INFORMATION CONTACT: Mr. John J. Lopez, NASA HQ, Office of Procurement, Contract and Grant Policy Division, LP–011, 300 E Street SW., Washington, DC 20456–0001. Telephone 202–358–3740; facsimile 202–358–3082.

SUPPLEMENTARY INFORMATION:

I. Background

This interim rule revises the NFS to implement revisions to the voucher submittal and payment process. These revisions are necessary due to section 893 of the National Defense Authorization Act for Fiscal Year 2016 (Pub. L. 114–92) prohibiting DCAA from performing audit work for non-Defense Agencies. Section 893 prohibits DCAA from performing audit work for non-Defense Agencies until DCAA’s backlog of incurred cost audits is below 18 months. DCAA’s current backlog of cost audits is greater than 18 months. NASA had delegated to DCAA the task of reviewing contractor requests for payment under its cost-type contracts. As a result of section 893, DCAA has ceased cost voucher audit support to NASA, in turn, jeopardizing timely payment to contractors for work performed. NASA has revised its cost voucher submission and payment process to ensure the continued prompt payment to its suppliers. Accordingly, the NFS needs to be immediately revised to implement procedural changes to minimize cost voucher submission and payment delays to NASA suppliers as well the potential accrual of Government interest payments to contractors.